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OFFICE OF GOVERNMENT ETHICS

5 CFR Parts 2634 and 2636

RIN 3209–AA45

2019 Civil Monetary Penalties Inflation Adjustments for Ethics in Government Act Violations

AGENCY: Office of Government Ethics.

ACTION: Final rule.

SUMMARY: In accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, the U.S. Office of Government Ethics is issuing this final rule to make the 2019 annual adjustments to the Ethics in Government Act civil monetary penalties.

DATES:

Effective Date: This final rule is effective February 26, 2019.

Applicability date: This final rule is applicable January 15, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Sikora Panza, Associate Counsel, General Counsel and Legal Policy Division, Office of Government Ethics, Telephone: 202–482–9300; TTY: 800–877–8339; FAX: 202–482–9237.

SUPPLEMENTARY INFORMATION:

I. Background

In November 2015, Congress passed the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the 2015 Act), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410). The 2015 Act required Federal agencies to make inflationary adjustments to the civil monetary penalties (CMPs) within their jurisdiction with an initial ''catch-up'' adjustment through an interim final rule effective no later than August 1, 2016, and further mandates that Federal agencies make subsequent annual inflationary adjustments of their CMPs, to be effective no later than January 15 of each year.

The Ethics in Government Act of 1978 as amended, 5 U.S.C. appendix (the Ethics Act) provides for five CMPs.[1] Specifically, the Ethics Act provides for penalties that can be assessed by an appropriate United States district court, based upon a civil action brought by the Department of Justice, for the following five types of violations:

(1) Knowing and willful failure to file, report required information on, or falsification of a public financial disclosure report, 5 U.S.C. appendix 104(a), 5 CFR 2634.701(b);

(2) knowing and willful breach of a qualified trust by trustees and interested parties, 5 U.S.C. appendix 102(f)(6)(C)(i), 5 CFR 2634.702(a);

(3) negligent breach of a qualified trust by trustees and interested parties, 5 U.S.C. appendix 102(f)(6)(C)(ii), 5 CFR 2634.702(b);

(4) misuse of a public report, 5 U.S.C. appendix 105(c)(2), 5 CFR 2634.703; and

(5) violation of outside employment/activities provisions, 5 U.S.C. appendix 504(a), 5 CFR 2636.104(a).

In compliance with the 2015 Act and guidance issued by the Office of Management and Budget (OMB), the U.S. Office of Government Ethics (OGE) made previous inflationary adjustments to the five Ethics Act CMPs, and is issuing this rulemaking to effectuate the 2019 annual inflationary adjustments to those CMPs. In accordance with the 2015 Act, these adjustments are based on the percent change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the date of the adjustment, and the prior year's October CPI–U. Pursuant to OMB guidance, the cost-of-living adjustment multiplier for 2019, based on the CPI–U for October 2018, not seasonally adjusted, is 1.02522. To calculate the 2019 annual adjustment, agencies must multiply the most recent penalty by the 1.02522 multiplier, and round to the nearest dollar.

Applying the formula established by the 2015 Act and OMB guidance, OGE is amending the Ethics Act CMPs through this rulemaking to:

(1) Increase the three penalties reflected in 5 CFR 2634.702(a), 5 CFR 2634.703, and 5 CFR 2636.104(a)—which were previously adjusted to a maximum of $19,639—to a maximum of $20,134;

(2) Increase the penalty reflected in 5 CFR 2634.702(b)—which was previously adjusted to a maximum of $9,819—to a maximum of $10,067; and

(3) Increase the penalty reflected in 5 CFR 2634.701(b)—which was previously adjusted to a maximum of $59,028—to a maximum of $60,517.

These adjusted penalty amounts will apply to penalties assessed after January 15, 2019 (the applicability date of this final rule) whose associated violations occurred after November 2, 2015.

OGE will continue to make future annual inflationary adjustments to the Ethics Act CMPs in accordance with the statutory formula set forth in the 2015 Act and OMB guidance.

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b), as Director of the Office of Government Ethics, I find that good cause exists for waiving the general notice of proposed rulemaking and public comment procedures as to these technical amendments. The notice and comment procedures are being waived because these amendments, which concern matters of agency organization, procedure and practice, are being adopted in accordance with statutorily mandated inflation adjustment procedures of the 2015 Act, which specifies that agencies shall adjust civil monetary penalties notwithstanding Section 553 of the Administrative Procedure Act. It is also in the public interest that the adjusted rates for civil monetary penalties under the Ethics in Government Act become effective as soon as possible in order to maintain their deterrent effect.

Regulatory Flexibility Act

As the Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule would not have a significant economic impact on a substantial number of small entities

[1] OGE has previously determined, after consultation with the Department of Justice, that the $200 late filing fee for public financial disclosure reports that are more than 30 days overdue (see section 104(d) of the Ethics Act, 5 U.S.C. appendix, 104(d), and 5 CFR 2634.704 of OGE's regulations thereunder) is not a CMP as defined under the Federal Civil Penalties Inflation Adjustment Act, as amended. Therefore, that fee is not being adjusted in this rulemaking (nor was it adjusted by OGE in previous CMP rulemakings), and will remain at its current amount of $200.

because it primarily affects current Federal executive branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 5, subchapter II), this rule would not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Executive Order 13563 and Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select the regulatory approaches that maximize net benefits (including 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. The Office of Management and Budget has determined that rulemakings such as this implementing annual inflationary adjustments under the 2015 Act are not significant regulatory actions under Executive Order 12866.

Executive Order 12988

As Director of the Office of Government Ethics, I have reviewed this rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects

5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Financial disclosure, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2636

Conflict of interests, Government employees, Penalties.

Dated: February 21, 2019.

Emory Rounds,

Director, U.S. Office of Government Ethics.

For the reasons set forth in the preamble, the U.S. Office of Government Ethics is amending 5 CFR parts 2634 and 2636 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. App.; 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note, as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 and Sec. 701, Pub. L. 114–74; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Section 2634.701 is amended by revising paragraph (b) to read as follows:

§ 2634.701 Failure to file or falsifying reports.

* * * * *

(b) *Civil action.* The Attorney General may bring a civil action in any appropriate United States district court against any individual who knowingly and willfully falsifies or who knowingly and willfully fails to file or report any information required by filers of public reports under subpart B of this part. The court in which the action is brought may assess against the individual a civil monetary penalty in any amount, not to exceed the amounts set forth in Table 1 to this section, as provided by section 104(a) of the Act, as amended, and as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

TABLE 1 TO § 2634.701

Date of violation	Penalty
Violation occurring between Sept. 14, 2007 and Nov. 2, 2015	$50,000
Violation occurring after Nov. 2, 2015	60,517

* * * * *

■ 3. Section 2634.702 is revised to read as follows:

§ 2634.702 Breaches by trust fiduciaries and interested parties.

(a) The Attorney General may bring a civil action in any appropriate United States district court against any individual who knowingly and willfully violates the provisions of § 2634.408(d)(1) or (e)(1). The court in which the action is brought may assess against the individual a civil monetary penalty in any amount, not to exceed the amounts set forth in Table 1 to this section, as provided by section 102(f)(6)(C)(i) of the Act and as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

TABLE 1 TO § 2634.702

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$11,000
Violation occurring after Nov. 2, 2015	20,134

(b) The Attorney General may bring a civil action in any appropriate United States district court against any individual who negligently violates the provisions of § 2634.408(d)(1) or (e)(1). The court in which the action is brought may assess against the individual a civil monetary penalty in any amount, not to exceed the amounts set forth in Table 2 to this section, as provided by section 102(f)(6)(C)(ii) of the Act and as adjusted in accordance with the inflation adjustment procedures of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

TABLE 2 TO § 2634.702

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$5,500
Violation occurring after Nov. 2, 2015	10,067

■ 4. Section 2634.703 is revised to read as follows:

§ 2634.703 Misuse of public reports.

(a) The Attorney General may bring a civil action against any person who obtains or uses a report filed under this part for any purpose prohibited by section 105(c)(1) of the Act, as incorporated in § 2634.603(f). The court in which the action is brought may assess against the person a civil monetary penalty in any amount, not to exceed the amounts set forth in Table 1 to this section, as provided by section 105(c)(2) of the Act and as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

TABLE 1 TO § 2634.703

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$11,000
Violation occurring after Nov. 2, 2015	20,134

(b) This remedy shall be in addition to any other remedy available under statutory or common law.

PART 2636—LIMITATIONS ON OUTSIDE EARNED INCOME, EMPLOYMENT AND AFFILIATIONS FOR CERTAIN NONCAREER EMPLOYEES

■ 5. The authority citation for part 2636 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996) and Sec. 701, Pub. L. 114–74 (Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 6. Section 2636.104 is amended by revising paragraph (a) to read as follows:

§ 2636.104 Civil, disciplinary and other action.

(a) *Civil action.* Except when the employee engages in conduct in good faith reliance upon an advisory opinion issued under § 2636.103, an employee who engages in any conduct in violation of the prohibitions, limitations and restrictions contained in this part may be subject to civil action under 5 U.S.C. app. 504(a) and a civil monetary penalty of not more than the amounts set in Table 1 to this section, as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, or the amount of the compensation the individual received for the prohibited conduct, whichever is greater.

TABLE 1 TO § 2636.104

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$11,000
Violation occurring after Nov. 2, 2015	20,134

* * * * *

[FR Doc. 2019–03288 Filed 2–25–19; 8:45 am]

BILLING CODE 6345–03–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2019–0030]

RIN 3150–AK28

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM 100 Cask System, Certificate of Compliance No. 1014, Amendment No. 13

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the Holtec International HI–STORM 100 Cask System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 13 to Certificate of Compliance No. 1014. Amendment No. 13 revises Appendix B of the technical specifications to update the initial uranium weight for the 16x16B and 16x16C assembly classes to match the value for 16x16A.

DATES: This direct final rule is effective May 13, 2019, unless significant adverse comments are received by March 28, 2019. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

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–2019–0030. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

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: Christian Jacobs, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6825; email: *Christian.Jacobs@nrc.gov* or Gregory R. Trussell, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6244; email: *Gregory.Trussell@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0030 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–2019–0030.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–

415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0030 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

This direct final rule is limited to the changes contained in Amendment No. 13 to Certificate of Compliance No. 1014 and does not include other aspects of the HI–STORM 100 Cask System design. The NRC is using the ''direct final rule procedure'' to issue this amendment because it represents a limited and routine change to an existing certificate of compliance that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The amendment to the rule will become effective on May 13, 2019. However, if the NRC receives significant adverse comments on this direct final rule by March 28, 2019, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, Certificate of Compliance, or technical specifications.

For detailed instructions on filing comments, please see the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[the Commission] shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule which added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on May 1, 2000 (65 FR 25241), that approved the HI–STORM 100 Cask System design and added it to the list of NRC-approved cask designs in 10 CFR 72.214 as Certificate of Compliance No. 1014.

IV. Discussion of Changes

On November 19, 2018, Holtec International submitted a request to the NRC to amend Certificate of Compliance No. 1014 by adding Amendment No. 13. Amendment 13 revises Table 2.1–2: Pressurized Water Reactor (PWR) Fuel Assembly Characteristics of Appendix B of the technical specifications to update the initial uranium weight for the 16x16B and 16x16C assembly classes to match the value for 16x16A.

As documented in the preliminary safety evaluation report, the NRC performed a safety review of the proposed Certificate of Compliance amendment request. Based on its review, the staff determined that there is reasonable assurance that: (1) The activities authorized by the amended certificate can be conducted without endangering the health and safety of the public, and (2) these activities will be conducted in compliance with the applicable regulations of 10 CFR part 72. There are no significant changes to cask design requirements in the proposed amendment. Considering the specific design requirements for each accident condition, the design of the cask would prevent loss of containment, shielding, and criticality control in the event of an accident. The amendment does not reflect a significant change in design or fabrication of the cask. In addition, any resulting occupational exposure or offsite dose rates from the implementation of Amendment No. 13 would remain well within the 10 CFR part 20 limits. There will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for, or consequences from, radiological accidents.

This direct final rule revises the Holtec International HI–STORM 100 Cask System listing in 10 CFR 72.214 by adding Amendment No. 13 to Certificate of Compliance No. 1014. This amendment consists of the changes

previously described, as set forth in the revised certificate of compliance and technical specifications. The revised technical specifications are identified in the preliminary safety evaluation report.

The amended Holtec International HI–STORM 100 Cask System design, when used under the conditions specified in the Certificate of Compliance, technical specifications, and the NRC's regulations, will meet the requirements of 10 CFR part 72; therefore, adequate protection of public health and safety will continue to be ensured. When this direct final rule becomes effective, persons who hold a general license under 10 CFR 72.210 may load spent nuclear fuel into HI–STORM 100 Cask System casks that meet the criteria of Amendment No. 13 to Certificate of Compliance No. 1014 under 10 CFR 72.212.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise the Holtec International HI–STORM 100 Cask System design listed in 10 CFR 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR. Although an Agreement State may not adopt program elements reserved to the NRC, and the Category ''NRC'' does not confer regulatory authority on the State, the State may wish to inform its licensees of certain requirements by means consistent with the particular State's administrative procedure laws.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

A. The Action

The action is to amend 10 CFR 72.214 to revise the Holtec International HI–STORM 100 Cask System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 13 to Certificate of Compliance No. 1014. Amendment No. 13 revises Table 2.1–2: PWR Fuel Assembly Characteristics of Appendix B of the technical specifications to update the initial uranium weight for the 16x16B and 16x16C assembly classes to match the value for 16x16A.

B. The Need for the Action

This direct final rule adds an amended Certificate of Compliance for the Holtec International HI–STORM 100 Cask System design to the list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites under a general license. Specifically, Amendment No. 13 revises Table 2.1–2: PWR Fuel Assembly Characteristics of Appendix B of the technical specifications to update the initial uranium weight for the 16x16B and 16x16C assembly classes to match the value for 16x16A.

C. Environmental Impacts of the Action

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was initially analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for Amendment No. 13 tiers off of the environmental assessment for the July 18, 1990 final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended.

The Holtec International HI–STORM 100 Cask System is designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation, the type of facility at which a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

Considering the specific design requirements for each accident condition, the design of the cask would prevent loss of confinement, shielding, and criticality control in the event of an accident. If there is no loss of confinement, shielding, or criticality control, the environmental impacts resulting from an accident would be insignificant. This amendment does not reflect a significant change in design or fabrication of the cask.

Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of Amendment No. 13 would remain well within the 10 CFR part 20 limits. Therefore, the proposed changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990 final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. The staff documented its safety findings in the preliminary safety evaluation report.

D. Alternative to the Action

The alternative to this action is to deny approval of Amendment No. 13 and end the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent nuclear fuel into the Holtec International HI–STORM 100 Cask System and utilize the technical specifications in accordance with the changes described in proposed Amendment No. 13, would have to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, interested licensees would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to

each licensee. Therefore, the environmental impacts would be the same, or more likely greater than, the proposed action.

E. Alternative Use of Resources

Approval of Amendment No. 13 to Certificate of Compliance No. 1014 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the foregoing environmental assessment, the NRC concludes that this direct final rule entitled ''List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM 100 Cask System, Certificate of Compliance No. 1014, Amendment No. 13,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and Holtec International. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if it notifies the NRC in advance, the spent fuel is stored under the conditions specified in the cask's Certificate of Compliance, and the conditions of the general license are met. A list of NRC-approved cask designs is contained in 10 CFR 72.214. On May 1, 2000 (65 FR 25241), the NRC issued an amendment to 10 CFR part 72 that approved the HI-STORM 100 Cask System design by adding it to the list of NRC-approved cask designs in 10 CFR 72.214.

On November 19, 2018, Holtec International submitted a request to the NRC to amend Certificate of Compliance No. 1014 by adding Amendment No. 13. Holtec International submitted this application to amend the Holtec International HI-STORM 100 Cask System as described in Section IV, ''Discussion of Changes,'' of this document.

The alternative to this action is to withhold approval of Amendment No. 13 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into the Holtec International HI-STORM 100 Cask System under the changes described in Amendment No. 13 to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary safety evaluation report and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory, and therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule revises Certificate of Compliance No. 1014 for the Holtec International HI-STORM 100 Cask System, as currently listed in 10 CFR 72.214, ''List of approved spent fuel storage casks.'' The revision requests changes to Table 2.1–2: PWR Fuel Assembly Characteristics of Appendix B of the technical specifications to update the initial uranium weight for the 16x16B and 16x16C assembly classes to match the value for 16x16A.

Amendment No. 13 to Certificate of Compliance No. 1014 for the Holtec International HI-STORM 100 Cask System was initiated by Holtec International and was not submitted in response to new NRC requirements, or an NRC request for amendment. Amendment No. 13 applies only to new casks fabricated and used under Amendment No. 13. These changes do not affect existing users of the Holtec International HI-STORM 100 Cask System, and the current Amendment No. 12 continues to be effective for existing users. While current users of this storage system may comply with the new requirements in Amendment No. 13, this would be a voluntary decision on the part of current users.

For these reasons, Amendment No. 13 to Certificate of Compliance No. 1014 does not constitute backfitting under 10 CFR 72.62 or 10 CFR 50.109(a)(1), or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52. Accordingly, the NRC staff has not prepared a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No./ Web link/**Federal Register** Citation
Letter from Holtec International dated November 19, 2018, Submitting Request for Amendment No. 13 to Certificate of Compliance No. 1014	ML18325A154
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Certificate of Compliance for Spent Fuel Storage Casks	ML18351A173
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix A	ML18351A174
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix B	ML18351A175
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix A–100U	ML18351A176
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix B–100U	ML18351A177
Certificate of Compliance No. 1014 Amendment No. 13, Preliminary Safety Evaluation Report	ML18351A178

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking website at *http://www.regulations.gov* under Docket ID NRC–2019–0030. The Federal Rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2019–0030); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance 1014 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1014.

Initial Certificate Effective Date: May 31, 2000.

Amendment Number 1 Effective Date: July 15, 2002.

Amendment Number 2 Effective Date: June 7, 2005.

Amendment Number 3 Effective Date: May 29, 2007.

Amendment Number 4 Effective Date: January 8, 2008.

Amendment Number 5 Effective Date: July 14, 2008.

Amendment Number 6 Effective Date: August 17, 2009.

Amendment Number 7 Effective Date: December 28, 2009.

Amendment Number 8 Effective Date: May 2, 2012, as corrected on November 16, 2012 (ADAMS Accession No. ML12213A170); superseded by Amendment 8, Revision 1 Effective Date: February 16, 2016.

Amendment Number 8, Revision 1 Effective Date: February 16, 2016.

Amendment Number 9 Effective Date: March 11, 2014, superseded by Amendment Number 9, Revision 1, on March 21, 2016.

Amendment Number 9, Revision 1, Effective Date: March 21, 2016, as corrected (ADAMS Accession No. ML17236A451).

Amendment Number 10 Effective Date: May 31, 2016, as corrected (ADAMS Accession No. ML17236A452).

Amendment Number 11 Effective Date: February 25, 2019.

Amendment Number 12 Effective Date: February 25, 2019.

Amendment Number 13 Effective Date: May 13, 2019.

Safety Analysis Report (SAR) Submitted by: Holtec International.

SAR Title: Final Safety Analysis Report for the HI-STORM 100 Cask System.

Docket Number: 72–1014.

Certificate Expiration Date: May 31, 2020.

Model Number: HI-STORM 100.

* * * * *

Dated at Rockville, Maryland, this 14th day of February, 2019.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2019–02886 Filed 2–25–19; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0643; Product Identifier 2018–NM–084–AD; Amendment 39–19572; AD 2019–03–20]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Dassault Aviation Model FALCON 7X airplanes. This AD was prompted by a determination that new and more restrictive maintenance requirements and airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new and more restrictive maintenance requirements and airworthiness limitations for airplane structures and systems. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 2, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 2, 2019.

ADDRESSES: For service information identified in this final rule, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; phone: 201–440–6700; internet: *http://www.dassaultfalcon.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. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0643.

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–2018–0643; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3226.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Dassault Aviation Model FALCON 7X airplanes. The NPRM published in the **Federal Register** on August 10, 2018 (83 FR 39630). The NPRM was prompted by a determination that new and more restrictive maintenance requirements and airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new and more restrictive maintenance requirements and airworthiness limitations for airplane structures and systems.

We issued a supplemental NPRM (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Dassault Aviation Model FALCON 7X airplanes. The SNPRM published in the **Federal Register** on November 15, 2018 (83 FR 57364). We issued the SNPRM to require the incorporation of revised and more restrictive airworthiness limitations than those proposed in the NRPM.

We are issuing this AD to address reduced structural integrity and reduced control of airplanes due to the failure of system components.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0101, dated May 3, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Dassault Aviation Model FALCON 7X airplanes. The MCAI states:

> The airworthiness limitations and certification maintenance instructions for Dassault Falcon 7X aeroplanes, which are approved by EASA, are currently defined and published in Dassault Falcon 7X AMM [airplane maintenance manual], Chapter 5–40. These instructions have been identified as mandatory for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition [*i.e.,* reduced structural integrity and reduced control of these airplanes due to the failure of system components].
>
> Previously, EASA issued AD 2015–0095 [which corresponds to FAA AD 2016–16–09, Amendment 39–18607 (81 FR 52752, August 10, 2016) (''AD 2016–16–09'')] to require accomplishment of the maintenance tasks, and implementation of the airworthiness limitations, as specified in Dassault Falcon 7X AMM, Chapter 5–40, at Revision 4.
>
> Since that [EASA] AD was issued, Dassault issued the ALS [airworthiness limitations section], which introduces new and more restrictive maintenance requirements and/or airworthiness limitations.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2015–0095, which is superseded, and requires accomplishment of the actions specified 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–2018–0643.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the SNPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

Related Service Information Under 1 CFR Part 51

Dassault Aviation has issued Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X Maintenance Manual (MM). This service information introduces new and more restrictive maintenance requirements and airworthiness limitations for airplane structures and systems. 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.

Costs of Compliance

We estimate that this AD affects 67 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

We have determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number 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 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 and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) 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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–03–20 Dassault Aviation: Amendment 39–19572; Docket No. FAA–2018–0643; Product Identifier 2018–NM–084–AD.

(a) Effective Date

This AD is effective April 2, 2019.

(b) Affected ADs

This AD affects AD 2014–16–23, Amendment 39–17947 (79 FR 52545, September 4, 2014) (''AD 2014–16–23'') and AD 2016–16–09, Amendment 39–18607 (81 FR 52752, August 10, 2016) (''AD 2016–16–09'').

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 7X airplanes, certificated in any category, with an original certificate of airworthiness or original export certificate of airworthiness issued on or before August 24, 2018.

Note 1 to paragraph (c) of this AD: Model FALCON 7X airplanes with modifications M1000 and M1254 incorporated are commonly referred to as ''Model FALCON 8X'' airplanes as a marketing designation.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time limits/maintenance checks.

(e) Reason

This AD was prompted by a determination that new and more restrictive maintenance requirements and airworthiness limitations are necessary. We are issuing this AD to address reduced structural integrity and reduced control of airplanes due to the failure of system components.

(f) Compliance

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

(g) Revise the Existing Maintenance or Inspection Program

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, by incorporating the information specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X Maintenance Manual (MM). The initial compliance times for the tasks specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X MM are at the applicable compliance times specified in Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X MM, or within 90 days after the effective date of this AD, whichever occurs later.

(h) Terminating Action for Other ADs

(1) Accomplishing the actions required by paragraph (g) of this AD terminates the requirements of paragraph (q) of AD 2014–16–23.

(2) Accomplishing the actions required by paragraph (g) of this AD terminates all requirements of AD 2016–16–09.

(i) No Alternative Actions, Intervals, and Critical Design Configuration Control Limitations (CDCCLs)

After the maintenance or inspection program, as applicable, has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), intervals, or CDCCLs may be used unless the actions, intervals, and CDCCLs are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(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 Dassault Aviation'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 AD 2018–0101, dated May 3, 2018, 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–2018–0643.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3226.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Chapter 5–40–00, Airworthiness Limitations, DGT 107838, Revision 7, dated August 24, 2018, of the Dassault Falcon 7X Maintenance Manual (MM).

(ii) [Reserved]

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; phone: 201–440–6700; internet: *http://www.dassaultfalcon.com.*

(4) 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 14, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03122 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0964; Product Identifier 2018–NM–127–AD; Amendment 39–19571; AD 2019–03–19]

RIN 2120–AA64

Airworthiness Directives; Saab AB, Saab Aeronautics (Formerly Known as Saab AB, Saab Aerosystems) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Saab AB, Saab Aeronautics Model SAAB 2000 airplanes. This AD was prompted by reports that certain fuel probes indicated misleading fuel quantities on the engine indicating and crew alerting system (EICAS). This AD requires a functional check of certain fuel probes, and replacement with a serviceable part if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 2, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 2, 2019.

ADDRESSES: For service information identified in this final rule, contact Saab AB, Saab Aeronautics, SE–581 88, Linköping, Sweden; telephone +46 13 18 5591; fax +46 13 18 4874; email *saab2000.techsupport@saabgroup.com;* internet *http://www.saabgroup.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. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0964.

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–2018–0964; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Saab AB, Saab Aeronautics Model SAAB 2000 airplanes. The NPRM published in the **Federal Register** on November 26, 2018 (83 FR 60374). The NPRM was prompted by reports that certain fuel probes indicated misleading fuel quantities on the EICAS. The NPRM proposed to require a functional check of certain fuel probes, and replacement with a serviceable part if necessary.

We are issuing this AD to address deteriorated capacity of the fuel probes, which could lead to incorrect fuel reading, possibly resulting in fuel starvation and uncommanded engine in-flight shutdown, and consequent reduced control of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2018–0187, dated August 29, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Saab AB, Saab Aeronautics Model SAAB 2000 airplanes. The MCAI states:

> Occurrences were reported that certain fuel probes, installed on SAAB 2000 aeroplanes, indicated misleading fuel quantities on the engine indicating and crew alerting system (EICAS). The investigation results suggest that this may be an aging phenomenon, leading to deteriorated capacity of the fuel probes.
>
> This condition, if not detected and corrected, could lead to incorrect fuel reading, possibly resulting in fuel starvation and uncommanded engine in-flight shut-down, with consequent reduced control of the aeroplane.
>
> To address this potential unsafe condition, SAAB issued the SB [service bulletin] to provide instructions for a functional check.
>
> For the reason described above, this [EASA] AD requires a one-time functional check of the fuel quantity system and the fuel low level EICAS warnings to determine whether any affected parts are out of tolerance and, depending on findings, replacement of those affected parts.

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–2018–0964.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Clarification of Paragraph (g)(2) of This AD

We have removed the words ''has reached'' from the definition in paragraph (g)(2) of this AD for clarity and to match the MCAI.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule with the change described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

Saab AB, Saab Aeronautics has issued Service Bulletin 2000–28–028, dated April 19, 2018. This service information describes procedures for a functional check of the fuel indicator gauging accuracy and the low level warning, and for replacing the affected part with a serviceable part if necessary.

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.

Costs of Compliance

We estimate that this AD affects 8 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
8 work-hours × $85 per hour = $680	$0	$680	$5,440

We estimate the following costs to do any necessary on-condition action that would be required based on the results of any required actions. We have no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTION

Labor cost	Parts cost	Cost per product
2 work-hours × $85 per hour = $170	$6,295	$6,465

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 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 and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) 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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–03–19 Saab AB, Saab Aeronautics (Formerly Known as Saab AB, Saab Aerosystems): Amendment 39–19571; Docket No. FAA–2018–0964; Product Identifier 2018–NM–127–AD.

(a) Effective Date

This AD is effective April 2, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Saab AB, Saab Aeronautics (formerly known as Saab AB, Saab Aerosystems) Model SAAB 2000 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Reason

This AD was prompted by reports that certain fuel probes indicated misleading fuel quantities on the engine indicating and crew alerting system (EICAS). We are issuing this AD to address deteriorated capacity of the fuel probes, which could lead to incorrect fuel reading, possibly resulting in fuel starvation and uncommanded engine in-flight shutdown, and consequent reduced control of the airplane.

(f) Compliance

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

(g) Definitions

(1) An affected part is a fuel probe having part number (P/N) 20136–0101, P/N 20136–0102, P/N 20136–0103, P/N 20136–0104, P/N 20136–0105, or P/N 20136–0106; with fuel low level sensors having P/N 20137–0101.

(2) A serviceable part is an affected part that has accumulated less than 1,500 total flight hours or 12 months since first installation on an airplane.

(h) Functional Check

Within 1,500 flight hours or 12 months after the effective date of this AD, whichever

occurs first, accomplish a functional check of the fuel indicator gauging accuracy and the low level warning, in accordance with the Accomplishment Instructions of Saab Service Bulletin 2000–28–028, dated April 19, 2018.

(i) Corrective Action

If the functional check required by paragraph (h) of this AD is found to be out of tolerance, within the limits and under the applicable conditions, as specified in the operator's Minimum Equipment List, replace the affected part with a serviceable part, in accordance with the Accomplishment Instructions of Saab Service Bulletin 2000–28–028, dated April 19, 2018.

(j) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, an affected part, unless it is a serviceable part, as defined in paragraph (g)(2) of this AD.

(k) 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 (l)(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 Saab AB, Saab Aeronautics's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2018–0187, dated August 29, 2018, 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–2018–0964.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Saab Service Bulletin 2000–28–028, dated April 19, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Saab AB, Saab Aeronautics, SE–581 88, Linköping, Sweden; telephone +46 13 18 5591; fax +46 13 18 4874; email *saab2000.techsupport@saabgroup.com;* internet *http://www.saabgroup.com.*

(4) 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 14, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03120 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0905; Product Identifier 2018–NM–115–AD; Amendment 39–19573; AD 2019–03–21]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Embraer S.A. Model ERJ 190–100 STD, –100 LR, –100 IGW airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes. This AD was prompted by reports of corrosion and chromium layer chipping of the forward and aft pintle pins of the main landing gear (MLG) shock struts. This AD requires repetitive inspections for discrepancies of affected forward and aft pintle pins of the MLG shock struts, and corrective actions if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 2, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 2, 2019.

ADDRESSES: For service information identified in this final rule, contact Embraer S.A., Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227–901 São Jose dos Campos—SP—Brazil; telephone: +55 12 3927–5852 or +55 12 3309–0732; fax: +55 12 3927–7546; email: *distrib@embraer.com.br;* internet: *http://www.flyembraer.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. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0905.

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–2018–0905; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Krista Greer, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3221.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Embraer S.A. Model ERJ 190–100 STD, –100 LR, –100 IGW, –200 STD, –200 LR, and –200 IGW airplanes. The NPRM published in the **Federal Register** on November 5, 2018 (83 FR 55297). The NPRM was prompted by reports of corrosion and chromium layer chipping of the forward and aft pintle pins of the MLG shock struts. The NPRM proposed to require repetitive inspections for discrepancies of affected forward and aft pintle pins of the MLG

shock struts, and corrective actions if necessary. We are issuing this AD to address discrepancies of affected forward and aft pintle pins of the MLG shock struts, which could result in the pintle pin shearing under normal load and consequent collapse of the MLG during takeoff or landing.

Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued Brazilian Airworthiness Directive 2018–07–01, effective July 24, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Embraer S.A. Model ERJ 190–100 STD, –100 LR, –100 IGW airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes. The MCAI states:

> This [Brazilian] AD was prompted by reports of corrosion and chromium layer chipping on the rearward and forward Pintle Pin of the Main Landing Gear (MLG) Shock Struts. We are issuing this [Brazilian] AD to detect and correct Pintle Pin[s] having [discrepancies including] corrosion or chromium layer chipping, which could cause the Pintle Pin[s] to shear under normal load and lead to collapse of the MLG during take-off or landing.

Corrective actions include repair or replacement of affected forward and aft pintle pins of the left- and right-hand MLG shock struts. 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–2018–0905.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Change Made to This Final Rule

We have changed this final rule to reference Task 32–11–001–1034, ''Main Landing Gear Shock Strut Pintle Pins—Internal,'' of the Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 12, dated September 27, 2018. In Revision 12, among other changes, the task interval is extended from 66 months to 72 months resulting from findings of an MLG sampling program.

We have also added Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 12, dated September 27, 2018, to paragraphs (i)(1) and (i)(2) of this AD to give credit for inspections that have been done before the effective date of this AD as specified in Task 57–50–007–1247, ''Main Landing Gear Trunnion Fittings—Inside Surfaces—Internal,'' and Task 32–11–00–001, ''Main Landing Gear (MLG)'' of Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 12, dated September 27, 2018.

We have also revised paragraph (i)(3) of this AD to refer to Task 32–11–001–1034, ''Main Landing Gear Shock Strut Pintle Pins—Internal,'' Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 11, dated May 10, 2017, and we have redesignated subsequent paragraphs.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

Embraer has issued Service Bulletin 190–32–0065, Revision 02, dated November 1, 2017. This service information describes procedures for repetitive detailed inspection for discrepancies of affected forward and aft pintle pins of the left- and right-hand MLG shock struts, and repair or replacement of any discrepant affected pintle pin.

Embraer has also issued Task 32–11–001–1034, ''Main Landing Gear Shock Strut Pintle Pins—Internal,'' of the Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 12, dated September 27, 2018. This service information describes procedures for the inspection of pintle pins of the MLG shock struts at areas covered by the MLG shock strut and trunnion.

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.

Costs of Compliance

We estimate that this AD affects 96 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 22 work-hours × $85 per hour = Up to $1,870.	$0	Up to $1,870 per inspection cycle	Up to $179,520 per inspection cycle.

We estimate the following costs to do any necessary on-condition actions that would be required based on the results of any required inspection. We have no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
6 work-hours × $85 per hour = $510 per MLG (replacement)	$1,750 per MLG	$2,260 per MLG
6 work-hours × $85 per hour = $510 per MLG (repair)	$0	$510 per MLG.

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 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 and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) 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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–03–21 Embraer S.A.: Amendment 39–19573; Docket No. FAA–2018–0905; Product Identifier 2018–NM–115–AD.

(a) Effective Date

This AD is effective April 2, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Model ERJ 190–100 STD, –100 LR, and –100 IGW airplanes; and Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes; certificated in any category; all serial numbers.

(d) Subject

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

(e) Reason

This AD was prompted by reports of corrosion and chromium layer chipping of the forward and aft pintle pins of the main landing gear (MLG) shock struts. We are issuing this AD to address discrepancies of affected forward and aft pintle pins of the MLG shock struts, which could result in the pintle pin shearing under normal load and consequent collapse of the MLG during takeoff or landing.

(f) Compliance

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

(g) Repetitive Inspections

At the applicable time specified in paragraph (g)(1) or (g)(2) of this AD: Do a detailed inspection for discrepancies of affected forward and aft pintle pins of the left- and right-hand MLG shock struts, in accordance with the Accomplishment Instructions of Embraer Service Bulletin 190–32–0065, Revision 02, dated November 1, 2017. Repeat the inspection thereafter at intervals not to exceed 72 months.

(1) For airplanes on which any MLG pintle pin having part number (P/N) 2821–0067 or 2821–0025 has accumulated fewer than 17,000 total flight cycles since new: Before the accumulation of 17,750 total flight cycles.

(2) For airplanes on which any MLG pintle pin having P/N 2821–0067 or 2821–0025 has accumulated 17,000 or more total flight cycles since new: Within 750 flight cycles after the effective date of this AD.

(h) Corrective Actions

If any discrepancy of any pintle pin is found during any inspection required by paragraph (g) of this AD: Before further flight, repair the affected pintle pin or replace it with a new pintle pin, as applicable, in accordance with the Accomplishment Instructions of Embraer Service Bulletin 190–32–0065, Revision 02, dated November 1, 2017.

(i) Credit for Previous Actions

This paragraph provides credit for the initial inspection required by paragraph (g) of this AD, if that inspection was performed before the effective date of this AD using the applicable service information identified in paragraphs (i)(1) through (i)(6) of this AD.

(1) Task 57–50–007–1247, ''Main Landing Gear Trunnion Fittings—Inside Surfaces—Internal,'' Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 11, dated May 10, 2017; or Revision 12, dated September 27, 2018.

(2) Task 32–11–00–001, ''Main Landing Gear (MLG),'' Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 11, dated May 10, 2017; or Revision 12, dated September 27, 2018.

(3) Task 32–11–001–1034, ''Main Landing Gear Shock Strut Pintle Pins—Internal,'' Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 11, dated May 10, 2017.

(4) Embraer Service Bulletin 190–32–0002, Revision 01, dated November 8, 2012.

(5) Embraer Service Bulletin 190–32–0065, dated August 31, 2016.

(6) Embraer Service Bulletin 190–32–0065, Revision 01, dated October 24, 2017.

(j) Equivalent Inspection

Performing a detailed inspection for discrepancies of affected forward and aft pintle pins of the left- and right-hand MLG shock struts, in accordance with Task 32–11–001–1034, ''Main Landing Gear Shock Strut Pintle Pins—Internal,'' of the Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 12, dated September 27, 2018, at intervals not to exceed 72 months, is equivalent to an inspection required by paragraph (g) of this AD.

(k) 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 (l)(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 Agência Nacional de Aviação Civil (ANAC); or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

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

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Brazilian Airworthiness Directive 2018–07–01, effective July 24, 2018, 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–2018–0905.

(2) For more information about this AD, contact Krista Greer, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3221.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(3) and (m)(4) of this AD.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Embraer Service Bulletin 190–32–0065, Revision 02, dated November 1, 2017.

(ii) Task 32–11–001–1034, ''Main Landing Gear Shock Strut Pintle Pins—Internal,'' of the Embraer 190/195 Maintenance Review Board Report MRB–1928, Revision 12, dated September 27, 2018.

(3) For service information identified in this AD, contact Embraer S.A., Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227–901 São Jose dos Campos—SP—Brazil; telephone: +55 12 3927–5852 or +55 12 3309–0732; fax: +55 12 3927–7546; email: *distrib@embraer.com.br;* internet: *http://www.flyembraer.com.*

(4) 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 14, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03127 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0962; Product Identifier 2018–NM–125–AD; Amendment 39–19560; AD 2019–03–08]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus SAS Model A350–941 airplanes. This AD was prompted by reports of an overheat failure mode of the hydraulic engine-driven pump (EDP), and a determination that the affected EDP needs to be replaced with an improved EDP. This AD requires replacement of a certain EDP with an improved EDP. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 2, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 2, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@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. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0962.

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–2018–0962; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A350–941 airplanes. The NPRM published in the **Federal Register** on November 23, 2018 (83 FR 59328). The NPRM was prompted by reports of an overheat failure mode of the hydraulic EDP, and a determination that the affected EDP needs to be replaced with an improved EDP. The NPRM proposed to require replacement of a certain EDP with an improved EDP.

We are issuing this AD to address the overheat failure mode of the hydraulic EDP, which may cause a fast temperature rise of the hydraulic fluid, and, if combined with an inoperative fuel tank inerting system, could lead to an uncontrolled overheat of the hydraulic fluid, possibly resulting in ignition of the fuel-air mixture of the affected fuel tank.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0178, dated August 23, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A350–941 airplanes. The MCAI states:

In the Airbus A350 design, the hydraulic fluid cooling system is located in the fuel tanks. Recently, an overheat failure mode of the hydraulic EDP was found, which may cause a fast temperature rise of the hydraulic fluid.

This condition, if not detected and corrected, combined with an inoperative fuel tank inerting system, could lead to an uncontrolled overheat of the hydraulic fluid, possibly resulting in ignition of the fuel-air mixture in the affected fuel tank.

To address this potential unsafe condition, Airbus issued a Major Event Revision (MER) of the A350 Master Minimum Equipment List (MMEL) that incorporates restrictions to avoid an uncontrolled overheat of the hydraulic system. Consequently, EASA issued Emergency AD 2017–0154–E to require implementation of these dispatch restrictions.

After EASA AD 2017–0154–E was issued, following further investigation, Airbus issued another MER of the A350 MMEL that expanded the number of restricted MMEL items. At the same time, Airbus revised Flight Operation Transmission (FOT) 999.0068/17, to inform all operators accordingly. Consequently, EASA issued AD 2017–0180, retaining the requirements of EASA Emergency AD 2017–0154–E, which was superseded, and requiring implementation of the new Airbus A350 MMEL MER and, consequently, restrictions for aeroplane dispatch.

After EASA AD 2017–0180 was issued, Airbus developed HMCA [Hydraulic Monitoring and Control Application] SW [software] S4.2, embodied in production through Airbus mod 112090, and introduced in service through Airbus SB [service bulletin] A350–29–P012. Consequently, EASA issued AD 2017–0200 [which corresponds to FAA AD 2018–19–19, Amendment 39–19419 (83 FR 48203, September 24, 2018)], retaining the requirements of EASA AD 2017–0180, which was superseded, and requiring modification of the aeroplane by installing HMCA SW S4.2.

Since EASA AD 2017–0200 was issued, it was determined that the affected part need to be replaced with improved EDP. Consequently, Airbus issued the SB [Service Bulletin A350–29–P013, dated March 12, 2018] to provide instructions to replace the affected parts with improved EDP, having P/N [part number] 53098–06, which are embodied in production through Airbus mod 112192.

For the reasons described above, this [EASA] AD retains the requirement of EASA AD 2017–0200, which is superseded, and requires replacement of each affected parts with improved EDP.

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–2018–0962.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comment received. Air Line Pilots Association, International stated that it supports the NPRM.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A350–29–P013, dated March 12, 2018. This service information describes procedures for replacing a certain EDP with an improved EDP.

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.

Costs of Compliance

We estimate that this AD affects 11 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 25 work-hours × $85 per hour = $2,125.	Up to $224,400	Up to $226,525	Up to $2,491,775.

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

Authority for This Rulemaking

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

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 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 and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

(2) 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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–03–08 Airbus SAS: Amendment 39–19560; Docket No. FAA–2018–0962; Product Identifier 2018–NM–125–AD.

(a) Effective Date

This AD is effective April 2, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Reason

This AD was prompted by reports of an overheat failure mode of the hydraulic engine-driven pump (EDP), and a determination that the affected EDP needs to be replaced with an improved EDP. We are issuing this AD to address the overheat failure mode of the hydraulic EDP, which may cause a fast temperature rise of the hydraulic fluid, and, if combined with an inoperative fuel tank inerting system, could lead to an uncontrolled overheat of the hydraulic fluid, possibly resulting in ignition of the fuel-air mixture of the affected fuel tank.

(f) Compliance

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

(g) Required Action

Before February 6, 2020, replace each EDP having part number (P/N) 53098–04 with an improved EDP, having P/N 53098–06, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A350–29–P013, dated March 12, 2018.

(h) Parts Installation Prohibition

At the applicable time specified in paragraph (h)(1) or (h)(2) of this AD: No person may install an EDP having P/N 53098–04 on any airplane.

(1) For airplanes that, as of the effective date of this AD, have any EDP having P/N 53098–04 installed: After modification of the airplane as specified by paragraph (g) of this AD.

(2) For airplanes that, as of the effective date of this AD, are post-Modification 112192 and do not have any EDP having P/N 53098–04 installed: As of the effective date of this AD.

(i) 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 (j)(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 SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0178, dated August 23, 2018, 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–2018–0962.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Service Bulletin A350–29–P013, dated March 12, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.com.*

(4) 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 8, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03125 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 33

[Docket No. RM19–4–000; Order No. 855]

Mergers or Consolidations by a Public Utility

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Final rule.

SUMMARY: Pursuant to ''An Act to amend section 203 of the Federal Power Act'' (Act), the Federal Energy Regulatory Commission (Commission) revises its regulations relating to mergers or consolidations by a public utility.

DATES: This rule will become effective March 27, 2019.

FOR FURTHER INFORMATION CONTACT: Eric Olesh (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6524, *Eric.Olesh@ferc.gov.*

Regine Baus (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8757, *Regine.Baus@ferc.gov.*

SUPPLEMENTARY INFORMATION: In this final rule, the Commission amends its regulations to establish that a public utility must seek authorization under amended section 203(a)(1)(B) of the Federal Power Act (FPA) to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever. In addition, as required by the Act, the Commission establishes a requirement to submit a notification filing for mergers or consolidations by a public utility if the facilities to be acquired have a value in excess of $1 million and such public utility is not required to secure Commission authorization under amended section 203(a)(1)(B).

I. Background

1. On November 15, 2018, the Commission issued a notice of proposed rulemaking (NOPR) [1] implementing ''An Act to amend section 203 of the Federal Power Act'' (Act), Public Law 115–247, 132 Stat. 3152. Section 1 of the Act amended section 203(a)(1)(B) to provide that no public utility shall, without first having secured an order of the Commission authorizing it to do so, merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever. Section 3 of the Act provides that the amendment to section 203(a)(1)(B) shall take effect 180 days after the date of enactment of the Act. The primary effect of this amendment is to establish a $10 million threshold on transactions that will be subject to the Commission's review and authorization under section 203(a)(1)(B).

2. In section 2 of the Act, Congress amended section 203(a) to add section 203(a)(7) to require notification for certain transactions. Section 203(a)(7) provides that, not later than 180 days after the date of the enactment of section 203(a)(7), the Commission shall promulgate a rule requiring any public utility that is seeking to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with those of any other person, to notify the Commission of such transactions not later than 30 days after the date on which the transaction is consummated if: (1) The facilities, or any part thereof, to be acquired are of a value in excess of $1 million; and (2) such public utility is not required to secure a Commission order under amended section 203(a)(1)(B).

3. The Act also specifies that, not later than two years after the date of enactment of this Act, the Commission shall submit to Congress a report that assesses the effects of the amendment made by section 1 and that such report shall take into account any information collected under section 203(a)(7). The Act also requires that the Commission provide for public notice and comment with respect to the report.

II. Discussion

4. As discussed below, commenters generally support the proposals in the NOPR, including the proposed changes to implement amended section 203(a)(1)(B) and to establish a notification filing requirement pursuant to section 203(a)(7). Certain commenters request clarification of the procedures associated with the notification filing while others recommend that the Commission require additional information about the transactions subject to the notification filing. In light of amended section 203(a)(1)(B), commenters also request clarification on the Commission's jurisdiction over acquisitions of facilities from non-public utilities. Lastly, commenters request that the Commission continue to consider and act on other pending Commission rulemakings. We address these issues below.

A. Section 203(a)(1)(B) Dollar Threshold

1. NOPR

5. In the NOPR, the Commission proposed two changes to part 33 of its regulations to bring them into conformance with the Act. First, the Commission proposed to revise § 33.1(a)(1)(ii) to provide that part 33 will apply to any public utility seeking authorization under section 203 to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever.[2]

2. Comments

6. American Public Power Association (APPA), Edison Electric Institute (EEI), Idaho Power Company (Idaho Power), International Transmission Company (ITC),[3] National Rural Electric Cooperative Association (NRECA), and Transmission Access Policy Study Group (TAPS) support the proposed changes to part 33 of the Commission's regulations to implement the $10 million dollar threshold in amended section 203(a)(1)(B). APPA, EEI, Idaho Power, NRECA, and TAPS add that the change appropriately reflects the amended language of section 203, and Idaho Power states that it will ensure the Commission focuses its time and effort on larger, potentially more impactful transactions.[4] EEI and ITC explain that it will also reduce administrative burdens on regulated entities and the Commission.[5]

3. Commission Determination

7. We will revise the language in § 33.1(a)(1)(ii) of the Commission's regulations as proposed in the NOPR.

B. Notification Filing

1. NOPR

8. The Commission also proposed to add § 33.12 to its regulations to require public utilities whose transactions are subject to section 203(a)(7) to file notification of such transactions with the Commission. In particular, the Commission proposed that any public utility that is seeking to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with those of any other person must

[1] *Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act,* Notice of Proposed Rulemaking, 83 FR 61338 (Nov. 29, 2018), 165 FERC ¶ 61,091 (2018).

[2] *Id.* P 3. In the NOPR, the Commission stated that public utilities required to maintain their books of account in accordance with the Commission's Uniform System of Accounts under 18 CFR part 101 must continue to file with the Commission proposed journal entries for the purchase or sale of electric plant, consistent with the instructions to Account 102, Electric Plant Purchased and Sold. The Commission explained that the dollar threshold proposed in the NOPR does not apply to this accounting filing requirement. *Id.* at n.1.

[3] ITC filed comments on behalf of itself, Michigan Electric Transmission Company, LLC, ITC Midwest LLC, and ITC Great Plains, LLC.

[4] *See* APPA Comments at 3; EEI Comments at 5; Idaho Power Comments at 1; NRECA Comments at 3; TAPS Comments at 3.

[5] *See* ITC Comments at 1; EEI Comments at 6.

notify the Commission of such transaction not later than 30 days after the date on which the transaction is consummated if: (1) The facilities, or any part thereof, to be acquired are of a value in excess of $1 million; and (2) such public utility is not required to secure an order of the Commission under section 203(a)(1)(B).[6]

9. The Commission proposed that public utilities subject to section 203(a)(7) file the following information in this notification filing: (1) The exact name of the public utility and its principal business address; and (2) a narrative description of the transaction, including the identity of all parties involved in the transaction and all jurisdictional facilities associated with or affected by the transaction, the location of such jurisdictional facilities involved in the transaction, the date on which the transaction was consummated, the consideration for the transaction, and the effect of the transaction on the ownership and control of such jurisdictional facilities.[7]

10. The Commission proposed that the notification filings be filed in the first docket for section 203 filings for the fiscal year (FY). For example, all notification filings made in FY2019 would be filed in Docket No. EC19–1–000; all notification filings made in FY2020 would be filed in Docket No. EC20–1–000, etc.[8]

2. Comments

11. Most commenters support the proposed notification filing.[9] NRECA explains that proposed § 33.12(a) implementing the notification requirement tracks the statutory language.[10] EEI supports the Commission's proposal regarding the notification requirement for transactions valued between $1 million but at or below $10 million, which it states is consistent with the legislative goals of reducing regulatory burden and paperwork burdens while still providing transparency.[11] Idaho Power also supports the proposal that there be no filing requirement for transactions involving facilities with a value of less than $1 million, which it states will streamline the process for utilities and reduce the oversight burden on the Commission.[12]

12. Some commenters request clarification on associated process and service requirements and notice procedures. EEI requests clarification on whether the notification filings can be filed in standard word-document formats via eFiling. EEI and ITC also ask whether these filings are purely informational. Specifically, they ask that the Commission clarify that: (1) It will not notice these proceedings for public comment; (2) other persons are not entitled to file responsive comments; and (3) the Commission will not take any action on the filings. EEI and ITC request clarification that persons are not obligated to serve copies of these notification filings under 18 CFR 385.2010 (Rule 2010 of the Commission's Rules of Practice and Procedure).[13] In contrast, Public Citizen, Inc. requests that the Commission clarify whether the proposed notification filing will be subject to public notice so that the public can track transactions valued between $1 million but at or below $10 million.[14]

13. Others contend that the information proposed to be collected in the notification filing is insufficient. American Antitrust Institute (AAI) suggests that more information should be included in the notification filing to account for (1) small, successive horizontal or vertical acquisitions that can result in accretion of market power over time (serial transactions); (2) acquisitions of partial ownership shares in strategic assets that can raise competitive concerns due to common and cross-ownership issues; and (3) strategic acquisitions. AAI explains that, through serial transactions, a utility may enhance its ability and incentive to engage in unilateral economic withholding of physical capacity or to strategically operate its transmission or fuel transportation assets to frustrate rivals' access to or foreclose them from wholesale markets.[15] In addition, AAI states that cross-ownership can facilitate the anticompetitive exchange of information and common ownership can dampen incentives to compete because more vigorous competition is less profitable than ''cooperation'' for investors with partial shares in each of those rivals. AAI explains that, for example, private equity firms, which are numerous and active in electricity markets, can control or influence managerial decision-making even with a partial or minority ownership share in an asset, and such influence may be obtained with an investment of less than $10 million.[16] Further, AAI states that, because electricity markets are susceptible to the exercise of market power due to the inelasticity of demand and supply during times when capacity is constrained. AAI also states that even small, strategic acquisitions can incentivize capacity withholding.[17]

14. AAI therefore recommends that the notification filing include: (1) The wholesale markets in which the jurisdictional facilities associated with or affected by the transaction participate; (2) a current, 10-year history of ownership changes involving the jurisdictional facilities associated with the transaction; and (3) the identity of all energy affiliates and energy subsidiaries owned by the acquirer of the jurisdictional facilities that are the subject of the transaction. AAI also encourages the Commission to undertake a technical conference to review how the Commission will analyze these transactions to monitor market changes, given that the Commission is required to submit a report to Congress within two years regarding the effects of amended section 203(a)(1)(B).[18]

15. APPA, NRECA, and TAPS also request that the notification filing include a requirement to identify energy affiliates and energy subsidiaries and to include pre- and post-transaction organizational charts.[19] APPA explains that the affiliate information is important because it will allow the Commission and other stakeholders to monitor whether a market participant is engaged in multiple accretive transactions valued at less than $10 million, which APPA notes was a concern of the Commission in a 2016 notice of inquiry on requirements for section 203 transactions and section 205 market-based rate applications.[20] NRECA and TAPS explain that the information will be useful because ownership structures and affiliate relationships are growing more complex.[21] APPA states that the affiliate information and organizational charts will result in only an incremental burden to paperwork, but that the

[6] NOPR, 165 FERC ¶ 61,091 at P 4.

[7] *Id.* P 5.

[8] *Id.* P 8.

[9] Idaho Power, EEI, APPA, ITC, and NRECA support the proposed notification filing.

[10] NRECA Comments at 4.

[11] EEI Comments at 7.

[12] Idaho Power Comments at 2.

[13] *See* EEI Comments at 7–8; ITC Comments at 3–4. Rule 2010 requires, among other things, that participants in a proceeding must serve copies of their documents according to specified guidelines. 18 CFR 385.2010.

[14] Public Citizen, Inc. Comments at 1–2.

[15] AAI Comments at 3–4.

[16] *Id.* at 5–7.

[17] *Id.* at 7–8.

[18] *Id.* at 9.

[19] *See* APPA Comments at 3–4; NRECA Comments at 5–6; TAPS Comments at 4.

[20] APPA Comments at 4–5 (citing *Modifications to Commission Requirements for Review of Transactions under Section 203 of the Federal Power Act and Market-Based Rate Applications under Section 205 of the Federal Power Act,* Notice of Inquiry, 81 FR 66649 (Sept. 28, 2016), 156 FERC ¶ 61,214 (2016) (Market Power NOI)).

[21] *See* NRECA Comments at 5–6; TAPS Comments at 5.

information will be useful to include in the Commission's report to Congress.[22] NRECA also requests that the Commission require information on the wholesale and transmission tariffs on file with the Commission that are related to the jurisdictional facilities involved in the transaction, which it claims will be useful to monitor the rates associated with those facilities.[23] TAPS maintains that the proposed notification filing includes little information compared to full section 203 applications and, because Congress required these filings, the information the Commission receives must be sufficient for consumer protection purposes and to produce a meaningful report for Congress.[24]

3. Commission Determination

16. We will add § 33.12 to the Commission's regulations as proposed in the NOPR to require that public utilities submit a notification filing for transactions subject to section 203(a)(7). In response to the comments, we first clarify filing requirements associated with the notification filings. Each notification filing should be filed in the first docket for section 203 filings of the FY. For example, all notification filings made in FY2019 would be filed in the Docket No. EC19–1–000; all notification filings for FY2020 would be filed in Docket No. EC20–1–000, etc. The notification filings may be filed in any format accepted in eLibrary as listed on the Commission's website.[25] In addition, we clarify that the notification filings are intended to be informational. The Commission will not notice the notification filings submitted into the placeholder docket (*i.e.,* Docket No. EC19–1–000, etc.) and will not accept responsive comments from any persons on the notification filings. The Commission will not act on the notification filings that it receives. Because the notification filings are informational in nature, there is no requirement to serve copies of the notification filings under Rule 2010 of the Commission's Rules of Practice and Procedure.

17. With one exception, we decline to require additional information as requested by certain commenters. Section 203(a)(7) provides the Commission with limited authority to collect information in the notification filings about transactions for which prior Commission authorization under section 203(a)(1) is no longer required. Because the Commission has limited authority to review these transactions under section 203, we will not hold a technical conference on how the Commission will analyze these transactions. Interested persons may track these transactions as they are filed in the placeholder dockets described above which provide a readily searchable format for doing so.

18. However, AAI, APPA, NRECA, and TAPS raise a compelling argument regarding the transparency of information as to energy affiliates. Therefore, in addition to the information that the NOPR proposed to be collected, we will require notification filings to contain a statement regarding whether the parties to the transaction are affiliates. This will allow additional transparency as to whether these transactions are negotiated at arm's length and whether these transactions could have an effect on a public utility's rates. We will add a requirement for such a statement in the description of the transaction in § 33.12(b)(2)(i).

19. As to the Commission's report to Congress that assesses the effects of amended section 203(a)(1)(B), the Commission will provide for public notice and comments on the report prior to submitting it to Congress.

C. Clarification on Jurisdiction of the Commission Under Section 203(a)(1)(B)

1. NOPR

20. In the NOPR, the Commission clarified that, except for mergers or consolidations that are valued at $10 million or less, the Commission will not change its interpretation of the transactions that are subject to the jurisdiction of the Commission under the ''merge or consolidate'' clause of section 203(a)(1)(B). The Commission further explained that it interprets the amendment by Congress to section 203(a)(1)(B) as establishing a $10 million threshold, but not removing the Commission's jurisdiction to review transactions with a higher value that involve a public utility's acquisition of facilities from non-public utilities[26] if those facilities will be subject to the Commission's jurisdiction after the transaction is consummated.[27]

2. Comments

21. Two commenters, EEI and ITC, take issue with the Commission's clarification on its jurisdiction. Specifically, EEI claims that the amended language of section 203(a)(1)(B) states that Commission approval is required only if the facilities being acquired by the public utility are subject to the Commission's jurisdiction, which is ''plainly read to mean that the facilities are jurisdictional before consummation of the proposed transaction.''[28] EEI states that the Commission should recognize that, as amended, the language of section 203(a)(1)(B) has materially changed from the language that preceded the amendment. As a result, EEI explains that the *Duke Power Co.* v. *FPC* case cited by the Commission does not squarely address the question raised by the amendment. EEI requests that, for regulatory certainty, the Commission reconsider and clarify its interpretation of the types of facilities to which amended section 203(a)(1)(B) will apply.[29]

22. Similarly, ITC argues that the plain language of amended section 203(a)(1)(B) does not grant the Commission authority to review transactions that involve a public utility's acquisition of facilities from non-public utilities. ITC asserts that, under amended section 203(a)(1)(B), a public utility must obtain Commission authorization only when proposing to merge or consolidate its own Commission-jurisdictional facilities with another person's Commission-jurisdictional facilities. ITC contends that if the facilities would be Commission-jurisdictional if owned by a jurisdictional entity, or will become so after the transaction is approved by the Commission and consummated, is immaterial because the statutory language requires that the facilities ''are'' within the jurisdiction of the Commission, not that they will be at some future time.[30] ITC also maintains that the Commission's reliance on *Duke Power Co.* is unavailing because the case involved the interpretation of older, no-longer effective section 203(a)(1)(B) language, which conferred upon the Commission authority to review a public utility's proposed merger or consolidation of its own facilities with the facilities of ''any other person.''[31] In addition, ITC claims that the court's observation about the Commission's

[22] APPA Comments at 5–6.

[23] NRECA Comments at 6–7.

[24] TAPS Comments at 4.

[25] FERC, *Acceptable File Formats, http://www.ferc.gov/docs-filing/elibrary/accept-file-formats.asp* (last updated Nov. 16, 2015).

[26] Non-public utilities refers to entities described in section 201(f) of the FPA. 16 U.S.C. 824(f).

[27] *See Duke Power Co.* v. *FPC,* 401 F.2d 930, 941 (DC Cir. 1968) (*Duke Power Co.*) (''We have no doubt that any acquisition from [a non-public utility] by a public utility of what would normally be a jurisdictional facility, such as a transmission line conducting interstate energy, would fall within the purview of the clause under consideration.'').

[28] EEI Comments at 9.

[29] *Id.* at 8–9.

[30] ITC Comments at 2–3.

[31] *Id.* at 3 (citing *Duke Power Co.*, 401 F.2d at 933).

jurisdiction in that case is dicta because the case concerned whether a public utility's acquisition of unambiguously non-jurisdictional distribution assets was within section 203(a)(1)(B)'s ambit.[32]

3. Commission Determination

23. We disagree with EEI's and ITC's interpretation of the language of amended section 203(a)(1)(B). Rather, we interpret the new statutory language as codifying the D.C. Circuit's holding in *Duke Power Co.* that the Commission has no jurisdiction over the acquisition of distribution or other facilities that are non-jurisdictional even when owned by a public utility. In amended section 203(a)(1)(B), the phrase ''subject to the jurisdiction of the Commission'' was used twice.[33] First, the phrase was used to describe the facilities of a ''public utility'' that must be involved in a transaction in order for the Commission to have jurisdiction. By adding ''subject to the jurisdiction of the Commission'' to describe the facilities of a ''public utility,'' we conclude that Congress intended to exclude facilities, such as distribution facilities, that are not otherwise subject to the jurisdiction of the Commission when owned by a public utility. When Congress again uses the phrase ''subject to the jurisdiction of the Commission'' to modify the facilities of a ''person,'' we interpret the phrase as having the same meaning, rather than removing the Commission's jurisdiction over a public utility's acquisition of transmission facilities previously owned by a non-public utility.

24. That Congress did not intend to limit the Commission's jurisdiction to the acquisition of transmission facilities subject to the Commission's jurisdiction prior to the transaction is further supported by the fact that Congress retained the language requiring that the facilities being acquired be owned by a ''person,'' instead of changing the language to require that the facilities be owned by a ''public utility.'' Under section 201(e), a ''public utility'' is ''any person who owns or operates facilities subject to the jurisdiction of the Commission under this part,''[34] which means that, if facilities being acquired are subject to the Commission's jurisdiction prior to the transaction, their owner by definition is a public utility. The use of the word ''person,'' and not ''public utility,'' when describing the facilities to be acquired suggests that Congress intended the Commission to have jurisdiction over the acquisition of facilities owned both by public utilities and non-public utilities, provided that those facilities are subject to the Commission's jurisdiction after their acquisition by the public utility.

25. Our interpretation is reinforced by the legislative history of the Act, which indicates that Congress intended amended section 203(a)(1)(B) only to establish a $10 million threshold for transactions subject to the Commission's jurisdiction and not to alter any other aspect of the Commission's jurisdiction over transactions. The House Report described the purpose of the amendment as ''amend[ing] the Federal Power Act to exempt facilities of a value of $10,000,000 or less from this prohibition.''[35] The Senate Report similarly describes the purpose of the amendment as to: ''reduce the compliance burden of certain transactions valued under $10 million, including significant legal and regulatory costs which are collected from customers.''[36] Notably, as part of its background discussion, the Senate Report also includes a discussion of the *Duke Power Co.* decision and its holding regarding the Commission's jurisdiction to approve transactions, but that report does not assert that the decision was erroneous or otherwise suggest that the amendment was intended to reverse the Commission's longstanding reliance on *Duke Power Co.* to assert jurisdiction over a public utility's acquisition of transmission facilities from a non-public utility.[37] That neither the House Report nor the Senate Report suggests that the amendment was intended to remove the Commission's jurisdiction over the acquisition of facilities from non-public utilities also supports the conclusion that the amendment should not be read to have such an effect.

D. Other Pending Proceedings

1. Comments

26. AAI requests that the Commission carefully consider whether the revised regulations for small transactions will have an effect on the questions posed in outstanding rulemakings. AAI argues, among other things, that if small transactions are excluded from Commission review under section 203(a)(1)(B), the Commission should maintain close oversight over the workings of regional transmission organization markets and not relieve sellers with market-based rate authority from filing a competitive analysis with the Commission, as was proposed in the Notice of Proposed Rulemaking in *Refinements to Horizontal Market Power Analysis for Sellers in Certain Regional Transmission Organization and Independent System Operator Markets.*[38] AAI further notes that the Commission has not acted on two critical rulemakings and requests that the Commission make these a high priority: *Data Collection for Analytics and Surveillance and Market-Based Rate Purposes* in Docket No. RM16–17–000 (Data Collection NOPR)[39] and *Modifications to Commission Requirements for Review of Transactions under Section 203 of the Federal Power Act and Market-Based Rate Applications under Section 205 of the Federal Power Act* in RM16–21–000.[40]

27. APPA and TAPS request that, if the Commission does not expand the information to be collected in the notification filing, it should act on the Data Collection NOPR and proceed with the relational database proposed therein.[41]

2. Commission Determination

28. We acknowledge commenters' support and requests for action on other pending rulemaking proceedings. However, we emphasize that this proceeding is limited in scope and only implements the changes specified in amended section 203. We will not address the status of other proceedings here. In addition, as explained above, we find that the information we will collect under § 33.12 is sufficient to satisfy the directive in the Act that the Commission establish a notification requirement.

III. Information Collection Statement

29. The Paperwork Reduction Act (PRA)[42] requires each federal agency to

[32] *Id.*

[33] Amended section 203(a)(1)(B) provides that no public utility shall, without first having secured an order of the Commission authorizing it to do so, ''merge or consolidate, directly or indirectly, its facilities *subject to the jurisdiction of the Commission,* or any part thereof, with the facilities of any other person, or any part thereof, that are *subject to the jurisdiction of the Commission* and have a value in excess of $10 million, by any means whatsoever.'' 16 U.S.C. 824b(a)(1)(B), *amended by* ''An Act to amend section 203 of the Federal Power Act,'' Public Law 115–247, 132 Stat. 3152 (2018) (emphasis added).

[34] 16 U.S.C. 824(e).

[35] H.R. Rep. No. 115–167, at 1 (2018).

[36] S. Rep. No. 115–253, at 2 (2018).

[37] *Id.* at 3.

[38] AAI Comments at 9–10 (citing *Refinements to Horizontal Market Power Analysis for Sellers in Certain Regional Transmission Organization and Independent System Operator Markets,* Notice of Proposed Rulemaking, 165 FERC ¶ 61,268 (2018)).

[39] *Id.* at 10.

[40] *Id.* (citing Market Power NOI, 81 FR 66649, 156 FERC ¶ 61,214).

[41] *See* APPA Comments at 6–7; TAPS Comments at 5–6.

[42] 44 U.S.C. 3501–3520.

seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to 10 or more persons or contained in a rule of general applicability. OMB's regulations [43] require approval of certain information collection requirements imposed by agency rules. Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of an agency rule will not be penalized for failing to respond to the collection of information unless the collection of information displays a valid OMB control number.

30. The revisions to the Commission's regulations required in this final rule will bring the regulations in conformance with the amendments to section 203 enacted by Congress. The first revision would implement Congress' amendment to section 203(a)(1)(B), which provides that a public utility must seek authorization to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever. In addition, this final rule adds § 33.12 to the Commission's regulations to implement the directive in new section 203(a)(7) that the Commission require a notification filing for mergers or consolidations by a public utility if the facilities to be acquired have a value in excess of $1 million and such public utility is not required to secure Commission authorization under amended section 203(a)(1)(B). We anticipate that the revisions to the Commission's regulations, once effective, would reduce regulatory burdens. The Commission will submit the proposed reporting requirements to OMB for its review and approval under section 3507(d) of the PRA.[44]

31. In the NOPR, the Commission solicited comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques. Nonetheless, while we expect that the regulatory revisions discussed herein will reduce the burdens on affected entities, we solicit public comment regarding the accuracy of the burden and cost estimates below.

32. *Internal Review:* The Commission has reviewed the changes and has determined that such changes are necessary.

33. *Burden Estimate* [45]: The estimated burden and cost for the requirements contained in this final rule follow.

FERC–519, AS MODIFIED BY THIS FINAL RULE IN DOCKET NO. RM19–4–000

Requirements	Number and type of respondents (1)	Number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours & cost per response (4)	Total burden hours & total cost (3) * (4)
FERC–519 (FPA Section 203 Filings) [46].	26	1	26	1 hr.; $79.00	26 hrs.; $2,054.00.

Title: FERC–519, Application under Federal Power Act Section 203.

OMB Control No.: 1902–0082.

Action: Amendment to 18 CFR part 33.

Respondents: Public utilities subject to Federal Power Act.

Abstract: Pursuant to ''An Act to amend section 203 of the Federal Power Act'', the Commission will revise part 33 of its regulations to establish that mergers or consolidations by a public utility of facilities subject to the jurisdiction of the Commission that have a value in excess of $10 million are subject to Commission authorization. In addition, the Commission will add § 33.12 to its regulations to establish a notification requirement for mergers or consolidations by a public utility if the facilities to be acquired have a value in excess of $1 million and such public utility is not required to secure Commission authorization under amended section 203(a)(1)(B).

Overview of the Data Collection: The FERC–519, ''Application under Federal Power Act section 203,'' is necessary to enable the Commission to carry out its responsibilities in implementing the statutory provisions of section 203. Section 203 requires a public utility to seek Commission authorization of transactions in which a public utility disposes of jurisdictional facilities, merges such facilities with the facilities owned by another person, or acquires the securities of another public utility. The Commission must authorize these transactions if it finds that they will be consistent with the public interest.

34. By entering into a certain transaction, a public utility may gain an increased incentive and ability to exercise market power that can be to the detriment of effective competition and customers. As a result, the Commission must review all jurisdictional dispositions, mergers, and acquisitions to evaluate that transaction's effect on competition. The Commission also evaluates whether such transactions have an effect on rates and regulation and whether they result in cross-subsidization. The Commission implements the filing requirements associated with this review in the *Code of Federal Regulations* (CFR) under 18 CFR part 33.

35. This final rule is limited to implementing amended FPA section 203(a)(1)(B) and proposing a notification requirement for certain transactions, both of which together represent a reduction in the filing requirements for public utilities under section 203. The Commission implements these changes by mandate of Congress.

[43] 5 CFR part 1320.

[44] 44 U.S.C. 3507(d).

[45] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[46] Commission staff estimates that approximately 26 section 203 filings will change from full section 203 filings to the notification filing described above and will take respondents one burden hour to complete. The number of respondents and responses is based on Commission staff's estimate that 13 percent of the approximately 200 section 203 filings received will be affected by the changes herein, which represents a significant reduction in burden hours.

36. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director] Email: *DataClearance@ferc.gov,* Phone: (202) 502–8663; fax: (202) 273–0873.

37. Comments concerning the collection of information and the associated burden estimate(s) may also be sent to: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. Due to security concerns, comments should be sent electronically to the following email address: *oira_submission@omb.eop.gov.* Please refer to FERC–519, OMB Control No. 1902–0082 in your submission.

IV. Environmental Analysis

38. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[47] We conclude that neither an Environmental Assessment nor an Environmental Impact Statement is required for this final rule under § 380.4(a) of the Commission's regulations, which provides a categorical exemption for ''approval of actions under section[] . . . 203 . . . of the Federal Power Act relating to . . . acquisition or disposition of property . . . .''[48]

V. Regulatory Flexibility Act

39. The Regulatory Flexibility Act of 1980 (RFA)[49] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small entity. These standards are provided in the SBA regulations at 13 CFR 121.201.[50] The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected.

40. The SBA size standards for electric utilities is based on the number of employees, including affiliates. Under SBA's standards, some transmission owners will fall under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.[51]

41. The Commission estimates that 26 respondents could file notification filings over the course of a year, with an estimated burden of 1 hour per response, at an estimated cost of $79.00 per respondent. The Commission believes that none of the filers will be small entities. Therefore, the Commission certifies that this final rule will not have a significant economic impact on small entities.

VI. Document Availability

42. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington DC 20426.

43. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

44. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

45. These regulations are effective March 27, 2019. The Commission has determined that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

[47] *Regulations Implementing the National Environmental Policy Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

[48] 18 CFR 380.4(a)(16).

[49] 5 U.S.C. 601–612.

[50] 13 CFR 121.201. *See also* U.S. Small Business Administration, *Table of Small Business Size Standards Matched to North American Industry Classification System Codes* (effective Feb. 26, 2016), *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

[51] 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control).

List of Subjects in 18 CFR Part 33

Electric utilities, Reporting and recordkeeping requirements, Securities.

By the Commission.

Issued: February 21, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission amends part 33, chapter I, title 18, *Code of Federal Regulations,* as follows:

PART 33—APPLICATIONS UNDER FEDERAL POWER ACT SECTION 203

■ 1. The authority citation for part 33 continues to read as follows:

Authority: 16 U.S.C. 791a-825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Amend § 33.1 by revising paragraph (a)(1)(ii) to read as follows:

§ 33.1 Applicability, definitions, and blanket authorizations.

(a) * * *

(1) * * *

(ii) Merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever;

* * * * *

■ 3. Add § 33.12 to read as follows:

§ 33.12 Notification requirement for certain transactions.

(a) Any public utility that is seeking to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with those of any other person, shall notify the Commission of such transaction not later than 30 days after the date on which the transaction is consummated if:

(1) The facilities, or any part thereof, to be acquired are of a value in excess of $1 million; and

(2) Such public utility is not required to secure an order of the Commission under section 203(a)(1)(B) of the Federal Power Act.

(b) Such notification shall consist of the following information:

(1) The exact name of the public utility and its principal business address; and

(2) A narrative description of the transaction, including:

(i) The identity of all parties involved in the transaction, whether such parties are affiliates, and all jurisdictional facilities associated with or affected by the transaction;

(ii) The location of such jurisdictional facilities involved in the transaction;

(iii) The date on which the transaction was consummated;

(iv) The consideration for the transaction; and

(v) The effect of the transaction on the ownership and control of such jurisdictional facilities.

[FR Doc. 2019–03326 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9848]

RIN 1545–BL39

Amendments to the Low-Income Housing Credit Compliance-Monitoring Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that amend the compliance monitoring regulations concerning the low-income housing credit under section 42 of the Internal Revenue Code (Code). These final regulations revise and clarify the requirement to conduct physical inspections and review low-income certifications and other documentation. The final regulations will affect owners of low-income housing projects that claim the credit, the tenants in those low-income housing projects, and the State and local housing credit agencies that administer the credit.

DATES: *Effective date:* These regulations are effective on February 26, 2019.

Applicability Dates: For dates of applicability see § 1.42–5(h)(2).

FOR FURTHER INFORMATION CONTACT: Barbara Campbell or YoungNa Lee, (202) 317–4137 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends 26 CFR part 1 to finalize rules relating to section 42 of the Code. On February 25, 2016, the Department of the Treasury (Treasury Department) and the IRS published temporary regulations (T.D. 9753) in the **Federal Register** (81 FR 9333), which amended § 1.42–5 of the Income Tax Regulations.

Section 42(m)(1) provides that the owners of an otherwise-qualifying building are not entitled to the housing credit dollar amount that is allocated to the building unless, among other requirements, the allocation is pursuant to a qualified allocation plan (QAP). A QAP provides standards by which a State or local housing credit agency or its Authorized Delegate within the meaning of § 1.42–5(f)(1) (Agency) is to make these allocations. A QAP also provides a procedure that an Agency must follow in monitoring for compliance with the provisions of section 42. A plan fails to be a QAP unless, in addition to other requirements, it provides a procedure that the agency (or an agent or other private contractor of such agency) will follow in monitoring for noncompliance with the provisions of section 42 and in notifying the Internal Revenue Service of such noncompliance which such agency becomes aware of and in monitoring for noncompliance with habitability standards through regular site visits. (Section 42(m)(1)(B)(iii)).

Section 1.42–5 (the compliance-monitoring regulations) describes some of the provisions that must be part of any QAP. As part of its compliance-monitoring responsibilities, an Agency must perform physical inspections and low-income certification review.

The compliance-monitoring regulations specifically provide that, for each low-income housing project, an Agency must conduct on-site inspections of all buildings within its jurisdiction by the end of the second calendar year following the year the last building in the project is placed in service (the all-buildings requirement). Prior to the issuance of the temporary regulations, the regulations also provided that, for at least 20 percent of the project's low-income units (the 20-percent rule), the Agency must both inspect the units and review the low-income certifications, the documentation supporting the certifications, and the rent records for the tenants in those same units (the same-units requirement).

Under the temporary regulations, guidance published in the Internal Revenue Bulletin may provide exceptions from, or alternative means of satisfying, the inspection provisions of § 1.42–5(d). Rev. Proc. 2016–15 (2016–11 I.R.B. 435) was published concurrently with the temporary regulations and provides that the U.S. Housing and Urban Development (HUD) Real Estate Assessment Center Protocol (the REAC protocol) satisfies both § 1.42–5(d) and the physical inspection requirements of § 1.42–5T(c)(2)(ii) and (iii). The revenue procedure provides that, in a low-income housing project, the minimum number of low-income units that must undergo physical inspection is the lesser of 20 percent of the low-income units in the project, rounded up to the nearest whole number of units, or the number of low-income units set forth in the Low-Income Housing Credit Minimum Unit Sample Size Reference Chart in the revenue procedure (the REAC numbers). The revenue procedure also applies the same rule to determine the minimum number of units that must undergo low-income certification review.

The temporary regulations also required that Agencies continue to comply with the all-buildings requirement unless guidance published in the Internal Revenue Bulletin pursuant to § 1.42–5T(a)(iii) provides otherwise. Rev. Proc. 2016–15 provides for such an exception. Under Rev. Proc. 2016–15, the all-buildings requirement does not apply to an Agency that uses the REAC protocol to satisfy the physical inspection requirement, because the Treasury Department and the IRS have determined that the REAC protocol is an acceptable method for satisfying both § 1.42–5(d) and the physical inspection requirement of § 1.42–5T(c)(2)(ii) and (iii).

Finally, the temporary regulations decoupled the physical inspection and low-income certification review and ended the same-units requirement. Accordingly, an Agency is no longer required to conduct a physical inspection and low-income certification review of the same unit. Because the units no longer needed to be the same, an Agency may choose a different number of units for physical inspection and for low-income certification review provided the Agency chooses at least the minimum number of low-income units. Further, an Agency may choose to conduct a physical inspection and low-income certification review at different times.

On the same day the temporary regulations were published, the Treasury Department and the IRS also published a notice of proposed rulemaking (REG–150349–12, 81 FR 9379) (the proposed regulations). The text of the proposed regulations incorporated by cross-reference the text of the temporary regulations. The Treasury Department and the IRS received written comments on the proposed regulations. No requests for a public hearing were made, and no public hearing was held.

The Treasury Department and the IRS considered the written comments in light of the questions presented in the preamble of the temporary regulations. The Treasury Department and the IRS

resolved those comments and questions concerning the temporary regulations and the interim guidance as discussed in this preamble and incorporated in this Treasury Decision.

Summary of Comments and Explanation of Provisions

I. Whether the REAC Numbers Should Replace the 20-Percent Rule for Physical Inspection and Low-Income Certification Review

Historically, the Treasury Department and the IRS have not required an Agency physically to inspect every low-income residential unit in a low-income project. Instead, if physical inspection of a representative random sample of units yielded satisfactory results, the Agency was permitted to infer that the uninspected units were similar. In such an exercise, a critical question is how large a sample is needed to support confidence in that inference. Decades ago, the Treasury Department and the IRS determined that a sample was adequate if it included at least 20 percent of a project's low-income units, regardless of the total number of low-income units in the project. (T.D. 8430, 57 FR 40121, September 2, 1992).

The REAC protocol requires sample sizes that differ from those that the Treasury Department and the IRS had required. In developing that protocol, HUD sought to determine sample sizes that would yield equally reliable inferences regardless of the size of the number of residential units in a project. HUD's statistical analysis produced minimum sample sizes that are much lower than 20 percent of large projects' units but somewhat higher than 20 percent of total units for small projects. The implication of the HUD conclusions was that the tax regulations' 20 percent requirement for low-income housing credit inspections may have been unnecessarily burdensome for large projects and may have failed adequately to assess habitability in smaller ones.

In the temporary regulations the Treasury Department and the IRS responded to that implication with a two-step process—minimum sample size was reduced for large projects, and taxpayers were asked whether analogous statistical considerations should be applied to increase minimum sample sizes for small ones.

First, under the temporary regulations, the 20-percent rule and the REAC numbers (if an Agency is using the REAC protocol) are used by an Agency for purposes of conducting physical inspections and the low-income certification reviews. Rev. Proc. 2016–15 provides that an Agency must conduct on-site inspections and low-income certification review of the lesser of—

(1) 20 percent of the low-income units in the low-income housing project, rounded up to the nearest whole number of units, or

(2) The Minimum Unit Sample Size set forth in the Low-Income Housing Credit Minimum Unit Sample Size Reference Chart. (The numbers in the chart come from the REAC protocol.)

Second, in the preamble to T.D. 9753, the Treasury Department and the IRS expressed concern about application of the 20-percent rule for projects with a relatively small number of low-income units. The concern is that, in smaller projects, physical inspections and the low-income certification review of 20 percent of units (even a representative random sample) may not produce a sufficiently accurate estimate of the uninspected units' overall compliance with habitability and low-income requirements. The preamble further states that the Treasury Department and the IRS intend to consider replacing Rev. Proc. 2016–15 with a requirement that does not permit use of the 20-percent rule for projects with a relatively small number of low-income units. Comments were requested.

One commenter responded that it was not concerned about ending the 20-percent rule for projects with a relatively small number of low-income units, because it is among those Agencies whose State or local rules require them to inspect a minimum number of units that exceeds the minimum numbers in Rev. Proc. 2016–15.

These final regulations remove the rule that allows minimum sample size to be the lesser of 20-percent of the total number of low-income units or the minimum unit sample size set forth in the Low-Income Housing Credit Minimum Unit Sample Size Reference Chart. Instead, under these final regulations, Agencies must inspect no fewer units than the number specified for projects of the relevant size as set forth in the Low-Income Housing Credit Minimum Unit Sample Size Reference Chart. The Treasury Department and the IRS have determined that the REAC numbers produce a statistically valid sampling of units, which establishes confidence in the compliance monitoring results for projects of varying size. The Treasury Department and the IRS have further determined that the REAC numbers reasonably balance burden on Agencies, tenants, and building owners with the need to adequately monitor habitability and compliance with the low-income housing credit income and gross-rent restrictions. Agencies, however, continue to have discretion to inspect and review more units as they see fit.

II. Whether the Final Regulations Should Retain the All-Buildings Requirement

The temporary regulations (§ 1.42–5T(c)(2)(iii)(A)(1) and (2)) require that an Agency physically inspect all buildings in a low-income housing project by the end of the second calendar year following the year the last building in the low-income housing project is placed in service and at least once every 3 years thereafter. However, Rev. Proc. 2016–15 excepts from this all-buildings requirement a project inspection conducted under the REAC protocol. The exception was specifically carved out based on confidence in, and deference to, an inspection done under HUD oversight.

Two commenters recommended that the final regulations also dispense with the all-buildings requirement for Agencies not using the REAC protocol. The final regulations do not adopt this recommendation. The REAC protocol requires that inspectors be specially trained in its use. When an Agency is not using that protocol, it may choose inspectors of diverse expertise to conduct inspections. The quality of these inspections may vary across projects and jurisdictions.

Under the all-buildings rule, if the randomly selected minimum number of low-income units to be inspected fails to include at least one unit in one or more buildings in a project, then an Agency may satisfy the requirement by inspecting some aspect of each omitted building. These aspects might include the building exterior, common area, HVAC system, etc. In the absence of HUD oversight, requiring that all-buildings be inspected serves as a quality control mechanism.

III. Whether the Final Regulations Should Shorten the Reasonable-Notice Time Frame

The temporary regulations require an Agency to select low-income units to inspect and low-income certifications to review in a manner that will not give advance notice that a particular low-income unit (or low-income certifications for a particular low-income unit) will or will not be inspected (or reviewed) for a particular year. The temporary regulations allow an Agency to give an owner reasonable notice that an inspection of the building and low-income units or review of low-income certifications will occur, whether or not an Agency is selecting

the same units for inspection and for low-income certification review. The temporary regulations provide that reasonable notice is generally no more than 30 days, but they also provide a very limited extension for certain extraordinary circumstances beyond an Agency's control such as natural disasters and severe weather conditions.

The Treasury Department and the IRS requested comments on whether the same maximum amount of notice is reasonable for physical inspections as for low-income certification review. Additionally, the Treasury Department and the IRS requested comments on whether, for physical inspections, the reasonable-notice time frame should be shortened. For example, under the REAC protocol, an inspector provides a 15-day notice of an upcoming HUD inspection of a project but same-day identification of the units to be inspected. No comments were received.

These final regulations shorten the reasonable notice requirement to a 15-day notice that a project will experience an upcoming physical inspection or review of low-income certification. The Treasury Department and Internal Revenue Service believe that the 15-day notice period gives building owners reasonable notice that a review of low-income certifications will occur and gives building owners and tenants reasonable notice that a project will be inspected and that low-income units will be inspected if they are in the random sample that will later be selected.

The statistical validity of inspecting only a sample of the low-income units in a project depends on the sample being random and representative. Thus, the validity would be destroyed if a project owner had an opportunity to selectively prepare the units in the sample for inspection. Consistent with preserving the validity of the inspection process, an Agency must select the low-income units to inspect in a manner that will not give advance notice that a particular low-income unit will or will not be inspected. Accordingly, the final regulations clarify that an Agency may notify the owner of the particular low-income units for inspection only on the day of inspection. The Treasury Department and IRS note that, under the REAC protocol, HUD or HUD-Certified REAC inspectors randomly select low-income units for inspection on the day of inspection.

IV. Whether the Final Regulations Should Allow an Agency To Treat a Scattered Site or Multiple Buildings With a Common Owner and Plan of Financing as One Low-Income Housing Project Absent a Multiple-Building Election Under Section 42(g)(3)(D)

Section 42(c)(2)(A) defines ''qualified low-income building'' as any building that is part of a qualified low-income housing project at all times throughout the compliance period. Section 42(g)(1) defines ''qualified low-income housing project'' as any project for residential rental property if the project meets the requirements of section 42(g)(1)(A), (B), or (C), whichever is elected by the taxpayer. Section 42(g)(7) provides for a scattered site project. Under that provision, buildings that would (but for their lack of proximity) be treated as a project shall be so treated if all of the dwelling units in each of the buildings are rent-restricted residential rental units. Section 42(g)(3)(D) provides that a project contains only one building unless, prior to the end of the first calendar year in the project period (as defined in section 42(h)(1)(F)(ii)), each building to comprise the project is identified in the form and the manner that the Secretary provides. Taxpayers make the multiple-building election on Form 8609 and by attaching a statement identifying each of the buildings in a project subject to the election.

Two commenters recommended that, for purposes of compliance monitoring (including determining how many units to inspect), the final regulations provide special treatment to a scattered site or multiple buildings with a common owner and plan of financing. The recommendation was that compliance monitoring be conducted as if the multiple buildings were part of a single project, even if the owner had not made a multiple-building election under section 42(g)(3)(D). If the low-income units in all of the buildings were treated as potentially representative of each other (as would be the case if the buildings were part of a single project), the size of the sample to be inspected would be lower than the aggregate number of units to be inspected if the buildings are considered separately. Because of this separate treatment, according to these commenters, the process of inspecting a number of small, single-building projects (for example, single family, duplex, or triplex buildings) located throughout a relatively large (possibly rural) geographic area is unnecessarily burdensome. In particular, separate treatment requires at least one unit of each of the building to be inspected. The Treasury Department and the IRS note that the multiple-building election is a statutory requirement. Other than treating these buildings as if such an election had been made, commenters did not suggest criteria according to which units in buildings in different projects could be treated as statistically representative of each other. For that reason, the Treasury Department and the IRS are not adopting this recommendation in the final regulations.

V. Certification and Review Provisions Under § 1.42–5(c)

One commenter recommended that the regulations clarify that for properties consisting of two or more separate projects, monitoring Agencies may accept one certification form as long as it contains an attachment that identifies all of the projects for which the certification is being made. The Treasury Department and the IRS decline to adopt the comment, because it is beyond the scope of the proposed regulations.

Effect on Other Documents

The temporary regulations authorize the IRS to provide in guidance published in the Internal Revenue Bulletin exceptions from, or alternative means of satisfying, the inspection provisions of § 1.42–5(d). Rev. Proc. 2016–15 was published concurrently with the temporary regulations and provides that the HUD REAC protocol satisfies both § 1.42–5(d) and the physical inspection requirements of the temporary regulations. These final regulations contain the guidance that Agencies need and do not rely on the IRS to provide in the Internal Revenue Bulletin exceptions from, or alternative means of satisfying the inspection provisions of § 1.42–5(d) or these final regulations. Accordingly, Rev. Proc. 2016–15 is obsolete with respect to an Agency as of the date on which the Agency's QAP is amended to reflect these final regulations. In all cases, however, Rev. Proc. 2016–15 is obsolete after December 31, 2020.

Applicability Date

The Department of Treasury and the IRS are aware that additional time may be needed for Agencies' QAPs to be amended. The final regulations allow Agencies a reasonable period of time to amend their QAPs, but QAPs must be amended no later than December 31, 2020.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive

Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations. Therefore, a regulatory impact assessment is not required. Because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses. No comments were received from the Small Business Administration.

Drafting Information

The principal authors of these regulations are Barbara Campbell and YoungNa Lee, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the entry for § 1.42–5T to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.42–0T [Amended]

■ **Par. 2.** Section 1.42–0T is amended by removing the entry for § 1.42–5T.

■ **Par. 3.** Section 1.42–5 is amended by:
■ 1. Removing paragraph (a)(2)(iii).
■ 2. Revising paragraphs (c)(2)(ii) and (iii).
■ 3. Revising paragraph (c)(3).
■ 4. Revising paragraph (h)(2).
■ 5. Removing paragraph (i).

The revisions and additions read as follows:

§ 1.42–5 Monitoring compliance with low-income housing credit requirements.

* * * * *

(c) * * *

(2) * * *

(ii) Require that, with respect to each low-income housing project, the Agency conduct on-site inspections and review low-income certifications (including in that term the documentation supporting the low-income certifications and the rent records for tenants).

(iii) Require that the on-site inspections that the Agency must conduct satisfy both the requirements of § 1.42–5(d) and the requirements in paragraph (c)(2)(iii)(A) through (D) of this section, and require that the low-income certification review that the Agency must perform satisfies the requirements in paragraphs (c)(2)(iii)(A) through (D) of this section. Paragraph (c)(2)(iii)(A) through (D) of this section provides rules determining how these on-site inspection requirements and how these low-income certification review requirements may be satisfied by an inspection or review, as the case may be, that includes only a sample of the low-income units.

(A) *Timing.* The Agency must conduct on-site inspections of all buildings in the low-income housing project and must review low-income certifications of the low-income housing project—

(*1*) By the end of the second calendar year following the year the last building in the low-income housing project is placed in service; and

(*2*) At least once every 3 years thereafter.

(B) *Number of low-income units.* The Agency must conduct on-site inspections and low-income certification review of not fewer than the minimum number of low-income units for the corresponding number of low-income units in the low-income housing project set forth in the table to paragraph (c)(2)(iii).

TABLE TO PARAGRAPH (c)(2)(iii)

Number of low-income units in the low-income housing project	Number of low-income units selected for inspection or for low-income certification review (minimum unit sample size)
1	1
2	2
3	3
4	4
5–6	5
7	6
8–9	7
10–11	8
12–13	9
14–16	10
17–18	11
19–21	12
22–25	13
26–29	14
30–34	15
35–40	16
41–47	17
48–56	18
57–67	19
68–81	20
82–101	21
102–130	22
131–175	23
176–257	24
258–449	25
450–1,461	26
1,462–9,999	27

(C) *Selection of low-income units for inspection and low-income certifications for review*—(*1*) *Random selection.* The Agency must select in a random manner the low-income units to be inspected and the units whose low-income certifications are to be reviewed. Agencies generally may not select the same low-income units of a low-income housing project for on-site inspections and low-income certification review, because doing so would usually give prohibited advance notice. See paragraph (c)(2)(iii)(C)(2) of this section. An Agency may choose a different number of units for on-site inspections and for low-income certification review, provided the Agency chooses at least the minimum number of low-income units in each case. The Agency must select the units for inspections or low-income certification review separately and in a random manner.

(*2*) *Advance notification limited to reasonable notice.* The Agency must select the low-income units to inspect and low-income certifications to review in a manner that does not give advance notice that a particular low-income unit (or low-income certifications for a particular low-income unit) will or will not be inspected (or reviewed) for a particular year. The Agency may notify the owner of the low-income units for on-site inspection only on the day of inspection. However, the Agency may give an owner reasonable notice that an inspection of the project and of not-yet-identified low-income units or review of low-income certifications will occur. The notice serves to enable the owner to assemble needed documentation for low-income certifications for review and to notify tenants of the possibility of physical inspection of their units.

(*3*) *Meaning of reasonable notice.* For purposes of paragraph (c)(2)(iii)(C)(*2*) of this section, reasonable notice is generally no more than 15 days. The notice period begins on the date the Agency informs the owner that an on-

site inspection of a project and low-income units or low-income certification review will occur. Notice of more than 15 days, however, may be reasonable in extraordinary circumstances that are beyond an Agency's control and that prevent an Agency from carrying out within 15 days an on-site inspection or low-income certification review. Extraordinary circumstances include, but are not limited to, natural disasters and severe weather conditions. In the event of extraordinary circumstances that result in a reasonable-notice period longer than 15 days, an Agency must select the relevant units and conduct the same-day on-site inspection or low-income certification review as soon as practicable.

(*4*) *Alternative means of conducting on-site inspections—Use of the REAC protocol.* An Agency may satisfy the requirements of paragraphs (c)(2)(ii) and (iii) of this section if the inspection is performed under the Department of Housing and Urban Development (HUD) Real Estate Assessment Center (REAC) protocol and the inspection satisfies the following requirements:

(*i*) Both vacant and occupied low-income units in a low-income housing project are included in the population of units from which units are selected for inspection;

(*ii*) The inspection complies with the procedural and substantive requirements of the REAC protocol, including the requirements of the most recent REAC Uniform Physical Condition Standards (UPCS) inspection software, or software accepted by HUD;

(*iii*) The inspection is performed by HUD or HUD-Certified REAC inspectors;

(*iv*) The inspection results are sent to HUD, the results are reviewed and scored within HUD's secure system without any involvement of the inspector who conducted the inspection, and HUD makes its inspection report available.

(*5*) *HUD Inspections that comply with the requirements of the REAC Protocol.* If, consistent with the requirements of paragraph (c)(2)(iii)(4) of this section, an Agency conducts on-site inspections under the REAC protocol, then—

(*i*) Paragraph (c)(2)(iii)(A) of this section is applied as if it did not contain the word ''all'';

(*ii*) The number of low-income units required to be inspected under the REAC protocol satisfies the requirements of paragraph (c)(2)(iii)(B) of this section concerning the number of low-income units an Agency must inspect; and

(*iii*) The manner in which the low-income units are selected for inspection under the REAC protocol satisfies the requirements of paragraph (c)(2)(iii)(C) of this section.

(*6*) *Income Certification Requirements for HUD Inspections that comply with the requirements of the REAC Protocol.* An agency that conducts on-site inspections under the REAC protocol is not excused from reviewing low-income certifications in accordance with paragraphs (c)(2)(ii) and (iii) of this section.

(*7*) *Applicability of reasonable notice limitation when the same units are chosen for inspection and file review.* If the Agency chooses to select the same units for on-site inspections and low-income certification review, the Agency must complete both the inspections and review before the end of the day on which the units are selected. See paragraph (c)(2)(iii)(C)(*1*) and (*2*) of this section.

(D) *Method of low-income certification review.* The Agency may review the low-income certifications wherever the owner maintains or stores the records (either on-site or off-site).

(3) *Frequency and form of certification.* A monitoring procedure must require that the certifications and reviews of § 1.42–5(c)(1) and (c)(2)(i) be made at least annually covering each year of the 15-year compliance period under section 42(i)(1). The certifications must be made under penalties of perjury. A monitoring procedure may require certifications and reviews more frequently than every 12 months, provided that all months within each 12-month period are subject to certification.

* * * * *

(h) * * *

(2) *Applicability dates.* The requirements in paragraphs (c)(2)(ii) and (iii) and (c)(3) of this section apply beginning on February 26, 2019. A state housing credit agency is allowed a reasonable period of time to amend its qualified allocation plan, but must amend its qualified allocation plan no later than December 31, 2020.

* * * * *

§ 1.42–5T [Removed]

■ **Par. 4.** Section 1.42–5T is removed.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: February 13, 2019.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2019–03388 Filed 2–22–19; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0084]

Safety Zone; Lower Mississippi River, Mile Markers 93 to 96 Above Head of Passes, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display located between mile marker (MM) 93 and MM 96, above Head of Passes, Mississippi River. This action is needed to provide for the safety of life on navigable waterways during the Riverwalk Marketplace/Lundi Gras Fireworks event.

DATES: The regulations in 33 CFR 165.801, Table 5, line 1 will be enforced from 6 p.m. through 7 p.m. on March 4, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email *Benjamin.P.Morgan@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone described in 33 CFR 165.801, Table 5, line 1, as the Riverwalk Marketplace/Lundi Gras Fireworks Display event from 6 p.m. through 7 p.m. on March 4, 2019. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801, specifies the location of the regulated area for the Riverwalk Marketplace/Lundi Gras Fireworks Display between mile markers 93 and 96 on the Mississippi River near New Orleans, Louisiana. During the enforcement period, as reflected in § 165.801(a)–(d), if you are the operator of a vessel in the safety zone, you must comply with directions from the Captain of the Port or a designated representative.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the local notice to mariners and marine information broadcasts.

Dated: February 20, 2019.

K.M. Luttrell,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2019–03253 Filed 2–25–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0032; FRL–9987–83]

Waxes and Waxy Substances, Rice Bran, Oxidized; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of waxes and waxy substances, rice bran, oxidized when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, on animals, and in antimicrobial formulations (food-contact surface sanitizing solutions). Spring Trading Company, on behalf of Clariant Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of waxes and waxy substances, rice bran, oxidized in accordance with the terms of the exemptions.

DATES: This regulation is effective February 26, 2019. Objections and requests for hearings must be received on or before April 29, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0032, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0032 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 29, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2018–0032, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL–9975–57), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11074) by Spring Trading Company, 203 Dogwood Trail, Magnolia, TX 77354, on behalf of Clariant Corporation. The petition requested that 40 CFR 180.910, 180.930, and 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583–80–9) (''rice bran wax oxidized''), when used as an inert ingredient as a flow aid, surface protection, film-forming, carrier, coating agent, and adjuvant in pesticide formulations applied on growing crops and raw agricultural commodities after harvest, to animals, and in antimicrobial formulations (food-contact surface sanitizing solutions). That document referenced a summary of the petition prepared by Spring Trading Company on behalf of Clariant Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to these comments is discussed in Unit V.C.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined

in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2) requires EPA to take into account the factors specified in subparagraphs (b)(2)(C) and (D) in making this safety determination. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for rice bran wax oxidized including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with rice bran wax oxidized follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by rice bran wax oxidized, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Available studies on rice bran wax oxidized include an acute oral toxicity study, a dermal irritation study, an eye irritation study, a dermal sensitization study, and an Ames assay. No subchronic or chronic studies are available for rice bran wax oxidized. Because data on rice bran wax oxidized is limited, surrogate data on various other long chain fatty acids, long chain fatty alcohols, and long chain fatty esters were used to support the safety finding for rice bran wax oxidized as rice bran wax oxidized is a natural substance comprised predominantly of long chain fatty acids, long chain fatty alcohols, and long chain fatty esters. Submitted data consisted of numerous subchronic, chronic, and reproductive/developmental studies on substances including carnauba wax, rice bran wax, a mixture of beeswax long chain alcohols, a mixture of sugar cane wax fatty acids, docosanol, docosanoic acid, and policosanol.

Rice ban wax oxidized was shown to have low acute oral toxicity. There were no acute dermal or inhalation studies submitted; however, dermal and eye irritation studies showed the rice bran wax oxidized was not an irritant. Rice bran wax oxidized was also not considered a skin sensitizer in related studies.

No endpoint of concern was identified for any of the acute, subchronic, chronic, or reproductive/developmental studies conducted at any dose level including the limit dose of 1000 mg/kg/day. There was also no evidence of carcinogenicity in any of the studies including chronic studies and studies on mutagenicity and cytotoxicity. In addition, no neuropathological changes or effects were reported in any of the studies. There is also no indication in the database that rice bran wax oxidized will be immunotoxic.

Furthermore, the potential for absorption of rice bran wax via the gastrointestinal (GI) tract is limited. The long-chain fatty acid esters present in plant-based waxes are generally thought to be poorly absorbed in the GI tract as uptake is thought to decrease as chain length and hydrophobicity increase. Rice bran wax is being used as a surrogate for rice bran wax oxidized based on its similar physical and chemical properties and expected potential for toxicity. Similar to rice bran wax, which is poorly absorbed, it is unlikely that rice bran wax oxidized would be systemically available for GI absorption, as both substance are comprised of very long carbon chain lengths which are not absorbed.

B. Toxicological Points of Departure/Levels of Concern

Available toxicity studies on rice bran wax oxidized indicate that it has a very low acute, subchronic, and chronic toxicity. No adverse effects were seen in any of the studies presented at the limit dose of 1000 mg/kg/day; therefore, no endpoint of concern has been identified for acute, subchronic, or chronic toxicity.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to rice bran wax oxidized, EPA considered exposure under the proposed exemption from the requirement of a tolerance and other natural sources of rice bran wax. EPA assessed dietary exposures from rice bran wax oxidized in food as follows:

Dietary exposure to rice bran wax oxidized may occur from eating foods naturally containing rice bran wax

(which is metabolized by the body to rice bran wax oxidized) and foods treated with pesticide formulations containing rice bran wax oxidized as an inert ingredient. Because no toxicological endpoint of concern was identified for rice bran wax oxidized, a quantitative dietary exposure assessment for rice bran wax oxidized was not conducted.

2. *Dietary exposure from drinking water.* Although drinking water exposures from use of pesticide formulations containing rice bran wax oxidized on food crops is possible, an endpoint of concern was not identified for the acute or chronic dietary assessment; therefore, a quantitative dietary exposure risk assessment for drinking water was not conducted.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Rice bran wax oxidized may be used as inert ingredient in pesticide products that are registered for specific uses that may result in indoor or outdoor residential exposures. Since there are no toxicological effects of concern at the limit dose in available studies, a quantitative assessment of residential (non-occupational) exposures and risks is not necessary.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Rice bran wax oxidized does not have toxic mode of action and therefore, cumulative risk assessment is not necessary.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) requires EPA to retain an additional tenfold margin of safety in the case of threshold effects to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. As noted in Unit IV.B., there is no indication of threshold effects being caused by rice bran wax oxidized at the limit dose. Therefore, due to the lack of any toxicological endpoints of concern at the limit dose, EPA is conducting a qualitative assessment of rice bran wax oxidized which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on rice bran wax oxidized, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to rice bran wax oxidized under reasonably foreseeable circumstances. Therefore, the establishment of exemptions from the requirement of a tolerance under 40 CFR 180.910, 180.930, and 180.940(a) for residues of waxes and waxy substances, rice bran, oxidized when used as an inert ingredient in pesticide formulations applied pre- and post-harvest, on animals, and in antimicrobial formulations (food-contact surface sanitizing solutions), is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comments

One comment was received in response to the Notice of Filing, generally stating that exposure to unnecessary pesticides needs to be decreased. The Agency recognizes that some individuals believe that pesticides should be limited or banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has provided no information that would support a conclusion that these exemptions are not safe.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.910, 180.930, and 180.940(a) for residues of waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583–80–9) when used as an inert ingredient (flow aid, surface protectant, film-forming agent, carrier, coating agent, or adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, to animals, and in antimicrobial formulations (food-contact surface sanitizing solutions).

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between

the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 21, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add alphabetically the inert ingredient ''Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583–80–9)'' to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
*	*	*
Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583–80–9).	.....	Flow aid, surface protectant, film-forming agent, carrier, coating agent, or adjuvant.
*	*	*

■ 3. In § 180.930, add alphabetically the inert ingredient ''Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583–80–9)'' to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
*	*	*
Waxes and waxy substances, rice bran, oxidized (CAS Reg. No. 1883583–80–9).	.....	Flow aid, surface protectant, film-forming agent, carrier, coating agent, or adjuvant.
*	*	*

■ 4. In § 180.940(a), add alphabetically the inert ingredient ''Waxes and waxy substances, rice bran, oxidized'' to the table to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *

* * * * *

Pesticide chemical	CAS Reg. No.	Limits
*	*	*
Waxes and waxy substances, rice bran, oxidized	1883583–80–9	None.
*	*	*

* * * * *

[FR Doc. 2019–03295 Filed 2–25–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

[MD Docket No. 18–397; FCC 19–4]

Memorializing the Significance of the FCC's Chief Information Officer's Role

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) adopted a change to a rule to incorporate a statutory update to the authorities of the FCC's Chief Information Officer (CIO) into the FCC's organizational rules. The purpose of this rule change is to demonstrate the FCC's commitment to ensuring that the FCC's CIO has a significant role in advancing the Commission's overall information technology capabilities.

DATES: *Effective* February 26, 2019.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Daniel Daly, *Daniel.Daly@fcc.gov,* of the FCC's Office of the Managing Director, (202) 418–1832.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, FCC 19–4, adopted January 29, 2019 and released on January 30, 2019. The full text of this document is available electronically via the FCC's Electronic Document Management System (EDOCS) website at *http://www.fcc.gov/edocs_public/* or via the FCC's Electronic Comment Filing System (ECFS) website at *https://www.fcc.gov/ecfs/.* (Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Information Center, which is located in Room CY–A257 at FCC Headquarters, 445 12th Street SW, 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.

Synopsis

Section 502 of the Repack Airwaves Yielding Better Access for Users of Modern Services Act of 2018 (RAY BAUM'S Act), Division P of Public Law 115–141, provides the Commission's CIO with enhanced responsibilities. The purpose of this Order is to amend 47 CFR 0.11 of the Commission's organizational rules to reflect the specific CIO functions included in the RAY BAUM'S Act. Section 0.11 relates to the functions of the FCC's Office of the Managing Director. The text of the language that is being added to 47 CFR 0.11 is the same as the language in Section 502 of the RAY BAUM'S Act. Section 502 is codified at 47 U.S.C. 155a. This update to the Commission's organizational rules is not required by law. However, this update demonstrates the FCC's commitment to ensuring that the CIO has a significant role in advancing the Commission's overall information technology capabilities.

Paperwork Reduction Act

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Congressional Review Act

The Commission will not send a copy of this Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of agency organization, procedure, or practice that do not ''substantially affect the rights or obligations of non-agency parties.''

List of Subjects in 47 CFR Part 0

Authority delegations (Government agencies), Organization and functions (Government agencies).

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 0 as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

Authority: Sec. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Section 0.11 is amended by adding paragraph (c) to read as follows:

§ 0.11 Functions of the Office.

* * * * *

(c) The Chief Information Officer shall have a significant role in: The decision-making process for annual and multi-year planning, programming, budgeting, and execution decisions, related reporting requirements, and reports related to information technology; the management, governance, and oversight processes related to information technology; and the hiring of personnel with information technology responsibilities. The Chief Information Officer, in consultation with the Chief Financial Officer and budget officials, shall specify and approve the allocation of amounts appropriated to the Commission for information technology, consistent with the provisions of appropriations Acts, budget guidelines, and recommendations from the Director of the Office of Management and Budget.

* * * * *

[FR Doc. 2019–03277 Filed 2–25–19; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register

Vol. 84, No. 38

Tuesday, February 26, 2019

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2019–0030]

RIN 3150–AK28

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM 100 Cask System, Certificate of Compliance No. 1014, Amendment No. 13

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel storage regulations by revising the Holtec International HI–STORM 100 Cask System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 13 to Certificate of Compliance No. 1014. Amendment No. 13 would revise Appendix B of the technical specifications to update the initial uranium weight for the 16x16B and 16x16C assembly classes to match the value for 16x16A.

DATES: Submit comments by March 28, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC 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–2019–0030. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

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: Christian Jacobs, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6825; email: *Christian.Jacobs@nrc.gov* or Gregory R. Trussell, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6244; email: *Gregory.Trussell@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments
II. Rulemaking Procedure
III. Background
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V. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0030 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–2019–0030.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0030 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on May 13, 2019. However, if the NRC receives significant adverse comments on this proposed rule by March 28, 2019, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to these proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

For procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[the Commission] shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule which added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled, ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on May 1, 2000 (65 FR 25241), that approved the HI–STORM 100 Cask System design and added it to the list of NRC-approved cask designs in 10 CFR 72.214 as Certificate of Compliance No. 1014.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No./web link/ **Federal Register** citation
Letter from Holtec International dated November 19, 2018, Submitting Request for Amendment No. 13 to Certificate of Compliance No. 1014.	ML18325A154
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Certificate of Compliance for Spent Fuel Storage Casks	ML18351A173
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix A	ML18351A174
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix B	ML18351A175
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix A–100U	ML18351A176
Proposed Certificate of Compliance No. 1014 Amendment No. 13, Technical Specifications, Appendix B–100U	ML18351A177
Certificate of Compliance No. 1014 Amendment No. 13, Preliminary Safety Evaluation Report	ML18351A178

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking website at *http://www.regulations.gov* under Docket ID NRC–2019–0030. The Federal Rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2019–0030); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is proposing to adopt the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969

(42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance 1014 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1014.

Initial Certificate Effective Date: May 31, 2000.

Amendment Number 1 Effective Date: July 15, 2002.

Amendment Number 2 Effective Date: June 7, 2005.

Amendment Number 3 Effective Date: May 29, 2007.

Amendment Number 4 Effective Date: January 8, 2008.

Amendment Number 5 Effective Date: July 14, 2008.

Amendment Number 6 Effective Date: August 17, 2009.

Amendment Number 7 Effective Date: December 28, 2009.

Amendment Number 8 Effective Date: May 2, 2012, as corrected on November 16, 2012 (ADAMS Accession No. ML12213A170); superseded by Amendment 8, Revision 1 Effective Date: February 16, 2016.

Amendment Number 8, Revision 1 Effective Date: February 16, 2016.

Amendment Number 9 Effective Date: March 11, 2014, superseded by Amendment Number 9, Revision 1, on March 21, 2016.

Amendment Number 9, Revision 1, Effective Date: March 21, 2016, as corrected (ADAMS Accession No. ML17236A451).

Amendment Number 10 Effective Date: May 31, 2016, as corrected (ADAMS Accession No. ML17236A452).

Amendment Number 11 Effective Date: February 25, 2019.

Amendment Number 12 Effective Date: February 25, 2019.

Amendment Number 13 Effective Date: May 13, 2019.

Safety Analysis Report (SAR) Submitted by: Holtec International.

SAR Title: Final Safety Analysis Report for the HI–STORM 100 Cask System.

Docket Number: 72–1014.

Certificate Expiration Date: May 31, 2020.

Model Number: HI–STORM 100.

* * * * *

Dated at Rockville, Maryland, this 14th day of February 2019.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2019–02887 Filed 2–25–19; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2019–BT–TP–0003]

Energy Conservation Program: Test Procedure for Direct Heating Equipment

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

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating a data collection process through this request for information (''RFI'') to consider whether to amend DOE's test procedure for direct heating equipment. To inform interested parties and to facilitate this process, DOE has gathered data, identifying several issues associated with the currently applicable test procedures on which DOE is interested in receiving comment. The issues outlined in this document mainly concern the evaluation of additional calculations relevant to the unvented direct heating equipment test procedure, updates to applicable industry standards incorporated by reference in the vented direct heating equipment test procedure, and any additional topics that may inform DOE's decisions in a future test procedure rulemaking, including methods to reduce regulatory burden while ensuring the procedure's accuracy. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI).

DATES: Written comments and information are requested and will be accepted on or before April 12, 2019.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2019–BT–TP–0003, by any of the following methods:

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

2. *Email:* To *DHE2019TP0003@ee.doe.gov.* Include docket number EERE–2019–BT–TP–0003 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, Test Procedure RFI for Direct Heating Equipment, Docket No. EERE–2019–BT–TP–0003, 1000 Independence Avenue SW, Washington, DC, 20585–0121. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC, 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at [*http://www.regulations.gov/docket?D=EERE-2019-BT-STD-0002*]. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III of this document for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Stephanie Johnson, U.S. *Department of Energy, Office of Energy Efficiency and Renewable Energy, Building* Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 586–5827. Email: *Eric.Stas@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–

1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction

Direct heating equipment (DHE) is included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(9)) The definition of ''direct heating equipment'' includes vented home heating equipment and unvented home heating equipment. 10 Code of Federal Regulations (CFR) 430.2. (Hereafter in this notice, the terms ''vented heater'' and ''unvented heater'' are used to describe the two types of direct heating equipment). DOE's test procedures for unvented heaters are prescribed at 10 CFR part 430, subpart B, appendix G (''Appendix G''). DOE's test procedures for vented heaters are prescribed at 10 CFR part 430, subpart B, appendix O (''Appendix O''). DOE prescribes energy conservation standards for vented heaters at 10 CFR 430.32(i). DOE does not currently prescribe energy conservation standards for unvented heaters. The following sections discuss DOE's authority to establish and amend test procedures for DHE, as well as relevant background information regarding DOE's consideration of test procedures for this product.

A. Authority and Background

The Energy Policy and Conservation Act of 1975 (''EPCA'' or ''the Act''),[1] Public Law 94–163 (42 U.S.C. 6291–6317, as codified), among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. (42 U.S.C. 6291–6317, as codified) Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include DHE, the subject of this RFI. (42 U.S.C. 6292(a)(9))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6291), energy conservation standards (42 U.S.C. 6295), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use and requires that the test procedure not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

If DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2))

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption into the overall energy efficiency, energy consumption, or other energy descriptor, taking into consideration the most current versions of Standards 62301 and 62087 of the International Electrotechnical Commission (''IEC''), unless the current test procedure already incorporates the standby mode and off mode energy consumption, or if such integration is technically infeasible. (42 U.S.C. 6295(gg)(2)(A)) If an integrated test procedure is technically infeasible, DOE must prescribe separate standby mode and off mode energy use test procedures for the covered product, if a separate test is technically feasible. (*Id.*)

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including DHE, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A)) If the Secretary determines, on his own behalf or in response to a petition by any interested person, that a test procedure should be prescribed or amended, the Secretary shall promptly publish in the **Federal Register** proposed test procedures and afford interested persons an opportunity to present oral and written data, views, and arguments with respect to such procedures. The comment period on a proposed rule to amend a test procedure shall be at least 60 days and may not exceed 270 days. In prescribing or amending a test procedure, the Secretary shall take into account such information as the Secretary determines relevant to such procedure, including technological developments relating to energy use or energy efficiency of the type (or class) of covered products involved. (42 U.S.C. 6293(b)(2)) If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. (42 U.S.C. 6293(b)(1)(A)(ii)) DOE is publishing this RFI to collect data and information to inform its decision in satisfaction of the 7-year review requirement specified in EPCA. (42 U.S.C. 6293(b)(1)(A))

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (Oct. 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

B. Rulemaking History

DOE's existing test procedures for unvented heaters and vented heaters appear at Appendix G and Appendix O, respectively. DOE originally established Appendix G in a final rule published in the **Federal Register** on May 10, 1978. 43 FR 20128, 20132–20146. DOE amended the test procedures for unvented home heating equipment on March 28, 1984 (''March 28, 1984 final rule'') to prescribe test procedures for fossil-fuel-fired unvented heaters and to add a calculation of the estimated operational cost per million British thermal unit (Btu) of output. 49 FR 12148, 12157–12158. DOE most recently updated Appendix G in a final rule published December 17, 2012 (''December 17, 2012 final rule'') to establish procedures for measuring energy consumption in standby mode and off mode, pursuant to EPCA. 77 FR 74559. 74571–74572. In the December 17, 2012 final rule, DOE did not incorporate standby mode and off mode energy into the annual energy consumption calculations for unvented heaters because it determined that a detailed annual energy consumption accounting was not appropriate for unvented heaters, as described further in section II.C of this document. 77 FR 74559, 74561.

DOE originally established Appendix O in a final rule published in the **Federal Register** on May 10, 1978. 43 FR 20147, 20182–20205. DOE amended the test procedures for vented home heating equipment in the March 28, 1984 final rule to include a simplified procedure for heaters with modulating controls, and to address manually controlled vented heaters, vented heaters equipped with thermal stack dampers, and floor furnaces. 49 FR 12148, 12169–12178. DOE amended the test procedure for vented heaters again on May 12, 1997 to add calculations for electrical energy consumption, to clarify the pilot light energy measurement for manually-controlled vented heaters, and to update the provisions for determining the efficiency of manually-controlled heaters with variable input rates. 62 FR 26140, 26156–26157. In the December 17, 2012 final rule, DOE established procedures for measuring power consumption in standby mode and off mode and for calculating the energy consumption associated with operation in standby mode and off mode. 77 FR 74559, 74561.

In the most recent test procedure rulemaking for DHE, DOE added provisions for testing vented home heating equipment that utilize condensing technology and incorporated by reference six industry test standards to replace the outdated test standards referred to in the then existing DOE test procedure. 80 FR 792 (Jan. 6, 2015) (''January 6, 2015 Final Rule''). DOE determined at that time not to amend the test procedures for unvented heaters. *Id.* at 793.

For unvented electric heaters that are the primary heating source for the home, Appendix G includes provisions for measuring electric power and calculating annual energy consumption. For all electric and gas unvented heaters, Appendix G includes provisions for determining the rated output. Appendix G does not contain provisions for determining energy efficiency, as all unvented heaters are generally considered to be 100-percent efficient. Accordingly, DOE has not established energy conservation standards for unvented heaters.

For vented heaters, Appendix O includes provisions for determining annual fuel utilization efficiency (''AFUE''), which is the efficiency metric used for determining compliance with the energy conservation standards. Appendix O also specifies provisions for determining annual energy consumption. Manufacturers must use the test procedures at Appendix O to demonstrate compliance with the current energy conservation standards for vented home heating equipment.

II. Request for Information

In the following sections, DOE has identified a variety of issues on which it seeks input to aid in the development of the technical and economic analyses regarding whether amended test procedures for DHE may be warranted. Specifically, DOE is requesting comment on any opportunities to streamline and simplify testing requirements for DHE.

Additionally, DOE welcomes comments on other issues relevant to the conduct of this process that may not be specifically identified in this document. In particular, DOE notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE are directed to manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (Feb. 3, 2017). Pursuant to that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations applicable to DHE consistent with the requirements of EPCA.

A. Scope and Definitions

The test procedures for DHE cover those products that meet the definitions of ''direct heating equipment'' and ''home heating equipment,'' as codified at 10 CFR 430.2 and defined as follows:

1. ''Direct heating equipment'' means vented home heating equipment and unvented home heating equipment.
2. ''Home heating equipment, not including furnaces'' means vented home heating equipment and unvented home heating equipment.

1. Unvented Heaters

The unvented heaters test procedure covers those products that meet the definitions for ''unvented home heating equipment,'' as codified at 10 CFR 430.2. DOE defines unvented heaters and the various sub-types of unvented heaters as follows:

1. ''Unvented home heating equipment'' means a class of home heating equipment, not including furnaces, used for the purpose of furnishing heat to a space proximate to such heater directly from the heater and without duct connections and includes electric heaters and unvented gas and oil heaters.
2. ''Electric heater'' means an electric appliance in which heat is generated from electrical energy and dissipated by convection and radiation and includes baseboard electric heaters, ceiling electric heaters, floor electric heaters, portable electric heaters, and wall electric heaters.
3. ''Primary heater'' means a heating device that is the principal source of heat for a structure and includes baseboard electric heaters, ceiling electric heaters, and wall electric heaters.
4. ''Supplementary heater'' means a heating device that provides heat to a space in addition to that which is supplied by a primary heater. Supplementary heaters include portable electric heaters.
5. ''Baseboard electric heater'' means an electric heater which is intended to be recessed in or surface mounted on walls at floor level, which is characterized by long, low physical dimensions, and which transfers heat by natural convection and/or radiation.
6. ''Ceiling electric heater'' means an electric heater which is intended to be recessed in, surface mounted on, or hung from a ceiling, and which transfers heat by radiation and/or convection (either natural or forced).
7. ''Floor electric heater'' means an electric heater which is intended to be recessed in a floor, and which transfers by radiation and/or convection (either natural or forced).

8. ''Portable electric heater'' means an electric heater which is intended to stand unsupported, and can be moved from place to place within a structure. It is connected to electric supply by means of a cord and plug, and transfers heat by radiation and/or convention (either natural or forced).

9. ''Wall electric heater'' means an electric heater (excluding baseboard electric heaters) which is intended to be recessed in or surface mounted on walls, which transfers heat by radiation and/or convection (either natural or forced) and which includes forced convectors, natural convectors, radiant heaters, high wall or valance heaters.

10. ''Unvented gas heater'' means an unvented, self-contained, free-standing, non-recessed gas-burning appliance which furnishes warm air by gravity or fan circulation.

11. ''Unvented oil heater'' means an unvented, self-contained, free-standing, non-recessed oil-burning appliance which furnishes warm air by gravity or fan circulation.

Issue A.1 DOE requests comment on the definitions currently applicable to unvented heaters and whether any of the definitions should be revised, and if so, how. Please provide a rationale for any suggested change. DOE notes that floor electric heaters are not currently listed among the other types of heaters included in the definition of a ''primary heater.'' DOE understands that floor electric heaters have similar heat output as the types of heaters listed in the definition of ''primary heater'' and may provide the primary source of heat in small dwellings. DOE requests comment on whether floor electric heaters should be specifically defined and also included in the definition of ''primary heater.''

2. Vented Heaters

The vented heaters test procedure covers those products that meet the definitions for ''vented home heating equipment,'' as codified at 10 CFR 430.2. DOE defines vented heaters and the various sub-types of vented heaters as follows:

1. ''Vented home heating equipment'' or ''vented heater'' means a class of home heating equipment, not including furnaces, designed to furnish warmed air to the living space of a residence, directly from the device, without duct connections (except that boots not to exceed 10 inches beyond the casing may be permitted) and includes: Vented wall furnace, vented floor furnace, and vented room heater.

2. ''Vented floor furnace'' means a self-contained vented heater suspended from the floor of the space being heated, taking air for combustion from outside this space. The vented floor furnace supplies heated air circulated by gravity or by a fan directly into the space to be heated through openings in the casing.

3. ''Vented room heater'' means a self-contained, free standing, non-recessed, vented heater for furnishing warmed air to the space in which it is installed. The vented room heater supplies heated air circulated by gravity or by a fan directly into the space to be heated through openings in the casing.

4. ''Vented wall furnace'' means a self-contained vented heater complete with grilles or the equivalent, designed for incorporation in, or permanent attachment to, a wall of a residence and furnishing heated air circulated by gravity or by a fan directly into the space to be heated through openings in the casing.

Issue A.2 DOE requests comment on the definitions currently applicable to vented heaters and whether any of the definitions should be revised, and if so, how. Please provide a rationale for any suggested change.

B. Updates to Industry Standards

DOE's current test procedures for DHE reference industry standards for various aspects of the test procedures. All materials incorporated by reference are listed at 10 CFR 430.3 and within Appendices G and O. DOE intends to fully review all the referenced standards in the DHE test procedures as part of this evaluation. The following is a list of the shorthand titles and full titles of all the referenced industry standards currently used in the DHE test procedures.

- ''ANSI/ASHRAE 103–2007'' means the test standard published by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers titled, ''Method of Test for Annual Fuel Utilization Efficiency of Residential Central Furnaces and Boilers.''
- ''ANSI Z21.86–2008'' means the standard published by the American National Standards Institute titled, ''Vented Gas-Fired Space Heating Appliances.''
- ''ASTM D2156–09'' means the standard published by the American Society of Testing and Materials International titled, ''Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels.''
- ''IEC 62301 (Second Edition)'' means the standard published by the International Electrotechnical Commission titled, ''Household electrical appliances—Measurement of standby power'' (Edition 2.0 2011–01).
- ''UL 729–2003'' means the test standard published by Underwriters Laboratories, Inc. titled, ''Standard for Safety for Oil-Fired Floor Furnaces.''
- ''UL 730–2003'' means the test standard published by Underwriters Laboratories, Inc. titled, ''Standard for Safety for Oil-Fired Wall Furnaces.''
- ''UL 896–1993'' means the test standard published by Underwriters Laboratories, Inc. titled, ''Standard for Safety for Oil-Burning Stoves.''

DOE conducted a preliminary examination of the available industry test standards and found that updates exist for all the incorporated standards except for ASTM D2156–09 and IEC 62301 (Second Edition). DOE reviewed all of those updated industry test standards.

However, when reviewing the revised versions of UL 729–2003 (last revised November 22, 2016), 730–2003 (last revised November 22, 2016), and 896–1993 (last revised November 22, 2016), DOE found that no revisions have been made to the sections incorporated by reference to the vented heaters test procedure.

Issue B.1 DOE requests any information in relation to the revisions to the existing standards that have been incorporated by reference, including the purpose of the updates and whether any of the updates would be expected to impact the test burden or measured energy consumption under the DOE test procedures for vented and unvented heaters.

1. ANSI/ASHRAE 103

DOE is aware that ANSI/ASHRAE 103–2007 has been superseded by ANSI/ASHRAE 103–2017. DOE examined both versions of the ANSI/ASHRAE 103 standard and found several changes to sections incorporated by reference within the vented heater test procedure. DOE understands many of the changes to be minor clarifications, such as adding metric units or changing the order of a sentence without affecting its intent. However, other changes could have a noticeable effect on the vented heater test procedure, if adopted by DOE. Specifically, in section 6.3, titled ''Pressure,'' the allowable error value for oil pressure measurement was removed, although the introductory text in the sections still states that it applies to oil. In section 6.8, titled ''Smoke,'' the referenced standard ASTM D2156–94 was updated to ASTM D2156–09, which is the standard that is currently incorporated by reference in the vented heater test procedure. In section 8.6, titled ''Jacket Loss Measurement,'' figures 12 and 13 were replaced by a set of equations. In section 9.10, titled

''Optional Test Procedures for Condensing Furnaces and Boilers That Have No Off-Period Flue Losses,'' the maximum post-purge period to use a value of 0.05 for D_F and D_P increased from less than 5 seconds to less than or equal to 30 seconds for units with no measurable airflow through the combustion chamber and heat exchanger.

Issue B.2 DOE requests comment on whether removing the allowable error in the oil pressure measurement value from section 6.3 of the ANSI/ASHRAE 103–2017 standard was intentional. If so, DOE requests comment on what allowable error measurement should be used within the vented heater test procedure (Note: ANSI/ASHRAE 103–2007 stated ±0.5 psi).

Issue B.3 DOE requests comment on whether the replacement of figures 12 and 13 with a set of equations in section 8.6 of ANSI/ASHRAE 103–2017 is appropriate for the vented heater test procedure.

Issue B.4 DOE requests comment on whether the maximum post-purge time should be increased from less than 5 seconds to less than or equal to 30 seconds for vented heaters with no measurable airflow through the combustion chamber and heat exchanger.

2. ANSI Z21.86

DOE is aware that ANSI Z21.86–2008 has been superseded by ANSI Z21.86–2016. DOE examined both versions of the ANSI Z21.86 standard and only found minor changes to sections incorporated by reference within the vented heater test procedure. Section 6 was moved to section 9, and section 8 was moved to section 11. The figures and tables referenced in these sections were moved from the ''Tables Referenced In Part 1, Part II and Exhibits'' and ''Figures Referenced In Part 1, Part II and Exhibits'' sections at the end of the standard to throughout the standard where they are first referenced. Accordingly, DOE expects that these changes would not substantively impact the test burden or measured energy consumption under the DOE test procedures.

C. Test Method for Unvented Heaters

For electric heaters, section 2.1 of Appendix G specifies measuring and recording the maximum electrical power consumed when heating, in terms of kilowatts, and section 3.3 specifies calculating a rated output. For primary electric heaters only, section 3.1 of Appendix G specifies the calculation for the national average annual energy consumption based on the maximum electrical power, and section 3.2 specifies a calculation for the annual energy consumption by geographic region. The calculation of national average annual energy consumption in section 3.1 of Appendix G is based on several assumptions, including the national average annual heating load hours of 2080, an adjustment factor of 0.77,[3] and a typical oversizing factor for primary electric heaters of 1.2.[4] The calculation of regional annual energy consumption in section 3.2 of Appendix G is based on the same assumptions as the national value, except that regional heating load hours are provided by a figure depicting geographic regions the United States and the associated heating load hours for each region.

Issue C.1 DOE requests comment on whether the assumptions for calculating the national and regional values of annual fuel energy consumption are still appropriate.

For unvented natural gas, propane, and oil heaters, section 2.2 of Appendix G specifies measuring the maximum fuel input rate of the heater over the course of one hour. Section 2.1 of Appendix G requires the maximum auxiliary electrical power to be recorded for unvented gas and oil heaters that use auxiliary electrical energy. Section 3.4 of Appendix G provides calculations to determine the rated output for unvented gas and oil heaters based on the measurements of the hourly input rate and maximum electrical power. DOE notes that Appendix G currently does not specify calculating annual fuel energy consumption for unvented gas and oil heaters.

Issue C.2 DOE requests comment on whether annual fuel energy consumption should be calculated for unvented natural gas, propane, and oil heaters. If annual fuel energy consumption should be calculated, DOE requests comment on what equations and assumptions should be used.

For unvented heaters equipped with a pilot light and/or that use electrical energy, sections 2.3 and 2.4 of Appendix G specify measuring the fossil fuel input rate and/or standby electrical power, respectively. These values are not used in any calculations. If the pilot light is designed to be turned off by the user when not in use, and the heater has instructions for turning the unit off provided on a label on the heater near the gas control valve, then section 2.3.1 of Appendix G specifies that the measurement of pilot light energy consumption is not required. Similarly, if the heater is designed to be turned off when not in use, if turning the control to ''off'' will shut off the electrical supply, and if an instruction to turn off the unit is provided on a label on the heater, then section 2.4.1 of Appendix G specifies that the standby electrical power does not need to be measured.

In the December 17, 2012 final rule, DOE determined not to include standby mode and off mode energy use in the annual energy consumption calculations for unvented heaters because a detailed annual energy consumption accounting was not deemed appropriate for this product type (*i.e.,* there is no annual accounting at all for supplemental heaters and only a simplified assigned value for primary heaters). 77 FR 74559, 74561. In the August 30, 2010 NOPR that preceded the December 17, 2012 final rule, DOE explained that the integration of standby mode and off mode energy was not necessary or appropriate for the following reasons:

1. The test procedure does not include energy efficiency or energy use metrics that would allow for the integration of standby mode and off mode energy use.
2. Standby mode energy use (defined as energy use during the heating season when the heater is not on) is as effective in heating the space as active mode energy use.
3. Off mode energy consumption (defined as non-heating-season energy consumption) could be considered ineffective energy use and, accordingly, could be minimized by prescribing a separate energy conservation standard. However, DOE lacked data on consumer use that would be needed to define a representative off mode for unvented heaters.[5]

See 75 FR 52892, 52898–52899 (Aug. 30, 2010).

Issue C.3 DOE requests comment on whether annual fuel energy consumption for unvented heaters should include standby mode and off mode energy use. DOE is also interested in detailed information on any additional test burden that would result from calculating annual fuel energy consumption with standby mode and off mode energy use and if so, the nature and extent of that burden.

Issue C.4 DOE requests any information in relation to annual and/or regional heating season data, heating mode operating hours, standby mode hours, and off mode hours for unvented heaters.

[3] The adjustment factor is a multiplier to adjust the heating load hours to the approximate burner operating hours actually experienced by the system.

[4] The oversizing factor accounts for space heating products generally being oversized when compared to the actual heating load.

[5] For example, DOE lacked information on the fraction of the year unvented heaters might be unplugged or otherwise disconnected from the energy source, and the extent to which pilot lights are turned off during the non-heating season.

D. Test Method for Vented Heaters

For vented heaters, Appendix O specifies provisions for determining the product's AFUE, which is the efficiency descriptor established by EPCA for direct heating equipment. (42 U.S.C. 6291(22)(A))

As discussed above, section 3.8 of Appendix O contains provisions for testing vented heaters that utilize condensing technology. Condensing technology is a design strategy that increases the efficiency of a heating appliance by extracting additional thermal energy from the flue gases.[6] These provisions are essentially the same as those contained in ANSI/ASHRAE 103–2007 that are applicable to condensing furnaces and boilers. However, because of the numerous additions and modifications needed to apply the condensing technology provisions to vented heaters, DOE includes the condensing provisions in Appendix O, rather than incorporating by reference the relevant provisions of ANSI/ASHRAE 103–2007.

Issue D.1 DOE requests comment and data on manufacturers' and test laboratories' experience with the condensing provisions in Appendix O. DOE requests detailed information regarding any test burden associated with conducting the condensing provisions, including the nature and extent of any such burden. DOE also requests comment on ways to potentially reduce any test burden of the provisions specific to condensing technology.

DOE has identified several areas of the vented heater test procedure that may warrant further review to determine whether additional detail or specification may be needed to improve the readability and ease of implementation of the test procedure.

In the definitions in section 1.0 of Appendix O, section 1.21 defines ''manually controlled vented heaters'' as either gas or oil fueled vented heaters equipped without thermostats. DOE believes some vented heaters could potentially be designed to operate with timers or electronic controls without being equipped with thermostats, but that are not manually controlled. DOE questions whether ''manually controlled vented heaters'' should be defined to exclude those ''without automatic means of control or operation,'' as opposed to only those ''without thermostats.''

Issue D.2 DOE requests comment on whether the definition for ''Manually controlled vented heater'' should be amended, and if so, how.

Issue D.3 DOE also requests comment on whether the other definitions provided in section 1.0 of Appendix O are all still appropriate, or if other updates are needed.

Within section 4.0 of Appendix O, titled ''Calculations,'' the balance point temperature (T_C) can be determined either with an equation or using the values provided in Table 3 of Appendix O. DOE recognizes that a value of T_C derived from the equation may not be the same as that obtained from Table 3.

Similarly, values for the fraction of the heating load and average outdoor temperature at the reduced and maximum operating modes (variables X_1, X_2, T_{OA}, and T_{OA*}) are determined using either Table 3 or Figure 1 of Appendix O (which provides a graph showing T_{OA}, and T_{OA*} variables for any balance point temperature between 16 °F and 62 °F), or Figure 2 of Appendix O (which provides a graph showing variables X_1 and X_2 for any balance point temperature between 0 °F and 62 °F). DOE recognizes that Table 3, Figure 1, and Figure 2 may yield different results because Table 3 provides discreet values for X_1, X_2, T_{OA}, and T_{OA*}, whereas Figure 1 and Figure 2 provide continuous graphical curves for determining the relevant variables. DOE reviewed a limited amount of test data in an effort to estimate the impact of the different methods for determining the aforementioned variables on the measured AFUE value. DOE found that the different methods resulted in a difference on the order of hundredths of a percentage point of AFUE, which DOE would not expect to affect the measured AFUE in most cases when rounded to a whole number. However, DOE seeks to further understand this issue and whether there are any known or potential impacts from the difference in values.

Issue D.4 DOE requests comment on whether the differences in the balance point temperature (T_C) produced by the equation and as obtained from Table 3 can result in different results in the values for the fraction of the heating load (X_1 and X_2) and average outdoor temperature at the reduced and maximum operating modes (T_{OA} and T_{OA*}), and if so, the extent of any such difference.

Issue D.5 DOE requests comment on whether any differences in the values of X_1, X_2, T_{OA}, and T_{OA*} within Table 3 and Figures 1 and 2 could produce different results, especially in AFUE, and if so, the extent of such differences. If any such difference in results would occur, DOE requests comment on whether any of these variables should be obtained using equations instead of Table 3 or Figures 1 and 2.

In a notice of proposed rulemaking published October 24, 2013, DOE proposed an optional use of a default jacket loss value of 1 percent for vented floor furnaces, as an alternative to performing a jacket loss test. 78 FR 63410, 63415. In the January 6, 2015 final rule, DOE decided not to adopt the 1 percent default jacket loss value for vented floor furnaces after reviewing test data that revealed an average jacket loss of 3.05 percent. 80 FR 792, 794.

Issue D.6 DOE requests comment and test data on whether a higher default jacket loss value should be considered for vented floor furnaces.

DOE previously stated that DHE that can operate in manual or automatic modes should be tested in automatic mode. 80 FR 792, 795 (Jan. 6, 2015).

Issue D.7 DOE requests comment on whether DHE that have multiple automatic operation modes exist, and if so, whether further direction regarding the tested operating mode is necessary.

Section 3.6.1 of Appendix O specifies that on units with no measurable airflow through the unit when not in heating mode (as determined by a smoke stick test defined in section 3.6.2 of Appendix O), both the off-cycle flue gas draft factor (D_F) and the ratio of flue gas mass flow during the off-period to the flue gas mass flow during the on-period (D_P) may be set equal to 0.05. DOE is considering whether to allow models using condensing or induced draft technology to automatically be considered to have no measurable airflow, and, thus, be able to use the defined value of 0.05 for D_F and D_P without performing the smoke stick test.

Issue D.8 DOE requests comment on the extent to which vented heaters currently use the provisions in 3.6.1 and 3.6.2 of Appendix O, whether models with induced draft or condensing technology are always capable of meeting the conditions to use the default draft factor, and whether provisions should be added to the vented heater test procedure to allow condensing or induced draft DHE to be considered to have no measurable airflow and to use a constant value of 0.05 for D_F and D_P without confirmation testing.

E. Performance and Utility

DHE provides space heating (warm air) directly to the consumer's living space without the use of duct

[6] In a condensing system, water vapor contained within the flue gas (as a byproduct of the combustion process) is condensed and drained out of the system. The process of condensing water vapor into liquid water releases latent heat, which is transferred to the air stream, thereby increasing the heating efficiency.

connections. Relevant to DHE may also be the ability to provide ''quiet'' operation, non-heating air circulation, and space humidification, as well as the aesthetic appearance of the unit.

Issue E.1 DOE requests comment whether the test procedures impact the availability of such features on DHE.

F. Other Test Procedure Topics

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of the existing test procedures for DHE not already addressed by the specific areas identified in this document. DOE particularly seeks information that would improve the repeatability, reproducibility, and consumer representativeness of the test procedures. DOE also requests information that would help DOE create a procedure that would limit manufacturer test burden through streamlining or simplifying testing requirements. Comments regarding the repeatability and reproducibility are also welcome.

DOE also requests feedback on any potential amendments to the existing test procedure(s) that could be considered to address impacts on manufacturers, including small businesses. Regarding the Federal test method, DOE seeks comment on the degree to which the DOE test procedure should consider and be harmonized with the most recent relevant industry standards for DHE and whether any changes to the Federal test method would provide additional benefits to the public. DOE also requests comment on the benefits and burdens of adopting any industry/voluntary consensus-based or other appropriate test procedure, without modification.

Additionally, DOE requests comment on whether the existing test procedures limit a manufacturer's ability to provide additional features to consumers of DHE. DOE particularly seeks information on how the test procedures could be amended to reduce the cost of new or additional features and make it more likely that such features are included on DHE.

III. Submission of Comments

DOE invites all interested parties to submit in writing by April 12, 2019, comments and information on matters addressed in this notice and on other matters relevant to DOE's consideration of amended test procedures for DHE. These comments and information will aid in the development of a test procedure NOPR for DHE if DOE determines that amended test procedures may be appropriate for these products.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or postal mail. Comments and documents submitted via email, hand delivery, or postal mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the item; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would

result from public disclosure; (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of this process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signed in Washington, DC, on February 13, 2019.

Steven Chalk,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–03269 Filed 2–25–19; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2019–BT–STD–0002]

Energy Conservation Program: Energy Conservation Standards for Direct Heating Equipment

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

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating an effort to determine whether to amend the current energy conservation standards for direct heating equipment. Under the Energy Policy and Conservation Act of 1975, as amended (''EPCA''), DOE must periodically review these standards and publish either a notice of proposed rulemaking (''NOPR'') to propose new standards for direct heating equipment or a notice of determination that the existing standards do not need to be amended. This request for information (''RFI'') solicits information from the public to help DOE determine whether amended standards for direct heating equipment would result in significant energy savings and whether such standards would be technologically feasible and economically justified. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI).

DATES: Written comments and information are requested and will be accepted on or before April 12, 2019.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2019–BT–STD–0002, by any of the following methods:

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

2. *Email: DHE2019STD0002@ee.doe.gov.* Include the docket number EERE–2019–BT–STD–0002 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, Energy Conservation Standards RFI for Direct Heating Equipment, Docket No. EERE–2019–BT–STD–0002, 1000 Independence Avenue SW, Washington, DC, 20585–0121. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC, 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *http://www.regulations.gov/#!docketDetail;D=EERE-2019-BT-STD-0002.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III of this document for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–5827. Email: *Eric.Stas@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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I. Introduction

A. Authority and Background

The Energy Policy and Conservation Act of 1975, as amended (''EPCA'' or ''the Act''),[1] Public Law 94–163 (42 U.S.C. 6291–6317, as codified), among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. (42 U.S.C. 6291–6317, as codified) Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include direct heating equipment (DHE), the subject of this document. (42 U.S.C. 6292(a)(9)) EPCA prescribed energy conservation standards for these products and directed DOE to conduct two cycles of rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(e)(3) and (4))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

DOE completed the first of the required rulemaking cycles in 2010 by publishing a final rule on April 16, 2010 (''April 2010 final rule'') that adopted amended performance standards for certain DHE (*i.e.,* vented home heating equipment) manufactured on or after April 16, 2013. 75 FR 20112. In the April 2010 final rule, DOE did not issue standards for unvented home heating equipment, a subset of DHE, finding that such standards would produce insignificant energy savings. *Id* at 20130. Additionally, DOE completed a second rulemaking cycle for DHE by issuing a final determination to not amend standards for vented home heating equipment and to not to adopt standards for unvented home heating equipment on October 17, 2016 (''October 2016 final determination''). 81 FR 71325. The current energy conservation standards for DHE are located in title 10 of the Code of Federal Regulations (''CFR'') part 430, section 32(i)(2). The currently applicable DOE test procedures for unvented and vented DHE appear at 10 CFR part 430, subpart B, appendix G and appendix O, respectively.

In the October 2016 final determination, DOE concluded that energy conservation standards should not be amended for DHE. DOE determined that the DHE market characteristics at the time were largely similar to those during the analysis for the April 2010 final rule, and that the technologies available for improving DHE energy efficiency had not advanced significantly since the publication of the April 2010 final rule. In addition, DOE determined that the conclusions reached in the April 2010 final rule regarding the benefits and burdens of more stringent standards for DHE were still relevant to the DHE market. Therefore, DOE concluded that amended energy conservation standards would not be economically justified. 81 FR 71325, 71325 (Oct. 17, 2016).

EPCA also requires that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE evaluate the energy conservation standards for each type of covered product, including those at issue here, and publish either a notice of determination that standards do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1)) EPCA further provides that, not later than 3 years after the issuance of a final determination not to amend standards, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(3)(B)) DOE must make the analysis on which the determination is based publicly available and provide an opportunity for written comment. (42 U.S.C. 6295(m)(2)) In making a determination, DOE must evaluate whether more-stringent standards would: (1) Yield a significant savings in energy use and (2) be both technologically feasible and economically justified. (42 U.S.C. 6295(m)(1)(A)) DOE is publishing this RFI to collect data and information to inform its decision consistent with its obligations under EPCA.

B. Rulemaking Process

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products. EPCA requires that any new or amended energy conservation standard be designed to achieve the maximum improvement in energy or water efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) To determine whether a standard is economically justified, EPCA requires that DOE determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the following seven factors:

(1) The economic impact of the standard on the manufacturers and consumers of the affected products;

(2) The savings in operating costs throughout the estimated average life of the product compared to any increases in the initial cost, or maintenance expenses;

(3) The total projected amount of energy and water (if applicable) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (Secretary) considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

DOE fulfills these and other applicable requirements by conducting a series of analyses throughout the rulemaking process. Table I.1 shows the individual analyses that are performed to satisfy each of the requirements within EPCA.

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (Oct. 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS

EPCA requirement	Corresponding DOE analysis
Technological Feasibility	• Market and Technology Assessment. • Screening Analysis. • Engineering Analysis.
Economic Justification:	
1. Economic impact on manufacturers and consumers	• Manufacturer Impact Analysis. • Life-Cycle Cost and Payback Period Analysis. • Life-Cycle Cost Subgroup Analysis. • Shipments Analysis.
2. Lifetime operating cost savings compared to increased cost for the product.	• Mark-ups for Product Price Determination. • Energy and Water Use Determination. • Life-Cycle Cost and Payback Period Analysis.
3. Total projected energy savings	• Shipments Analysis. • National Impact Analysis.
4. Impact on utility or performance	• Screening Analysis. • Engineering Analysis.
5. Impact of any lessening of competition	• Manufacturer Impact Analysis.
6. Need for national energy and water conservation	• Shipments Analysis. • National Impact Analysis.
7. Other factors the Secretary considers relevant	• Employment Impact Analysis. • Utility Impact Analysis. • Emissions Analysis. • Monetization of Emission Reductions Benefits. • Regulatory Impact Analysis.

As detailed throughout this RFI, DOE is publishing this document seeking input and data from interested parties to aid in the development of the technical analyses on which DOE will ultimately rely to determine whether (and if so, how) to amend the standards for direct heating equipment.

II. Request for Information and Comments

In the following sections, DOE has identified a variety of issues on which it seeks input to aid in the development of the technical and economic analyses regarding whether amended standards for DHE may be warranted. Additionally, DOE welcomes comments on other issues relevant to this request for information that may not specifically be identified in this document. In particular, DOE notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE are directed to manage the costs associated with the imposition of expenditures required to comply with Federal regulations. *See* 82 FR 9339 (Feb. 3, 2017). Pursuant to that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its energy conservation standards rulemakings, recordkeeping and reporting requirements, and compliance and certification requirements applicable to DHE while remaining consistent with the requirements of EPCA.

A. Products Covered by This Process

The definitions for DHE were most recently amended in a test procedure final rule. 80 FR 792 (Jan. 6, 2015). This RFI covers those products that meet the definitions of ''direct heating equipment'' and ''home heating equipment,''[3] as codified at 10 CFR 430.2 and defined as follows:

(1) ''Direct heating equipment'' means vented home heating equipment and unvented home heating equipment.

(2) ''Home heating equipment, not including furnaces'' means vented home heating equipment and unvented home heating equipment.

1. Unvented Heaters

Unvented heaters are those products that meet the definitions for ''unvented home heating equipment,'' as codified at 10 CFR 430.2. DOE defines unvented heaters and the various sub-types of unvented heaters as follows:

(1) ''Unvented home heating equipment'' means a class of home heating equipment, not including furnaces, used for the purpose of furnishing heat to a space proximate to such heater directly from the heater and without duct connections and includes electric heaters and unvented gas and oil heaters.

(2) ''Electric heater'' means an electric appliance in which heat is generated from electrical energy and dissipated by convection and radiation and includes baseboard electric heaters, ceiling electric heaters, floor electric heaters, portable electric heaters, and wall electric heaters.

(3) ''Primary heater'' means a heating device that is the principal source of heat for a structure and includes baseboard electric heaters, ceiling electric heaters, and wall electric heaters.

(4) ''Supplementary heater'' means a heating device that provides heat to a space in addition to that which is supplied by a primary heater. Supplementary heaters include portable electric heaters.

(5) ''Baseboard electric heater'' means an electric heater which is intended to be recessed in or surface mounted on walls at floor level, which is characterized by long, low physical dimensions, and which transfers heat by natural convection and/or radiation.

(6) ''Ceiling electric heater'' means an electric heater which is intended to be recessed in, surface mounted on, or hung from a ceiling, and which transfers heat by radiation and/or convection (either natural or forced).

(7) ''Floor electric heater'' means an electric heater which is intended to be recessed in a floor, and which transfers by radiation and/or convection (either natural or forced).

(8) ''Portable electric heater'' means an electric heater which is intended to stand unsupported, and can be moved from place to place within a structure.

[3] DOE notes that DHE is defined at 10 CFR 430.2 as ''vented home heating equipment'' and ''unvented home heating equipment''; however, the existing energy conservation standards apply only to product classes of vented home heating equipment. There are no existing energy conservation standards for unvented home heating equipment.

It is connected to electric supply by means of a cord and plug, and transfers heat by radiation and/or convention (either natural or forced).

(9) ''Wall electric heater'' means an electric heater (excluding baseboard electric heaters) which is intended to be recessed in or surface mounted on walls, which transfers heat by radiation and/or convection (either natural or forced) and which includes forced convectors, natural convectors, radiant heaters, high wall or valance heaters.

(10) ''Unvented gas heater'' means an unvented, self-contained, free-standing, non-recessed gas-burning appliance which furnishes warm air by gravity or fan circulation.

(11) ''Unvented oil heater'' means an unvented, self-contained, free-standing, non-recessed oil-burning appliance which furnishes warm air by gravity or fan circulation.

Issue A.1 DOE requests comment on the definitions currently applicable to unvented heaters and whether any of the definitions should be revised, and if so, how. Please provide a rationale for any suggested change. DOE notes that floor electric heaters are not currently listed among the other types of heaters included in the definition of a ''primary heater.'' DOE understands that floor electric heaters have similar heat output as the types of heaters listed in the definition of ''primary heater'' and may provide the primary source of heat in small dwellings. DOE requests comment on whether floor electric heaters should be specifically defined and also included in the definition of ''primary heater.''

2. Vented Heaters

Vented heaters are those products that meet the definitions for ''vented home heating equipment,'' as codified at 10 CFR 430.2. DOE defines vented heaters and the various sub-types of vented heaters as follows:

(1) ''Vented home heating equipment'' or ''vented heater'' means a class of home heating equipment, not including furnaces, designed to furnish warmed air to the living space of a residence, directly from the device, without duct connections (except that boots not to exceed 10 inches beyond the casing may be permitted) and includes: vented wall furnace, vented floor furnace, and vented room heater.

(2) ''Vented floor furnace'' means a self-contained vented heater suspended from the floor of the space being heated, taking air for combustion from outside this space. The vented floor furnace supplies heated air circulated by gravity or by a fan directly into the space to be heated through openings in the casing.

(3) ''Vented room heater'' means a self-contained, free standing, non-recessed, vented heater for furnishing warmed air to the space in which it is installed. The vented room heater supplies heated air circulated by gravity or by a fan directly into the space to be heated through openings in the casing.

(4) ''Vented wall furnace'' means a self-contained vented heater complete with grilles or the equivalent, designed for incorporation in, or permanent attachment to, a wall of a residence and furnishing heated air circulated by gravity or by a fan directly into the space to be heated through openings in the casing.

(5) ''Unvented home heating equipment'' means a class of home heating equipment, not including furnaces, used for the purpose of furnishing heat to a space proximate to such heater directly from the heater and without duct connections and includes electric heaters and unvented gas and oil heaters.

Issue A.2 DOE requests comment on whether the definitions applicable to DHE require any revisions, and if so, how those definitions should be revised. Please provide a rationale for any suggested change. DOE also requests feedback on whether the sub-category definitions currently in place are appropriate or whether further modifications are needed. If these sub-category definitions need modifying, DOE seeks specific input on how to define these terms.

Issue A.3 DOE requests comment on whether additional product definitions are necessary to close any potential gaps in coverage between product types. DOE also seeks input on whether such products currently exist in the market or whether they are being planned for introduction.

B. Market and Technology Assessment

The market and technology assessment that DOE routinely conducts when analyzing the impacts of a potential new or amended energy conservation standard provides information about the DHE industry that will be used in DOE's analysis throughout the rulemaking process. DOE uses qualitative and quantitative information to characterize the structure of the industry and market. DOE identifies manufacturers, estimates market shares and trends, addresses regulatory and non-regulatory initiatives intended to improve energy efficiency or reduce energy consumption, and explores the potential for efficiency improvements in the design and manufacturing of the subject products. DOE also reviews product literature, industry publications, and company websites, as well as information from trade journals, government agencies, and trade organizations. Additionally, DOE routinely conducts interviews with manufacturers to improve its assessment of the market and available technologies for DHE.

1. Product Classes

When evaluating and establishing energy conservation standards, DOE may divide covered products into product classes by the type of energy used, or by capacity or other performance-related features that justify a different standard. (42 U.S.C. 6295(q)) In making a determination whether capacity or another performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE deems appropriate. *Id.*

For DHE, the current energy conservation standards specified in 10 CFR 430.32(i)(2) are based on 11 product classes divided by equipment type (*i.e.,* wall, floor, or room), heat circulation type (*i.e.,* fan or gravity), and input capacity. Table II.1 lists the current product classes for DHE.

TABLE II.1—CURRENT DIRECT HEATING EQUIPMENT PRODUCT CLASSES

DHE type	Heat circulation type	Input rate, Btu/h
Wall ..	Fan	≤42,000.
		>42,000.
	Gravity	≤27,000.
		>27,000 and ≤46,000.
		>46,000.
Floor	All	≤37,000.
		>37,000.
Room	All	≤20,000.
		>20,000 and ≤27,000.
		>27,000 and ≤46,000.
		>46,000.

Issue B.1 DOE requests feedback on the current DHE product classes and whether changes to these individual product classes and their descriptions should be made or whether certain classes should be merged or separated. DOE further requests feedback on whether combining certain classes could impact product utility by eliminating any performance-related features or impact the stringency of the current energy conservation standard for these products. DOE also requests comment on separating any of the existing product classes and whether it would impact product utility by eliminating any performance-related

features or reduce any compliance burdens.

Issue B.2 DOE seeks information regarding any other new product classes it should consider for inclusion in its analysis. Specifically, DOE requests information on the performance-related features (*e.g.,* input capacity, equipment type, heater type, *etc.*) that provide unique consumer utility and data detailing the corresponding impacts on energy use that would justify separate product classes (*i.e.,* explanation for why the presence of these performance-related features would increase energy consumption).

2. Technology Assessment

In analyzing the feasibility of potential new or amended energy conservation standards, DOE uses information about existing and past technology options and prototype designs to help identify technologies that manufacturers could use to meet and/or exceed a given set of energy conservation standards under consideration. In consultation with interested parties, DOE intends to develop a list of technologies to consider in its analysis. That analysis will likely include a number of the technology options DOE previously considered during its most recent rulemaking for DHE. A complete list of those prior options appears in Table II.2. DOE has conducted a preliminary review and did not identify any new options.

TABLE II.2—PREVIOUSLY CONSIDERED TECHNOLOGY OPTIONS FOR DIRECT HEATING EQUIPMENT FROM THE APRIL 2010 FINAL RULE AND OCTOBER 2016 FINAL DETERMINATION [4]

Technology options
Increased heat exchanger surface area
Multiple flues
Multiple turns in flue
Direct vent (concentric)
Increased heat transfer coefficient
Electronic ignition
Thermal vent damper
Electrical vent damper
Power burner
Induced draft

[4] See chapter 3, section 3.3.2.2 in the April 2010 final rule technical support document (TSD) published during the rulemaking process, document #149 on *https://regulations.gov in docket ID EERE–2006–STD–0129.*

TABLE II.2—PREVIOUSLY CONSIDERED TECHNOLOGY OPTIONS FOR DIRECT HEATING EQUIPMENT FROM THE APRIL 2010 FINAL RULE AND OCTOBER 2016 FINAL DETERMINATION [4]—Continued

Technology options
Two-stage and modulating operation
Improved fan or blower motor efficiency
Increased insulation
Condensing
Condensing Pulse Combustion
Air circulation fan
Sealed combustion

Issue B.3 DOE seeks information on the technologies listed in Table II.2 regarding their applicability to the current market and how these technologies may impact the efficiency of DHE as measured according to the DOE test procedure. DOE also seeks information on how these technologies may have changed since they were considered in the October 2016 Final Determination analysis. Specifically, DOE seeks information on the range of efficiencies or performance characteristics that are currently available for each technology option.

Issue B.4 DOE seeks comment on other technology options that it should consider for inclusion in its analysis. DOE is particularly interested in information for any potential new technology options regarding their market adoption, costs, and any concerns with incorporating them into products (*e.g.,* impacts on consumer utility, potential safety concerns, manufacturing/production/implementation issues).

C. Screening Analysis

The purpose of the screening analysis is to evaluate the technologies that improve equipment efficiency to determine which technologies will be eliminated from further consideration and which will be passed to the engineering analysis for further consideration.

DOE determines whether to eliminate certain technology options from further consideration based on the following criteria:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on equipment utility or equipment availability.* If a technology is determined to have significant adverse impact on the utility of the equipment for significant subgroups of consumers, or result in the unavailability of any covered equipment type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as equipment generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology will have significant adverse impacts on health or safety, it will not be considered further.

10 CFR part 430, subpart C, appendix A, sections 4(a)(4) and 5(b).

Technology options identified in the technology assessment are evaluated against these criteria using DOE analyses and inputs from interested parties (*e.g.,* manufacturers, trade organizations, and energy efficiency advocates). Technologies that pass through the screening analysis are referred to as ''design options'' in the engineering analysis. Technology options that fail to meet one or more of the four criteria are eliminated from consideration.

Additionally, DOE notes that the four screening criteria do not directly address the proprietary status of technology options. DOE only considers potential efficiency levels achieved through the use of proprietary designs in the engineering analysis if they are not part of a unique pathway to achieve the efficiency level (*i.e.,* if there are other non-proprietary technologies capable of achieving the same efficiency level).

Table II.3 summarizes the technology options that DOE screened out in the April 2010 final rule, and the applicable screening criteria.

TABLE II.3—PREVIOUSLY SCREENED OUT TECHNOLOGY OPTIONS FROM THE APRIL 2010 FINAL RULE [5]

Screened technology option	EPCA Criteria (X = basis for screening out)			
	Technological feasibility	Practicability to manufacture, install, and service	Adverse impact on product utility	Adverse impacts on health and safety
Increased heat transfer coefficient		X		
Power burner		X		
Condensing Pulse Combustion	X			
Improved fan or blower motor efficiency		X		

Issue C.1 DOE requests feedback on what impact, if any, the screening criteria described in this section would have on each of the technology options listed in Table II.2 with respect to DHE. Similarly, DOE seeks information regarding how these same criteria would affect any other technology options not already identified in this document with respect to their potential use in DHE.

Issue C.2 With respect to the screened out technology options listed in Table II.3, DOE seeks information on whether these options should, based on current and projected assessments regarding each of them, remain screened out under the screening criteria described in this section. With respect to each of these technology options, what steps, if any, could be (or have already been) taken to facilitate the introduction of each option as a means to improve the energy performance of DHE?

D. Engineering Analysis

The engineering analysis estimates the cost-efficiency relationship of products at different levels of increased energy efficiency (''efficiency levels''). This relationship serves as the basis for the cost-benefit calculations for consumers, manufacturers, and the Nation. In determining the cost-efficiency relationship, DOE estimates the change in manufacturer production cost (''MPC'') associated with increasing the efficiency of products above the baseline, up to the maximum technologically feasible (''max-tech'') efficiency level for each product class.

DOE historically has used the following three methodologies to generate incremental manufacturing costs and establish efficiency levels (''ELs'') for analysis: (1) The design-option approach, which provides the incremental costs of adding to a baseline model design options that will improve its efficiency; (2) the efficiency-level approach, which provides the relative costs of achieving increases in energy efficiency levels, without regard to the particular design options used to achieve such increases; and (3) the cost-assessment (or reverse engineering) approach, which provides ''bottom-up'' manufacturing cost assessments for achieving various levels of increased efficiency, based on detailed cost data for parts and material, labor, shipping/packaging, and investment for models that operate at particular efficiency levels.

In the analysis for the April 2010 final rule, DOE analyzed four product classes that were representative of the 11 total classes. Specifically, for each type of DHE (*i.e.,* wall fan, wall gravity, floor, room), DOE selected one ''representative'' input range for analysis and applied that analysis across all other input rate ranges for the given type of DHE. DOE developed a cost-efficiency relationship for each of these analyzed representative product classes that were used as the input for the downstream analyses conducted in support of that rulemaking. See chapter 5 of the April 2010 final rule TSD for the cost-efficiency curves developed in that rulemaking.

Issue D.1 DOE requests comment on whether it is necessary to individually analyze all 11 product classes, or whether the approach of analyzing a representative sub-set of product classes is appropriate for any potential future DHE energy conservation standards rulemaking. For example, analysis on the gas wall fan less than or equal to 42,000 Btu/h product classes may not be necessary if the analysis on the corresponding gas wall fan greater than 42,000 Btu/h product classes is applicable to both product classes. Additionally, DOE welcomes comment on potential approaches to apply the analyzed representative product class results to the other product classes, including the approach used for the April 2010 final rule. If it is necessary to individually analyze each of the 11 product classes (or more than the 11 classes), please provide information on why aggregating certain products is not appropriate. If this approach is not appropriate, what alternative approaches should DOE consider using and why? [6]

1. Baseline Efficiency Levels

For each product class that is analyzed, DOE selects a baseline model as a reference point against which any changes resulting from new or amended energy conservation standards can be measured. The baseline model in each product class represents the characteristics of common or typical products in that class. Typically, a baseline model is one that just meets the current minimum energy conservation standards and provides basic consumer utility.

DOE uses baseline models for comparison in several phases of the analyses, including the engineering analysis, life-cycle cost (''LCC'') analysis, payback period (''PBP'') analysis, and national impact analysis (''NIA''). In the engineering analysis, to determine the changes in price to the consumer that result from amended standards, DOE compares the price of a baseline model to the price of a model at each higher efficiency level.

If it determines that a rulemaking is necessary, consistent with this analytical approach, DOE tentatively plans to consider the current minimum energy conservations standards (which went into effect April 16, 2013) to establish the baseline efficiency levels for each product class. The current standards for each product class are based on DHE type (wall, floor, or room), heat circulation type (fan or gravity), and input capacity. The current standards for DHE are found at 10 CFR 430.32(i)(2).

Issue D.2 DOE requests feedback on whether using the current established energy conservation standards for DHE are appropriate baseline efficiency levels for DOE to apply to each product class in evaluating whether to amend

[5] See chapter 4, section 4.2.2 in the April 2010 final rule TSD published during the rulemaking process, document #149 on *https://regulations.gov in docket ID EERE–2006–STD–0129.*

[6] See chapter 5, section 5.3 in the April 2010 final rule TSD published during the rulemaking process, document #149 on *https://regulations.gov in docket ID EERE–2006–STD–0129.*

the current energy conservation standards for these products. DOE requests data and suggestions to evaluate the baseline efficiency levels in order to better evaluate the potential for amending energy conservation standards for these products.

Issue D.3 DOE requests feedback on the appropriate baseline efficiency levels for any newly analyzed product classes that are not currently in place or for any contemplated combined or separated product classes, as discussed in section II.B.1 of this document. For product classes that would be newly analyzed (if any), DOE requests energy use data to develop a baseline relationship between energy use and input capacity.

2. Maximum Available and Maximum Technologically Feasible Levels

As part of DOE's analysis when considering potential amended standards, DOE determines the maximum available efficiency level and the maximum technologically feasible (''max-tech'') efficiency level for each product class analyzed. The maximum available efficiency level is the highest-efficiency model currently available on the market for that class. The max-tech efficiency level represents the theoretical maximum possible efficiency if all available design options are incorporated in a model. In some cases, models at the max-tech efficiency level are not commercially available because, although the level is technically achievable, manufacturers have determined that it is not economically feasible (either for the manufacturer to produce or for consumers to purchase). However, DOE seeks to determine the max-tech level for purposes of its analyses. The current maximum available efficiencies for the 11 existing product classes are included in Table II.4, along with the maximum available efficiencies from the April 2010 final rule and the October 2016 final determination.

TABLE II.4—MAXIMUM AVAILABLE EFFICIENCY LEVELS—CURRENT AND PREVIOUS RULEMAKINGS

DHE type	Heat circulation type	Input rate, Btu/h	AFUE		
			April 2010 *	October 2016 **	Current ***
Wall	Fan	≤42,000	83	92	93
		>42,000	† 80	80	80
	Gravity	≤27,000	80	80	72
		>27,000 and ≤46,000	† 69	69	69
		>46,000	69	70	70
Floor	All	≤37,000	57	57	57
		>37,000	† 58	58	58
Room	All	≤20,000	59	71	71
		>20,000 and ≤27,000	63	66	66
		>27,000 and ≤46,000	† 81	68	68
		>46,000	70	70	70

* Gas Appliance Manufacturers Associated Directory for Direct Heating Equipment downloaded March 2, 2009.
** Combination of Air-Conditioning, Heating, & Refrigeration Institute (AHRI) and DOE's Compliance Certification Management System (CCMS) databases downloaded on July 16, 2015.
*** Combination of AHRI and CCMS databases download on September 10, 2018.
† Representative product classes analyzed in the April 2010 final rule.

In the April 2010 final rule, DOE determined max-tech efficiency levels using the technology options available at that time. For gas wall fan DHE with an input rate over 42,000 Btu/h, DOE identified a max-tech efficiency level design with induced draft combustion, resulting in an AFUE of 80 percent. For gas wall gravity DHE with an input rate over 27,000 Btu/h and up to 46,000 Btu/h, DOE identified 70 percent AFUE as a theoretical max-tech level, which was achievable with an improved heat exchanger design and electronic ignition. For gas floor DHE with an input rate over 37,000 Btu/h, DOE identified the max-tech efficiency level as 58 percent AFUE, which DOE stated could be reached using an improved heat exchanger design. For gas room DHE with an input rate over 27,000 Btu/h and up to 46,000 Btu/h, DOE identified a theoretical max-tech efficiency level of 83 percent AFUE, which manufacturers could achieve using an electronic ignition and improved heat exchanger. 75 FR 20112, 20145–20146 (April 16, 2010).

In the October 2016 final determination, DOE noted that condensing gas wall fan DHE models with input rates at or below 42,000 Btu/h had become available, and DOE considered this the max-tech level for gas wall fan DHE. Based on information obtained during manufacturer interviews and a manufacturer production cost found through a teardown analysis performed for the proposed determination (81 FR 21276, 21280 (April 11, 2016)), DOE determined that condensing technology was not economically justified for gas wall fan DHE at that time. 81 FR 71325, 71328 (Oct. 17, 2016). During manufacturer interviews conducted leading up to the proposed determination, manufacturers indicated that condensing models are significantly more expensive to produce than non-condensing models, which DOE confirmed through its teardown analysis, which showed a 23 percent manufacturing cost increase for condensing units. Manufacturers also indicated that shipments were so low as to be negligible, and DOE noted that only one manufacturer produced a condensing gas wall fan DHE at that time. DOE stated in the final determination that manufacturers would need to make substantial investments in order to produce these units on a scale large enough to support a Federal minimum standard and that severe manufacturer impacts would be expected if an energy conservation standard were adopted at a level met through use of condensing technology. Therefore, DOE concluded the condensing technology option would not be economically justified at that time when analyzed for the Nation as a whole. *Id.* In DOE's preliminary research for this RFI, it found that 2 out of the 4 manufacturers of gas wall fan DHE currently make products incorporating condensing technology.

Issue D.4 DOE seeks input on whether the maximum available

efficiency levels are appropriate and technologically feasible for consideration as possible energy conservation standards for the products at issue, and if not, why not. DOE also seeks input on whether other maximum efficiency levels are possible with technologies, or combinations of technologies, not currently incorporated in available designs.

Issue D.5 DOE seeks feedback on what design options would be incorporated at a max-tech efficiency level, and the efficiencies associated with those levels. As part of this request, DOE also seeks information as to whether there are limitations on the use of certain combinations of design options.

3. Manufacturer Production Costs and Manufacturing Selling Price

As described at the beginning of this section, the main outputs of the engineering analysis are cost-efficiency relationships that describe the estimated increases in manufacturer production cost (MPC) associated with higher-efficiency products for the analyzed product classes. For the April 2010 final rule, DOE developed the cost-efficiency relationships by estimating the efficiency improvements and costs associated with incorporating specific design options into the assumed baseline model for each analyzed product class. 75 FR 20112, 20147–20149 (April 16, 2010).

Issue D.6 DOE requests feedback on how manufacturers would incorporate the technology options listed in Table II.2 to increase energy efficiency in DHE beyond the baseline. This includes information on the order in which manufacturers would incorporate the different technologies to incrementally improve the efficiencies of products. DOE also requests feedback on whether the increased energy efficiency would lead to other design changes that would not occur otherwise. DOE is also interested in information regarding any potential impact of design options on a manufacturer's ability to incorporate additional functions or attributes in response to consumer demand.

Issue D.7 DOE also seeks input on the change in MPC associated with incorporating each particular design option. Specifically, DOE is interested in whether and how the costs estimated for design options in the April 2010 final rule have changed since the time of that analysis. DOE also requests information on the investments necessary to incorporate specific design options, including, but not limited to, costs related to new or modified tooling (if any), materials, engineering, and development efforts to implement each design option, and manufacturing/production impacts.

Issue D.8 DOE requests comment on whether certain design options may not be applicable to (or incompatible with) specific product classes.

To account for manufacturers' non-production costs and profit margin, DOE applies a non-production cost multiplier (the manufacturer mark-up) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. For the April 2010 final rule, DOE used a manufacturer mark-up of 1.35 for all DHE. See chapter 5 of the April 2010 final rule TSD.

Issue D.9 DOE requests feedback on whether a manufacturer mark-up of 1.35 is appropriate for all DHE.

E. Mark-Up Analysis

The mark-ups analysis develops appropriate mark-ups (*e.g.,* for wholesalers, mechanical contractors, general contractors) in the distribution chain (*i.e.,* how the products are distributed from the manufacturer to the consumer) and sales taxes to convert the manufacturer sales prices (''MSP'') derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analyses and other analyses. At each step in the distribution channel, companies mark up the price of the equipment to cover business costs and profit margin.

1. Distribution Channels

In generating end-user price inputs for the LCC analysis and NIA, DOE must identify distribution channels (*i.e.,* how the products are distributed from the manufacturer to the consumer) and estimate relative sales volumes through each channel. Two different markets exist for DHE: (1) Replacements and new owners,[7] and (2) new construction. DOE intends to use similar distribution channels in its analysis as found in the April 2010 final rule. DHE is mainly a replacement product.[8] For replacement and new owner applications, most sales go through distributors to contractors, and then to consumers as follows:

Manufacturer → Wholesaler → Mechanical Contractor → Consumer

In new home applications, most sales go through distributors to contractors hired by the builder as follows:

Manufacturer → Wholesaler → Mechanical Contractor → General Contractor → Consumer

Issue E.1 DOE requests information on the existence of any distribution channels that are used to distribute the products at issue into the market. DOE also requests data on the fraction of DHE sales in the residential sector that go through any identified channels.

2. Mark-Ups

To develop mark-ups for the parties involved in the distribution of the equipment, DOE plans to primarily utilize: (1) The Heating, Air Conditioning & Refrigeration Distributors International (''HARDI'') 2013 Profit Report[9] (for wholesalers) and 3. U.S. Census Bureau 2012 Economic Census data[10] on the residential building construction industry (for general contractors and mechanical contractors). DOE also plans to use the 2005 Air Conditioning Contractors of America's (''ACCA'') Financial Analysis on the Heating, Ventilation, Air-Conditioning, and Refrigeration (''HVACR'') contracting industry[11] to disaggregate the mechanical contractor mark-ups into replacement and new construction markets. DOE will also consider updates to any of these materials that may publish during DOE's evaluation.

In addition to the mark-ups, DOE will derive State and local taxes from data provided by the Sales Tax Clearinghouse.[12] These data represent weighted-average taxes that include county and city rates. DOE will derive shipment-weighted-average tax values for each region considered in the analysis.

Issue E.2 DOE requests recent data and recommendations regarding data sources to establish the mark-ups for the

[7] New owners are defined as existing buildings that acquire a DHE for the first time during the analysis period. An example of new owner for DHE would be someone with an addition to an existing house where it would not be feasible to extend the house's primary heating system to the new space.

[8] The Air-Conditioning, Heating, and Refrigeration Institute (AHRI) stated that less than 5 percent of DHE sales are for new construction projects. AHRI, *Comment #7 for RFI for Energy Conservation Standards for Energy Conservation Standards for Direct Heating Equipment and Pool Heaters* (April 27, 2015) (Available at: *https://www.regulations.gov/document?D=EERE-2015-BT-STD-0003-0007*) (Last accessed Oct. 2, 2018).

[9] Heating, Air Conditioning & Refrigeration Distributors International (HARDI), *2013 HARDI Profit Report* (Available at: *http://hardinet.org/*) (Last accessed Oct. 2, 2018).

[10] U.S. Census Bureau, *2012 Economic Census Data* (Available at: *http://www.census.gov/econ/*) (Last accessed Sept. 12, 2018).

[11] Air Conditioning Contractors of America (ACCA), *Financial Analysis for the HVACR Contracting Industry* (2005) (Available at: *http://www.acca.org/store/*) (Last accessed Oct. 2, 2018).

[12] Sales Tax Clearinghouse Inc., *State Sales Tax Rates Along with Combined Average City and County Rates.* 2018 (Available at; *http://thestc.com/STrates.stm*) (Last accessed Oct. 2, 2018).

parties involved with the distribution of DHE.

F. Energy Use Analysis

DOE conducts an energy use analysis to identify how products are used by consumers, and thereby determine the energy savings potential of energy efficiency improvements. DOE uses the annual energy consumption and energy-savings potential in the LCC and PBP analysis to establish the operating costs savings at various product efficiency levels. DOE will estimate the annual energy consumption of direct heating equipment at specified energy efficiency levels across a range of applications, household types, and climate zones. The annual energy consumption includes use of natural gas, liquefied petroleum gas (LPG (*i.e.,* propane)), and electricity.

1. Sample Development

DOE intends to base the energy use analysis on key characteristics from the Energy Information Administration's (''EIA'') 2015 Residential Energy Consumption Survey (''RECS'') [13] for the subset of residential buildings that use DHEs. DOE also plans to include in its analysis DHE used in the commercial sector using EIA's 2012 Commercial Building Energy Consumption Survey (''CBECS'').[14]

RECS and CBECS data include information on the DHE type, physical characteristics of buildings, fuels used, energy consumption and expenditures, and other relevant characteristics.[15] Based on RECS 2015 and CBECS 2012 data, DOE will develop a representative population of buildings for DHE. In addition, DOE intends to review other data sets (*e.g.,* data from the 2016 Residential Building Stock Assessment for the Northwest,[16] 2014 Commercial Building Stock Assessment for the Northwest,[17] 2015 Residential Statewide Baseline Study of New York State,[18] 2006 California Commercial End-Use Survey,[19] and 2009 Residential Appliance Saturation Study [20]) to compare these to the RECS 2015 and CBECS 2012 data for the corresponding region.

Issue F.1 DOE requests comment on the overall method to determine the building sample for direct heating equipment and whether other factors should be considered in developing the building sample. In addition, DOE requests information on the installation applications of DHE, including, but not limited to the fraction of DHEs that are installed in residential and commercial applications, as well as how many DHE are typically installed per building.

2. Energy Use Calculations

To determine the site energy consumption by the DHEs installed in the building, DOE intends to use a methodology based on the energy use equations from the DOE test procedure for DHEs (10 CFR part 430, subpart B, appendix O, section 4.6). For each household or building in the sample, DOE plans to use RECS 2015 and CBECS 2012 reported heating energy consumption to estimate the heating load of the housing unit or building.[21] The estimation of heating loads requires data on the existing DHE characteristics (such as DHE type, fuel type, equipment size, and efficiency of the DHE). DOE intends to assign DHE characteristics of existing systems based on the distributions of DHE provided in historical versions of the AHRI model certification directory [22] and any other available historical data. The estimation of heating loads also requires calculating the electricity consumption of the blower (when applicable), because heat from the blower contributes to heating the housing unit. A large fraction of DHE are used as secondary heating equipment; therefore, DOE intends to adjust the house heating load for households that use the direct heating equipment as secondary heating equipment by using the reported fraction of heating energy consumption attributable to secondary heating products in RECS 2015. To complete the analysis, DOE plans to calculate the energy consumption of more energy efficient DHE alternatives replacing the existing DHE.

Issue F.2 DOE requests comment on the overall method to determine energy use of direct heating equipment and if other factors should be considered in developing the energy use methodology.

G. Life-Cycle Cost and Payback Period Analysis

DOE plans to conduct LCC and PBP analyses to evaluate the economic impacts on residential and commercial consumers of potential standards for DHEs. The effect of new or amended standards on residential and commercial consumers usually involves a reduction in operating cost and an increase in purchase cost.

DOE intends to analyze the potential for variability by performing the LCC and PBP calculations on a representative sample of residential and commercial consumers. DOE plans to utilize the sample of buildings developed for the energy use analysis. DOE plans to model uncertainty in many of the inputs to the LCC and PBP analysis using Monte Carlo simulation and probability distributions. As a result, the LCC and PBP results will be presented as distributions of impacts compared to the no-new-standards case (*i.e.,* the case without amended standards).

Inputs to the LCC and PBP analysis are categorized as: (1) Inputs for establishing the purchase expense, otherwise known as the total installed cost, and (2) inputs for calculating the operating costs. Each type of input is discussed in the paragraphs that follow.

1. Total Installed Cost

The primary inputs for establishing the total installed cost are the baseline customer price, incremental customer price increases resulting from a potential standard, and installation costs. Baseline prices and standard-level price increases will be determined by applying mark-ups to manufacturer selling price estimates and sales tax.

The installation cost is added to the customer price to arrive at a total

[13] Energy Information Administration (EIA), *2015 Residential Energy Consumption Survey (RECS)* (Available at: *https://www.eia.gov/consumption/residential/*) (Last accessed Oct. 2, 2018).

[14] Energy Information Administration (EIA), *2012 Commercial Building Energy Consumption Survey (CBECS)* (Available at: *http://www.eia.gov/consumption/commercial/*) (Last accessed Oct. 2, 2018).

[15] From RECS 2015, DOE intends to use households listed as using primary gas heating equipment from ''built-in room heater burning gas, oil, or kerosene'' (138 home sample is estimated to represent 2.8 million homes in 2015) and ''built-in floor/wall pipeless furnace'' (41 home sample is estimated to represent 0.8 million homes in 2015) and as secondary gas heating equipment from ''some other equipment'' (221 home sample is estimated to represent 4.2 million homes in 2015).

[16] Northwest Energy Efficiency Alliance (NEEA), *Residential Building Stock Assessment (2016)* (Available at: *https://dev.neea.org/data/residential-building-stock-assessment*) (Last accessed Oct. 2, 2018).

[17] Northwest Energy Efficiency Alliance (NEEA), *Commercial Building Stock Assessment (2014)* (Available at: *https://dev.neea.org/data/commercial-building-stock-assessments*) (Last accessed Oct. 2, 2018).

[18] New York State Energy Research and Development Authority (NYSERDA), *Residential Statewide Baseline Study of New York State (July 2015)* (Available at: *https://www.nyserda.ny.gov/About/Publications/Building-Stock-and-Potential-Studies/Residential-Statewide-Baseline-Study-of-New-York-State*) (Last accessed Oct. 2, 2018).

[19] California Energy Commission (CEC), *2006 California Commercial End-Use Survey (2006)* (Available at: *http://www.energy.ca.gov/ceus/2006_enduse.html*) (Last accessed Oct. 2, 2018).

[20] California Energy Commission (CEC), *2009 Residential Appliance Saturation Study (RASS) (2009)* (Available at: *http://www.energy.ca.gov/appliances/rass/*) (Last accessed Oct. 2, 2018).

[21] The heating load represents the amount of heating required to keep a housing unit comfortable throughout an average year.

[22] AHRI, *Directory of Certified Product Performance for Direct Heating Equipment* (Available at: *https://www.ahridirectory.org/*) (Last accessed Oct. 2, 2018).

installed cost. DOE intends to develop installation costs using the most recent RS Means data available.[23] DOE also intends to use regional labor costs to more accurately estimate installation costs by applying the appropriate regional labor cost from RS Means to each sampled DHE installation.

In conducting its analyses, DOE intends to utilize an installation cost methodology that is customized for each DHE product class. For DHEs in new owner installations or new construction, DOE plans to include costs such as adding gas piping, putting the DHE in place, and additional set-up. For replacement cases, in addition to the costs considered for new installations, DOE also plans to include the installation cost associated with disconnecting and removing the old DHE, as well as removal/disposal and permit fees, if applicable. In addition, DOE intends to assess whether installation costs vary with equipment efficiency, including design options that require a new electrical outlet (many existing DHE installations currently do not have electrical power input) or condensing DHE units that require new PVC venting and condensate withdrawal.

Issue G.1 DOE seeks input on any available installation cost data for DHEs. DOE also seeks input on the approach it intends to use to develop DHE installation costs, specifically, its intention to use the most recent RS Means Mechanical Cost Data.

2. Operating Costs

The primary inputs for calculating the operating costs of DHEs are energy consumption, equipment efficiency, energy prices, maintenance and repair costs, equipment lifetime, and discount rates. Both equipment lifetime and discount rates are used to calculate the present value of future operating costs.

The product energy consumption is the site energy use associated with providing space heating to the room of a building. DOE intends to utilize the site energy use calculation methodology described in section II.F of this document to determine product energy use. DOE also plans to assess the potential applicability of the ''rebound effect'' in the energy consumption for DHE. A rebound effect occurs when a product that is made more efficient is used more intensively, so that the expected energy savings from the efficiency improvement may not fully materialize. However, at this time, DOE is not aware of any information about a rebound effect for DHE.

Issue G.2 DOE seeks comments and data on any rebound effect that may be associated with more-efficient DHE.

The repair cost is the expense to repair or replace components of the covered product that have failed. The maintenance cost is the expense of regular scheduled product maintenance to ensure the continued operation of the covered product over time. These costs cover all labor and material costs associated with the repair or maintenance. DOE intends to develop repair and maintenance costs using the most recent RS Means data available[24] and manufacturer literature.

DOE intends to assess whether repair or maintenance costs vary with equipment efficiency and product class. In addition, DOE plans to consider the cases in which the equipment is covered by warranty, service, and/or maintenance agreements. More specifically, DOE intends to account for the maintenance cost associated with the manufacturer-recommended annual maintenance prior to the heating season.

DOE will determine the repair cost using an approach that reflects the cost and the service life of the components that are likely to fail. DOE plans to consider component repair costs that might fail during the lifetime of the product, including the pilot ignition, electronic ignition, circulating blower, and induced draft fan.

Issue G.3 DOE requests feedback and data on whether maintenance costs differ in comparison to the baseline maintenance costs for any of the specific technology options listed in Table II.2 and Table II.3. To the extent that these costs differ, DOE seeks supporting data and the reasons for those differences.

Issue G.4 DOE requests information and data on the frequency of repair and repair costs by product class for the technology options listed in Table II.2 and Table II.3. DOE is also interested in whether consumers simply replace the products when they fail as opposed to repairing them.

Issue G.5 DOE also seeks comment on the extent to which repair or maintenance costs are covered by warranty, service, and/or maintenance agreements.

Equipment lifetime is the age at which a unit is retired from service. DOE intends to conduct a literature review of DHE lifetime data together with any stakeholder lifetime data to develop a Weibull probability distribution to characterize DHE lifetime.[25]

Issue G.6 DOE requests product lifetime data and information on whether product lifetime varies based on DHE product class, application, or efficiency.

DOE measures LCC and PBP impacts of potential standard levels relative to a no-new-standards case that reflects the likely market in the absence of amended standards. DOE plans to develop efficiency market shares (*i.e.,* the distribution of product shipments by efficiency) for DHEs, for the anticipated year in which compliance with any potential amended standards would be required. DOE is not aware of any shipment data to estimate the market shares of different DHE energy efficiency levels in the no-new-standards case. DOE is particularly interested in receiving such data. If no market share data become available, DOE intends to use data on the number of DHE models at different energy efficiency levels, as reported in DOE's compliance certification database,[26] historical versions of the AHRI model certification directory,[27] and from manufacturer literature.

Issue G.7 DOE requests information on the DHE market, including but not limited to, the current market share by different efficiency level and by product class, similar historical data, and information on expected future trends in the efficiency of DHEs.

H. Shipments Analysis

DOE develops shipments forecasts of DHE to calculate the national impacts of potential amended energy conservation standards on energy consumption, net present value (''NPV''), and future manufacturer cash flows. DOE shipments projections are based on available historical data broken out by product class, input capacity, and efficiency. Current sales estimates allow for a more accurate model that captures recent trends in the market. From the April 2010 final rule, DOE has DHE historical shipment data from AHRI for

[23] RS Means, *2018 Mechanical Cost Data* (Available at: *https://www.rsmeans.com/products/books.aspx*) (Last accessed Oct. 2, 2018).

[24] RS Means, *2018 Facilities Maintenance & Repair Cost Data* (Available at: *https://www.rsmeans.com/products/books.aspx*) (Last accessed Oct. 2, 2018).

[25] A Weibull probability distribution is a continuous distribution function typically used in reliability engineering and equipment failure analysis. If the data are available, DOE also plans to take into account differences in DHE lifetime based on usage and application.

[26] U.S. Department of Energy, Compliance Certification Database: Unfired Hot Water Storage Tanks—Commercial (Available at: *https://www.regulations.doe.gov/certification-data/products.html*) (Last accessed Oct. 2, 2018).

[27] AHRI, *Directory of Certified Product Performance for Direct Heating Equipment* (Available at: *https://www.ahridirectory.org/*) (Last accessed Oct. 2, 2018).

wall furnaces from 1990 to 1998 and from 2000 to 2006, for floor furnaces from 1990 to 2007, and for room heaters from 1990 to 2005.[28] [29] DOE has limited disaggregated shipments for fan and gravity wall furnaces and by input capacity.[30]

Issue H.1 DOE requests annual sales data (*i.e.,* number of shipments) for each DHE product class from 2008–2018.

An example table of the types of data requested for 2008–2018 shipments can be found in Table II.5. Interested parties are also encouraged to provide additional shipment data as may be relevant including data before 2008.

TABLE II.5—SUMMARY TABLE OF SHIPMENTS—RELATED DATA REQUESTS

Equipment type	Heat circulation type	Input rate, Btu/h	Annual shipments (number sold)										
			2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Wall	Fan	≤42,000.											
		>42,000.											
	Gravity	≤27,000.											
		>27,000 and ≤46,000.											
		>46,000.											
Floor	All	≤37,000.											
		>37,000.											
Room	All	≤20,000.											
		>20,000 and ≤27,000.											
		>27,000 and ≤46,000.											
		>46,000.											

If disaggregated fractions of annual sales are not available at the product type level, DOE requests more aggregated fractions of annual shipments at the category level.

Issue H.2 If available, DOE requests the same information in Table II.5 by efficiency.

I. Manufacturer Impact Analysis

The purpose of the manufacturer impact analysis (''MIA'') is to estimate the financial impact of new or amended energy conservation standards on manufacturers of DHE, and to evaluate the potential impact of such standards on direct employment and manufacturing capacity. The MIA includes both quantitative and qualitative aspects. The quantitative part of the MIA primarily relies on the Government Regulatory Impact Model (''GRIM''), an industry cash-flow model adapted for each product in this analysis, with the key output being the industry net present value (''INPV''), which is used to assess the financial impacts of a potential standard. The qualitative part of the MIA addresses the potential impacts of energy conservation standards on manufacturing capacity and industry competition, as well as factors such as product characteristics, impacts on particular subgroups of firms, and important market and product trends.

As part of the MIA, DOE intends to analyze impacts of potential amended energy conservation standards on subgroups of manufacturers of covered products, including small business manufacturers. DOE uses the Small Business Administration's (''SBA'') small business size standards to determine whether manufacturers qualify as small businesses, which are listed by the applicable North American Industry Classification System (''NAICS'') code.[31] Manufacturing of consumer DHE is classified under NAICS 333414, ''Heating Equipment (except Warm Air Furnaces) Manufacturing,'' and the SBA sets a threshold of 500 employees or less for a domestic entity to be considered as a small business. This employee threshold includes all employees in a business's parent company and any other subsidiaries.

One aspect of assessing manufacturer burden involves examining the cumulative impact of multiple DOE standards and the product-specific regulatory actions of other Federal agencies that affect the manufacturers of a covered product or equipment. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

Issue I.1 To the extent feasible, DOE seeks the names and contact information of any domestic or foreign-based manufacturers that distribute DHE in the United States.

Issue I.2 DOE identified small businesses as a subgroup of manufacturers that could be disproportionally impacted by amended energy conservation standards. DOE requests the names and contact information of small business manufacturers, as defined by the SBA's size threshold, that distribute DHE products in commerce in the United States. In addition, DOE requests comment on any other manufacturer subgroups that could be disproportionally impacted by amended energy conservation standards for DHE. DOE requests feedback on any potential approaches that could be considered to address impacts on manufacturers, including small businesses.

[28] AHRI, *AHRI Shipments Data,* March 3, 2008. (Note: 1990–2006 Wall furnaces data disaggregated by vented wall furnaces and direct-vent wall furnaces).

[29] AHRI, *AHRI Floor Furnace Supplemental Shipments Data,* March 11, 2008.

[30] AHRI, *AHRI Wall Furnace Supplemental Shipments Data,* May 19, 2008. (Note: 2002–2006 shipments for wall gravity furnace over 27 to 46 kBtu/h and wall fan furnace above over 42 kBtu/h only).

[31] Available online at: *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

Issue I.3 DOE requests information regarding the cumulative regulatory burden impacts on manufacturers of DHE associated with: (1) Other DOE standards applying to different products that these manufacturers may also make and (2) product-specific regulatory actions of other Federal agencies. DOE also requests comment on its methodology for computing cumulative regulatory burden and whether there are any flexibilities it can consider that would reduce this burden while remaining consistent with the requirements of EPCA.

J. Other Energy Conservation Standards Topics

1. Market Failures

In the field of economics, a market failure is a situation in which the market outcome does not maximize societal welfare. Such an outcome would result in unrealized potential welfare. DOE welcomes comment on any aspect of market failures, especially those in the context of amended energy conservation standards for DHE.

2. Market-Based Approaches to Energy Conservation Standards

As part of its regulatory reform efforts, DOE published a request for information discussing key issues and requesting feedback on market-based approaches to energy conservation standards. 82 FR 56181 (Nov. 28, 2017). DOE requests comment on how market-based approaches to energy conservation standards might impact standards for these products, and specifically seeks comment on any considerations with respect to DHE.

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of energy conservation standards for DHE not already addressed by the specific areas identified in this document.

III. Submission of Comments

DOE invites all interested parties to submit in writing by April 12, 2019, comments and information on matters addressed in this notice and on other matters relevant to DOE's consideration of amended energy conservations standards for DHE. After the close of the comment period, DOE will review the public comments received and may begin collecting data and conducting the analyses discussed in this RFI.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* web page requires you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies Office staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or postal mail. Comments and documents submitted via email, hand delivery, or postal mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimilies (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not contain special characters or any form of encryption, and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of the process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process or would like to request a public meeting should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signed in Washington, DC, on February 13, 2019.

Steven Chalk,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–03270 Filed 2–25–19; 8:45 am]

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DEPARTMENT OF TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 3 and 32

[Docket ID OCC–2018–0030]

RIN 1557–AE44

FEDERAL RESERVE SYSTEM

12 CFR Part 217

[Docket R–1629]

RIN 7100–AF22

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 324

RIN 3064–AE80

Notice, Extension of Comment Period; Standardized Approach for Calculating the Exposure Amount of Derivatives Contracts

AGENCY: The Board of Governors of the Federal Reserve System; the Federal Deposit Insurance Corporation, and the Office of the Comptroller of the Currency, Treasury.

ACTION: Notice; extension of comment period.

SUMMARY: On December 17, 2018, the Board of Governors of the Federal Reserve System (Board), the Federal Deposit Insurance Corporation (FDIC), and the Office of the Comptroller of the Currency (OCC) (collectively, the agencies) published in the **Federal Register** a proposal to amend the agencies' capital rule to implement the Standardized Approach for Calculating the Exposure Amount of Derivatives Contracts. The agencies have determined that an extension of the comment period until March 18, 2019, is appropriate.

DATES: Comments must be received by March 18, 2019.

ADDRESSES: You may submit comments by any of the methods identified in the proposal.

FOR FURTHER INFORMATION CONTACT:

OCC: Guowei Zhang, Risk Expert, Capital Policy, (202) 649–7106; Kevin Korzeniewski, Counsel, (202) 649–5490; or Ron Shimabukuro, Senior Counsel, (202) 649–5490, or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

Board: Constance M. Horsley, Deputy Associate Director, (202) 452–5239; David Lynch, Deputy Associate Director, (202) 452–2081; Elizabeth MacDonald, Manager, (202) 475–6316; Michael Pykhtin, Manager, (202) 912–4312; Mark Handzlik, Senior Supervisory Financial Analyst, (202) 475–6636; Sara Saab, Supervisory Financial Analyst, (202) 872–4936; or Noah Cuttler, Senior Financial Analyst, (202) 912–4678; Division of Supervision and Regulation; or Benjamin W. McDonough, Assistant General Counsel, (202) 452–2036; Gillian Burgess, Senior Counsel, (202) 736–5564; Mark Buresh, Counsel, (202) 452–5270; Andrew Hartlage, Counsel, (202) 452–6483; Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf, (202) 263–4869.

FDIC: Bobby R. Bean, Associate Director, *bbean@fdic.gov;* Irina Leonova, Senior Policy Analyst, *ileonova@fdic.gov;* Peter Yen, Senior Policy Analyst, *pyen@fdic.gov,* Capital Markets Branch, Division of Risk Management Supervision, (202) 898–6888; or Michael Phillips, Counsel, *mphillips@fdic.gov;* Catherine Wood, Counsel, *cawood@fdic.gov;* Supervision Branch, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: On December 17, 2018, the Board, FDIC, and OCC published in the **Federal Register** a proposal to amend the agencies' capital rule to implement the Standardized Approach for Calculating the Exposure Amount of Derivatives Contracts.[1] The notice of proposed rulemaking stated that the comment period would close on February 15, 2019. The agencies have received requests to extend the comment period. An extension of the comment period will provide additional opportunity for the public to consider the proposal and prepare comments, including to address the questions posed by the agencies. Therefore, the agencies are extending the end of the comment period for the proposal from February 15, 2019, to March 18, 2019.

Dated: February 19, 2019.

Joseph M. Otting,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, February 14, 2019.

Ann E. Misback,

Secretary of the Board.

Dated at Washington, DC, on February 15, 2019.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2019–03249 Filed 2–25–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2019–0051]

RIN 1625–AA08

Special Local Regulation; Choptank River, Cambridge, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations for certain waters of the Choptank River. This action is necessary to provide for the safety of life on these navigable waters located at Cambridge, MD, during a swim event on the morning of May 11, 2019. This proposed

[1] 83 FR 64660 (December 17, 2018).

rulemaking would prohibit persons and vessels from entering the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before March 28, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0051 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ron Houck, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
PATCOM Coast Guard Patrol Commander
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The TCR Event Management of St. Michaels, MD, notified the Coast Guard that it will be conducting the Maryland Freedom Swim on the morning of May 11, 2019. The open water swim consists of approximately 250 participants competing on a designated 1.75-mile linear course. The course starts at the beach of Bill Burton Fishing Pier State Park at Trappe, MD, proceeds across the Choptank River along and between the fishing piers and the Senator Frederick C. Malkus, Jr. Memorial (US–50) Bridge, and finishes at the beach of the Dorchester County Visitors Center at Cambridge, MD. Hazards from the swim competition include participants swimming within and adjacent to the designated navigation channel and interfering with vessels intending to operate within that channel, as well as swimming within approaches to local public and private marinas and public boat facilities. The Captain of the Port (COTP) Maryland-National Capital Region has determined that potential hazards associated with the swim would be a safety concern for anyone intending to participate in this event or for vessels that operate within specified waters of the Choptank River.

The purpose of this rulemaking is to protect event participants, spectators and transiting vessels on certain waters of the Choptank River before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231, which authorizes the Coast Guard to establish and define special local regulations.

III. Discussion of Proposed Rule

The COTP Maryland-National Capital Region proposes to establish special local regulations from 8 a.m. through 11 a.m. on May 11, 2019. There is no alternate date planned for this event. The regulated area would cover all navigable waters of the Choptank River, from shoreline to shoreline, within an area bounded on the east by a line drawn from latitude 38°35′14.2″ N, longitude 076°02′33.0″ W, thence south to latitude 38°34′08.3″ N, longitude 076°03′36.2″ W, and bounded on the west by a line drawn from latitude 38°35′32.7″ N, longitude 076°02′58.3″ W, thence south to latitude 38°34′24.7″ N, longitude 076°04′01.3″ W, located at Cambridge, MD. The regulated area is approximately 2,800 yards in length and 900 yards in width.

The proposed duration special local regulations and size of the regulated area are intended to ensure the safety of life on these navigable waters before, during, and after the open water swim, scheduled from 9 a.m. to 10:45 a.m. on May 11, 2019. The COTP and the Coast Guard Patrol Commander (PATCOM) would have authority to forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area would be required to immediately comply with the directions given by the COTP or PATCOM. If a person or vessel fails to follow such directions, the Coast Guard may expel them from the area, issue them a citation for failure to comply, or both.

Except for Maryland Freedom Swim participants and vessels already at berth, a vessel or person would be required to get permission from the COTP or PATCOM before entering the regulated area. Vessel operators can request permission to enter and transit through the regulated area by contacting the PATCOM on VHF–FM channel 16. Vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols would be considered a spectator. Official Patrols are any vessel assigned or approved by the Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

If permission is granted by the COTP or PATCOM, a person or vessel would be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels would be required to operate at a safe speed that minimizes wake while within the regulated area. Official patrol vessels will direct spectator vessels while within the regulated area. Vessels would be prohibited from loitering within the navigable channel. Only participant vessels and official patrol vessels would be allowed to enter the race area.

The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on size, time of day and duration of the regulated area, which would impact a small designated area of the Choptank River for 3 hours. The Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the status of the regulated area. Moreover, the rule would allow vessels to seek permission to enter the regulated area, and vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves implementation of regulations within 33 CFR part 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users and shore side activities in the event area lasting for 3 hours. Normally such actions are categorically excluded from further review under paragraph L[61] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

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

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 33 U.S.C. 1233; 33 CFR 1.05–1.

■ 2. Add § 100.501T05–0051 to read as follows:

§ 100.501T05–0051 Special Local Regulation; Choptank River, Cambridge, MD.

(a) *Definitions.* As used in this section:

Captain of the Port (COTP) Maryland-National Capital Region means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region or any Coast Guard commissioned, warrant or petty officer who has been authorized by the COTP to act on his behalf.

Coast Guard Patrol Commander (PATCOM) means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

Official Patrol means any vessel assigned or approved by Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Participants means all persons and vessels registered with the event sponsor as participating in the Flying Point Park Outboard Regatta or otherwise designated by the event sponsor as having a function tied to the event.

Spectators means all persons and vessels not registered with the event sponsor as participants or assigned as official patrols.

(b) *Location.* All coordinates reference Datum NAD 1983.

(1) *Regulated area.* All navigable waters of the Choptank River, from shoreline to shoreline, within an area bounded on the east by a line drawn from latitude 38°35′14.2″ N, longitude 076°02′33.0″ W, thence south to latitude 38°34′08.3″ N, longitude 076°03′36.2″ W, and bounded on the west by a line drawn from latitude 38°35′32.7″ N, longitude 076°02′58.3″ W, thence south to latitude 38°34′24.7″ N, longitude 076°04′01.3″ W, located at Cambridge, MD.

(2) Reserved.

(c) *Special local regulations:* (1) The COTP Maryland-National Capital Region or PATCOM may forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area shall immediately comply with the directions given by the patrol. Failure to do so may result in the Coast Guard expelling the person or vessel from the area, issuing a citation for failure to comply, or both. The COTP Maryland-National Capital Region or PATCOM may terminate the event, or a participant's operations at any time the COTP Maryland-National Capital Region or PATCOM believes it necessary to do so for the protection of life or property.

(2) Except for participants and vessels already at berth, a person or vessel within the regulated area at the start of enforcement of this section must immediately depart the regulated area.

(3) A spectator must contact the PATCOM to request permission to either enter or pass through the regulated area. The PATCOM, and official patrol vessels enforcing this regulated area, can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz). If permission is granted, the spectator must pass directly through the regulated area as instructed by PATCOM. A vessel within the regulated area must operate at safe speed that minimizes wake. A spectator vessel must not loiter within the navigable channel while within the regulated area.

(4) A person or vessel that desires to transit, moor, or anchor within the regulated area must obtain authorization from the COTP Maryland-National Capital Region or PATCOM. A person or vessel seeking such permission can contact the COTP Maryland-National Capital Region at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz) or the PATCOM on Marine Band Radio, VHF–FM channel 16 (156.8 MHz).

(5) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event date and times.

(d) *Enforcement officials.* The Coast Guard may be assisted with marine event patrol and enforcement of the regulated area by other Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 8 a.m. to 11 a.m. on May 11, 2019.

Dated: February 19, 2019.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2019–03254 Filed 2–25–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2017–0035; FXES11130900000–189–FF09E30000]

RIN 1018–BA43

Endangered and Threatened Wildlife and Plants; Removing the Borax Lake Chub From the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service or USFWS), propose to remove the Borax Lake chub (currently listed as *Gila boraxobius*), a fish native to Oregon, from the Federal List of Endangered and Threatened Wildlife on the basis of recovery. This proposal is based on a review of the best available scientific and commercial information, which indicates that the threats to the Borax Lake chub have been eliminated or reduced to the point where the species no longer meets the definition of an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). We are seeking information and comments from the public regarding this proposed rule.

DATES: We will accept comments received or postmarked on or before April 29, 2019. Please note that if you are using the Federal eRulemaking Portal (see **ADDRESSES**, below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern time on this date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by April 12, 2019.

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–2017–0035, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!'' Please ensure that you have found the correct rulemaking before submitting your comment.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R1–ES–2017–

0035, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments,* below, for more information).

Document availability: This 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 our Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266; telephone 503–231–6179.

FOR FURTHER INFORMATION CONTACT: Paul Henson, State Supervisor, telephone: 503–231–6179. Direct all questions or requests for additional information to: BORAX LAKE CHUB QUESTIONS, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266. 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 removal from the List of Endangered and Threatened Wildlife (*i.e.,* ''delisting'') if it no longer meets the definition of endangered or threatened. A species is an ''endangered species'' for purposes of the Act if it is in danger of extinction throughout all or a significant portion of its range and is a ''threatened species'' if it is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Borax Lake chub is currently listed as endangered, and we are proposing to delist the species because we have determined it no longer meets the definition of endangered and is not likely to become endangered in the foreseeable future. We can only delist a species by issuing a rule to do so.

The basis for our action. A species may be determined to be an endangered species or threatened species because of any 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 have determined that the Borax Lake chub is no longer at risk of extinction, and the following criteria for delisting described in the species recovery plan have been met or exceeded:

- The presence of a naturally reproducing population of Borax Lake chub in Borax Lake that is free of exotic species;
- Permanent protection of the 160-acre (ac) (65-hectare (ha)) parcel of land surrounding and including Borax Lake;
- Removal of threats to subsurface waters from geothermal energy exploration or development;
- Reestablishment of ponds and natural marshes adjacent to Borax Lake in order to create more chub habitat;
- A viable, self-sustaining population of Borax Lake chub;
- Permanent protection of the 160-ac (65-ha) parcel of land to the north of Borax Lake;
- Withdrawal of Borax Lake waters from appropriation (*i.e.,* diversion and use under water right);
- Establishment of a fence around the 640-ac (259-ha) critical habitat area to prevent vehicle entry;
- Establishment of monitoring programs to survey habitat and fish population status; and
- Lack of any new threats to the species or ecosystem for 5 consecutive years.

Information Requested

Public Comments

We intend that any final rule resulting from this proposal will be based on the best available scientific and commercial data and will be as accurate and effective as possible. Therefore, we invite Tribal, State, and governmental agencies; the scientific community; industry; and 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) Biological information concerning the Borax Lake chub and information on the Borax Lake ecosystem;

(2) Relevant data concerning presence or absence of current or future threats to the Borax Lake chub and its habitat;

(3) Information regarding management plans or other mechanisms that provide protection to the Borax Lake chub and its habitat;

(4) Information on the potential for changes in precipitation levels and air and water temperatures to affect the Borax Lake chub due to changes in the climate or other reasons (including any modeling data and projections for the Alvord Basin);

(5) Information regarding potential for geothermal energy development in the vicinity of Borax Lake, and any information useful for determining the extent of potential effects to Borax Lake; and

(6) Any information relevant to whether the species falls within the definition of either an endangered species under section 3(6) of the Act (16 U.S.C. 1531 *et seq.*) or a threatened species under section 3(20) of the Act, including information on the five listing factors under section 4(a)(1) of the Act and any other factors meeting the criteria to support the recovery and removal of the species from the List of Endangered and Threatened Wildlife (List; 50 CFR 17.11(h)).

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 threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

We will take into consideration all comments and any additional information we receive. Such information 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 administrative record.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We will not consider comments sent by email, by fax, or to an address not listed in **ADDRESSES**. If you submit your comments electronically, your comments must be submitted through the Federal eRulemaking Portal (*http://www.regulations.gov*) before 11:59 p.m. Eastern time on the date specified in **DATES**. We will not consider hand-delivered comments that we do not receive by the date specified in **DATES**, or mailed comments that are not postmarked by that date.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* If you provide

personal identifying information in your comment, 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.

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, Oregon Fish and Wildlife Office (see *Document availability* under **ADDRESSES**, above).

Public Hearing

Section 4(b)(5)(E) of the Act provides for one or more public hearings on this proposal, if requested. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** within 45 days after the date of this **Federal Register** publication (see **DATES**, above). We will schedule at least one public hearing on this proposal, if any are requested, and announce the date, time, and place of the hearing(s), as well as how to obtain reasonable accommodations, in the **Federal Register** at least 15 days before any first hearing.

Peer Review

In accordance with our policy, ''Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities,'' which was published 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 Actions

On May 28, 1980, we published a rule in the **Federal Register** to emergency-list the Borax Lake chub (as *Gila* sp.) as endangered and to designate critical habitat for the species (45 FR 35821). The emergency rule provided protection to this species for 240 days, until January 23, 1981.

On October 16, 1980, we proposed to list the Borax Lake chub (as *Gila boraxobius*) as an endangered species and to designate critical habitat (45 FR 68886). The distribution of the Borax Lake chub is limited to Borax Lake, its outflow, and Lower Borax Lake in Harney County, Oregon. The proposed listing action was taken because proposed geothermal development in and around Borax Lake, and human modification of the lake, threatened the integrity of the species' habitat and, hence, its survival.

On October 5, 1982, we published a final rule in the **Federal Register** (47 FR 43957) listing the Borax Lake chub (as *Gila boraxobius*) as endangered and designating areas totaling 640 acres (ac) (259 hectares (ha)) in and around Borax Lake as critical habitat for the Borax Lake chub. A recovery plan for the species was completed on February 4, 1987 (USFWS 1987).

A 5-year review of the Borax Lake chub's status was completed on August 23, 2012 (USFWS 2012); this review concluded that the Borax Lake chub's status had substantially improved since listing, and that the Borax Lake chub no longer met the definition of an endangered species, but may meet the definition of a threatened species throughout all of its range, under the Act. Therefore, the review recommended the Borax Lake chub be reclassified from endangered to threatened (*i.e.,* ''downlisted''). However, this proposed rule, which is based on information contained in the 5-year review as well as additional information that has become available since completion of the 5-year review, proposes to remove the Borax Lake chub from the List (*i.e.,* to ''delist'' the species).

Although we acknowledged in the 5-year review that recovery criteria had largely been met, we recommended downlisting instead of delisting due to the potential threat of geothermal development that, at the time, was represented by a 2012 proposed geothermal development on private lands within 1 to 3 miles (mi) (1.6 to 4.8 kilometers (km)) of Borax Lake. In addition to the recommendation to reclassify, the 5-year review further recommended three remaining actions: (1) Completion of the Borax Lake Chub Cooperative Management Plan (CMP); (2) acquisition of groundwater and surface rights to geothermal development on private lands to complement the Federal land mineral withdrawal within the Alvord Known Geothermal Resource Area; and (3) monitoring of the Borax Lake chub and the Borax Lake ecosystem.

Since completion of the 2012 5-year review, the Service, Bureau of Land Management (BLM), Oregon Department of Fish and Wildlife (ODFW), and The Nature Conservancy (TNC) have continued to implement recovery actions; the CMP has been finalized; a fence to eliminate vehicle access to critical habitat has been completed around Borax Lake; and monitoring of Borax Lake chub and the Borax Lake ecosystem has been conducted. Although the recovery plan did not call for acquisition of groundwater and surface rights to geothermal development on private lands outside the two 160-ac (65-ha) parcels eventually acquired by TNC and designated critical habitat, the Service's 2012 5-year review and CMP make that conservation recommendation. Although we will continue to work with our partners to seek opportunities to reduce potential risk from geothermal development on private lands in proximity to Borax Lake, we no longer view geothermal development as an operative threat such that the Borax Lake chub meets the definition of an endangered or a threatened species under the Act. The Pueblo Valley Geothermal LLC (Limited Liability Company), the last entity showing interest in geothermal development in the Alvord Basin, did not file a formal permit application with the BLM or the State of Oregon's Department of Geology and Mineral Industries (DOGAMI), and the LLC was dissolved in 2013. We are unaware of any current proposals to develop geothermal energy production in the Alvord Basin.

Species Information

At the time of listing, the genus *Gila* was considered to include three subgenera: *Gila, Siphateles* (including the Borax Lake chub), and *Snyderichthys* (Uyeno 1961, pp. 84–85; Bailey and Uyeno 1964, pp. 238–239). Since our final listing determination (47 FR 43957; October 5, 1982), analysis of lepidological (scale morphology and arrangement) and osteological (structure and function of bones) characters (Coburn and Cavender 1992, pp. 344–347) and mitochondrial ribosomal RNA sequences (Simons and Mayden 1997, p. 194; 1998, p. 315; Simons *et al.* 2003, pp. 71–76) have indicated that the genus *Gila* in the broad sense was not descended from a common ancestor not shared with other groups. Therefore, the three subgenera were elevated to genera. The American Fisheries Society (Page *et al.* 2013, p. 78) has also followed this approach and classified the Borax Lake chub within the genus *Siphateles.* Consequently, the current scientific name of the Borax Lake chub is *Siphateles boraxobius.* This taxonomic

revision changed the name of the listed entity from *Gila boraxobius* to *Siphateles boraxobius,* but did not alter the description, distribution, range, or listing status of the species from what it was at the time of listing. Based on this revision, we consider *Siphateles boraxobius* to be the most appropriate scientific name for this taxon. Because we are proposing to remove the species from the List, we are not proposing to amend the species' scientific name on the List, but future documents, such as the post-delisting monitoring plan for the species, should reflect this usage.

The Borax Lake chub is a small minnow (Family: Cyprinidae) endemic to Borax Lake and its outflows. Borax Lake is a 10.2-ac (4.1-ha) geothermally heated, alkaline spring-fed lake in southeastern Oregon. The lake is perched 30 feet (ft) (10 meters (m)) above the desert floor on large sodium-borate deposits (Williams and Bond 1980, p. 297). Water depth averages approximately 3.3 ft (1.0 m), with a maximum measured depth of 88.6 ft (27 m) at the thermal vent (Scheerer and Jacobs 2005, p. 6). The lake bottom includes patches of bedrock and fine gravel, with a sparse growth of aquatic plants, and is covered with thick, fluffy silt. Average lake temperatures range from a high of 39.2 degrees Celsius (°C) (102.6 degrees Fahrenheit (°F)) to a low of 22 °C (71.6 °F) near the shoreline (Scheerer *et al.* 2013, pp. 3–6). Borax Lake chub prefer the shallow habitats along the margins of the lake (Perkins *et al.* 1996, p. 8).

The Borax Lake chub is an opportunistic omnivore. The diets of juveniles and adults are very similar and include aquatic and terrestrial insects, algae, mollusks and mollusk eggs, aquatic worms, fish scales, spiders, and seeds (Williams and Williams 1980, p. 113). Males, and some females, reach reproductive maturity within one year. Spawning occurs primarily in the spring but can occur year-around (Williams and Bond 1983, pp. 412–413). The reproductive behavior and length of incubation is unknown.

Population abundance estimates for the Borax Lake chub were conducted annually from 1986 to 1997, from 2005 to 2012, and from 2015 to 2017. Over this period, the population abundance has shown a high degree of variability, ranging from a low of 1,242 in 2015, to a record high of 76,931 in 2017 (Scheerer *et al.* 2015, p. 3; M. Meeuwig *in litt.* 2017). A pattern of population reduction followed by a 1- to 5-year period of rebuilding has been observed multiple times during the period of record. The mechanisms contributing to variability in abundance are not entirely clear, but Scheerer *et al.* (2012, p. 16) surmised that because Borax Lake chub experience water temperatures that are at or near their thermal critical maximum (Williams and Bond 1983, p. 412), survival and recruitment are likely higher during years when water temperatures are cooler in the lake. Water temperatures in Borax Lake are influenced both by air temperatures and by the water temperature of the lake's primary source of inflow, a deep geothermal aquifer.

Recovery

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 List (*i.e.,* adding, removing, or reclassifying a species) must reflect 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.'' Therefore, recovery criteria should help indicate when we would anticipate that an analysis of the five threat factors under section 4(a)(1) would result in a determination that the species is no longer an endangered species or threatened species (see Summary of Factors Affecting the Species, below).

While recovery plans provide important guidance to the Service, States, and other partners on methods of minimizing threats to listed species and measurable objectives 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 or remove it from the List is ultimately based on an analysis of the best scientific and commercial data 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.

Recovery plans may be revised to address continuing or new threats to the species as new substantive information becomes available. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that set a trigger for review of the species' status, and methods for monitoring recovery progress. Recovery plans are intended to establish goals for long-term conservation of listed species and define criteria that are designed to indicate when the threats facing a species have been removed or reduced to such an extent that the species may no longer need the protections of the Act.

There can be many paths to accomplishing recovery of a species, and because a status determination must be based on a current analysis of the five threat factors under section 4(a)(1), it may be possible to achieve recovery without fully meeting the recovery criteria that were identified at the time the recovery plan was completed. For example, a five-factor analysis may determine that current information on threats and species status indicates the threats have been minimized sufficiently to delist or downlist while the recovery criteria have been partially or fully met or exceeded in various combinations. 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 that earlier criteria need to be met for recognizing recovery of the species. Recovery of a species is a dynamic process requiring adaptive management that may, or may not, fully follow the guidance provided in a recovery plan.

The Borax Lake Chub Recovery Plan (USFWS 1987, pp. 27–30) described an ''interim objective'' for potential reclassification to threatened status, as well as a ''primary objective'' for recovery that could result in removal of the species from the List (*i.e.,* delisting). It established the following four conditions as criteria for reclassification from endangered to threatened status (*i.e.,* downlisting):

(1) The presence of a naturally reproducing population of the Borax Lake chub in Borax Lake that is free of exotic species;

(2) Permanent protection of the 160-ac (65-ha) parcel of land surrounding and including Borax Lake (T37S, R33E,

sec. 14) by TNC or other appropriate public resource agency;

(3) Removal of threats to subsurface waters from geothermal energy exploration or development; and

(4) Reestablishment of ponds and natural marshes adjacent to Borax Lake in order to create more chub habitat, and reestablishment of Lower Borax Lake by waters from Borax Lake in order to create more habitat.

The recovery plan stated that conditions to meet the primary objective of recovery (*i.e.,* delisting) include the above four downlisting conditions as well as the following six additional conditions:

(1) A viable, self-sustaining population of Borax Lake chub, which is defined as a naturally sustaining population that is free of exotic species and fluctuates in size within the seasonal ranges observed in 1986–1987;

(2) Permanent protection of the 160-ac (65-ha) parcel of land to the north of Borax Lake (T37S, R33E, sec. 11) by TNC or another appropriate public resource agency;

(3) Withdrawal of Borax Lake waters from appropriations (*i.e.,* diversion and use under water right);

(4) Establishment of a fence around the 640-ac (259-ha) critical habitat area to prevent vehicle entry;

(5) Establishment of monitoring programs to survey habitat and fish population status; and

(6) Lack of any new threats to the species or ecosystem for 5 consecutive years.

Recovery Plan Implementation

Significant conservation objectives that address the primary threats to the Borax Lake chub have been accomplished through implementing the 1987 recovery plan, including protection of the Borax Lake ecosystem from disturbances through acquisition of key private lands, protection of subsurface and surface waters, closure of fragile lands to vehicle access, removal of livestock grazing, monitoring, and other recovery actions. The following discussion summarizes information on recovery actions that have been implemented under each downlisting and delisting criterion.

Downlisting Criteria

Downlisting Criterion 1: The presence of a naturally reproducing population of Borax Lake chub in Borax Lake that is free of exotic species. This criterion has been met. To be considered naturally reproducing, Borax Lake chub need to reproduce in their natural habitat in Borax Lake with no human intervention, such as supplementation with hatchery- or aquarium-raised fish. The Borax Lake chub population has never been supplemented with hatchery- or aquarium-raised fish and continues to reproduce naturally on an annual basis. In the 3 decades Borax Lake chub have been monitored, there has been only one documented occurrence of an exotic fish species. In 2013, an ODFW biologist observed a nonnative fish that was believed to be a bass given observed morphology (Scheerer *et al.* 2013, pp. 2–3, 9–10). Subsequent efforts to capture or observe this fish or other nonnative fishes were unsuccessful, and none has been seen in subsequent monitoring. The survival in Borax Lake of this nonnative fish, or of any other commonly introduced nonnative fishes, is unlikely given the geothermally heated high water temperatures.

We consider this criterion met based on the lack of need for conservation actions supporting the species' reproductive success and the fact that only a single occurrence of a nonnative species has been documented. As noted above, we determined the likelihood of survival of this nonnative fish was low, and no observations or detections of this or other nonnative fishes have been made during subsequent surveys. See *Delisting Criterion 1* and *C. Disease or Predation* for additional discussion regarding the potential for exotic species introduction into Borax Lake.

Downlisting Criterion 2: Permanent protection for the 160-acre parcel of land surrounding and including Borax Lake (T37S, R33E, sec. 14) by TNC or other appropriate public resource agency. This criterion has been met. In 1983, TNC leased two 160-ac (65-ha) private land parcels, one surrounding Borax Lake and the other immediately to the north. In 1993, TNC acquired both parcels. TNC also acquired subsurface mineral rights to the land surrounding Borax Lake. TNC designated the land surrounding Borax Lake, and the 160-ac (65-ha) parcel to the north, as a preserve for the purpose of conserving the Borax Lake ecosystem. With the purchase of the two parcels by TNC, all lands designated as critical habitat are in public or conservation ownership. The diversion of water for irrigation and livestock grazing within designated critical habitat ceased. TNC no longer permits vehicular access to the preserve except for access for people with disabilities or for scientific research.

In addition to the above, in 1983, the BLM designated 520 ac (210 ha) of public land surrounding Borax Lake as an ''area of critical environmental concern'' (ACEC) to protect Borax Lake chub and its habitat. In 2005, the record of decision for the resource management plan for the Andrews Resource Area added 80 ac (32 ha), for a total 600-ac (243-ha) Borax Lake ACEC (BLM 2005a, p. 70). Following this designation, the area was fenced to exclude livestock grazing. The lake is now completely enclosed by fencing, including most of the 640 ac (259 ha) of designated critical habitat, except for a small portion that serves as a parking area for pedestrian access to the lake.

Downlisting Criterion 3: Removal of threats to subsurface waters from geothermal energy exploration or development. This criterion has been met. While this criterion does not identify a geographic area for which threats of geothermal energy exploration or development should be removed, the recovery plan's step-down outline and narrative describing recovery actions clearly identify this criterion as pertaining to Borax Lake and two 160-ac (65-ha) parcels of private land surrounding Borax Lake (USFWS 1987, pp. 30–45). These lands were eventually purchased by TNC and designated critical habitat for Borax Lake chub, thereby removing the threat of geothermal development within close proximity to Borax Lake. Although the recovery plan did not explicitly call for removal of potential geothermal development threats outside of designated critical habitat, the Service has acknowledged that geothermal development outside critical habitat, but in proximity to Borax Lake, may constitute a potential threat (USFWS 2012, p. 24).

Numerous geologic studies have been conducted in the vicinity of Borax Lake, yet there is limited detailed information regarding the extent of the geothermal aquifer and the configuration of geothermal fluid flow pathways surrounding Borax Lake (Schneider and McFarland 1995, entire; Fairley *et al.* 2003, entire; Fairley and Hinds 2004, pp. 827–828; Cummings 1995, pp. 12–19). As such, the best available scientific information does not allow us to determine the precise geographic distance over which geothermal development may represent a threat to the Borax Lake chub and the Borax Lake ecosystem. Given the lack of scientific information (*i.e.,* depth, extent, source of water, etc.) on the Borax Lake aquifer, a reasonable position is that geothermal development outside of critical habitat may represent a potential threat to Borax Lake chub and that the closer the development is to critical habitat, the greater the likelihood that development could affect the Borax Lake chub and the Borax Lake ecosystem.

With the passage of the Steens Mountain Cooperative Management and

Protection Act of 2000 (Steens Act; 16 U.S.C. 460nnn *et seq.*) and the completion of the Steens Andrews Resource Management Plan, the BLM has withdrawn the Alvord Known Geothermal Resource Area from mineral and geothermal exploration and development (BLM 2005a, p. 49). The Steens Act congressionally designated a ''mineral withdrawal area'' encompassing approximately 900,000 ac (364,217 ha) on BLM-administered lands. The mineral withdrawal area contains the majority of the Alvord Known Geothermal Resource Area (Alvord KGRA), including Borax Lake and surrounding public lands, with the exception of 332 ac (134 ha) of BLM-administered land located approximately 4.5 mi (7.2 km) from Borax Lake (BLM 2005a, p. I–2; BLM 2005b, p. 4).

Private lands within the vicinity of Borax Lake are not affected by the mineral withdrawal. Approximately 2,000 ac (809 ha) of privately owned lands occur within a radius of approximately 1 to 3 mi (1.6 to 4.8 km) from Borax Lake. Based on geothermal development investigated by various entities over the last 3 decades, it is reasonable to assume that future geothermal development may be explored on private land in the vicinity of Borax Lake. However, as of 2018 there are no active proposals in place for such development (A. Mauer, *in litt.* 2018).

The most recent exploration for geothermal resource development occurred in 2008, when the BLM received an inquiry from Pueblo Valley Geothermal LLC regarding permitting processes for geothermal exploratory drilling and the potential for developing a geothermal electrical generation plant in the Alvord Lake basin potentially within 3 to 5 mi (4.8 to 8.0 km) of Borax Lake. Pueblo Valley Geothermal LLC submitted a proposal to the BLM on January 31, 2012, for a binary geothermal plant that would produce 20 to 25 megawatts. Pueblo Valley Geothermal LLC also sought to acquire approximately 3,360 ac (1,360 ha) of BLM land via land exchange in order to develop their project. The BLM responded with a letter (Karges *in litt.* 2012) explaining that the BLM-managed lands surrounding the private lands under lease are part of the Leasable and Saleable mineral withdrawal enacted by the Steens Act and implemented under the Steens Mountain Cooperative Management and Protection Area Resource Management Plan. The BLM informed Pueblo Valley Geothermal LLC that they would not be able to complete an exchange for various reasons, including: (1) Difficulties in proposing and mitigating a project that would alter land designated as Visual Resource Management Class 2 (the visual resource management objective for class 2 is to retain the existing character of the landscape, and the level of change to the characteristic landscape should be low); (2) the lack of time and staffing to complete a feasibility analysis; and (3) the BLM's requirement that the exchange demonstrate a clear public benefit. The BLM suggested the best route would be to find a geothermal resource outside of the mineral withdrawal area and pursue exploration and development there. Pueblo Valley Geothermal LLC subsequently has become inactive and filed to dissolve their LLC status in the State of Oregon on December 26, 2013.

As stated previously, although the passage of the Steens Act designated a mineral withdrawal area on public lands surrounding Borax Lake, it does not include 322 ac (134 ha) of BLM-administered lands and 2,000 ac (809 ha) of private land located within a radius of approximately 1 to 4.5 mi (1.6 to 7.24 km) from Borax Lake. Therefore, while we view this downlisting criterion as having been met, we acknowledge there remains a potential for geothermal development on lands not formally withdrawn from geothermal or mineral development in the Alvord Basin and that future development of these resources constitutes a potential threat to Borax Lake chub. That said, we have determined the likelihood of this threat becoming operative in the foreseeable future is low.

See *Delisting Criterion 3* and *D. The Inadequacy of Existing Regulatory Mechanisms* for additional discussion regarding the threat of geothermal resource development.

Downlisting Criterion 4: Reestablishment of ponds and natural marshes adjacent to Borax Lake in order to create more chub habitat, and reestablishment of Lower Borax Lake by waters from Borax Lake in order to create more habitat. This criterion has been met with the exception of the reestablishment of Lower Borax Lake. However, the 5-year review (USFWS 2012, pp. 7, 26) concluded that Lower Borax Lake does not provide suitable habitat for Borax Lake chub due to desiccation during summers with low precipitation and to unsuitable habitat in the winter due to freezing. As a result, we no longer consider reestablishment of Lower Borax Lake to be a necessary action for Borax Lake chub recovery.

Numerous actions to maintain lake levels and restore natural outflows have occurred at Borax Lake since the Borax Lake chub was listed. Begun in 1983, TNC, with assistance from the BLM and the ODFW, repaired holes in the northern and eastern shorelines of the lake, and deepened the outflow channel on the southwestern shoreline to promote flow to Lower Borax Lake (USFWS 1987, p. 23). In 1984, the Service and TNC manually constructed several channels diverting water from the southwestern outflow channel into the adjacent marsh (USFWS 1987, p. 25). By 2003, there was no open-water connection between Borax Lake and Lower Borax Lake, but Lower Borax Lake did contain water at that time (Williams and Macdonald 2003, p. 7).

The only habitat outside of Borax Lake that provides habitat for Borax Lake chub is the wetland (referred to as ''the marsh'' in the 1982 listing rule (47 FR 43957; October 5, 1982)) to the south of Borax Lake, the overflow channel that connects the wetland to Borax Lake, and a second overflow channel on the northern end of the lake. Although the wetland at times maintains water year-round, water levels are variable and are influenced by a groundwater vent in the wetland and overflow from Borax Lake. The seasonal pattern and overall contribution of groundwater inputs to the wetland are not understood. In September 2015, the wetland was dry, due in part from reduced flow from Borax Lake caused by a vegetation plug in the overflow channel and presumably no or reduced contribution from groundwater. Later that fall, the wetland was observed to be full, presumably due to increased groundwater inputs. In response to the reduced flow in the overflow channel, the ODFW manually removed vegetation in spring 2016, to provide a more consistent flow through the overflow channel (P. Scheerer 2016, pers. comm.). Therefore, while groundwater inputs to the wetland are unpredictable, the increased flow through the overflow channel due to manual vegetation removal by the ODFW is anticipated to increase the likelihood of maintaining habitat in the wetland for the Borax Lake chub. While the wetland and several overflow channels do not represent a large amount of habitat for the Borax Lake chub, they are potentially important cool-water refuge habitats during periods of above-average air temperatures when suitable cool-water habitat in Borax Lake may be reduced. An associated discussion can be found under *Delisting Criterion 1* and *A. The Present or Threatened Destruction,*

Modification, or Curtailment of Its Habitat or Range in this proposed rule.

Delisting Criteria

In addition to the four downlisting criteria, the recovery plan also identified six additional criteria for delisting.

Delisting Criterion 1: A viable, self-sustaining population of Borax Lake chub, which is defined as a naturally sustaining population that is free of exotic species and fluctuates in size within the seasonal ranges observed in 1986 to 1987. This criterion has been met. Data collected from 1986 through 2017 show a self-sustaining population persists at Borax Lake. (In 2013 and 2014, surveys were not conducted based on an assessment of the need for annual population data in relation to potential take associated with monitoring.) The population is naturally sustaining without the need for supplementation, such as propagation in a hatchery or in aquaria.

The Borax Lake chub is a species that demonstrates high annual variability in population abundance, ranging from a low of 1,242 estimated fish in 2015, to a high of 76,931 in 2017 (see table, below). As recently as 2010 and 2011, the population estimates were 25,489 and 26,571, respectively. Prior to 2015, the lowest population estimate was 4,132 in 1988. Such population variability, with opportunistic demographic resilience, is relatively common for small desert fishes (Winemiller 2005, pp. 878–879). In the case of the Borax Lake chub, population variation likely results from a combination of short life span and occurrence in water temperatures at the edge of the species' thermal tolerance. Given our improved knowledge of natural variability as described above, we have concluded that the portion of this delisting criterion that called for population levels to fluctuate within the narrow range of population estimates conducted in 1986 and 1987 is unrealistic, and is no longer reasonable to maintain as a recovery goal for this species.

TABLE OF POPULATION MARK—RECAPTURE ESTIMATES FOR BORAX LAKE CHUB FROM 1986 TO 2017, INCLUDING ADJUSTED LINCOLN-PETERSON AND HUGGINS CLOSED CAPTURE MODELS (1)

Year (2)	Estimate	Lower 95% confidence limit	Upper 95% confidence limit
1986	15,276	13,672	17,068
1987	8,578	7,994	9,204
1988	4,132	3,720	4,589
1989	14,052	13,016	15,172
1990	19,165	18,117	20,273
1991	33,000	31,795	34,251
1992	25,255	24,170	26,388
1993	35,650	34,154	37,212
1994	13,421	12,537	14,368
1995	35,465	33,533	37,510
1996	8,259	7,451	9,153
1997	10,905	10,377	11,459
2005	14,680	12,585	17,120
2006	8,246	6,715	10,121
2007	9,384	7,461	11,793
2008	12,401	10,681	14,398
2009	14,115	12,793	15,573
2010	25,489	23,999	27,071
2011	26,571	24,949	28,301
2012	9,702	9,042	10,452
2015	1,242	1,077	1,456
2016	9,003	8,045	10,560
2017	76,931	68,444	86,952

(1) Adjusted Lincoln-Peterson and Huggins closed capture models are referenced in Scheerer *et al.* 2012, p. 7. See Salzer 1992, p. 17; Salzer 1997, no pagination; Scheerer and Bangs 2011, p. 4; Scheerer *et al.* 2012, pp. 6–7; Scheerer *et al* 2015, p. 3; Scheerer *et al.* 2016, p. 5; and M. Meeuwig *in litt.* 2017.

(2) Surveys were not conducted from 1998 to 2004, and from 2013 to 2014.

In the summer of 2015, above-average air temperatures may have influenced water temperatures in Borax Lake, causing a population decline. In 2016, however, perhaps supported by cooler air and water temperatures, the population estimate rebounded to over 9,000 individuals (Scheerer *et al.* 2016, p. 3). These observations indicate that temperature may annually affect Borax Lake chub survival and abundance in Borax Lake. Borax Lake chub frequently experience water temperatures that are at or near their thermal critical maximum of 34.5 °C (94.1 °F) (Williams and Bond 1983, p. 412). Therefore, Borax Lake chub survival and recruitment appear to be higher during years when lake temperatures are cooler. In prior years, when Borax Lake's daily maximum water temperatures were substantially cooler than the 12-year average (for example, in 2010 and 2011, there were fewer days above the 12-year mean), Borax Lake chub abundance estimates exceeded 25,000 fish and were some of the highest abundance estimates recorded (Scheerer *et al.* 2016, p. 8). Borax Lake water temperatures were substantially higher than the 12-year average in June and July of 2015. The elevated temperatures may have contributed to the substantial decline in Borax Lake chub abundance observed between 2012 and 2015 (Scheerer *et al.* 2016, p. 9). In late July through the rest of the summer 2015, and in the mid to late summer of 2016, water temperatures in the lake were typically at or below the 12-year average, which may have contributed to improved Borax Lake chub survival and the significant increase in abundance (625 percent) observed in 2016 (Scheerer *et al.* 2016, p. 8). The population estimate in 2017 was 76,931, the largest count on record (M. Meeuwig *in litt.* 2017). While air and water

temperature information for 2017 has not been analyzed, given the recent trend of increasing abundance and prior observations, we speculate lake temperatures were likely cooler than the 12-year average during 2017. Thus, while the 2015 estimate of 1,242 fish represents the lowest estimate on record, the pattern of variability observed over 3 decades of monitoring population abundance underscores the resiliency of this species and its ability to rebound quickly (see table, above).

With one exception, periodic surveys since 2005 have not identified any exotic species within Borax Lake (Scheerer and Jacobs 2005, 2006, 2007, 2008, 2009, and 2010; Scheerer and Bangs 2011; Scheerer *et al.* 2012, 2015, and 2016). However, in 2013, during shoreline surveys conducted by the ODFW, biologists noted a large fish with paired dorsal fins (presumably a bass) (Scheerer *et al.* 2013, p. 10). No additional sightings of the bass occurred during the ODFW surveys (S. Hurn *in litt.* 2014, unpaginated) or during subsequent efforts to capture the bass (see *C. Disease or Predation,* below). Survival of the bass is believed to be unlikely given the high water temperatures in Borax Lake. No known occurrence of disease or predation affecting the population of Borax Lake chub has occurred since the time of listing (47 FR 43957; October 5, 1982). The best available scientific data indicate Borax Lake chub are a viable, self-sustaining population in habitat currently free from exotic species.

Delisting Criterion 2: Permanent protection for the 160-acre parcel of land to the north of Borax Lake (T37S, R33E, sec. 11) by TNC or other appropriate public resource agency. This criterion has been met. In 1983, TNC leased two 160-ac (65-ha) private land parcels, one surrounding Borax Lake and the other immediately to the north of the lake. TNC purchased these two parcels in 1993, placing both parcels in public or conservation ownership and protection.

Delisting Criterion 3: Withdrawal of Borax Lake waters from appropriations. This criterion has been met. With the acquisition of Borax Lake by TNC, surface waters on their land cannot be appropriated by others. Additionally, in 1991, the ODFW filed an application for the water rights to Borax Lake for conservation purposes. The water right was certified and issued to the Oregon Water Resources Department on December 16, 1998, for the purpose of providing habitat for the Borax Lake chub (Oregon Water Resources Department *in litt.* 2018).

Delisting Criterion 4: Establishment of a fence around the 640-acre critical habitat area to prevent vehicle entry. This criterion has been mostly met. The Andrews/Steens Resource Area, Burns District BLM, has constructed facilities to modify public access and enhance public understanding of the Borax Lake area. The Burns District BLM closed access roads in the vicinity of Borax Lake, realigned the fence surrounding Borax Lake to limit vehicle access, and designated visitor parking. Partial funding for the fencing project came from the BLM's Threatened and Endangered Species Recovery Fund, an initiative started in 2010 that supports projects targeting key recovery actions for federally listed and candidate species occurring on BLM lands. The BLM plans to install interpretive signs at the designated parking area (USFWS *et al.* 2018, p. 7). The lake is now completely enclosed by fencing, although approximately 30 ac (12 ha) of critical habitat remains outside the fenced portion of the critical habitat, leaving approximately 0.6 mi (1 km) of road accessible to vehicles within designated critical habitat. The remaining area of the critical habitat will remain unfenced to provide for vehicle access, parking, and interpretative signs, while still protecting the Borax Lake environment. The BLM and ODFW will continue to assess the effectiveness of the vehicle closure for protection of the Borax Lake area. Barring any new information indicating that the existing fencing is insufficient to protect the Borax Lake chub, fencing of the remaining critical habitat appears to be unnecessary.

Delisting Criterion 5: Establishment of monitoring programs to survey habitats and fish population status. This criterion has been met. Numerous studies of the ecology and habitat of Borax Lake have been conducted (Salzer 1992; Scoppettone *et al.* 1995; Furnish *et al.* 2002; Scheerer and Jacobs 2005, 2006, 2007, 2008, 2009, 2010; Scheerer and Bangs 2011; Scheerer *et al.* 2012, 2013). TNC conducted abundance estimates from 1986 through 1997. The ODFW conducted mark-recapture population surveys from 2005 through 2012, and again in 2015 and 2016; developed a survey protocol; and recommended a long-term monitoring strategy (Scheerer and Jacobs 2005, 2006, 2007, 2008, 2009, 2010; Scheerer and Bangs 2011; Scheerer *et al.* 2012, 2013, 2015, 2016). The ODFW also conducted surveys to monitor the condition of the lake shoreline, outflows, and adjacent wetlands. Additional physical data, including hydrologic information, substrate mapping, outflow monitoring, tracking of water levels, and geological and slope stability, were gathered in the 1990s (Scoppettone *et al.* 1995; Wilson 2000).

The Service, ODFW, and BLM collaboratively developed the Borax Lake Chub CMP to outline individual agency roles and responsibilities, and commitments into the future, regarding Borax Lake chub, the Borax Lake ecosystem, and surrounding lands (USFWS *et al.* 2018). While this proposed rule does not rely on the CMP, the CMP significantly enhances progress made towards meeting this delisting criterion and other delisting criteria, including ongoing conservation actions.

Delisting Criterion 6: Lack of any new threats to the species or ecosystem for 5 consecutive years. This criterion has been met. Although this proposed rule identifies climate change as a new potential stressor in the future, we have determined it is not operative on the species or its habitat currently, and is not anticipated to negatively affect the species in the foreseeable future. While potential increases in ambient air temperatures may cause warming of Borax Lake water or, more accurately, slow the cooling of the geothermal waters, we anticipate that thermal refuge associated with shallow margin habitat and cool and cold water vents in the lake along with the species' ability to rebound quickly following periods of higher than normal air and water temperatures, will provide resilience against any future potential effects of climate change. See our discussion under *A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* below, for a more detailed description on potential effects of climate change.

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 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 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 human made factors affecting its continued existence. We must consider these same five factors in delisting a species. We may delist a species according to 50 CFR 424.11(d) if the best available scientific and commercial data indicate that the species is neither endangered nor threatened for the following reasons: (1) The species is extinct; (2) the species has recovered and is no longer endangered or threatened; and/or (3) the original scientific data used at the time the species was classified were in error.

A recovered species is one that no longer meets the Act's definition of endangered or threatened. Determining whether a species is recovered requires consideration of the same five categories of threats specified in section 4(a)(1) of the Act. For species that are already listed as endangered or threatened, this analysis of threats is an evaluation of both the threats currently facing the species and the threats that are reasonably likely to affect the species in the foreseeable future following delisting or downlisting (*i.e.,* reclassification from endangered to threatened) and the removal or reduction of the Act's protections.

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.'' The word ''range'' in the significant portion of its range phrase refers to the general geographical area in which the species occurs at the time a status determination is made. For the purposes of this analysis, we will evaluate whether the currently listed species, the Borax Lake chub, should be considered endangered or threatened.

The Act does not define the term ''foreseeable future.'' For the purpose of this proposed rule, we define the ''foreseeable future'' to be the extent to which, given the amount and substance of available data, we can anticipate events or effects, or reliably extrapolate threat trends, such that we reasonably believe that reliable predictions can be made concerning the future as it relates to the status of the Borax Lake chub. In considering the foreseeable future as it relates to the status of the Borax Lake chub, we consider the factors affecting the Borax Lake chub, historical abundance trends, and ongoing conservation efforts. Our period of record for monitoring the Borax Lake chub and its associated habitat extends upwards of 30 years which, when combined with our knowledge of factors affecting the species, allows us to reasonably predict future conditions, albeit with diminishing precision over time. Given the best available scientific and commercial information, for the purposes of this proposed rule we consider the foreseeable future for Borax Lake chub to be a range of 20 to 30 years.

We also expect the ODFW, BLM, and TNC to continue to manage Borax Lake and to conserve Borax Lake chub for the foreseeable future. This expectation is based on the fact that for over 3 decades, the ODFW, BLM, and TNC have taken actions benefiting the Borax Lake chub and the Borax Lake ecosystem.

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 status review, 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 examining threats to narrowly distributed endemic species such as Borax Lake chub, we must also consider that natural rarity (*i.e.,* a species that only exists in one or a few locations, thought it may be abundant there), in and of itself, does not constitute a threat under the Act. Natural rarity may increase risk or vulnerability if threats are operative on the species or its habitat now or in the foreseeable future, but rarity alone, in the absence of an operative threat, does not warrant protection to a species under the Act.

In the following analysis, we evaluate the status of the Borax Lake chub through the five-factor analysis of threats currently affecting, or that are likely to affect, the species within the foreseeable future.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

At the time of listing in 1982 (47 FR 43957; October 5, 1982), the primary threats to the Borax Lake chub consisted of potential impacts from geothermal energy development on BLM and private lands near Borax Lake, diversion of the lake's outflows by alteration of the shoreline crust, and potential development of a recreation facility. Since the time of listing, actions have been taken to reduce or eliminate these threats, as discussed below. We also include an analysis of the effects of climate change as a potential threat in the foreseeable future.

Recreation, Water Diversion, and Shoreline Habitat Alteration

The recreation facility discussed in the 1982 listing rule was never developed, and acquisition of the property by TNC eliminated the potential for development of a recreation facility at the Borax Lake site (Williams and Macdonald 2003, p. 12).

The ODFW filed for water rights at Borax Lake in 1991, and that water right is now certified to the Oregon Water Resources Department, to prevent further attempts at diverting the water and to ensure maintenance of the water elevation in Borax Lake (see *Delisting Criterion 3* discussion, above). The purpose of the water right is to provide the required habitat conditions for Borax Lake chub. The right is established under Oregon Revised Statute 537.341, with a priority date of August 21, 1991. The right is limited to the amount of water necessary to maintain a surface water elevation of 4,081 ft (1,244 m) above mean sea level. For purposes of water distribution, the instream right shall not have priority over human or livestock consumption. The right has been recorded in the State record of Water Right Certificates as 75919 (Oregon Water Resources Department *in litt.* 2018).

The 160-ac (65-ha) private land parcel containing Borax Lake was purchased by TNC in 1993. Subsurface mineral rights are included. Since TNC acquisition, surface waters on their land, upon which Borax Lake is located, can no longer be appropriated by others. Additionally, TNC ended the practice of actively diverting surface water from the eastern side of the lake to reduce the impact from prior water diversions. The BLM designated the adjacent 600 ac (243 ha) of public lands as an ACEC for the conservation of Borax Lake chub, and the area was fenced to exclude

livestock grazing (see *Downlisting Criterion 2* discussion, above).

Off-road vehicle damage along the lake shoreline has been documented in the past (Scheerer and Jacobs 2005, p. 6; 2006, p. 7; 2007, p. 6; 2008, p. 6; 2009, p. 8; 2010, p. 4; Scheerer and Bangs 2011, p. 9; Scheerer *et al.* 2012, p. 13; Scheerer *et al.* 2013, p. 6). As a result, in 2011, the BLM and TNC completed a perimeter fence surrounding the lake and most of the associated critical habitat to exclude unauthorized vehicles, and in 2013, they installed locks on all access gates. Due to the completion of the perimeter fence, the threat to Borax Lake chub and its habitat from shoreline habitat alteration by vehicles has been addressed.

Geothermal Development

Geothermal exploration and development has been pursued in the Alvord Known Geothermal Resource Area and specifically in the vicinity of Borax Lake from the early 1970s (Wassinger and Koza 1980, p. 1) to 2013. The Alvord Known Geothermal Resource Area is a 176,835-ac (71,563-ha) area within the Alvord Basin (Wassinger and Koza 1980, p. 7). Development of geothermal resources was considered in 1980, and exploratory wells were drilled in 1982 (47 FR 43957; October 5, 1982). In 1994, Anadarko proposed additional geothermal exploration and development, and the BLM prepared a notice of intent to prepare an environmental impact statement (EIS). After receiving public scoping comments, Anadarko withdrew its development proposal, and no EIS was written (T. Geisler 2009, pers. comm.).

The passage of the Steens Act in 2000, and the finalization of the BLM Resource Management Plan (RMP) (BLM 2005a, p. 71), withdrew mineral and geothermal resources from development on Federal lands within the Alvord Known Geothermal Resource Area. The BLM retained 332 ac (134 ha) of land with high potential for geothermal resources west of Fields and within 4.5 mi (7.2 km) of Borax Lake open for leasable mineral and geothermal development (BLM 2005a, p. I–2). Private lands within this area are not affected by the mineral withdrawal.

In 2008, the BLM and DOGAMI received inquiries on behalf of private landowners in Alvord Basin regarding the development of geothermal resources. The BLM was contacted regarding electrical transmission and right-of-way (ROW) access to cross BLM lands in order to explore and develop commercial geothermal electrical power (K. Bird 2008, pers. comm.). The developer, Pueblo Valley Geothermal LLC, met with the BLM in 2008, to discuss their interest in obtaining an ROW permit to access private land and construct a power plant. Although the Steens Act and subsequent RMP withdrew the Alvord Known Geothermal Resource Area from geothermal development, the RMP could allow a ROW permit because the area in question is not within the Cooperative Management and Protection Area boundary. ROWs are a valid use of public lands under sections 302 and 501 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), as amended (BLM 2005a, p. 59). The BLM would be responsible under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) to analyze any proposed ROW project, including the connected actions, such as exploratory well drilling and power line construction.

The proposed power plant was anticipated to generate 1 to 10 megawatts. Pueblo Valley Geothermal LLC acquired a 53-year lease on approximately 2,000 ac (809 ha) from landowners located south of Alvord Lake, and within 3 mi (4.8 km) and as close as 1 mi (1.6 km) from Borax Lake (P. Hall 2009, pers. comm.). Pueblo Valley Geothermal LLC also placed an advertisement in the publication ''Geothermal Energy Weekly'' seeking investors for a 20- to 25-megawatt geothermal facility (Geothermal Energy Association 2010, no pagination). The developer indicated in 2011 that they were progressing with resource assessments regarding the total megawatt and economic potential (P. Hall 2011, pers. comm.). No formal permit applications were received by the BLM or DOGAMI in 2011 (R. Houston 2008, pers. comm.; 2010, pers. comm.; R. Houston *in litt.* 2011), and as of 2018 we are not aware of such (A. Mauer, *in litt.* 2018).

Pueblo Valley Geothermal LLC submitted an informal proposal to the BLM on January 31, 2012, seeking to acquire 3,360 ac (1,360 ha) of BLM land in the vicinity of the Borax Lake geothermal aquifer in the interest of developing an air-cooled binary geothermal plant to produce 20 to 25 megawatts of electricity (T. McLain *in litt.* 2012). The BLM responded with a letter on March 14, 2012, explaining that due to various reasons including resource concerns, funding, and staffing priorities, such a land exchange was not feasible at that time (Karges *in litt.* 2012). Pueblo Valley Geothermal LLC indicated to us that the proposal to develop geothermal energy on private land in the vicinity of Borax Lake was not active (P. Hall 2014, pers. comm.). The Oregon Secretary of State Office maintains an online business registry of Limited Liability Company (LLC) companies. The list was consulted, and we found that the company, Pueblo Valley Geothermal LLC, filed an article of dissolution on December 26, 2013. A review of the Harney County Assessor's property records show that 320 ac (129 ha) of land previously leased by Pueblo Valley LLC, which is approximately 1 mi (1.6 km) west of Borax Lake, is now owned by Oregon Geothermal LLC. We do not have any new information on permit applications from Oregon Geothermal LLC or any other new geothermal proposals that may arise in the foreseeable future.

Potential impacts resulting from geothermal development that were identified at the time of listing include effects to water elevation in Borax Lake due to the interconnecting aquifers or springs. Drilling could disrupt the hot water aquifer that supplies Borax Lake. Potential impacts from geothermal energy drilling could include changes to the aquifer pressure or temperature and the potential to lessen or eliminate inflows to the lake from the geothermal aquifer. Changes to water flow and water temperature may have an adverse impact on the Borax Lake chub. Although the species tolerates thermal waters, excessive warming of the lake's water could cause adverse effects, and, at extremes, would be lethal to the Borax Lake chub.

In summary, proposals to develop geothermal energy resources in the Borax Lake vicinity have occurred sporadically in the 1970s, in the 1980s, in 1994, and in 2008 through 2012. However, none of these proposals has moved forward with permitting and implementation over a 4-decade period, and this history leads us to conclude that the likelihood of geothermal energy development now and in the foreseeable future is low. Furthermore, while geothermal development in the vicinity of Borax Lake has been considered a potential threat to the Borax Lake chub, the precise effects of possible geothermal development on the species are uncertain and unpredictable. The potential effects to the species would depend upon the specifics, such as the scale of the project and proximity to Borax Lake, of any geothermal energy development that might proceed to the implementation phase. Depending on the particular circumstances of any particular project, such development could potentially have a negative effect on the species, or it might have no or negligible effects. The effects of any future geothermal project proposal on

Borax Lake chub would be assessed based on specific project details and other data available at the time. If an assessment suggested a future geothermal project would likely cause significant risk to Borax Lake and the well-being of Borax Lake chub, and existing regulatory mechanisms did not deter or result in modifications to the development to minimize or eliminate likelihood of impacts to the chub, we have the discretion to use the emergency listing authorities under section 4(b)(7) of the Act, such as we used in the May 28, 1980, emergency listing of Borax Lake chub (45 FR 35821). The possibility of geothermal development in the vicinity of Borax Lake will continue to represent a potential threat to Borax Lake chub and its habitat, but we have determined the likelihood of this threat becoming operative in the foreseeable future is low.

Effects of Climate Change

The terms ''climate'' and ''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). ''Climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2007, p. 78). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (*e.g.,* temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2007, p. 78). Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (*e.g.,* habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). In our analysis, we use expert judgment to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

As is the case with all stressors we assess, even if we conclude that a species is currently affected or is likely to be affected in a negative way by one or more climate-related impacts, it does not necessarily follow that the species meets the definition of an ''endangered species'' or a ''threatened species'' under the Act. If a species is listed as endangered or threatened, knowledge regarding the vulnerability of the species to, and known or anticipated impacts from, climate-associated changes in environmental conditions can be used to help devise appropriate strategies for its recovery.

Global climate projections are informative and, in some cases, the only or the best scientific information available for us to use. However, projected changes in climate and related impacts can vary substantially across and within different regions of the world (*e.g.,* IPCC 2007, pp. 8–12). Therefore, we use ''downscaled'' projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling).

With regard to our analysis for the Borax Lake chub, we evaluated downscaled projections from the National Climate Change Viewer (Alder and Hostetler 2014, 2017). These projections are based on the mean of 30 models that can be used to predict changes in air temperature for the Alvord Lake basin in Harney County, Oregon. The models predict that during the period from 2025 to 2049, the July mean maximum air temperature will increase by 2.4 °C (4.3 °F) from the historical mean, and the January mean minimum air temperature will increase by 2.3 °C (4.1 °F). The model predicts very little change in the mean annual precipitation and runoff for the Alvord Lake basin (Alder and Hostetler 2014, pp. 3–5; 2017, unpaginated).

Increases in ambient air temperatures may cause warming of Borax Lake water or, more accurately, slow the cooling of the geothermal waters. During the warmest times of the year, this may reduce the amount and suitability of habitat available for Borax Lake chub because Borax Lake chub use the edges of the lake, areas around cool and cold water vents within the lake, several overflow channels, and a wetland where waters are shallower and the temperatures have cooled from the geothermal source to suitable water temperatures for Borax Lake chub survival. Scheerer *et al.* (2015, p. 9) suggested there is likely a correlation between water temperatures and chub population abundance. Monitoring of lake temperatures since 2005 indicates that high population abundance in 2010 and 2011 (greater than 25,000 individuals) correspond with lake temperatures that were cooler during this period when compared to temperatures recorded in 2006 to 2009 and 2012 to 2016. Higher water temperatures since 2012 and lower population abundance during this time provide additional evidence towards this potential relationship between water temperatures and annual survival rates (Scheerer *et al.* 2015, p. 8). The lowest estimated population abundance on record (1,242) for Borax Lake chub occurred in 2015, following unseasonably warm air and water temperatures in June and July of that year in conjunction with reduced access to cool water refugia through the overflow channel (Scheerer *et al.* 2016, p. 8). A similar die-off was suspected to have occurred in July 1987, during a period of unseasonably warm temperatures when mortalities were documented and fish were observed congregating in the coolest portions of the lake (Scheerer *et al.* 2015, pp. 6–7). In 2016, water temperatures and air temperatures were cooler than average and the overflow channel had been cleared; the population of Borax Lake chub then rebounded to an estimated 9,003 individuals (Scheerer *et al.* 2016, p. 3), similar to previous rebounds following population declines.

Although a specific analysis has not been conducted to determine the amount and suitability of thermal refuge habitat that may be available under various lake temperature conditions, information presented in Scheerer and Bangs 2011, pp. 5–8, and Scheerer *et al.* 2012, pp. 7–11, suggest the availability of shallow margin habitat around the perimeter of the lake, along with the outflow channel and wetland, likely provide thermal refuge (*i.e.,* cooler water) habitat for the species during these events. In addition, monitoring by the ODFW in 2011 and 2012 documented cool and cold water vents within portions of the lake that likely contribute to moderating lake temperatures and provide additional areas of thermal refuge (P. Scheerer, pers. comm. 2018). While there is evidence these cool and cold water vents, as well as warm and hot vents within the lake (in addition to the primary vent) vary in temperature year to year, the aggregate of these thermal refuge habitats, along with the species' ability to rebound quickly following periods of higher than normal air and water temperatures, are anticipated to provide resilience against potential future effects of climate change.

Changes to precipitation, drought, aquifer recharge, or vegetative community around Borax Lake as a result of climate change would not likely have an impact on the Borax Lake chub. Borax Lake is perched above the valley floor, there is no inflow of water from above-ground sources, and the

vegetative community is not likely to change due to the temperature increases predicted.

Summary of Factor A

Since the time of listing in 1982 (47 FR 43957; October 5, 1982), actions have been taken to reduce or eliminate the destruction and modification of Borax Lake chub habitat. This includes the acquisition of Borax Lake and surrounding lands by TNC, the BLM's designation of adjacent lands as an ACEC, protection of subsurface and surface waters, protection from mineral withdrawal, and closure of fragile lands to livestock grazing and unauthorized vehicle access. Although these measures have removed and minimized various threats to Borax Lake and surrounding lands, the potential for geothermal development, and consequent possible impacts to Borax Lake chub and its habitat, remains. The possibility of geothermal development in the vicinity of Borax Lake will continue to represent a potential threat to Borax Lake chub and its habitat, but we have determined the likelihood of this threat becoming operative in the foreseeable future is low.

Increase in the ambient air temperature from climate change could slow the cooling of the geothermal waters that create Borax Lake. Cooling of the waters of Borax Lake, especially the shallow margin areas including several overflow channels and the wetland, is important to the Borax Lake chub during warm times of the year given that temperatures in some areas of the lake often exceed the thermal maximum for this species (Scheerer and Bangs 2011, p. 8) reported as 34.5 degrees Celsius (94 degrees Fahrenheit) (Williams and Bond 1983, p. 412).

Above-average air temperatures in the summer of 2015 correlate with the above-average water temperatures documented in Borax Lake during the same time frame and may have contributed to the low population estimate that fall (Scheerer *et al.* 2016, p. 9). In the future, changes in water temperature due to increases in ambient air temperatures caused by climate change could result in a reduction in the amount of habitat available at suitable water temperatures, thus reducing the overall amount of habitat available for the Borax Lake chub during warm periods of the year. It is reasonable to assume the frequency of these events due to climate change may increase such that there is a possibility for consecutive year events of drought and associated abnormally warm air and water temperatures. We anticipate that thermal refuge associated with shallow margin habitat and cool and cold water vents in the lake along with the species' ability to rebound quickly following periods of higher than normal air and water temperatures, will provide resilience against potential future effects of climate change.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overutilization for commercial, recreational, scientific, or educational purposes was not a factor in listing (47 FR 43957; October 5, 1982) and is currently not known to be a threat to the Borax Lake chub, nor is it likely to become so in the foreseeable future.

C. Disease or Predation

Disease was not a factor in listing of the Borax Lake chub (47 FR 43957; October 5, 1982) and is currently not known to be a threat to Borax Lake chub, nor is it likely to become so in the foreseeable future.

Likewise, predation was not noted as a factor in the listing of Borax Lake chub (47 FR 43957; October 5, 1982). Although we do not believe predation is a threat currently or in the foreseeable future, a single observation of an exotic fish did occur in 2013 (see *Delisting Criterion 1,* above, for more discussion). Exotic fish were not observed in repeated surveys, and no known impacts to Borax Lake chub occurred. The high water temperatures in Borax Lake, which likely limited the long-term survival of this exotic fish, also limit the overall likelihood of establishment of exotic species in Borax Lake. The establishment of a perimeter fence around Borax Lake by the BLM and TNC in 2011 further reduced the likelihood of purposeful or accidental introductions of exotic species to the extent that we conclude that the threat of predation has been addressed.

As noted previously in this proposed rule, the BLM, ODFW, and the Service developed a CMP that will guide future monitoring for nonnative species, monitoring of Borax Lake chub, vehicle access restrictions, and public outreach and education (USFWS *et al.* 2018). While the CMP provides agency commitments for long-term stewardship of Borax Lake and Borax Lake chub, this proposed rule does not rely on the actions described in the CMP.

D. The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine the stressors identified within the other factors as ameliorated or exacerbated by any existing regulatory mechanisms or conservation efforts. Section 4(b)(1)(A) of the Act requires that the Service take into account ''those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species . . .'' In relation to Factor D under the Act, we interpret this language to require the Service to consider relevant Federal, State, and Tribal laws, regulations, and other such binding legal mechanisms that may ameliorate or exacerbate any of the threats we describe in threat analyses under the other four factors or otherwise enhance the species' conservation. Our consideration of these mechanisms is described in detail within each of the threats or stressors to the species (see full discussion under this section, Summary of Factors Affecting the Species).

The following provides an overview of the existing regulatory protections that protect the Borax Lake ecosystem and Borax Lake chub.

The Nature Conservancy

The 160-ac (65-ha) private land parcel containing Borax Lake and the 160-ac parcel to the north were purchased by TNC in 1993. Subsurface mineral rights are included. Since TNC acquisition, surface waters on their land, upon which Borax Lake is located, can no longer be appropriated by others. Additionally, TNC ended the practice of actively diverting surface water from the eastern side of the lake to reduce the impact from prior water diversions.

BLM—Federal Land and Rights-of-Way

The passage of the Steens Act of 2000 and the completion of the Steens Andrews Resource Management Plan (RMP) withdrew the Alvord KGRA from mineral and geothermal exploration and development (BLM 2005). The Steens Act congressionally designated a mineral withdrawal area encompassing 900,000 ac (364,217.1 ha) of the planning area on BLM-administered lands. The mineral withdrawal area contains the majority of the Alvord KGRA, including Borax Lake and surrounding public lands, with the exception of 332 ac (134.4 ha) located approximately 4.5 mi (7.242 km) from Borax Lake (BLM 2005). Private lands within this area are not affected by the mineral withdrawal. Approximately 2,000 ac (809.4 ha) of privately owned land occur within a 3-mi (4.83-km) radius of Borax Lake and are not subject to BLM's withdrawal. The BLM has responsibility to review all applications for geothermal development within the Alvord KGRA that occur on BLM lands and some applications for development on private lands if the development

requires ROW for access or transmission lines across BLM-managed lands. ROWs are a valid use of public lands under sections 302 and 501 of the Federal Land Policy and Management Act of 1976 (BLM 2005). The BLM would be responsible under the National Environmental Policy Act to analyze any proposed ROW project including the connected action (*i.e.,* energy development on private lands).

In 1983, the BLM designated 520 ac (210 ha) of public land surrounding Borax Lake as an ACEC to protect Borax Lake chub and its habitat. In 2005, the record of decision for the RMP for the Andrews Resource Area added 80 ac (32 ha), for a total 600-ac (243-ha) Borax Lake ACEC (BLM 2005a, p. 70).

Off-road vehicle damage along the lake shoreline has been documented in the past (Scheerer and Jacobs 2005, p. 6; 2006, p. 7; 2007, p. 6; 2008, p. 6; 2009, p. 8; 2010, p. 4; Scheerer and Bangs 2011, p. 9; Scheerer *et al.* 2012, p. 13; Scheerer *et al.* 2013, p. 6). As a result, in 2011, the BLM and TNC completed a perimeter fence surrounding the lake and most of the associated critical habitat to exclude unauthorized vehicles, and in 2013, they installed locks on all access gates. Due to the completion of the perimeter fence, the threat to the Borax lake chub from shoreline habitat alteration by vehicles has been addressed.

State of Oregon, Department of Geology and Mineral Industries (DOGAMI)

In Oregon, Oregon Revised Statute (ORS) chapter 522 authorizes DOGAMI to control drilling, re-drilling, and deepening of wells for the discovery and production of geothermal resources. Under this authority, a developer undertaking geothermal exploration on all land (public and private) must first obtain a permit from DOGAMI (Oregon Administrative Rule (OAR) 632–020–0028). DOGAMI process requires circulation of any permit application to other State agencies that manage natural resources such as the Water Resources Department, ODFW, Department of Environmental Quality, State Parks and Recreation Department, Department of Land Conservation and Development, Department of State Lands, and the governing body of the county and geothermal heating district in which the well will be located (ORS 522.125(1)). Any of these agencies can suggest conditions under which a permit should be granted or denied. DOGAMI is required to take State agency comments into consideration when deciding to grant a permit (OAR 632–020–0170). As part of the conditions for geothermal development on private land, a developer is required by DOGAMI to provide baseline information needed to show there would be no connection to geothermal or groundwater continuity in areas of environmental concern (*i.e.,* Borax Lake or the BLM's designated ACEC near Borax Lake). Therefore, the DOGAMI is required to accept comment, and consider protective measures. This additional review through the DOGAMI process may benefit the Borax Lake chub through the addition of conservation measures necessary to obtain a permit for geothermal exploration.

State of Oregon, Oregon Department of Energy's Energy Facility Siting Council (EFSC)

The EFSC has regulatory and siting responsibility for proposed generating facilities greater than 35 megawatts in Oregon. The OAR–345–022–0040 prohibits the EFSC from issuing site certificates for energy development in protected areas such as BLM ACECs and State natural heritage areas such as TNC's Borax Lake Preserve. For proposed energy developments in unprotected areas, the EFSC applies Division 22 siting standards for fish and wildlife habitat (OAR 345–022–0060), threatened and endangered species (OAR 345–022–0070), and general standards of review (OAR 345–022–000). Specific to Borax Lake chub, OAR 345–022–0060 requires that a proposed facility comply with the habitat mitigation goals and standards of the ODFW as defined in OAR 635–415–0025. The ODFW defines Borax Lake chub habitat as a Habitat Category 1 under the habitat mitigation standard. The mitigation goal for Habitat Category 1 is no loss of either habitat quantity or quality. The ODFW is required to protect habitats in Category 1 by recommending or requiring: (1) Avoidance of impacts through alternatives to the proposed development action, or (2) no authorization of the proposed development action if impacts cannot be avoided. To issue a site certificate, the EFSC must find that the design, construction, and operation of the facility, taking into account mitigation, are consistent with the fish and habitat mitigation goals and standards of OAR 635–415–0025 (OAR 345–022–0060 Fish and Wildlife Habitat).

State of Oregon, Oregon Department of Fish and Wildlife

The Borax Lake chub was listed as endangered in 1987, and then reclassified to threatened in 2017 under the Oregon Endangered Species Act (Oregon ESA), which prohibits the ''take'' (killing or obtaining possession or control) of listed species without an incidental take permit. The State of Oregon determined that Borax Lake chub fit the definition of threatened rather than endangered due to substantial progress in conservation and recovery of the species. The State criteria for recovery of Borax Lake chub is met due to (1) the protected ownership by TNC; (2) natural reproductive potential is not endangered; (3) primary habitat is protected; (4) habitat is protected from commercial use; (5) public access is restricted to foot traffic; (6) no harvest is allowed; (7) only infrequent scientific or educational use occurs; (8) most surrounding land is protected from geothermal development on Federal lands; and (9) water rights of the lake were obtained by the ODFW for the purpose of conserving Borax Lake chub.

The Oregon ESA applies to actions of State agencies on State-owned or leased land, and does not impose any additional restrictions on the use of private lands (ORS 496.192). The Oregon ESA is implemented by the State independently from the Federal Endangered Species Act; thus, if finalized, this proposed rule would not directly impact the current State listing of Borax Lake chub. Under the Oregon ESA, State agencies (other than State land-owning or land-managing agencies) determine the role they may serve in contributing toward conservation or take avoidance (OAR 635–100–0150). The Oregon Endangered Species List is a nonregulatory tool that helps focus wildlife management and research with the goal of preventing species from declining to the point of extinction (ORS 496.171, 496.172, 496.176, 496.182, and 496.192).

Per OAR 635–415–0025 (Habitat Mitigation Policy), the ODFW would provide comments and recommendations on risks to all native fish and wildlife from a proposed geothermal development project in the Alvord Basin through all State and county permitting processes. If there was any indication that a proposed geothermal development project would have a geothermal or groundwater connection with Borax Lake, the ODFW would recommend that alternatives be developed or that the action not be permitted (ODFW 2012, p. 9).

The ODFW filed for water rights at Borax Lake in 1991, and that right is now certified to the Oregon Water Resources Department, to prevent further attempts at diverting the water and to ensure maintenance of the water elevation in Borax Lake (see *Delisting Criterion 3* discussion, above). The

purpose of the water right is to provide the required habitat conditions for the Borax Lake chub. The right is established under Oregon Revised Statute 537.341, with a priority date of August 21, 1991. The right is limited to the amount of water necessary to maintain a surface water elevation of 4,081 ft (1,244 m) above mean sea level. For purposes of water distribution, the instream right shall not have priority over human or livestock consumption. The right has been recorded in the State record of Water Right Certificates as 75919.

Thus, the protections of the Oregon ESA, ODFW policy on geothermal development permitting, and the establishment of a dedicated water right for conservation at Borax Lake provide for significant ongoing protection and allow for critical review of future development projects.

Summary of Factor D

Conservation ownership of Borax Lake and surrounding lands by TNC (320 ac; 129 ha), withdrawal of Borax Lake waters from appropriation, the mineral withdrawal within the Alvord KGRA under the 2000 Steens Act, and the mineral withdrawal and management guidelines under the BLM's ACEC around Borax Lake (600 ac; 243 ha) provide significant regulatory protections to the Borax Lake ecosystem that would remain unchanged should this proposal to delist the Borax Lake chub be finalized. While State and Federal regulatory mechanisms exist that would protect the Borax Lake ecosystem from potential effects of development of geothermal resources on 2,000 ac (809 ha) of private land in proximity to Borax Lake, these regulatory mechanisms do not guarantee a development proposal would not legally proceed to implementation. However, these regulatory mechanisms ensure State and Federal natural resource agencies will be made aware of any proposals moving forward for permitting (*e.g.,* DOGAMI) and that comments by applicable State and Federal resource agencies will be considered. As noted previously, DOGAMI requires geothermal developers to provide baseline information to show there would be no connection to geothermal or groundwater in areas of environmental concern (*e.g.,* Borax Lake or the BLM's designated ACEC near Borax Lake). Similarly, the EFSC requires that a proposed facility comply with the habitat mitigation goals and standards of the ODFW as defined in OAR 635–415–0025. These regulatory mechanisms do not completely remove potential risk to the Borax Lake chub from geothermal development, but they do reduce the likelihood of impact from development on private lands in the vicinity of Borax Lake.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

The 1982 listing rule (47 FR 43957; October 5, 1982) did not identify any other natural or human-made factors affecting Borax Lake chub or its habitat. No threats have arisen under this threat factor since that time, and none is anticipated in the foreseeable future. Potential impacts of climate change are addressed in this proposed rule under *A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* above.

Overall Summary of Factors Affecting the Borax Lake Chub

The primary factors that threatened the Borax Lake chub at the time of listing (47 FR 43957; October 5, 1982) were potential impacts from geothermal energy development, diversion of the lake's outflows by alteration of the shoreline crust, and potential development of a recreation facility. Most of these threats or potential threats have been removed or ameliorated by implementing actions identified in the Borax Lake Chub Recovery Plan (see the discussion of downlisting criteria under *Recovery,* above). Actions that have been taken to reduce or eliminate the destruction and modification of Borax Lake chub habitat (Factor A) include acquisition of Borax Lake by TNC, the BLM's designation of adjacent lands as an ACEC, protection of subsurface and surface waters, protection from mineral withdrawal, and closure of fragile lands to livestock grazing and unauthorized vehicle access.

Proposals to develop geothermal energy resources in the Borax Lake vicinity have occurred sporadically over the last 4 decades, and for that reason, it is reasonable to expect additional proposals to develop geothermal energy are likely in the foreseeable future. However, none of these proposals has moved forward with implementation over a 4-decade period, and this history leads us to conclude that the likelihood of geothermal energy development in the vicinity of Borax Lake in the foreseeable future is low. Furthermore, while geothermal development in the vicinity of Borax Lake is considered a potential threat to Borax Lake chub, the precise effects of possible geothermal development on the species are uncertain and unpredictable given the unknown nature of geothermal fluids and their behavior deep underground. The response of the species would depend upon the specifics of any geothermal energy development that might proceed to the implementation phase (*e.g.,* scale of the project and proximity to Borax Lake). Depending on the circumstances of any particular project, such development could potentially have a negative effect on the species or it might have no or negligible effects. The possibility of geothermal development in the vicinity of Borax Lake will continue to represent a potential threat to Borax Lake chub and its habitat, but we have determined the likelihood of this threat becoming operative in the foreseeable future is low.

An increase in ambient air temperatures due to climate change may reduce the amount and suitability of habitat for Borax Lake chub during the warmest times of the year (June through August) due to water temperatures that can meet or sometimes exceed thermal maximums for the species. However, shallow-water thermal refuge habitats around the margins of Borax Lake (the overflow channel and wetland), cool and cold water vents within the lake, along with the species' ability to rebound quickly following periods of low population abundance, are expected to provide resilience against potential future effects of climate change to the Borax Lake chub.

Factor B (overutilization for commercial, recreational, scientific, or educational purposes), Factor C (disease and predation), and Factor E (other natural or manmade factors affecting its continued existence) were not identified as threat factors in the listing of Borax Lake chub in 1982 (47 FR 43957; October 5, 1982), and these factors are currently not known to be threats to the Borax Lake chub now or in the foreseeable future.

We conclude that existing regulatory mechanisms (Factor D) provide significant protections to Borax Lake chub and its habitat, especially on Federal lands, and address most of the reasons that the species was listed. No regulatory mechanisms are in place that fully prevent geothermal development on private lands in the vicinity of Borax Lake. However, we determined that this potential threat is not likely to manifest in the foreseeable future; therefore, no threats remain that require regulatory mechanisms to address them in the event that the species were delisted and the protections of the Act were no longer in place.

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 an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following 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.

Determination of Status Throughout All of the Species' Range

As required by section 4(a)(1) of the Act, we conducted a review of the status of the Borax Lake chub and assessed the five factors to evaluate whether it is endangered or threatened throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by the species. Significant threats identified at the time of listing (47 FR 43957; October 5, 1982) have been eliminated or reduced. We conclude that under Factor A (the present or threatened destruction, modification, or curtailment of its habitat or range), the possibility of geothermal development in the vicinity of Borax Lake will continue to represent a potential threat to Borax Lake chub and its habitat, but we have determined the likelihood of this threat becoming operative in the foreseeable future is low. We did not identify any other threats from development on private lands in the vicinity of Borax Lake. We have identified climate change as a new potential threat to Borax Lake chub, but the magnitude and frequency of this potential threat is generally unknown at this time. We conclude that Factor B (overutilization for commercial, recreational, scientific, or educational purposes) and Factor C (disease or predation) are not threats to Borax Lake chub. We conclude that under Factor D (the inadequacy of existing regulatory mechanisms), the existing regulatory mechanisms provide significant protections to Borax Lake chub and its habitat, especially on Federal lands, but they do not address potential impacts of geothermal development on private lands. However, as discussed above, we have determined that the likelihood of the threat of geothermal development in the vicinity of Borax Lake becoming operative in the foreseeable future is low; therefore, no regulatory mechanisms are needed to address this potential threat. All of these threats apply similarly throughout the range of the species in Borax Lake.

Thus, after assessing the best available information, we conclude that the Borax Lake chub is not currently in danger of extinction, and is not likely to become so within the foreseeable future throughout all of its range.

Because we have determined that the Borax Lake chub is not in danger of extinction or likely to become so in the foreseeable future throughout all of its range, we will consider whether there are any significant portions of its range in which the species is in danger of extinction or likely to become so in the foreseeable future.

Determination of Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range (SPR). Having determined that the Borax Lake chub is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range, we now consider whether it may be in danger of extinction or likely to become so in the foreseeable future in an SPR. The range of a species can theoretically be divided into portions in an infinite number of ways, so we first screen the potential portions of the species' range to determine if there are any portions that warrant further consideration. To do this, we look for portions of the species' range for which there is substantial information indicating that: (1) The portion may be significant, and (2) the species may be in danger of extinction or likely to become so in the foreseeable future in that portion. A portion only warrants further consideration if there is substantial information that both of these statements are true for that portion. Therefore, for a particular portion, if we determine that there is not substantial information that one of these statements is true, then the species does not warrant listing because of its status in that portion of its range.

We evaluated the range of the Borax Lake chub to determine if any area may be a significant portion of the range. The Borax Lake chub is a narrow endemic that occurs in Borax Lake in the Alvord Basin. The historical known natural range of the Borax Lake chub is limited to Borax Lake and associated outflows and wetlands. Based on the small range of the Borax Lake chub, approximately 10.2-ac (4.1-ha), we determined that the species is a single, contiguous population and that there are no separate areas of the range that are likely to be of greater biological or conservation importance than any other areas due to natural biological reasons alone. Therefore, there is not substantial information that logical, biological divisions exist that would support delineating one or more portions within the species' range.

Based on our determination that no natural biological divisions are delineating separate portions of the Borax Lake chub population, we conclude that there are no portions of the species' range for which both (1) the portions are likely to be significant and (2) the species is likely to be in danger of extinction or likely to become so in the foreseeable future in those portions. This makes it unnecessary for us to undertake any further consideration or analysis of whether this species is endangered or threatened throughout an SPR. We conclude therefore that there is no significant portion of the species' range where it is an endangered species or a threatened species. Our approach to analyzing SPR in this determination is consistent with the court's holding in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018).

Our review of the best available scientific and commercial information indicates that the Borax Lake chub is not in danger of extinction nor likely to become endangered within the foreseeable future throughout all or a significant portion of its range. Therefore, we find that the Borax Lake chub does not meet the definition of a threatened species, and we propose to remove the Borax Lake chub from the List.

Effects of the Proposed Rule

This proposal, if made final, would revise 50 CFR 17.11(h) by removing the Borax Lake chub from the Federal List of Endangered and Threatened Wildlife.

The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to this species. Federal agencies would no longer be required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect the Borax Lake chub. Critical habitat for Borax Lake chub at 50 CFR 17.95(e) would be removed if this proposal is made final. State laws related to Borax Lake chub would remain in place, be enforced, and continue to provide protection for this species.

Post-Delisting Monitoring

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

A draft post-delisting monitoring (PDM) plan has been developed for the Borax Lake chub, building on and continuing the research that was conducted during the listing period. The draft PDM plan will be peer reviewed by specialists and will be available for public comment upon the publication of this proposed rule at *http://www.regulations.gov,* under docket number FWS–R1–ES–2017–0035. Public and peer review comments submitted in response to the draft PDM plan will be addressed within the body of the plan and summarized in an appendix to the plan. The draft PDM plan was developed by the Service and is based on actions outlined in the CMP developed by the Service, BLM, and ODFW. The draft PDM plan consists of: (1) A summary of the species' status at the time of proposed delisting; (2) an outline of the roles of PDM cooperators; (3) a description of monitoring methods; (4) an outline of the frequency and duration of monitoring; (5) an outline of data compilation and reporting procedures; and (6) a definition of thresholds or triggers for potential monitoring outcomes and conclusions of the PDM.

The draft PDM plan proposes to monitor Borax Lake chub following the same sampling protocol used by the ODFW prior to delisting. Monitoring would consist of three components: Borax Lake chub abundance, potential adverse changes to Borax Lake chub habitat due to environmental or anthropogenic factors, and monitoring DOGAMI for drilling applications. The PDM would consist of surveys to estimate population abundance conducted once every 3 years over a 9-year period (four population surveys total), which would begin after the final delisting rule is published. Given the Borax Lake chub is a short lived fish (few survive beyond 1 year; Scoppettone *et al.* 1995, p. 36), periodic monitoring over this time period would allow us to address any possible negative effects to the Borax Lake chub. Additionally, the chub experienced wide fluctuation in its population year-to-year. Limited data points for a widely fluctuating population can lead to weak information. Therefore, we chose to extend the time sequence to ensure we can accurately measure changes in trends.

The draft PDM plan identifies measurable management thresholds and responses for detecting and reacting to significant changes in the Borax Lake chub's protected habitat, distribution, and persistence. If declines are detected equaling or exceeding these thresholds, the Service, in combination with other PDM participants, would investigate causes of these declines, including considerations of habitat changes, substantial human persecution, stochastic events, or any other significant evidence. The result of the investigation would be to determine if the Borax Lake chub warrants expanded monitoring, additional research, additional habitat protection, or relisting as an endangered or a threatened species under the Act. If such monitoring data or an otherwise updated assessment of threats (such as specific information on proposed geothermal development projects) indicate that relisting the Borax Lake chub is warranted, emergency procedures to relist the species may be followed, if necessary, in accordance with section 4(b)(7) of the Act.

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 environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, Government-to-Government Relations with Native American Tribal Governments (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Native American culture, and to make information available to Tribes.

We do not believe that any Tribes would be affected if we adopt this rule as proposed. However, we have contacted the Burns Paiute Tribe to coordinate with them regarding this proposed rule.

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–2017–0035 or upon request from the Oregon Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are staff members of our Oregon Fish and Wildlife Office.

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.

§ 17.11 [Amended]

■ 2. Amend § 17.11(h) by removing the entry for ''Chub, Borax Lake'' under FISHES from the List of Endangered and Threatened Wildlife.

§ 17.95 [Amended]

■ 3. Amend § 17.95(e) by removing the entry for ''BORAX LAKE CHUB (*Gila boraxobius*).''

Dated: December 7, 2018.

Margret E. Everson,

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

[FR Doc. 2019–02979 Filed 2–25–19; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register

Vol. 84, No. 38

Tuesday, February 26, 2019

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 21, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 28, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Biofuels Infrastructure Partnership (BIP).

OMB Control Number: 0560–0284.

Summary of Collection: The Farm Service Agency (FSA) announced the availability of competitive grants to fund States, the Commonwealth of Puerto Rico, and Washington, DC with respect to activities designed to expand the infrastructure for renewable fuels. The goal is for grantees to provide funds on a one-to-one basis to receive matching Commodity Credit Corporation (CCC) funds under the authority in section 5€ of CCC Charter Act (15 U.S.C. 714c(e)). This information collection is needed for FSA to identify eligible States for blender pump funding to encourage increased ethanol use. FSA requires each State interested to apply for BIP grant through *www.grants.gov.*

Need and Use of the Information: FSA will use the collected information to determine whether participants meet the eligibility requirements to be a recipient of grant funds. Lack of adequate information to make the determination could result in the improper administration and appropriation of Federal grants funds.

Description of Respondents: State, Local and Tribal Government.

Number of Respondents: 19.

Frequency of Responses: Recordkeeping; Reporting: Other (once).

Total Burden Hours: 109.

Farm Service Agency

Title: Market Facilitation Program.

OMB Control Number: 0560–0292.

Summary of Collection: This information collection is required for the Farm Service Agency (FSA) to make Market Facilitation Program (MFP) payments to domestic crop and commodity producers. Specifically, the Commodity Credit Corporation (CCC) Charter Act (15 U.S.C. 714c) authorizes CCC to assist in the disposition of surplus commodities and to increase the domestic consumption of agricultural commodities by expanding or aiding in the expansion of domestic markets or by developing or aiding in the development of new and additional markets, marketing facilities, and uses for such commodities.

Need and Use of the Information: The information collection is needed to provide assistance through the MFP with respect to commodities that have been significantly impacted by actions of foreign governments resulting in the loss of traditional exports. In order to determine whether a producer is eligible for MFP and to calculate a payment, a producer is required to submit the following forms: CCC–901—MFP Application, *CCC–902—Farm Operating Plans for an Individuall, CCC–941—Average Adjusted Gross Income (AGI) Certification and Consent to Disclosure of Tax Information, FSA 578—Report of Acreage, and AD–1026—Highly Erodible Land Conservation (HELC) and Wetland Conservation Certification. Lack of adequate information to make the determination could result in the improper administration and appropriation of CCC funds.*

Description of Respondents: Farms.

Number of Respondents: 898,600.

Frequency of Responses: Reporting; Other (one-time).

Total Burden Hours: 669,850.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–03239 Filed 2–25–19; 8:45 am]

BILLING CODE 3410–05–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the New Hampshire Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), thata meeting of the New Hampshire Advisory Committee to the Commission will convene by conference call at 3:00 p.m. (EST) on Thursday, February 28, 2019. The purpose of the meeting is for project planning.

DATES: Thursday, February 28, 2019, at 3:00 p.m. (EST).

Public Call-In Information: Conference call-in number: 1–800–667–5617 and conference call 7737084.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–800–667–5617 and conference call 7737084. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 1–800–667–5617 and conference call 7737084.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlXAAQ;* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

February 28, 2019, Thursday; 3:00 p.m. (EST)

- Roll Call
- Project Planning
- Open Comment
- Adjourn

Dated: February 21, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–03281 Filed 2–25–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–05–2019]

Foreign-Trade Zone (FTZ) 93—Raleigh/Durham, North Carolina, Notification of Proposed Production Activity, GlaxoSmithKline, PLC (Pharmaceutical Products), Zebulon, North Carolina

The Triangle J Council of Governments, grantee of FTZ 93, submitted a notification of proposed production activity to the FTZ Board on behalf of GlaxoSmithKline, PLC (GlaxoSmithKline), located in Zebulon, North Carolina. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on February 13, 2019.

GlaxoSmithKline already has authority to produce certain pharmaceutical products within Site 6 of FTZ 93. The current request would add finished products and a foreign-status material/component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status material/component (dolutegravir sodium) and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt GlaxoSmithKline from customs duty payments on the foreign-status material/component used in export production. On its domestic sales, for foreign-status dolutegravir sodium (duty rate, 6.5%) and foreign-status components in the existing scope of authority, GlaxoSmithKline would be able to choose the duty-free rate during customs entry procedures that applies to: Dolutegravir sodium/rilpivirine HCl; Juluca tablets® (anti-viral); dolutegravir sodium tablets (anti-viral); Tivicay tablets® (anti-viral); abacavir sulfate/dolutegravir sodium/lamivudine tablets (anti-viral); Triumeq tablets® (anti-viral); dolutegravir/lamivudine tablets (anti-viral); Dovato tablets® (anti-viral); umeclidinium bromide/vilanterol trifenatate ellipta (respiratory inhaler); Anoro Ellipta® (respiratory inhaler); umeclidinium bromide ellipta (respiratory inhaler); Incruse Ellipta® (respiratory inhaler); fluticasone furoate/umeclidinium bromide/vilanterol trifenatate ellipta (respiratory inhaler); and, Trelegy Ellipta® (respiratory inhaler). GlaxoSmithKline would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 8, 2019.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: February 19, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–03236 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–57–2018]

Foreign-Trade Zone (FTZ) 149—Freeport, Texas, Authorization of Production Activity, DSM Nutritional Products, LLC (Vinylol), Freeport, Texas

On September 11, 2018, the Port of Freeport, grantee of FTZ 149, submitted a notification of proposed production activity to the FTZ Board on behalf of DSM Nutritional Products, LLC, within Subzone 149B, in Freeport, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 47131, September 18, 2018). On February 19, 2019, the applicant was notified of the FTZ Board's decision that no further

review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: February 19, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–03238 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–21–2019]

Foreign-Trade Zone 40—Cleveland, Ohio, Application for Subzone Expansion, Swagelok Company, Ravenna, Ohio

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Cleveland Cuyahoga County Port Authority, grantee of FTZ 40, requesting an expansion of Subzone 40I on behalf of Swagelok Company (Swagelok). The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on February 19, 2019.

Subzone 40I currently consists of the following sites: *Site 1* (70 acres) 29500 Solon Rd & 29495 FA Lennon Dr., Solon, Cuyahoga County; *Site 2* (13.3 acres) 31400 Aurora Rd., Solon, Cuyahoga County; *Site 3* (5 acres) 29500 Ambina Dr., Solon, Cuyahoga County; *Site 4* (7.82 acres) 26651 & 26653 Curtiss Wright Parkway, Willoughby Hills, Cuyahoga County; *Site 5* (16.8 acres) 318,348, & 358 Bishop Rd., Highland Heights, Cuyahoga County; *Site 6* (23.95 acres) 6050, 6060, & 6100 Cochran Rd., Solon, Cuyahoga County; *Site 7* (3 acres) 29900 Solon Industrial Parkway, Solon, Cuyahoga County; *Site 8* (5 acres) 32550 Old South Miles Rd., Solon, Cuyahoga County; and, *Site 9* (9.5 acres) 15400 Foltz Parkway, Strongsville, Cuyahoga County.

The proposed expanded subzone would include the following additional site: *Site 10* (8.87 acres), 935 N Freedom St., Ravenna, Portage County. Because the proposed site is outside FTZ 40's Alternative Site Framework (ASF) service area, authorization of the expanded subzone would not be under the ASF. No authorization for expanded production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 40.

In accordance with the FTZ Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is April 8, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to April 22, 2019.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: February 19, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–03235 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–23–2019]

Foreign-Trade Zone 262—Southaven, Mississippi; Application for Subzone; WPG Americas Inc.; Southaven, Mississippi

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Northern Mississippi FTZ, Inc., grantee of FTZ 262, requesting subzone status for the facility of WPG Americas Inc., located in Southaven, Mississippi. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on February 19, 2019.

The proposed subzone (1.25 acres) is located at 481 Airport Industrial Drive, Suite 102, Southaven, Mississippi. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 262.

In accordance with the Board's regulations, Qahira El-Amin of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 8, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to April 22, 2019.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Qahira El-Amin at *Qahira.El-Amin@trade.gov* or (202) 482–5928.

Dated: February 19, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–03237 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–856]

Corrosion-Resistant Steel Products From Taiwan: Notice of Court Decision Not in Harmony With Final Determination of Antidumping Duty Investigation and Notice of Amended Final Determination of Investigation

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

SUMMARY: On December 20, 2018, the United States Court of International Trade (Court) issued a final judgment in *Prosperity Tieh Enterprise Co., Ltd. et al.* v. *United States,* Consol. Court No. 16–00138; Slip Op. 18–175 (CIT Dec. 20, 2018), sustaining the Department of Commerce's (Commerce) remand results for the final determination of the antidumping investigation of certain corrosion-resistant steel products (CORE) from Taiwan, covering the period of investigation (POI) April 1, 2014, through March 31, 2015. Commerce is notifying the public that the Court has made a final judgment that is not in harmony with Commerce's amended final determination of the antidumping investigation, and that

Commerce is amending the final determination.

DATES: Applicable December 30, 2018.

FOR FURTHER INFORMATION CONTACT: Shanah Lee, AD/CVD Operations Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6386.

SUPPLEMENTARY INFORMATION:

Background

On June 2, 2016, Commerce published its *Final Determination,* and on July 25, 2016, Commerce published its *Amended Final Determination and Order* concerning the antidumping investigation of CORE from Taiwan.[1] The plaintiffs in this litigation, consisting of the two-mandatory respondents, Prosperity Tieh Enterprise Co., Ltd. (Prosperity) and Yieh Phui Enterprise Co., Ltd. (Yieh Phui) timely filed complaints with the Court challenging certain aspects of Commerce's investigation. The petitioners in the investigation, AK Steel Corporation, Nucor Corporation, Steel Dynamics, Inc., California Steel Industries, Inc., ArcelorMittal USA LLC, and United States Steel Corporation intervened as defendant-intervenors.

On January 23, 2018, the Court remanded three aspects of Commerce's findings, in *Prosperity Tieh I.*[2] First, the Court held that Commerce's determination to deny Yieh Phui's and Synn Industrial Co., Ltd.'s post-sale rebate adjustments ''violated its own regulations,'' and remanded to Commerce to ''correct this error.'' [3] Second, the Court remanded Commerce's determination to collapse Prosperity, Yieh Phui, and Synn pursuant to its analysis under 19 CFR 351.401(f), because ''the collapsing decision was based on erroneous findings of fact.'' [4] Third, the Court remanded Commerce's application of partial adverse facts available to Prosperity based on Commerce's finding that Prosperity misclassified certain of its products in reporting sales in the databases by placing these products in the wrong yield strength category.[5] The Court held that, in reporting its yield strength, ''Prosperity complied with the instructions as Commerce wrote them.'' [6] The Court ruled that ''Commerce may not use facts otherwise available as a substitute for information that is now on the administrative record of the investigation, but indicated that ''the type of corrective action is a matter for Commerce to decide'' as to this remanded issue.[7]

In its Final Results Redetermination, Commerce: (1) Granted, under protest, downward price adjustments to the home market sales price equal to the amount of Yieh Phui's post-sale rebates granted to the company's home market customers; (2) continued to treat Prosperity, Yieh Phui, and Synn as a single-entity consistent with 19 CFR 351.401(f); and (3) revised, under protest, the Yieh Phui/Prosperity/Synn entity's weighted-average dumping margin by using Prosperity's reported yield strength data.[8] After accounting for all such changes and issues in the Final Results Redetermination, the resulting antidumping margin for the Yieh Phui/Prosperity/Synn entity is 3.66 percent.[9] On December 20, 2018, the Court sustained the Final Results Redetermination, in *Prosperity II.*[10]

Timken Notice

In its decision in *Timken,*[11] as clarified by *Diamond Sawblades,*[12] the Court of Appeals for the Federal Circuit (Federal Circuit) held that, pursuant to section 516A of the Tariff Act of 1930, as amended (Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision.[13] The Court's December 20, 2018, judgment constitutes a final decision of the Court that is not in harmony with Commerce's *Final Determination* and *Amended Final Determination and Order.* As such, Commerce has published this notice in fulfillment of the publication requirement of *Timken.*

Amended Final Determination and Amended Order

Because there is now a final court decision, Commerce is amending the *Final Determination* and *Amended Final Determination and Order* with respect to the weighted-average dumping margin for the Yieh Phui/Prosperity/Synn entity. Furthermore, in the *Amended Final Determination and Order,* and in accordance with section 735(c)(5)(A) of the Act, for companies not individually investigated, we applied an ''all-others'' rate of 10.34 percent.[14] This rate was determined based on assigning the Yieh Phui/Prosperity/Synn entity's rate as the all-others rate.[15] As noted above, the Yieh Phui/Prosperity/Synn's amended weighted-average dumping margin is now 3.66 percent. Therefore, for purposes of this amended *Final Determination,* Commerce will instruct CBP that the all-others rate is to be amended to 3.66 percent.[16] Accordingly, the revised weighted-average dumping margin for the collapsed Yieh Phui/Prosperity/Synn entity and for all-others is as follows:

Producer	Weighted-average dumping margin (percent)
Prosperity Tieh Enterprise Co., Ltd., Yieh Phui Enterprise Co., Ltd., and Synn Industrial Co., Ltd	3.66
All-Others	3.66

Cash Deposit Requirements

Since the *Final Determination,* Commerce has established a new cash deposit rate for Prosperity and Yieh Phui/Synn.[17] Therefore, this amended final determination does not change the

[1] *Certain Corrosion-Resistant Steel Products from Taiwan: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, in Part,* 81 FR 35313 (June 2, 2016), and accompanying Issues and Decision Memorandum (IDM) (*Final Determination*), as amended by *Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016) (*Amended Final Determination and Order*).

[2] *See Prosperity Tieh Enterprise Co., Ltd. et al.* v. *United States,* Consol. Court No. 16–00138; Slip Op. 18–5, at 2, 31–32 (CIT January 23, 2018) (*Prosperity Tieh I*).

[3] *Id.* at 6–15.

[4] *Id.* at 15–20.

[5] *Id.* at 20–31.

[6] *Id.* at 28.

[7] *Id.* at 30–31.

[8] *See* Final Results of Redetermination Pursuant to *Prosperity Tieh Enterprise Co., Ltd. et al.* v. *United States,* Consol. Court No. 16–00138; Slip. Op. 18–5, dated May 23, 2018 (Final Results Redetermination).

[9] *Id.* at 31.

[10] *See Prosperity Tieh Enterprise Co., Ltd. et al.* v. *United States,* Consol. Court No. 16–00138, Slip. Op. 18–175 (CIT December 20, 2018) (*Prosperity II*) (this opinion was made public on February 11, 2019).

[11] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[12] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[13] *See* sections 516A(c) and (e) of the Act.

[14] *See Amended Final Determination and Order,* 81 FR at 48391; *Final Determination,* 81 FR at 35314.

[15] *See Final Determination,* 81 FR at 35314.

[16] *See United States Steel Corp.* v. *United States,* Slip Op. 18–139, at 8 (CIT October 17, 2018).

[17] *See Certain Corrosion-Resistant Steel Products from Taiwan: Final Results of Antidumping Administrative Review; 2016–2017,* 83 FR 64527 (December 17, 2018) (*First Administrative Review Final Results*). As a result of this administrative review, Commerce continued to treat Yieh Phui and Synn as a single entity and determined that Prosperity should no longer be collapsed with Yieh Phui and Synn.

later-established cash deposit rates for those producers and/or exporters. For all-other producers and/or exporters, except for companies that subsequently received their own rates in the first administrative review,[18] Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection, adjusting the cash deposit rate for all-other producers and/or exporters to 3.66 percent, effective December 30, 2018.

Lastly, we note that, at this time, Commerce remains enjoined by Court order from liquidating entries that were produced and/or exported by Prosperity and imported by Prosperity Tieh USA, that were the subject of the *First Administrative Review Final Results,* and that were entered, or withdrawn from warehouse, on or after June 2, 2016, up to and including June 30, 2017. These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e), 751(a)(1), and 777(i)(1) of the Act.

Dated: February 19, 2019.

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. 2019–03240 Filed 2–25–19; 8:45 am]

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[18] *Id.,* at 64528.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–868]

Large Residential Washers From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) determines that LG Electronics, Inc. (LGE), a producer/exporter of large residential washers from the Republic of Korea (Korea), did not make sales at prices below normal value during the February 1, 2017, through January 31, 2018, period of review (POR).

DATES: Applicable February 26, 2019.

FOR FURTHER INFORMATION CONTACT: David Goldberger, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC, 20230; telephone: (202) 482–4136.

SUPPLEMENTARY INFORMATION: On November 5, 2018, Commerce published the *Preliminary Results* and invited comments from interested parties.[1] No interested party submitted comments. Commerce conducted this administrative review in accordance with sections 751(a)(1) and (2) of the Tariff Act of 1930, as amended (the Act). Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 28, 2019.[2] If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. The revised deadline for the final results of this review is now April 15, 2019.

Scope of the Order

The products covered by the order are all large residential washers and certain subassemblies thereof from Korea. The products are currently classifiable under subheadings 8450.20.0040 and 8450.20.0080 of the Harmonized Tariff System of the United States (HTSUS). Products subject to this order may also enter under HTSUS subheadings 8450.11.0040, 8450.11.0080, 8450.90.2000, and 8450.90.6000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.[3]

Changes Since the Preliminary Results

As no parties submitted comments on the *Preliminary Results,* we made no changes in the final results of this review.

Final Results of the Review

As a result of this review, Commerce determines that a weighted-average dumping margin of 0.00 percent exists for LGE for the period February 1, 2017, through January 31, 2018.

[1] *See Large Residential Washers From the Republic of Korea: Preliminary Results of the Antidumping Duty Administrative Review; 2017–2018,* 83 FR 55346 (November 5, 2018) (*Preliminary Results*).

[2] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[3] For a full descripition of the scope of the order, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2017–2018 Administrative Review of the Antidumping Duty Order on Large Residential Washers from the Republic of Korea,'' dated October 29, 2018.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

Because we calculated a zero margin for LGE in the final results of this review, we intend to instruct CBP to liquidate without regard to antidumping duties all shipments of subject merchandise manufactured and exported by LGE, entered or withdrawn from warehouse, for consumption, during the POR. In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by LGE for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[4]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for merchandise produced and/or exported by LGE will be zero; (2) for previously reviewed or investigated companies not covered by this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 11.80 percent, the all-others rate established in the LTFV investigation.[5] These

[4] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) for a full discussion of this practice.

[5] *See Large Residential Washers from Mexico and the Republic of Korea: Antidumping Duty Orders,* 78 FR 11148 (February 15, 2013).

deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation, which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: February 13, 2019.

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. 2019–03309 Filed 2–25–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2016–2017

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

SUMMARY: The Department of Commerce (Commerce) determines that GGB Bearing Technology (Suzhou) Co., Ltd. (GGB) sold tapered roller bearings and parts thereof, finished and unfinished (TRBs) from the People's Republic of China (China) at less than normal value (NV) during the period of review (POR), June 1, 2016, through May 31, 2017.

DATES: Applicable February 26, 2019.

FOR FURTHER INFORMATION CONTACT: Andrew Medley or Alex Wood, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4987 or (202) 482–1959, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on July 12, 2018.[1] For events subsequent to the *Preliminary Results, see* Commerce's Issues and Decision Memorandum.[2] On August 2, 2018, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the deadline for issuing the final results until January 8, 2019.[3] Commerce exercised its discretion to toll all deadlines affected by the partial Federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[4] If the tolled deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. The revised deadline for the final results is now February 19, 2019.

Scope of the Order

The merchandise covered by the *Order*[5] includes tapered roller bearings and parts thereof. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.70.6060, 8708.99.2300, 8708.99.4850, 8708.99.6890, 8708.99.8115, and 8708.99.8180. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the order is dispositive.[6]

Analysis of Comments Received

In the Issues and Decision Memorandum, we addressed all issues raised in parties' case and rebuttal briefs. Appendix I to this notice provides a list of the issues raised by parties. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the *Preliminary Results*

Based on our review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain revisions to the margin calculations for GGB,[7] and to the rate assigned to the non-examined, separate rate respondents.[8]

Separate Rate Respondents

In the *Preliminary Results,* we determined that GGB and six other companies demonstrated their eligibility for separate rates. We received no comments or argument since the issuance of the *Preliminary Results* that provide a basis for reconsideration of these determinations. Therefore, for these final results, we continue to find that each of the companies listed in the

[1] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Preliminary Results and Intent to Rescind the Review in Part; 2016–2017,* 83 FR 32263 (July 12, 2018) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Antidumping Duty Administrative Review: Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China; 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Extension of Deadline for the Final Results of Antidumping Duty Administrative {Review},'' dated October 16, 2018.

[4] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See Notice of Antidumping Duty Order; Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China,* 52 FR 22667 (June 15, 1987) (*Order*).

[6] *See* Issues and Decision Memorandum for a complete description of the scope of the *Order.*

[7] *See* Memorandum ''Calculations for GGB Bearing Technology (Suzhou) Co., Ltd. for the Final Results,'' dated concurrently with this notice.

[8] *See* Issues and Decision Memorandum for a summary of these revisions.

table in the ''Final Results'' section of this notice is eligible for a separate rate.

Further, we determined in the *Preliminary Results* that each of 12 companies failed to demonstrate an absence of *de facto* government control, and, thus, Commerce did not grant them a separate rate.[9] No party provided comments with respect to 10 of the 12 companies, and, thus, we continue to find that those 10 companies listed are not eligible for separate rates.[10] Further, we received comments from the remaining two companies, Zhejiang Machinery Import & Export Corp. (Zhejiang Machinery) and Zhejiang Zhaofeng Mechanical & Electronic Co., Ltd. (Zhaofeng) with regards to their separate rate claims. We continue to find, based on record evidence, that Zhejiang Machinery failed to demonstrate an absence of *de facto* government control; accordingly, we also are not granting a separate rate to Zhejiang Machinery.[11] With respect to Zhaofeng, we have further considered the information on the record and find that Zhaofeng has demonstrated the absence of *de jure* and *de facto* government control, and thus, we are granting Zhaofeng a separate rate for these final results.[12]

Finally, one additional company, Dingli, could not demonstrate that it had a suspended entry during the POR. In the *Preliminary Results,* we erroneously stated that we were rescinding the review with respect to Dingli because it failed to provide evidence of a suspended entry during the POR. However, rather than rescind the review with respect to Dingli, we have determined that it is ineligible for a separate rate, and thus is part of the China-wide entity.

Rate for Non-Examined Separate-Rate Respondents

The statute and our regulations do not address the rate to be assigned to respondents not selected for individual examination when we limit our examination of companies subject to the administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, we look to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents not individually examined in an administrative review. Section 735(c)(5)(A) of the Act articulates a preference for not calculating an all-others rate using rates which are zero, *de minimis,* or based entirely on facts available.[13] Accordingly, we generally will determine the weighted-average dumping margin for companies not individually examined by weight averaging the weighted-average dumping margins for the individually examined respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[14]

For the final results, we calculated a rate only for GGB. Therefore, for these final results, following the practice described above, we have assigned to the companies that have not been individually examined, but have demonstrated their eligibility for a separate rate, the weighted-average dumping margin calculated for GGB.

Final Results of the Administrative Review

Because Zhejiang Machinery and 11 other companies did not demonstrate that they are entitled to a separate rate, Commerce finds these 12 companies (listed in Appendix II of this notice) to be part of the China-wide entity.[15] Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,[16] we did not conduct a review of the China-wide entity. The rate previously established for the China-wide entity is 92.84 percent and is not subject to change as a result of this review.

For companies subject to this review, which established their eligibility for a separate rate, Commerce determines that the following weighted-average dumping margins exist for the period June 1, 2015, through May 31, 2016:

Exporter	Weighted-average dumping margin (percent)
GGB Bearing Technology (Suzhou) Co., Ltd	7.04
CNH Industrial Italia SpA	7.04
GSP Automotive Group Wenzhou Co. Ltd	7.04
Hangzhou Hanji Auto Parts Co., Ltd	7.04
Hangzhou Radical Energy-Saving Technology Co., Ltd	7.04
Ningbo Xinglun Bearings Import & Export Co., Ltd	7.04
Zhejiang Sihe Machine Co., Ltd	7.04
Zhejiang Zhaofeng Mechanical & Electronic Co., Ltd	7.04

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For GGB, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1). Where an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[17]

Pursuant to Commerce's assessment practice, for entries that were not reported in the U.S. sales data submitted by GGB, we will instruct CBP to liquidate such entries at the China-wide rate.[18]

For the respondents which were not selected for individual examination in this administrative review and which qualified for a separate rate, the assessment rate will be equal to the weighted-average dumping margin

[9] *See* Appendix II of this notice for a list of the 11 companies which Commerce continues to find ineligible for a separate rate. Note that this list also includes a twelfth company, Hangzhou Xiaoshan Dingli Machinery Co., Ltd. (Dingli), which is discussed further below.

[10] *Id.*

[11] For further discussion, *see* Comment 1 of the accompanying Issues and Decision Memorandum.

[12] For further discussion, *see* Comment 2 of the accompanying Issues and Decision Memorandum.

[13] *See Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[14] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[15] In the *Preliminary Results,* we erroneously stated that we preliminarily were rescinding the review with respect to Dingli because it failed to provide evidence of a suspended entry during the POR. However, rather than rescind the review with respect to Dingli, we have determined that it is ineligible for a separate rate.

[16] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity (NME) in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013).

[17] *See* 19 CFR 351.106(c)(2).

[18] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

determined for GGB in the final results of this administrative review.

For the companies identified in Appendix II as part of the China-wide entity, because Commerce determined that these companies did not qualify for a separate rate, we will instruct CBP to assess dumping duties on the companies' entries of subject merchandise at the rate of 92.84 percent.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review; (2) for previously investigated or reviewed China and non-China exporters not listed above that currently have a separate rate, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding where the exporter received that separate rate; (3) for all China exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity, 92.84 percent; and (4) for all non-China exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the China exporter that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Notifications to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) 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 Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notifications to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return 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.

We are issuing and publishing these results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: February 19, 2019.

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

List of Topics Discussed in the Issues and Decision Memorandum

Summary
Background
Scope of the Order
Changes Since the *Preliminary Results*
Discussion of the Issues
1. Zhejiang Machinery's Separate Rate Status
2. Zhaofeng's Separate Rate Status
3. Irrecoverable Value Added Taxes
4. Alleged Ministerial Error
5. GGB's ''Supplier Quality Issue'' Parts
6. TRB Parts from GGB's Suppliers
7. Rollers from GGB's Suppliers
8. Surrogate Values for Steel Plate
9. Surrogate Values for Packing Materials
10. Surrogate Financial Ratios
Conclusion

Appendix II

Companies Not Eligible for a Separate Rate and To Be Treated as Part of the China-Wide Entity

Company

1. Apex Maritime Shanghai Co., Ltd.
2. Crossroads Global Trading Co., Ltd.
3. Hangzhou Xiaoshan Dingli Machinery Co., Ltd.
4. Honour Lane Shipping Ltd.
5. Kinetsu World Express China Co., Ltd.
6. Luoyang Bearing Corporation (Group)
7. Pacific Link Intl Freight Forwarding Co., Ltd.
8. Shanghai Dizhao Industrial Trading Co., Ltd.
9. Thi Group Shanghai Ltd.
10. Weifang Haoxin-Conmet Mechanical Products Co., Ltd.
11. Yantai Huilong Machinery Parts Co., Ltd.
12. Zhejiang Machinery Import & Export Corp.

[FR Doc. 2019–03308 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; National Institute of Standards and Technology (NIST), Generic Clearance for Community Resilience Data Collections

AGENCY: National Institute of Standards and Technology, 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 April 29, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 1401 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 Jennifer Helgeson, Economist, NIST, 100 Bureau Drive, MS 8603, Gaithersburg, MD 20899–1710, telephone 301–975–6133, or via email to *jennifer.helgeson@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Through acts such as the National Construction Safety Team Act (NCSTA) and the NIST Organic Act, among others, as well as the President's Climate Action Plan (2013), NIST conducts research and develops guidance and other related tools to promote and enhance the safety and well-being of people in the face of a hazard event. With this in mind, NIST proposes to conduct a number of data collection efforts within the topic areas of disaster and failure studies and community resilience and sustainability, including studies of specific disaster events (*e.g.,* wildfire, urban fire, structure collapse, hurricane, earthquake, tornado, and flood events), assessments of community resilience and sustainability, and evaluations of the usability and utility of NIST guidance or other products.

These data collection efforts may be either qualitative or quantitative in

nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, and focus groups. NIST will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. The results of the data collected will be used to decrease negative impacts of disasters on society, and, in turn, increase community resilience within the U.S. communities. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

This notice pertains to both a revision and an extension of a previously approved submission. The NIST Engineering Laboratory utilizes this clearance to conduct research in support of topic areas of disaster and failure studies, community resilience (including studies of specific disaster events such as wildfire, urban fire, structure collapse, hurricane, earthquake, tornado, and flood events).

This type of research is directly related to a range of disasters which are unpredictable in their number during a given year. Additionally, some disasters may require multiple studies resulting in multiple collections. Therefore, in preparation of the upcoming disaster season, NIST is requesting to increase the ICR Annual Response allotment from 15,000 to 20,000 Responses; and the ICR Annual Hours allotment from 12,000 to 15,000. NIST assures that no changes will be made to any the individual information collection requests that have been approved for use.

II. Method of Collection

NIST will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. NIST may also utilize observational techniques to collect this information.

III. Data

OMB Control Number: 0693–0078.

Form Number(s): None.

Type of Review: Revision.

Affected Public: Individuals or households; first responders; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal government; Federal government; Standards-making bodies; Universities.

Estimated Number of Respondents: 20,000.

Estimated Time per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire may be 15 minutes or 2 hours to participate in an interview.

Estimated Total Annual Burden Hours: 15,000.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

NIST invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) 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.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–03243 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; ''Madrid Protocol''

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the 1995 Paperwork Reduction Act.

Agency: United States Patent and Trademark Office, Commerce.

Title: Madrid Protocol.

OMB Control Number: 0651–0051.

Form Number(s):

- PTO–1663
- PTO–1683
- PTO–2132
- PTO–2133
- TEAS Global Form

Type of Request: Regular.

Number of Respondents: 14,691 responses per year.

Average Hours Per Response: The USPTO estimates that it will take the public approximately between 20 minutes (0.33 hours) and seventy-five minutes (1.25 hours) to complete the information in this collection. This includes the time to gather the necessary information, prepare the forms or documents, and submit the completed request to the USPTO.

Burden Hours: 4878.97 hours per year.

Cost Burden: $12,182,379.50 per year.

Needs and Uses:

The public uses this collection to submit applications for international registration and related requests to the USPTO under the Madrid Protocol. The information in this collection is a matter of public record and is used by the public for a variety of private business purposes related to establishing and enforcing international trademark rights. The information is available at USPTO facilities and is also accessible through the USPTO website.

Frequency: On occasion.

Respondent's Obligation: Mandatory to Obtain or Retain Benefits

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov*

Once submitted, the request will be publicly available in electronic format through *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- Email: *InformationCollection@uspto.gov.* Include ''0651–00## information request'' in the subject line of the message.
- Mail: Marcie Lovett, Records and Information Governance Branch Chief, Office of the Chief Technology Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before March 28, 2019 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Chief, Records and Information Governance Branch, Office of the Chief Administrative Officer, USPTO.

[FR Doc. 2019–03224 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; Practitioner Conduct and Discipline

The United States Patent and Trademark Office (USPTO) 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: United States Patent and Trademark Office, Commerce.

Title: Practitioner Conduct and Discipline.

OMB Control Number: 0651–0017.

Form Number(s): ;No forms associated.

Type of Request: Regular.

Number of Respondents: 11,145.

Average Hours Per Response: The USPTO estimates that it will take the public between 1 and 20 hours, depending upon the complexity of the situation, to gather the necessary information, prepare, and submit the requirements in this collection.

Burden Hours: 12,465 hours annually.

Cost Burden: $1,630.80.

Needs and Uses: This information is required by 35 U.S.C. 2, 32, and 33 and administered by the USPTO through 37 CFR 11.101–11.901 and 37 CFR 11.19–11.61. The information is used by the Director of the Office of Enrollment and Discipline (OED) to investigate and, where appropriate, prosecute practitioners for violations of the USPTO Rules of Professional Conduct. Registered practitioners are required to maintain proper documentation so that they can fully cooperate with an investigation in the event of a report of an alleged violation. There are no forms associated with this collection of information.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.* Once submitted, the request will be publicly available in electronic format through *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information may be requested by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0017 copy request'' in the subject line of the message.
- *Mail:* Marcie Lovett, Chief, Records and Information Governance Branch, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before March 28, 2019 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Chief, Records and Information Governance Branch, Office of the Chief Administrative Officer, USPTO.

[FR Doc. 2019–03223 Filed 2–25–19; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for Grantee Progress Report (GPR) Data Collection

AGENCY: Corporation for National and Community Service (CNCS).

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, CNCS is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by April 29, 2019.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, Attention Sarah Yue, 250 E Street SW, Washington, DC, 20525.

(2) By hand delivery or by courier to the CNCS mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Sarah Yue, 202–606–6894, or by email at *syue@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Progress Report (GPR) Data Collection.

OMB Control Number: [3045–0175].

Type of Review: Renewal.

Respondents/Affected Public: Businesses and Organizations; State, Local or Tribal Governments.

Total Estimated Number of Annual Responses: 300 total respondents for AmeriCorps State and National. 52 respondents each for Commission Support Grants and Commission Investment Funds. 20 respondents for Volunteer Generation Fund.

Total Estimated Number of Annual Burden Hours: 4,540.

Abstract: CNCS uses information collected via the Grantee Progress Reports to assess grantee progress toward meeting approved objectives; to identify areas of challenge and opportunity; to guide the allocation of training and technical assistance resources; and to compile portfolio-wide data to report to external stakeholders. CNCS seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on April 30, 2020.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. 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. 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. All written comments will be available for public inspection on *regulations.gov.*

Dated: January 30, 2019.

Sarah Yue,

Senior Program and Project Specialist, AmeriCorps State and National.

[FR Doc. 2019–03273 Filed 2–25–19; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–OS–0042]

Notice of Availability for Finding of No Significant Impact for the Environmental Assessment Addressing Upgrade of the Main Gate Access Control Point at Defense Distribution Depot, San Joaquin, California, and Surrounding Area

AGENCY: Defense Logistics Agency (DLA), Department of Defense (DoD).

ACTION: Notice of availability (NOA).

SUMMARY: This NOA documents DLA's decision to proceed with the proposed action to upgrade the Main Gate Access Control Point at Defense Distribution Depot, San Joaquin California, and Surrounding Area following the completion of an Environmental Assessment (EA). The EA was prepared as required under the National Environmental Policy Act (NEPA) of 1969.

FOR FURTHER INFORMATION CONTACT: Ira Silverberg at 571–767–0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EST) or by email: *ira.silverberg@dla.mil.*

SUPPLEMENTARY INFORMATION: DLA completed an EA to address the potential environmental consequences associated with the Proposed Action. This Finding of No Significant Impact (FONSI) incorporates the EA by reference, summarizes the results of the analyses in the EA, and documents DLA's decision to upgrade the Main Gate ACP at Defense Distribution Depot, San Joaquin and surrounding area. DLA has determined that the Proposed Action is not a major federal action that significantly affects the quality of the human environment within the context of NEPA, and that no significant impacts on the human environment are associated with this decision.

DLA consulted with the California State Historic Preservation Officer (SHPO) at the California Department of Parks and Recreation, Office of Historic Preservation, and the Buena Vista Rancheria of Me-Wuk Indians, Ione Band of Miwok Indians, North Valley Yokuts Tribe, Southern Sierra Miwuk Nation, Wilton Rancheria, and United Auburn Indian Community of the Auburn Rancheria for this Proposed Action. The SHPO concurred that the Proposed Action would not affect historic properties. The Buena Vista Rancheria of Me-Wuk Indians provided a response indicating the Tribe was not aware of any cultural resources, but requested notification if any issues arise during the Proposed Action and if undeveloped soil would be disturbed. DLA did not receive responses to the consultation requests with the other tribes. The SHPO and tribal consultation documents and the responses from the SHPO and the Buena Vista Rancheria of Me-Wuk Indians are in Appendix A of the revised EA.

On July 12, 2018, a **Federal Register** NOA was published announcing the availability of the EA for a 30-day public comment period that ended August 13, 2018. One comment letter, from the San Joaquin County Department of Public Works, was received during the EA public comment period. The San Joaquin County Department of Public Works had no comments, but requested to be included on the distribution list for future project documents. The comment letter was added to Appendix A of the revised EA. The revised EA is available electronically at the Federal eRulemaking Portal at *http://www.regulations.gov* within Docket ID: DOD–2018–OS–0042.

Purpose and Need for Action: The purpose of the Proposed Action is to provide the Defense Distribution Depot, San Joaquin with a safe and secure ACP at the Main Gate for light vehicles (*e.g.,* standard dual-axle trucks and cars), bicycles, and pedestrians that is compliant with DoD Unified Facilities Criteria (UFC) 4–022–01, *Security Engineering: Entry Control Facilities/Access Control Points,* and UFC 4–010–01, *DoD Minimum Antiterrorism Standards for Buildings,* under all force-protection conditions. The Proposed Action would also provide adequate space on installation property for vehicle queuing entering the ACP, so that queuing does not occur on Chrisman Road. The Proposed Action is needed because the existing 58-year-old Main Gate ACP does not meet current DoD UFC requirements. Additionally, the Proposed Action is needed to reduce existing queuing issues along Chrisman Road during high-volume employee shift changes.

Proposed Action and Alternatives: Under the Proposed Action, DLA would demolish and remove existing buildings and infrastructure within the proposed ACP footprint; construct a new, permanent ACP at the Main Gate on the installation; and implement off-installation road improvements. The proposed ACP would consist of a visitor center, identification check point, vehicle inspection area, gatehouse, overwatch building, active and passive vehicle barriers and security fencing, utilities, and ancillary components. The existing Main Gate ACP, a warehouse, roadways and other pavements would be demolished; two fabric tent structures would be relocated; and infrastructure (*i.e.,* utilities, fencing, and asphalt pavement) would be removed and replaced. The Proposed Action would also require the installation of a traffic signal at the intersection of Chrisman and Valpico Road, and the restriping of one lane of Chrisman Road leading to the intersection. After completion of construction, the proposed ACP would operate as a secondary ACP (*i.e.,* an ACP that operates during regular hours, but less than 24 hours per day), similar to the existing Main Gate ACP. Light vehicles would continue to have access to the installation via the Truck Gate, which is currently open and would remain open 24 hours per day, during the hours the proposed ACP is closed. Gate 2 and the Employee Gate, which are currently used under limited circumstances, would be permanently closed. No new DLA personnel would be required to operate the proposed ACP.

Description of the No Action Alternative: Under the No Action Alternative, DLA would not upgrade the Main Gate ACP at Defense Distribution Depot, San Joaquin. The ACP enhancements would not be provided, and operational conditions would not be improved. Gate 2 and the Employee Gate would remain open. Compliance with DoD UFCs 4–010–01 and 4–022–01 would not be met. Critical logistic and security operations at Defense Distribution Depot, San Joaquin would be vulnerable to disruption and potentially long-term denial of service, which could have an immediate impact on the command and control of these operations. DLA police would continue to use inadequate facilities to inspect incoming light vehicles. The No Action Alternative would not meet the purpose of and need for the Proposed Action.

Potential Environmental Impacts: No significant effects on environmental resources would be expected from the Proposed Action. Insignificant adverse effects on noise, air quality, geological resources, water resources, biological resources, health and safety, infrastructure and transportation, and hazardous materials and wastes would be expected. Insignificant beneficial effects on geological resources, water resources, health and safety, infrastructure and transportation, and hazardous materials and wastes would be expected. No impacts on land use or environmental justice would be expected. Details of the environmental consequences are discussed in the EA, which is hereby incorporated by reference.

Determination: DLA has determined that implementation of the Proposed Action will not have a significant effect on the human environment. Human environment was interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment. Specifically, no highly uncertain or controversial impacts, unique or unknown risks, or cumulatively significant effects were identified. Implementation of the Proposed Action will not violate any federal, state, or local laws. Based on the results of the analyses performed during preparation of the EA and consideration of comments received during the public comment period, Mr. Gordon B. Hackett III, Director, DLA Installation Management, concludes that implementation of the Proposed Action at Defense Distribution Depot, San Joaquin does not constitute a major federal action that would significantly affect the quality of the human environment within the context of NEPA. Therefore, an environmental impact statement for the Proposed Action is not required.

Dated: February 20, 2019.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–03208 Filed 2–25–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Renewal of federal advisory committee.

SUMMARY: The Department of Defense is publishing this notice to announce that it is renewing the charter for the National Security Education Board (''the Board'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board's charter is being renewed pursuant to 50 U.S.C. 1903(a) and in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., App) and 41 CFR 102–3.50(a). The Board's charter and contact information for the Board's Designated Federal Officer (DFO) can be found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The Board, pursuant to 50 U.S.C. 1903(d) and, shall perform the following functions: a. Develop criteria for awarding scholarships, fellowships, and grants under 50 U.S.C. Ch. 37, including an order of priority in such awards that favors individuals expressing an interest in national security issues or pursuing a career in national security positions. b. Provide for wide dissemination of information regarding the activities assisted under 50 U.S.C. Ch. 37. c. Establish qualifications for students desiring scholarships or fellowships, and institutions of higher education desiring grants, under 50 U.S.C. Ch. 37, including, in the case of students desiring a scholarship or fellowship, a requirement that the student have a demonstrated commitment to the study of the discipline for which the scholarship or fellowship is to be awarded. d. After taking into account the annual analyses of trends in language, international, area, and counter-proliferations studies under 50 U.S.C. 1906(b)(1), make recommendations to the Secretary of Defense regarding: i. Which countries are not emphasized in other U.S. study abroad programs, such as countries in which few U.S. students are studying and countries which are of importance to the national security interests of the United States, and are, therefore, critical countries for the purpose of 50 U.S.C. 1902(a)(1)(A); ii. which areas within the disciplines described in 50 U.S.C. 1902(a)(1)(B) relating to the national security interests of the United States are areas of study in which U.S. students are deficient in learning and are, therefore, critical areas within those disciplines for the purposes of that section; iii. which areas within the disciplines described in 50 U.S.C. 1902(a)(1)(C) are areas in which U.S. students, educators, and Government employees are deficient in learning and in which insubstantial numbers of U.S. institutions of higher education provide training and are, therefore, critical areas within those disciplines for the purpose of that section; iv. how students desiring scholarships or fellowships can be encouraged to work for an agency or office of the Federal Government involved in national security affairs or national security policy upon completion of their education; and v. which foreign languages are critical to the national security interests of the United States for purposes of 50 U.S.C. 1902(a)(1)(D) (relating to grants for the National Flagship Language Initiative) and 50 U.S.C. 1902(a)(1)(E) (relating to the scholarship program for advanced English language studies by heritage community citizens). e. Encourage applications for fellowships under 50 U.S.C. Ch. 37 from graduate students having an educational background in any academic discipline, particularly in the areas of science or technology. f. Provide the Secretary of Defense biennially with a list of scholarship recipients and fellowship recipients, including an assessment of their foreign area and language skills, who are available to work in a national security position. g. Not later than 30 days after a scholarship or fellowship recipient completes the study or education for which assistance was provided under the Program, provide the Secretary of Defense with a report fully describing the foreign area and language skills obtained by the recipient as a result of the assistance. h. Review the administration of the Program required under 50 U.S.C. Ch. 37. i. To the extent provided by the Secretary of Defense, oversee and coordinate the activities of the national Language Service Corps (''the Corps'') under 50 U.S.C. 1913,

including: i. Assessing on a periodic basis whether the Corps is addressing the needs identified by the head of departments and agencies of the Federal Government for personnel with skills in various foreign languages; ii. Recommending plans for the Corps to address foreign language shortfalls and requirements of the departments and agencies of the Federal Government; iii. Recommending effective ways to increase public awareness of the need for foreign languages skills and career paths in the Federal Government that use those skills; and, iv. Overseeing the Corps efforts to work with Executive agencies and State and local governments to respond to interagency plans and agreements to address overall foreign language shortfalls and to utilize personnel to address the various types of crises that warrant foreign language skills.

The Secretary of Defense, pursuant to 50 U.S.C. 1906, shall submit to the President and to the Congressional intelligence committees an annual report of the conduct of the Program required by 50 U.S.C. Ch. 37. During preparation of this annual report, the Secretary of Defense shall consult with the members of the Board, who shall each submit to the Secretary an assessment of their hiring needs in the areas of language and area studies and projection of the deficiencies in such areas. The Secretary shall include all assessments in the annual report.

Pursuant to 50 U.S.C. 1903(b), the Board shall be composed of the following 15 individuals or the representative of such individuals: i. The Secretary of Defense, who shall serve as the Chair of the Board. ii. The Secretary of Education. iii. The Secretary of State. iv. The Secretary of Commerce. v. The Secretary of Homeland Security. vi. The Secretary of Energy. vii. The Director of National Intelligence. viii. The Chair of the National Endowment for the Humanities. ix. Six individuals appointed by the President, who shall be experts in the fields of international, language, area, and counter-proliferation studies education and who shall be experts in the fields of international, language, area, and counter-proliferation studies education who may not be officers or employees of the Federal Government.

Consistent with 50 U.S.C. 1903, the Secretary of Defense designates the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) as the Chair of the Board. If the USD(P&R) is unavailable to chair a specific session of the Board, then the Assistant Secretary of Defense for Readiness shall perform the function of the Chair of the Board while the USD(P&R) is unavailable. The authority to chair the Board may not be further delegated.

Pursuant to 50 U.S.C. 1903(c), individuals appointed by the President shall receive no compensation for service on the Board. All members shall receive reimbursement of official Board-related travel and per diem.

The public or interested organizations may submit written statements to the Board membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board. All written statements shall be submitted to the DFO for the Board, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: February 13, 2019.

Shelly Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2019–03227 Filed 2–25–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Policy Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Policy, Defense Policy Board, 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 Policy Board (DPB) will take place.

DATES:

Day 1—Closed to the public Wednesday, March 13, 2019 from 8:00 a.m. to 5:00 p.m.

Day 2—Closed to the public Thursday, March 14, 2019 from 8:00 a.m. to 12:00 p.m.

ADDRESSES: The closed meeting will be held at The Pentagon, 2000 Defense Pentagon, Washington, DC 20301–2000.

FOR FURTHER INFORMATION CONTACT: Marcus Bonds, (703) 571–0854 (Voice), 703–697–8606 (Facsimile), marcus.bonds.civ@mail.mil (Email). Mailing address is 2000 Defense Pentagon, Washington, DC 20301–2000.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., App.), the Government in the Sunshine Act (''the Sunshine Act'') (5 U.S.C. 552b), and the General Services Administration's Federal Advisory Committee Management; Final Rule (''the FACA Final Rule''). (41 CFR 101–6 and 102–3).

Purpose of the Meeting: To obtain, review, and evaluate classified information related to the DPB's mission to advise on (a) issues central to strategic DoD planning; (b) policy implications of U.S. force structure and force modernization and on DoD's ability to execute U.S. defense strategy; (c) U.S. regional defense policies; and (d) other research and analysis of topics raised by the Secretary of Defense, the Deputy Secretary of Defense, or the Under Secretary of Defense for Policy.

Agenda: On March 13th and 14th, the DPB will have Secret level or higher discussions on national security issues regarding 5G Technology. On March 13th, Topics and speakers include (1) 5G Telecommunications from a National Security Perspective, Kristen Baldwin (Department of Defense) and Jeffrey Baum (Department of Defense); (2) Intelligence Community Threat, Raymond Gabany (National Security Agency); (3) Spectrum, Standards, Supply Chain, and Technology Leadership, Honorable Dana Deasy (Department of Defense) and Earl Comstock (Department of Commerce); (4) Warfighter Perspectives, General Paul Nakasone (Department of Defense) and Lt General Bradford Shwedo (Department of Defense) (5); 5G Industry Panel, Nate Tibbets (Qualcomm), Andre Fuetsch (AT&T) and Chandra McMahon (Verizon); Government to Industry Partnering, Mr. David Redl (Department of Commerce) and Ajit Pai (Federal Communications Commission). On March 14th the DPB will deliberate and report out to the John Rood, Under Secretary of Defense for Policy.

Meeting Accessibility: Pursuant to the Sunshine Act, the FACA, and the FACA Final Rule (41 CFR 101–6), the DoD has determined that this meeting shall be closed to the public. The Under Secretary of Defense (Policy), in consultation with the DoD FACA Attorney, has determined in writing that this meeting be closed to the public because the discussions fall under the purview of Section 552b(c)(1) of the Sunshine Act and are so inextricably intertwined with unclassified material that they cannot reasonably be segregated into separate discussions without disclosing secret or higher classified material.

Committee's Designated Federal Officer or Point of Contact: Marcus

Bonds, *osd.pentagon.ousd-policy.mbx.defense-board@mail.mil.*

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140(c) and section 10(a)(3) of the FACA, the public or interested organizations may submit written statements to the membership of the DPB at any time regarding its mission or in response to the stated agenda of a planned meeting. Written statements should be submitted to the DPB's Designated Federal Officer (DFO), which is listed in this notice or can be obtained from the GSA's FACA Database—*http://www.facadatabase.gov/.* Written statements that do not pertain to a scheduled meeting of the DPB may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at a planned meeting, then these statements must be submitted no later than five business days prior to the meeting in question. The DFO will review all submitted written statements and provide copies to all members.

Dated: February 21, 2019.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–03287 Filed 2–25–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. IS18–766–000; IS18–767–000]

Mid-America Pipeline Company, LLC, Seminole Pipeline Company LLC; Notice Rescheduling Technical Conference

The technical conference that has been rescheduled for February 20, 2019, is hereby postponed due to the forecast of inclement weather. Information regarding the new date for this conference will be forthcoming in subsequent notice.[1]

Dated: February 19, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03261 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

[1] See the *Notice of Technical Conference* issued on December 12, 2018, for additional details regarding this conference.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2445–027]

Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process: Green Mountain Power Corporation

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 2445–027.

c. *Date Filed:* December 21, 2018.

d. *Submitted By:* Green Mountain Power Corporation (Green Mountain).

e. *Name of Project:* Center Rutland Project.

f. *Location:* On Otter Creek in the Town of Rutland, Rutland County, Vermont. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* 18 CFR 5.3 and 5.5 of the Commission's regulations.

h. *Potential Applicant Contact:* Jason Lisai, Director of Generation Operations, Green Mountain Power Corporation, 163 Acorn Lane, Colchester, VT 05446; (802) 655–8723; email at *Jason.Lisai@greenmountainpower.com.*

i. *FERC Contact:* John Baummer at (202) 502–6837; or email at *john.baummer@ferc.gov.*

j. Green Mountain filed its request to use the Traditional Licensing Process on December 21, 2018, and provided public notice of the request on December 20, 2018. In a letter dated February 19, 2019, the Director of the Division of Hydropower Licensing approved Green Mountain's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Vermont State Historic Preservation Officer, as required by section 106 of the National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Green Mountain as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Green Mountain filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website (*http://www.ferc.gov*), using the eLibrary link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERConlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at 2152 Post Road, Rutland, VT 05701.

o. The licensee states its unequivocal intent to submit an application for a subsequent license for Project No. 2445. Pursuant to 18 CFR 16.20, each application for a subsequent license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by December 31, 2021.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: February 19, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03265 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2685–029]

New York Power Authority; Notice of Availability of Final Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a new license for the Blenheim-Gilboa Pumped Storage Project, located on Schoharie Creek, in

the Towns of Blenheim and Gilboa in Schoharie County, New York, and has prepared a final Environmental Assessment (EA) for the project.

The final EA contains Commission staff's analysis of the potential environmental effects of the project, and concludes that relicensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the final EA is available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's website at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

For further information, contact Andy Bernick at (202) 502–8660.

Dated: February 14, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03259 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 8417–004]

Sparhawk, LLC; Notice of Comment Period Extension

On November 27, 2018, the Commission issued a notice setting December 27, 2019, as the end of the formal period to file comments, motions to intervene, and protests on the surrender application for the Old Sparhawk Mill Hydroelectric Project No. 8417. The document published in the **Federal Register** on December 3, 2018, at 83 FR 62317. Due to the funding lapse at certain federal agencies between December 22, 2018 and January 25, 2019, the Commission is extending the comment period until March 26, 2019.

Dated: February 19, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03275 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6916–011]

Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, and Terms and Conditions: City and County of Denver, Colorado

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for Non-capacity Amendment and Conversion of License to an Exemption of Small Hydroelectric Power Project from Licensing.

b. *Project No:* P–6916–011.

c. *Date Filed:* January 4, 2019.

d. *Applicant:* City and County of Denver, Colorado (Denver Water).

e. *Name of Project:* Strontia Springs Hydroelectric Project.

f. *Location:* The project is located on the South Platte River, in Douglas and Jefferson Counties, Colorado.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Brian Gogas, Denver Water, 1600 West 12th Avenue, Denver, Colorado 80204, (303) 628–6000.

i. *FERC Contact:* Zeena Aljibury, (202) 502–6065, *zeena.aljibury@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* 60 days from the issuance date of this notice by the Commission; reply comments are due 105 days from the issuance date of this notice by the Commission.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, or recommendations 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–6916–011.

k. *Description of Request:* City and County of Denver proposes to upgrade its turbine generator unit, which would increase the total installed capacity of the project to 1.25–MW, and to convert its license to an exemption. Denver Water is also proposing to construct a new switchyard adjacent to the powerhouse, and to adjust the existing project boundary to include the primary power line. During construction, the project would continue to operate normally, without any changes to the surface area, surface elevation, or existing impoundment. The construction activities are expected to take approximately three years to complete.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number P–6916 in the docket number field to access the documents. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above and at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title COMMENTS,

PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license amendment. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: February 19, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03266 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IN12–17–000]

Total Gas & Power North America, Aaron Hall and Therese Tran; Updated Notice of Designation of Commission Staff as Non-Decisional

With respect to an order issued by the Commission on April 28, 2016 in the above-captioned docket,[1] with the exceptions noted below, the staff of the Office of Enforcement are designated as non-decisional in deliberations by the Commission in this docket. Accordingly, pursuant to 18 CFR 385.2202 (2018), they will not serve as advisors to the Commission or take part in the Commission's review of any offer of settlement. Likewise, as non-decisional staff, pursuant to 18 CFR 385.2201 (2018), they are prohibited from communicating with advisory staff concerning any deliberations in this docket.

Exceptions to this designation as non-decisional are:

Reudi Abersold
Demetra Anas
Jeffrey Fang
Martin Lawera
Lisa Owings
Eric Primosch
Felice Richter
Derek Shiau
Nicholas Stavlas
Andrew Tamayo
David Zlotnick

Dated: February 19, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03258 Filed 2–25–19; 8:45 am]

BILLING CODE 6717–01–P

[1] *Total Gas & Power North America, Aaron Hall and Therese Tran,* 155 FERC 61,105 (2016).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2003–0004; FRL–9986–69]

Access to Confidential Business Information by Abt Associates Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized its contractor, Abt Associates Inc. (Abt) of Rockville, MD, to access information which has been submitted to EPA under all sections of the Toxic Substances Control Act (TSCA). Some of the information may be claimed or determined to be Confidential Business Information (CBI).

DATES: Access to the confidential data will occur no sooner than March 5, 2019.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Recie Reese, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8276; email address: *reese.recie@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to all who manufacture, process, or distribute industrial chemicals. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2003–0004, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the Agency taking?

Under EPA contract number GS–00F–252CA, order number EP–G18H–01464, contractor Abt of 4550 Montgomery Avenue, Suite 800 North, Bethesda, MD and 55 Wheeler Street, Cambridge, MA will assist the Office of Pollution Prevention and Toxics (OPPT) by providing support to the methodological development of a uniform data output and analytics of TRI/TSCA data information; developing chemical profiles that focus on TSCA workplan chemicals, or on sets of chemicals based on commercial or industrial use; provide support for the updates to the EasyRSEI the internal EPA and public Qlik applications; create any new applications, as directed, including but not limited to a RSEI-related pollution prevention Qlik App and expanded TSCA Qlik application; and explore feasibility of integrating novel data streams in support of TRI and TSCA-related efforts.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA contract number GS–00F–252CA, order number EP–G18H–01464, Abt will require access to CBI submitted to EPA under all sections of TSCA to perform successfully the duties specified under the contract. Abt contractors will be

given access to information submitted to EPA under all sections. Some of the information may be claimed or determined to be CBI.

EPA is issuing this notice to inform all submitters of information under all sections of TSCA that EPA may provide Abt access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at EPA Headquarters and Abt's sites located in Bethesda, MD and Cambridge, MA in accordance with EPA's *TSCA CBI Protection Manual.*

Access to TSCA data, including CBI, will continue until December 28, 2022. If the contract is extended, this access will also continue for the duration of the extended contract without further notice.

Abt's contractor personnel will be required to sign nondisclosure agreements and will be briefed on appropriate security procedures before they are permitted access to TSCA CBI.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 12, 2018.

Pamela Myrick,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2019–03293 Filed 2–25–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2019–0027; FRL–9989–96–OAR]

Proposed Information Collection Request; Comment Request; Information Collection Request for the Greenhouse Gas Reporting Program

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an Information Collection Request (ICR), ''Information Collection Request for the Greenhouse Gas Reporting Program'' (EPA ICR No. 2300.18, OMB Control No. 2060–0629) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection request as described below. This is a proposed extension of the ICR, which is currently approved through September 30, 2019. 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.

DATES: Comments must be received on or before April 29, 2019.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2019–0027, online using *www.regulations.gov* (our preferred method), by email to *A-and-R-Docket@epa.gov*; or by mail to EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to the Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Rachel Schmeltz, Climate Change Division, Office of Atmospheric Programs (MC–6207A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 343–9124; fax number: (202) 343–2342; email address: *GHGReporting@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: In response to the FY2008 Consolidated Appropriations Act (H.R. 2764; Pub. L. 110–161) and under authority of the Clean Air Act, the EPA finalized the Mandatory Reporting of Greenhouse Gases Rule (GHG Reporting Rule) (74 FR 56260; October 30, 2009). The GHG Reporting Rule, which became effective on December 29, 2009, establishes reporting requirements for certain large facilities and suppliers. It does not require control of greenhouse gases. Instead, it requires that sources emitting GHGs above certain threshold levels of carbon dioxide equivalent (CO_2e) monitor and report emissions.

Subsequent rules have promulgated requirements for additional facilities, suppliers, and mobile sources; provided clarification and corrections to existing requirements; finalized confidentiality business information (CBI) determinations, amended recordkeeping requirements, and implemented an alternative verification approach. Collectively, the GHG Reporting Rule and its associated rulemakings are referred to as the Greenhouse Gas Reporting Program (GHGRP).

The purpose for this ICR is to renew and revise the GHG Reporting Rule ICR to update the burdens and costs.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are suppliers of certain products that will emit GHG when released, combusted, or oxidized; facilities in certain industrial categories that emit greenhouse gases; and facilities that emit 25,000 metric tons or more of carbon dioxide equivalent (CO_2e) per year.

Respondent's obligation to respond: Mandatory (Section 114 of the Clean Air Act provides EPA authority to require the information mandated by the Greenhouse Gas Reporting Program because such data will inform and are relevant to future policy decisions).

Estimated number of respondents: 13,654 (total).

Frequency of response: Annual.

Total estimated burden: 726,577 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $86,958,000 (per year), includes $28,802,000 annualized capital or operation and maintenance costs.

Changes in Estimates: There is a decrease of 12,608 hours in total estimated respondent burden compared with the ICR currently approved by OMB. The decrease reflects an adjustment in the number of respondents from the previous ICR, an adjustment of labor rates and capital costs to reflect 2017 dollars, and a complete re-evaluation of the activities and costs associated with all subparts of the GHGRP. This decrease also reflects the removal of burden hours from collection of GHG-related data for mobile sources, which are now captured in other EPA ICR vehicles including OMB Control Nos. 2060–0287, 2060–0292, 2060–0338, 2060–0641, 2060–0680, and 2060–0710.

Dated: February 14, 2019.

Paul M. Gunning,

Director, Climate Change Division, Office of Air and Radiation.

[FR Doc. 2019–03292 Filed 2–25–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–CERCLA Docket No. V–W–19–C–003; FRL–9989–94–Region 5]

Proposed CERCLA Administrative Settlement Agreement and Order on Consent; City of Kalamazoo, Michigan, and City of Kalamazoo Brownfields Redevelopment Authority; Allied Paper Portage Creek/Kalamazoo River Superfund Site, Operable Unit 1, Panelyte Property, Kalamazoo Michigan

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed Settlement Agreement and request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) hereby gives notice of a proposed Administrative Settlement Agreement and Order on Consent (Settlement) pertaining to a 22-acre parcel of land (the Panelyte Property) located in Kalamazoo, Michigan. The Panelyte Property is located adjacent to, and is partially contaminated by waste from, Operable Unit 1 (OU1) of the Allied Paper/Portage Creek/Kalamazoo River Superfund Site. EPA invites public comment on the Settlement for thirty (30) days following publication of this notice. The Settlement requires the City of Kalamazoo and the City of Kalamazoo Brownfield Redevelopment Authority to conduct certain short-term and long-term response actions at the Panelyte Property and at OU1. These response actions include: Cooperation with periodic reviews; compliance with and performance of activities related to institutional controls; assistance with community relations activities; property clearance activities; oversight of traffic management issues; and to cooperate with OU1 remedy component placement on the Panelyte Property and the performance of inspections of such remedy components.

DATES: Comments must be post marked or received on or before March 28, 2019.

ADDRESSES: The proposed Settlement and related site documents can be viewed at the Superfund Records Center, (SRC–7J), United States Environmental Protection Agency, Region 5, 77 W Jackson Blvd., Chicago, IL 60604, (312) 886–4465. Electronic copies online will be found at *www.epa.gov/superfund/allied-paper-kalamazoo.*

FOR FURTHER INFORMATION CONTACT: Further information or a copy of the Settlement may be obtained from Diane Russell, Community Involvement Coordinator, U.S. EPA Region 5 Superfund Division Community Information Office, 1300 Bluff St., Suite 140, Flint, MI 48504. Telephone: 989–395–3493. Email: *russell.diane@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed Settlement pertaining to the Panelyte Property, a 22-acre parcel of land located in Kalamazoo, Michigan. The Panelyte Property is located adjacent to, and is partially contaminated by hazardous substances from, Operable Unit 1 (OU1) of the Allied Paper Portage Creek/Kalamazoo River Superfund Site. The Settlement is with the following settling parties: The City of Kalamazoo, Michigan and the City of Kalamazoo Brownfield Redevelopment Authority. The Settlement requires the settling parties to perform certain work and to comply with property requirements. The settling parties will cooperate with EPA in potentially placing components of the EPA-selected remedy for OU1 on the Panelyte Property. The settling parties will cooperate with EPA's periodic reviews of the OU1 remedy, including the compilation, reporting, and the review and analysis of data, reports, and other information in their possession. The settling parties will also place and comply with any necessary institutional controls on properties they presently control, will assist EPA in obtaining institutional controls on other properties, and will assist EPA with future review and maintenance of the institutional controls. The settling parties will assist EPA in performing community relation activities related to the Panelyte Property and OU1, will assist in performing property clearing activities (trees, brush, undergrowth) at the Panelyte Property related to OU1 remedy components, and will perform inspections of OU1 remedy components placed on the Panelyte Property. The settling parties shall prepare and oversee implementation of the traffic management plan related to construction activities under the OU1 remedy.

The Settlement includes a covenant by the United States not to sue the settling parties, pursuant to Sections 106 and Section 107(a) of CERCLA, 42 U.S.C. 106 and 107(a).

II. Opportunity To Comment

A. General Information

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the Settlement. The Agency will consider all comments received and may modify or withdraw its consent to the Settlement if comments received disclose facts or considerations which indicate that the Settlement is inappropriate, improper, or inadequate.

B. Where do I send my comments or view responses?

Your comments should be mailed to Diane Russell, Community Involvement Coordinator, U.S. EPA Region 5 Superfund Division Community Information Office, 1300 Bluff St., Suite 140, Flint, MI 48504. Telephone: 989–395–3493. Email: *russell.diane@epa.gov.* Be sure to label the comments with the Docket Number at the top of this notice and/or the property name. The Agency's response to any comments received will be available for public inspection at the Superfund Records Center.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit ANY information you think or know is CBI to EPA through an agency website or via email. Clearly mark on your written comments all the information that you claim to be CBI. If you mail EPA your comments on a disk or CD–ROM (CD), mark the outside of the CD as CBI and then identify electronically within the CD the specific information that is claimed as CBI. In addition to one

complete version of your comments that includes all the information claimed as CBI, you must submit for inclusion in the public docket a second copy of your comments that does not contain the information claimed as CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for Preparing Your Comments. When submitting comments, remember to:

- Identify the subject of your comments by the docket number and the site name in the title of this notice or the **Federal Register** publication date and page number.
- Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree with the terms of the Settlement; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the identified comment period deadline.

Dated: February 7, 2019.

Thomas R. Short,

Acting Director, Superfund Division.

[FR Doc. 2019–03291 Filed 2–25–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0500]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before April 29, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0500.

Title: Section 76.1713, Resolution of Complaints.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 10,750 respondents and 21,500 responses.

Estimated Hours per Response: 1–17 hours.

Frequency of Response: Recordkeeping and third-party disclosure requirements; annual reporting requirement.

Total Annual Burden: 193,500 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 4(i), 303 and 308 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 76.1713 state cable system operators shall establish a process for resolving complaints from subscribers about the quality of the television signal delivered. Commission and franchising authorities, upon request. These records shall be maintained for at least a one-year period. Prior to being referred to the Commission, complaints from subscribers about the quality of the television signal delivered must be referred to the local franchising authority and the cable system operator.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–03231 Filed 2–25–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0600 and OMB 3060–0995]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to

further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before April 29, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0600.

Title: Application to Participate in an FCC Auction, FCC Form 175.

Form Number: FCC Form 175.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal governments.

Estimated Number of Respondents and Responses: 500 respondents and 500 responses.

Estimated Time per Response: 90 minutes.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in sections 154(i) and 309(j)(5) of the Communications Act, as amended, 47 U.S.C. 4(i), 309(j)(5), and sections 1.2105, 1.2110, 1.2112 of the Commission's rules, 47 CFR 1.2105, 1.2110, 1.2112.

Estimated Total Annual Burden: 750 hours.

Total Annual Costs: None.

Nature and Extent of Confidentiality: Information collected on FCC Form 175 is made available for public inspection, and the Commission is not requesting that respondents submit confidential information on FCC Form 175. Respondents seeking to have information collected on FCC Form 175 withheld from public inspection may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules, 47 CFR 0.459.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: A request for extension of this information collection (no change in requirements) will be submitted to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three year clearance from OMB.

The Commission's auction rules and related requirements are designed to ensure that the competitive bidding process is limited to serious qualified applicants, deter possible abuse of the bidding and licensing process, and enhance the use of competitive bidding to assign Commission licenses in furtherance of the public interest. The information collected on FCC Form 175 is used by the Commission to determine if an applicant is legally, technically, and financially qualified to participate in a Commission auction. Additionally, if an applicant applies for status as a particular type of auction participant pursuant to Commission rules, the Commission uses information collected on FCC Form 175 to determine whether the applicant is eligible for the status requested. Commission staff reviews the information collected on FCC Form 175 for a particular auction as part of the pre-auction process, prior to the auction being held. Staff determines whether each applicant satisfies the Commission's requirements to participate in the auction and, if applicable, is eligible for the status as a particular type of auction participant it requested. Without the information collected on FCC Form 175, the Commission will not be able to determine if an applicant is legally, technically, and financially qualified to participate in a Commission auction and has complied with the various applicable regulatory and statutory auction requirements for such participation. The Commission plans to continue to use the FCC Form 175 for its upcoming non-reverse spectrum auctions, including the forward auction component of any incentive auction, collecting only the information necessary for each particular auction.

OMB Control Number: 3060–0995.

Title: Section 1.2105(c), Bidding Application and Certification Procedures; Sections 1.2105(c) and 1.2205, Prohibition of Certain Communications.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal governments.

Estimated Number of Respondents and Responses: 10 respondents and 10 responses.

Estimated Time per Response: 1.5 hours to 2 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in sections 154(i), 309(j), and 1452(a)(3) of the Communications Act, as amended, 47 U.S.C. 4(i), 309(j)(5), 1452(a)(3), and sections 1.2105(c) and 1.2205 of the Commission's rules, 47 CFR 1.2105(c), 1.2205.

Estimated Total Annual Burden: 50 hours.

Total Annual Costs: $9,000.

Nature and Extent of Confidentiality: The Commission will take all reasonable steps to protect the confidentiality of all Commission-held data of a reverse broadcast incentive auction applicant consistent with the confidentiality requirements of the Spectrum Act and the Commission's rules. *See* 47 U.S.C. 1452(a)(3); 47 CFR 1.2206. In addition, to the extent necessary, auction applicants and other covered parties may request confidential treatment pursuant to section 0.459 of the Commission's rules, 47 CFR 0.459, for any report of a prohibited communication submitted to the Commission that is not already being treated as confidential.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: A request for extension of this information collection (no change in requirements) will be submitted to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three year clearance from OMB.

The Commission's rules prohibiting certain communications in Commission auctions are designed to reinforce existing antitrust laws, facilitate detection of collusive conduct, and deter anticompetitive behavior, without being so strict as to discourage pro-competitive arrangements between auction participants. They also help assure participants that the auction process will be fair and objective, and not subject to collusion. The information collected under this information collection allows the Commission to enforce the prohibition on auction applicants and other covered parties by making clear the responsibility of parties who receive information that potentially violates the rules to promptly report to the Commission. It also enables the Commission to ensure that no bidder

gains an unfair advantage over other bidders in its auctions, thereby enhancing the competitiveness and fairness of Commission spectrum auctions. The information collected will be reviewed and, if warranted, referred to the Commission's Enforcement Bureau for possible investigation and administrative action. The Commission may also refer allegations of anticompetitive auction conduct to the Department of Justice for investigation.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–03232 Filed 2–25–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Communications Security, Reliability, and Interoperability Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC or Commission) Communications Security, Reliability, and Interoperability Council (CSRIC) VI will hold its eighth and final meeting.

DATES: March 8, 2019.

ADDRESSES: Federal Communications Commission, Room TW–C305 (Commission Meeting Room), 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jeffery Goldthorp, Designated Federal Officer, (202) 418–1096 (voice) or *jeffery.goldthorp@fcc.gov* (email); or Suzon Cameron, Deputy Designated Federal Officer, (202) 418–1916 (voice) or *suzon.cameron@fcc.gov* (email).

SUPPLEMENTARY INFORMATION: The meeting will be held on March 8, 2019, from 1:00 p.m. to 5:00 p.m. in the Commission Meeting Room of the Federal Communications Commission, Room TW–C305, 445 12th Street SW, Washington, DC 20554.

The CSRIC is a Federal Advisory Committee that will provide recommendations to the FCC regarding best practices and actions the FCC can take to help ensure the security, reliability, and interoperability of communications systems. On March 19, 2017, the FCC, pursuant to the Federal Advisory Committee Act, renewed the charter for the CSRIC for a period of two years through March 18, 2019. The meeting on March 8, 2019, will be the eighth and final meeting of the CSRIC under the current charter. The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will provide audio and/or video coverage of the meeting over the internet from the FCC's web page at *http://www.fcc.gov/live.* The public may submit written comments before the meeting to Jeffery Goldthorp, CSRIC Designated Federal Officer, by email to *jeffery.goldthorp@fcc.gov* or U.S. Postal Service Mail to Jeffery Goldthorp, Associate Bureau Chief, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW, Room 7–A325, Washington, DC 20554.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted, but may be impossible to fill.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2019–03233 Filed 2–25–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0999]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before April 29, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0999.

Title: Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

Form Number: FCC Form 655.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 934 respondents; 934 responses.

Estimated Time per Response: 13.9710921 hours per response (average).

Frequency of Response: On occasion and annual reporting requirements, Recordkeeping requirement and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151, 154(i), 157, 160, 201, 202, 214, 301, 303,

308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

Total Annual Burden: 13,049 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: Information requested in the reports may include confidential information. However, covered entities can request that such materials submitted to the Commission be withheld from public inspection.

Needs and Uses: After the 60-day comment period expires, the Commission will submit the revised information collection to the Office of Management and Budget (OMB) to obtain a full three-year clearance. The changes being made to the information collect concern the Commission's wireless hearing aid combability rules as they relate to the obligations of wireless service providers to post certain information on their websites, retain information and to file annual compliance certifications. No changes are being made to the website posting and reporting burdens of wireless handset manufacturers. Further, no changes are being made to the information collection as related to standards development, labeling and disclosure requirements, and the approved number of estimated respondents/responses.

The revisions to the information collection are necessitated by a Report and Order in WT Docket No. 17–228, FCC 18–167, adopted on November 15, 2018. In this Report and Order, the Commission revised its rules requiring service providers to post on their publicly accessible websites information regarding the hearing aid compatibility of their offered handsets and required them to retain certain information regarding the hearing aid compatibility of handsets they previously offered. Through this information, consumers will have access to the most recent data about hearing aid-compatible handsets and the Commission will be able to ensure compliance with the hearing aid compatibility rules and requirements. In addition, the Commission determined that service providers are no longer required to file FCC Form 655 on an annual basis. Instead, providers must file an annual certification indicating whether they are compliant with the hearing aid compatibility rules.

As part of these revisions to the wireless hearing aid compatibility information collection, the Commission is requesting approval of certain changes to the form and the related instructions. These changes to the form and its instructions implement the new certification compliance requirement for service providers and maintain the existing compliance requirements for device manufacturers. These changes to the form reduce service providers' regulatory burden while continuing to allow the Commission to monitor compliance with the hearing aid compatibility rules.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–03234 Filed 2–25–19; 8:45 am]

BILLING CODE 6712–01–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 March 25, 2019.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *Orrstown Financial Services, Shippensburg, Pennsylvania;* to merge with Hamilton Bancorp, Townson, MD, and thereby indirectly acquire Hamilton Bank, Townson, Maryland.

B. *Federal Reserve Bank of Atlanta* (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *LexPark Holdings—STC, LLC, SouthernTrust Group, LP & SouthernTrust Holdings, Inc., Orlando, Florida;* to become a bank holding company by acquiring voting shares of First City Bank of Florida, Fort Walton Beach, Florida.

Board of Governors of the Federal Reserve System, February 21, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–03297 Filed 2–25–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4367]

Bioavailability Studies Submitted in New Drug Applications or Investigational New Drug Applications—General Considerations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' This draft guidance provides recommendations to sponsors planning to include bioavailability (BA) information for drug products in investigational new drug applications (INDs), new drug applications (NDAs), and NDA supplements. This draft guidance revises and replaces FDA's March 2014 draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations,'' which addresses BA or bioequivalence (BE) studies for INDs, NDAs, and NDA supplements.

DATES: Submit either electronic or written comments on the draft guidance by May 28, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4367 for ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dakshina Chilukuri, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1515.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' Determining the BA of formulations is critical during the life cycle of drug products and aids in FDA's evaluation of the safety and effectiveness of a product in an IND, NDA, or NDA supplements. This draft guidance provides recommendations to sponsors planning to include BA information for drug products in INDs, NDAs, and NDA supplements. This draft guidance contains recommendations on how to meet the BA requirements set forth in 21 CFR part 320 as they apply to dosage forms intended for oral administration. The draft guidance is also applicable to non-orally administered drug products when it is appropriate to rely on systemic exposure measures to determine the BA of a drug (*e.g.,* transdermal delivery systems and certain rectal and nasal drug products). The draft guidance provides recommendations on conducting relative BA studies during the IND period for an NDA and BE studies during the postapproval period for certain changes to drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Bioavailability Studies in NDAs or INDs—General Considerations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information submitted under 21 CFR part 312 (INDs) has been approved under OMB control number 0910–0014; and the collection of information submitted under 21 CFR part 314 (NDAs) has been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03246 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3017]

Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the notice entitled ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of November 20, 2018. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on November 20, 2018 (83 FR 58574). Submit either electronic or written comments by April 29, 2019.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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–3017 for ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the notice to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave. Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 3330, Silver Spring, MD 20993, 301–796–0151, *chris.wheeler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 20, 2018 (83 FR 58574), FDA published a notice with a 60-day comment period to request comments on the notice entitled ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments.'' FDA is reopening the comment period until April 29, 2019. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments.

II. Electronic Access

Persons with access to the internet may obtain the notice at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03241 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4368]

Assessing the Effects of Food on Drugs in Investigational New Drug Applications and New Drug Applications—Clinical Pharmacology Considerations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' This draft guidance provides recommendations to sponsors planning to conduct food-effect trials for orally administered products as part of investigational new drug applications (INDs), new drug applications (NDAs), and supplements to these applications. This draft guidance, when final, revises and replaces part of the 2002 FDA guidance for industry entitled ''Food-Effect Bioavailability and Fed Bioequivalence Studies'' (2002 Food Effect Guidance).

DATES: Submit either electronic or written comments on the draft guidance by April 29, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4368 for ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Vikram Arya or Brian Booth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1499 or 301–796–1508.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' Food-drug interactions can significantly impact patient outcomes by affecting the pharmacokinetics and pharmacodynamics of some drugs. These interactions can potentially lead to reduced drug absorption and decreased efficacy or increased drug absorption and increased efficacy. Food can also have either a positive or negative effect on the incidence and severity of adverse events associated with drug use. The timely conduct of well-designed food-effect studies is critical to optimize the safety and efficacy of the drug product. This draft guidance provides recommendations on the following items: (1) When and how to conduct food-effect studies; (2) how to report the study results; and (3) how to include appropriate language regarding administration of the drug with food in the labeling.

FDA is specifically seeking feedback on the following issues:

- Please comment on the definition of the meal content. Should meal types be defined solely by the calorie and fat content, or should carbohydrates and proteins also be included?
- Please comment on the definition of the low-fat meal. Are the 400–500 calories and 25 percent fat a sufficient definition of a low-fat meal (refer also to table 2)?
- Please comment on the Biopharmaceutics Classification System-based waiver for food-effect trials. Does current science support this biowaiver?

Information on fed bioequivalence (BE) studies to be submitted in abbreviated new drug applications (ANDAs) can be found in the FDA draft guidance for industry entitled ''Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.'' Specific recommendations concerning fed comparability trials are now found in the FDA draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' When finalized these guidances will represent the current thinking of FDA on these topics.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 314 (21 CFR part 314), including §§ 314.50 and 314.94, have been approved under OMB control number 0910–0001. The collections of information in part 312 (21 CFR part 312), including § 312.23, have been approved under OMB control number 0910–0014. The collection of information in 21 CFR parts 50 and 56 have been approved under OMB control numbers 0910–0755 and 0910–0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information related to pharmacogenomic data have been approved under OMB control number 0910–0557.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03247 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0143]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 28, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Foreign Supplier Verification Programs (FSVP) for Food Importers

OMB Control Number 0910–0752—Extension

This information collection supports FDA regulations at 21 CFR part 1, subpart L—Foreign Supplier Verification Programs for Food Importers, as well as associated guidance. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. The regulations are intended to help ensure that food imported into the United States is produced in compliance with specific processes and procedures, including reasonably appropriate risk-based preventive controls. The regulations establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances that a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions.

To assist respondents with understanding the regulatory requirements, we have developed Agency guidance, which is available at: *https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm.*

In the **Federal Register** of October 22, 2018 (83 FR 53271), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section(s)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food for research 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
DUNS number for filing with U.S. Customs and Border Protection 1.509, 1.511, 1.512.	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity; 21 CFR section(s)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Controls for low-acid canned foods; 1.502(b)	2,443	4	9,772	1	9,772
FSVP Recordkeeping, including hazard determination, written procedures, reevaluation; audits; and corrective actions:					
Determine and document hazards; 1.504(a)	11,701	1	11,701	3.5	40,954
Review hazard analysis; 1.504(d)	11,701	7	81,907	0.33 (20 minutes)	27,029
Evaluation of food and foreign supplier; 1.505(a)(2), 1.511(c)(1).	11,701	1	11,701	4	46,804
Approval of suppliers; 1.505(b), 1.512(c)(1)(iii)	8,191	1	8,191	12	928,292
Reevaluation of food and foreign supplier; 1.505(c), 1.512(c)(1)(ii)(A).	11,701	365	4,270,865	0.25 (15 minutes)	1,067,716
Confirm or change requirements of foreign supplier verification activity; 1.505(c), 1.512(c)(1)(ii)(A).	2,340	1	2,340	2	4,680
Review of other entities assessments; 1.505(d), 1.512(c)(1)(iii).	3,510	1	3,510	1.2	4,212
Written procedures for use of approved foreign suppliers; 1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i).	11,701	1	11,701	8	93,608
Review of written procedures; 1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii).	11,701	1	11,701	1	11,701
Written procedures for conducting verification activities; 1.506(b), 1.511(c)(3).	11,701	1	11,701	2	23,402
Determination and documentation of appropriate supplier verification activities; 1.506(d)(1)–(2) 1.511(c)(5)(i).	11,701	4	46,804	3.25	152,113
Review of appropriate supplier verification activities determined by another entity; 1.506(d)(3) 1.511(c)(5)(iii).	11,701	2	23,402	0.33 (20 minutes)	7,723
Conduct/review audits; 1.506(e)(1)(i), 1.511(c)(4)(ii)(A).	11,701	2	23,402	3	70,206
Conduct periodic sampling/testing; 1.506(e)(1)(ii), 1.511(c)(4)(ii)(B).	11,701	2	23,402	1	23,402
Review records; 1.506(e)(1)(iii), 1.511(c)(4)(ii)(C)	11,701	2	23,402	1.6	37,443
Document your review of supplier verification activity records; 1.506(e)(3), 1.511(c)(4)(iii).	11,701	6	70,206	0.25 (15 minutes)	17,552
Document hazard controls; 1.507(a)(1)	11,701	3.17	37,092	1.25	46,365
Written assurances; 1.507(a)(2), (a)(3), and (a)(4).	11,701	8.72	102,038	0.50 (30 minutes)	51,019
Disclosures that accompany assurances; 1.507(a)(2), (a)(3), and (a)(4).	102,038	1	102,038	0.50 (30 minutes)	51,019
Document assurances from customers; 1.507(c)	36,522	2.8	102,262	0.25 (15 minutes)	25,566
Document corrective actions; 1.508(a), 1.512(b)(4).	2,340	1	2,340	2	4,680
Investigate and determine FSVP adequacy; 1.508(b), 1.511(c)(1).	2,340	1	2,340	5	11,700
Subtotal for FSVP Recordkeeping Itemized Above.			4,984,046		1,917,186
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511(b).	11,701	2.88	33,699	2.25	75,823
Document very small importer/certain small foreign supplier status; 1.512(b)(1).	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier 1.512(b)(3).	50,450	2.8	141,260	2.25	317,835

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Information collection activity; 21 CFR section(s)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					2,361,294

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

We are retaining the currently approved burden estimates. The FSVP requirements became effective May 30, 2017, and we continue to evaluate associated burden.

Dated: February 21, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03282 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Opportunity To Co-Sponsor OMH National Minority Health Month Steps Challenge

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Office of Minority Health (OMH), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: OMH announces the opportunity for public and non-profit entities to co-sponsor the National Minority Health Month National Steps Challenge for April 2019. Potential co-sponsors must have a demonstrated interest in reducing health disparities among minority communities, advancing the HHS Physical Activity Guidelines and improving the health of Americans through promoting regular physical activity.

DATES: To receive consideration for this opportunity, a two-page proposal to participate as a co-sponsor must be received by OMH by 5 p.m. EST on March 7, 2019 at the address listed below. Co-sponsorship proposals will meet the deadline if they are either (1) received or (2) postmarked on or before the deadline. Privately metered postmarks will not be accepted as proof of timely mailing. Proposals received after the established deadline will not be considered.

ADDRESSES: Proposals for co-sponsorship should be sent to Mr. Anthony Welch, HHS Office of Minority Health, 1101 Wootton Parkway, Suite 600, Tower Building, Rockville, Maryland 20852. Requests may also be emailed to *Anthony.Welch@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Welch, HHS Office of Minority Health Quality, 1101 Wootton Parkway, Suite 600, Tower Building, Rockville, Maryland 20852; (240) 453–2882.

SUPPLEMENTARY INFORMATION: The mission of the Office of Minority Health (OMH) at the U.S. Department of Health and Human Services (HHS) is to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. Key strategies of the OMH mission include:

- Developing and promoting policies, programs and practices to achieve health equity;
- Funding demonstration programs at the regional, state and local level that can contribute to health policy and the effectiveness of strategies for improving health;
- Improving data collection, reporting and sharing for ethnic and racial minority populations;
- Fostering research and evaluation; and
- Establishing and strengthening networks, coalitions and partnerships to identify and solve health problems.

OMH observes National Minority Health Month every year in April to highlight the health disparities that persist among racial and ethnic minority populations and the ways in which policies, programs and partnerships can help advance health equity. The HHS OMH establishes the national theme and serves as the lead HHS office for the observance of National Minority Health Month.

The theme for 2019 is Active & Healthy and is intended to help promote the second edition of the HHS Physical Activity Guidelines and the Move Your Way Campaign from the HHS Office of Disease Prevention and Health Promotion, especially among racial and ethnic minorities. OMH's main activity for this year's observance is the National Minority Health Month Steps Challenge (Challenge). The Challenge will occur throughout the month of April and OMH will enlist teams and individuals to participate from federal, state and local governments, community-based organizations and tribal communities, who want to show their commitment to an active lifestyle. Activities and materials throughout the month will highlight the overall message that physical activity promotes health and reduces the risk of chronic disease.

Eligibility for Co-Sponsorship

To be eligible, a potential co-sponsor shall: (1) Have a demonstrated understanding, commitment, and experience in conducting large-scale steps challenges; (2) be knowledgeable about strategies to promote health & active lifestyles; (3) have a track record and the ability to manage an online platform to host multiple teams in the challenge; (4) participate substantively in the co-sponsored activity, not just provide logistical support; and (5) have an organizational mission that is consistent with OMH and HHS. The selected co-sponsoring organization shall furnish the necessary personnel, materials, services, and facilities to administer its proposed portion of the responsibility for the Challenge. These duties will be outlined in a co-sponsorship agreement with OMH that will set forth the details of the co-sponsored activity.

Co-Sponsorship Proposal

Each co-sponsorship proposal shall contain a description of: (1) The entity or organization's background and history; (2) its ability to satisfy the co-sponsorship criteria detailed above; and (3) its proposed involvement in the co-sponsored activity. The co-sponsorship proposal should not exceed two (2) pages in length and should be double-spaced in Times New Roman.

Evaluation Criteria

After engaging in exploratory discussions with potential co-sponsors that respond to this notice, representatives of OMH will select the co-sponsor using the following evaluation criteria:

(1) Qualifications and capability to fulfill co-sponsorship responsibilities;

(2) Creativity related to enhancing the National Minority Health Month event;

(3) Potential for reaching and generating participants from among key stakeholders, including federal, state and local organizations, member-based organizations and the general public.

(4) Experience operating steps challenges;

(5) Past or current work specific to health equity and physical activity promotion;

(6) Professional qualifications and specific expertise with promoting physical activity;

(7) Availability and description of online platform to support the challenge; and

(8) Proposed plan for managing the co-sponsorship with OMH.

Dated: February 15, 2019.

Felicia Collins,

Capt., Deputy Assistant Secretary for Minority Health, (HHS Office of Minority Health).

[FR Doc. 2019–03296 Filed 2–25–19; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute on Alcohol Abuse and Alcoholism.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute on Alcohol Abuse and Alcoholism.

Date: September 18, 2019.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, Conference Room I–2330, 10 Center Drive, Bethesda, MD 20892.

Contact Person: George Kunos, M.D., Ph.D., Scientific Director, Office of the Scientific Director, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5625 Fishers Lane, Room 2S–24A, Rockville, MD 20852, 301–443–2069, *gkunos@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: February 20, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03207 Filed 2–25–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0032]

Agency Information Collection Activities: Importers of Merchandise Subject to Actual Use Provisions

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than April 29, 2019) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0032 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email.* Submit comments to: *CBP_PRA@cbp.dhs.gov.*

(2) *Mail.* Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to 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. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Importers of Merchandise Subject to Actual Use Provisions.

OMB Number: 1651–0032.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: In accordance with 19 CFR 10.137, importers of goods subject to the actual use provisions of the Harmonized Tariff Schedule of the United States

(HTSUS) are required to maintain detailed records to establish that these goods were actually used as contemplated by the law, and to support the importer's claim for a free or reduced rate of duty. The importer shall maintain records of use or disposition for a period of three years from the date of liquidation of the entry, and the records shall be available at all times for examination by CBP.

Estimated Number of Respondents: 12,000.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 12,000.

Estimated Time per Response: 65 minutes.

Estimated Total Annual Burden Hours: 13,000.

Dated: February 20, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–03211 Filed 2–25–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0035]

Agency Information Collection Activities: Holders or Containers Which Enter the United States Duty Free

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than April 29, 2019) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0035 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) Email. Submit comments to: *CBP_PRA@cbp.dhs.gov*.

(2) Mail. Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov*. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/*.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to 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. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Holders or Containers Which Enter the United States Duty Free.

OMB Number: 1651–0035.

Current Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (with no change).

Affected Public: Businesses.

Abstract: Items 9801.00.10 and 9803.00.50 under the Harmonized Tariff Schedules of the United States (HTSUS), codified as 19 U.S.C. 1202, provides for the duty-free entry of substantial holders or containers of foreign manufacture if duty had been paid upon a previous importation pursuant to the provisions of 19 CFR 10.41b.

19 CFR 10.41b provides that substantial holders or containers are to have prescribed markings in clear and conspicuous letters of such a size that they will be easily discernable. Section 10.41b of the CBP regulations eliminates the need for an importer to file entry documents by instead requiring the marking of the containers or holders to indicate the HTSUS numbers that provide for duty free treatment of the containers or holders.

In order to comply with 19 CFR 10.41b in the case of serially numbered holders or containers of United States manufacture for which free clearance under 9801.00.10 HTSUS is claimed, the owner of the holder or container is required to place the markings on a metal tag or plate containing the following information: 9801.00.10, HTSUS; the name of the owner; and the serial number assigned by the owner. In the case of serially numbered holders or containers of foreign manufacture for which free clearance under 9803.00.50 HTSUS is claimed, the owner must place markings containing the following information: 9803.00.50 HTSUS; the port code numbers of the port of entry; the entry number; the last two digits of the fiscal year of entry covering the importation of the holders and containers on which duty was paid; the name of the owner; and the serial number assigned by the owner.

Estimated Number of Respondents: 20.

Estimated Number of Responses per Respondent: 18.

Estimated Number of Total Annual Responses: 360.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 90.

Dated: February 20, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–03210 Filed 2–25–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CR–NR–NHL PPWOCRADI0, PCU00RP14.50000; OMB Control Number 1024–0276]

Agency Information Collection Activities; National Historic Landmarks Nomination Form

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection request; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 28, 2019.

ADDRESSES: Send written comments on this information collection (IC) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to Phadrea D. Ponds, Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference OMB Control Number 1024–0276 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Patty Henry by email at *patty_henry@nps.gov,* or by telephone at 202–354–2216. You may also view the IC at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on November 23, 2018 (83 FR 59413). No comments were received.

We are again soliciting comments on the proposed IC that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the NPS, (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

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

Abstract: The NPS is authorized by Historic Sites Act of 1935 (54 U.S.C. 320101 *et seq.*); 36 CFR part 65; the National Historic Preservation Act of 1966 (54 U.S.C. 300101 *et seq.*) to collect this information on behalf of the Secretary of the Interior. In accordance with the law and 36 CFR part 65, private citizens, businesses, and organizations; Federal agencies (FPO); State and local public agencies; State Historic Preservation Officers (SHPOs); territories; and Indian tribes (THPO) may submit nominations for National Historic Landmark (NHL) designation. All interested parties must inquire by letter or email about the eligibility of properties to be considered for NHL designation. The inquiry will include the name, location, brief description and historical summary of property.

If determined eligible for consideration the respondent will use NPS Form 10–934 (National Historic Landmarks Nomination Form) to nominate a property. The form is used to collect the following information related to the property: (1) Name and location (2) significance data; (3) any withholding of sensitive information; (4) geographical data; (5) significance statements and discussions (6) description and statement of integrity; (7) major bibliographic references; and (8) name, organization, address, phone number, and email of the person completing the form.

Title of Collection: National Historic Landmarks Nomination Form.

OMB Control Number: 1024–0276.

Form Number: NPS Form 10–934.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Private individuals; state, tribal and local governments; businesses; educational institutions; and nonprofit organizations.

Total Estimated Number of Annual Respondents: 50.

Total Estimated Number of Annual Responses: 50.

Estimated Completion Time per Response: Varies from 256 hours to 603 hours, depending on respondent and/or activity.

Total Estimated Number of Annual Burden Hours: 10,360.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

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

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea D. Ponds,

Acting NPS Information Collection Clearance Officer, National Park Service.

[FR Doc. 2019–03226 Filed 2–25–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NRSS–BRD–FR00000039; PPWONRADB0PPMRSNR1Y.NM0000]; OMB Control Number 1024–0275]

Agency Information Collection Activities; Using Web and Mobile-Based Applications During NPS Citizen Science Events

AGENCY: National Park Service, Interior.

ACTION: Notice of Information Collection Request; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before March 28, 2019.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to Phadrea D. Ponds, Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference Information Collection Request 1024–0275 in the subject line.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Kriston Barnes, Natural Resource Stewardship and Science Directorate, National Park Service, 1201 Oakridge Dr. Suite 200 Fort Collins, CO 80525 (mail); *kriston_barnes@nps.gov* (email); or: 970–658–6013 (phone). You may also view the IC at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on November 23rd, 2018. (83 FR 59413). No comments were received.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the NPS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The NPS is authorized by the National Park Service Protection Interpretation and research in System (54 U.S.C. 100701) to collect this information. The NPS is requesting approval to use mobile and web-based applications (*e.g.,* iNaturalist, eBird, etc) as a means to collect natural history observational information from park visitors during citizen science events. The information will be used to substantiate the occurrence of plant, wildlife and invertebrate species within NPS units during these events. By using citizen science applications, this information will be immediately available to all parks and others interested in species identification and advancing the knowledge of the natural world. Using mobile and web-based applications will enable parks to increase the number of natural history observation records that will contribute to greater understanding of the biodiversity within the park systems.

Title of Collection: Using web and mobile-based applications during NPS Citizen Science events.

OMB Control Number: 1024–0275.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: General public, individual households, and non-federal scientists.

Total Estimated Number of Annual Respondents: 7,500.

Total Estimated Number of Annual Responses: 112,500.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 9,375 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

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

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Phadrea Ponds,

Acting NPS Information Collection Clearance Officer, National Park Service.

[FR Doc. 2019–03225 Filed 2–25–19; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1087]

Certain Batteries and Electrochemical Devices Containing Composite Separators, Components Thereof, and Products Containing Same; Commission Determination Not To Review an Initial Determination Granting a Joint Motion To Terminate the Investigation Based Upon Settlement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 42) of the presiding administrative law judge (''ALJ'') granting a joint motion to terminate the investigation based upon settlement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 28, 2017, based on a complaint, as supplemented, filed by LG Chem, Ltd. of South Korea; LG Chem Michigan Inc. of Holland, Michigan; LG Chem Power Inc. of Troy, Michigan; and Toray Industries, Inc. of Japan. *See* 82 FR 56265 (Nov. 28, 2017). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), based upon the importation into the United States, the sale for importation, and the sale within the United States after

importation of certain batteries and electrochemical devices containing composite separators, components thereof, and products containing same, by reason of infringement of certain claims of U.S. Patent No. 7,662,517; U.S. Patent No. 7,638,241; and U.S. Patent No. 7,709,152. *See id.* The notice of investigation names Amperex Technology Limited of Hong Kong; DJI Technology Co., Ltd. of Shenzhen, China; DJI Technology, Inc. of Burbank, California; Guangdong OPPO Mobile, Telecommunications Corp., Ltd. of Guangdong, China; and OPPO Digital, Inc. of Menlo Park, California, as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is not a party to this investigation. *See id.*

On January 30, 2019, the parties filed a joint motion to terminate the investigation based on settlement. On February 4, 2019, the ALJ issued the subject ID (Order No. 42) granting the joint motion. The ID finds that ''[c]onsistent with Commission rule 210.21(b), the parties have filed confidential and public versions of the settlement agreement'' and that ''the parties state that '[t]here are no other agreements, written or oral, express or implied, between the parties concerning the subject matter of the Investigation.' '' *See* ID at 1–2 (citing 19 CFR 210.2l(b)(1)). The ID also considers the public interest under Commission Rule 210.50(b)(2), 19 CFR 210.50(b)(2), and finds ''no evidence . . . indicating that terminating this investigation on the basis of settlement would adversely affect the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.'' *See* ID at 2.

No petition for review of the subject ID was filed. The Commission has determined not to review the ID. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: February 21, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–03294 Filed 2–25–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0021]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

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:

(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 submission of responses.

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees from Grants to Enhance Culturally and Linguistically Specific Services for Victims of Domestic Violence, Dating Violence, Sexual Assault, and Stalking Program (Culturally and Linguistically Specific Services Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* 1122–0021. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 50 grantees of the Culturally and Linguistically Specific Services Program. The program funds projects that promote the maintenance and replication of existing successful domestic violence, dating violence, sexual assault, and stalking community-based programs providing culturally and linguistically specific services and other resources. The program also supports the development of innovative culturally and linguistically specific strategies and projects to enhance access to services and resources for victims of violence against women.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 50 respondents (Culturally and Linguistically Specific Services Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Culturally and Linguistically Specific Services Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 100 hours, that is 50 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution

Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: February 21, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–03305 Filed 2–25–19; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–NEW]

Agency Information Collection Activities; Proposed eCollection; eComments Requested Extension With Change, of a Previously Approved Collection National Criminal Justice Reference Service (NCJRS) Online Subscription Center

AGENCY: Office of Justice Programs' Office of Communications, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs (OJP), Office of Communications (OCOM) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to U.S. Department of Justice, Office of Justice Programs, Office of Communications, 810 Seventh Street NW, Washington, DC 20531. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* National Criminal Justice Reference Service (NCJRS) online subscription center: *https://www.ncjrs.gov/App/Secure/Registration/Register.aspx/.*

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* Agency form number: 1121–NEW.

Sponsoring component: Department of Justice, Office of Justice Programs, Office of Communications.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Currently, constituents can sign-up for communications, such as new publications, funding opportunities, events, and other news and announcements from NCJRS and the NCJRS federal sponsors, place online orders, and track their order status by creating a detailed profile on *NCJRS.gov.* End Users can also subscribe to specific Bureau, Program Office, and shared email notification lists and newsletters when creating an NCJRS account. This action can also be accomplished on various Bureau, Program Office, or GovDelivery web pages.

However, the NCJRS online subscription center is more than 14 years old and subscription form selections have remained relatively unchanged for more than 20 years. Moreover, the subscription process includes 19 required fields and 7 different screens, creating an undue burden for End Users.

An evaluation of the current use of the information collected through the form and its impact to End Users was conducted to see where updates can be made to make for a better user experience while enabling customer segmentation strategies for targeted outreach. The goals for revising the subscription process are to increase subscriptions by making the sign-up process less cumbersome for users and collect meaningful customer information to assist segmentation strategies for targeted outreach and upselling of Bureau and Program Office products and services.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* An estimated 75 End Users use the NCJRS online subscription center on a monthly basis to register. Based on pilot testing, an average of 2–4 minutes per respondent is needed to complete form 1121–NEW. The estimated range of burden for respondents is expected to be between 2 minutes to 4 minutes for completion.

(6) *An estimate of the total public burden (in hours) associated with the collection:* It is estimated that respondents will take 2–4 minutes to complete their profile. The estimated public burden hours associated for End Users to subscribe is 5 hours per month (75 respondents × 4 minutes = 300 minutes/60 minutes = 5 hours) or 60 hours per year (5 hours × 12 months = 60 hours).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 21, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–03302 Filed 2–25–19; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0028]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day Notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

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:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Semi-annual Progress Report for Children and Youth Exposed to Violence Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0028. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 25 grantees under the Consolidated Grant Program to Address Children and Youth Experiencing Domestic and Sexual Assault and Engage Men and Boys as Allies (hereafter referred to as the Consolidated Youth Program) enacted in the FY 2012–2018 appropriation acts, which consolidated four previously authorized and appropriated programs into one comprehensive program. The four programs included in these consolidations were: Services to Advocate for and Respond to Youth (Youth Services), Grants to Assist Children and Youth Exposed to Violence (CEV), Engaging Men and Youth in Preventing Domestic Violence (EMY), and Supporting Teens through Education and Prevention (STEP).

The Consolidated Youth Program supports projects designed to provide coordinated community responses that support child, youth and young adult victims through direct services, training, coordination and collaboration, effective intervention, treatment, response, and prevention strategies. The Consolidated Youth Program creates a unique opportunity for communities to increase collaboration among non-profit victim service providers; violence prevention, and children (0–10), youth (11–18), young adult (19–24) and men-serving organizations; tribes and tribal governments; local government agencies; schools; and programs that support men's role in combating sexual assault, domestic violence, dating violence and stalking.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 25 respondents (grantees from the Consolidated Youth Program) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Consolidated Youth Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 50 hours, that is 25 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: February 21, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–03306 Filed 2–25–19; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

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:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act as Amended.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0001. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes STOP formula grantees (50 states, the District of Columbia and five territories (Guam, Puerto Rico, American Samoa, Virgin Islands, Northern Mariana Islands). The STOP Violence Against Women Formula Grant Program was authorized through the Violence Against Women Act of 1994 and reauthorized and amended in 2000, 2005, and 2013. The purpose of the STOP Formula Grant Program is to promote a coordinated, multi-disciplinary approach to improving the criminal justice system's response to violence against women. It envisions a partnership among law enforcement, prosecution, courts, and victim advocacy organizations to enhance victim safety and hold offenders accountable for their crimes of violence against women. The Department of Justice's Office on Violence Against Women (OVW) administers the STOP Formula Grant Program funds which must be distributed by STOP state administrators according to statutory formula (as amended in 2000, 2005 and 2013).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 56 respondents (state administrators from the STOP Formula Grant Program) less than one hour to complete a Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act, as Amended.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the Certification is less than 56 hours.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: February 21, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–03303 Filed 2–25–19; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0022]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

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:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Annual Progress Report for the Sexual Assault Services Formula Grant Program (SASP).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0022. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 606 administrators and subgrantees of the SASP. SASP grants support intervention, advocacy, accompaniment, support services, and related assistance for adult, youth, and child victims of sexual assault, family and household members of victims, and those collaterally affected by the sexual assault. The SASP supports the establishment, maintenance, and expansion of rape crisis centers and other programs and projects to assist those victimized by sexual assault. The grant funds are distributed by SASP state administrators to subgrantees as outlined under the provisions of the Violence Women Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 606 respondents (SASP administrators and subgrantees) approximately one hour to complete an annual progress report. The annual

progress report is divided into sections that pertain to the different types of activities in which subgrantees may engage. A SASP subgrantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection form is 606 hours, that is 606 administrators and subgrantees completing a form once a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: February 21, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–03304 Filed 2–25–19; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On February 13, 2019, the Department of Justice lodged a proposed Consent Decree (''Consent Decree'') with the United States District Court for the Western District of New York in the lawsuit entitled *United States* v. *Hillcrest Industries, Inc.,* Civil Action No. 1:18–cv–99. In the filed Complaint, the United States, on behalf of the U.S. Environmental Protection Agency (''EPA''), alleges that Hillcrest Industries, Inc. (''Hillcrest'') is liable under the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9607(a), for the response costs EPA incurred to respond to the releases and/or threatened releases of hazardous substances into the environment from a parcel of property Hillcrest owns and operates. The Consent Decree requires Hillcrest to pay $350,000 in quarterly installment payments of $20,000 each.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Hillcrest Industries, Inc.,* D.J. Ref. No. 90–11–3–11525. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $9.50 (25 cents per page reproduction cost), payable to the United States Treasury.

Robert Maher,

Assistant Section Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 2019–03276 Filed 2–25–19; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Prohibited Transaction Exemption 2019–01; Exemption Application No. D–11988]

Exemption Involving UBS Assets Management (Americas) Inc.; UBS Realty Investors LLC; UBS Hedge Fund Solutions LLC; UBS O'Connor LLC; and Certain Future Affiliates in UBS's Asset Management and Global Wealth Management U.S. Divisions (Collectively, the Applicants or the UBS QPAMs) Located in Chicago, Illinois; Hartford, Connecticut; New York, New York; and Chicago, Illinois, Respectively

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of exemption.

SUMMARY: This document contains a notice of exemption issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). The exemption affects the ability of certain entities with specified relationships to UBS, UBS Securities Japan, and UBS France to continue to rely upon relief provided by Prohibited Transaction Exemption 84–14.

DATES: This exemption will be in effect for one year from the date of the judgment in the French First Instance Court against UBS and/or UBS France in case number 1105592033.

FOR FURTHER INFORMATION CONTACT: Mr. Brian Mica of the Department at (202) 693–8402. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On February 13, 2019, the Department published a notice of proposed exemption in the **Federal Register** at 84 FR 3818, for certain entities with specified relationships to UBS to continue to rely upon the relief provided by PTE 84–14 for a period of one year,[1] notwithstanding certain criminal convictions, as described herein (the Convictions) and the 2019 French Judgment Against UBS/UBS France.

The Department is granting this exemption to ensure that Covered Plans[2] with assets managed by an asset manager within the corporate family of UBS may continue to benefit from the relief provided by PTE 84–14. This exemption will be in effect for one year from the date of the judgment in the French First Instance Court against UBS and/or UBS France. No inference should be drawn from the Department's granting of this one-year exemption that the Department will grant additional relief for UBS QPAMs to continue to rely on the relief in PTE 84–14 following the end of the one-year period.

No relief from a violation of any other law is provided by this exemption, including any criminal convictions or

[1] 49 FR 9494, March 13, 1984, as corrected at 50 FR 41430 (October 10, 1985), as amended at 70 FR 49305 (August 23, 2005) and as amended at 75 FR 38837 (July 6, 2010), hereinafter referred to as PTE 84–14 or the QPAM exemption.

[2] ''Covered Plan'' is a plan subject to Part 4 of Title 1 of ERISA (''ERISA-covered plan'') or a plan subject to section 4975 of the Code (''IRA'') with respect to which a UBS QPAM relies on PTE 84–14, or with respect to which a UBS QPAM (or any UBS affiliate) has expressly represented that the manager qualifies as a QPAM or relies on the QPAM class exemption (PTE 84–14). A Covered Plan does not include an ERISA-covered plan or IRA to the extent the UBS QPAM has expressly disclaimed reliance on QPAM status or PTE 84–14 in entering into its contract, arrangement, or agreement with the ERISA-covered plan or IRA.

criminal conduct described in the proposed exemption. Furthermore, the Department cautions that the relief in this exemption will terminate immediately if, among other things, an entity within the UBS corporate structure is convicted of a crime described in Section I(g) of PTE 84–14 (other than the Convictions or the 2019 French Judgment Against UBS/UBS France) during the Exemption Period. The terms of this exemption are designed to promote adherence to basic fiduciary standards under ERISA and the Code. This exemption also aims to ensure that Covered Plans can terminate relationships in an orderly and cost effective fashion in the event the fiduciary of a Covered Plan determines it is prudent to terminate the relationship with a UBS QPAM. The Department notes that its determination that the requisite findings under ERISA section 408(a) have been met is premised on adherence to all of the conditions of the exemption. Accordingly, affected parties should be aware that the conditions incorporated in this exemption are, taken as a whole, necessary for the Department to grant the relief requested by the Applicant. Absent these or similar conditions, the Department would not have granted this exemption.

The Applicants requested an individual exemption pursuant to section 408(a) of ERISA and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011). Effective December 31, 1978, section 102 of the Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue administrative exemptions under section 4975(c)(2) of the Code to the Secretary of Labor. Accordingly, this exemption is being granted solely by the Department.

Department's Comment

The Department cautions that the relief in this exemption will terminate immediately if an entity within the UBS corporate structure is convicted of a crime described in Section I(g) of PTE 84–14 (other than the Convictions and the 2019 French Judgment Against UBS/UBS France) during the Exemption Period. Although the UBS QPAMs could apply for a new exemption in that circumstance, the Department would not be obligated to grant the exemption. The terms of this exemption have been specifically designed to permit plans to terminate their relationships in an orderly and cost effective fashion in the event of an additional conviction, or the expiration of this exemption without additional relief, or a determination that it is otherwise prudent for a plan to terminate its relationship with an entity covered by the exemption.

Written Comments

The Department invited all interested persons to submit written comments and/or requests for a public hearing with respect to the notice of proposed exemption, published in the **Federal Register** at 84 FR 3818 on February 13, 2019. All comments and requests for a hearing were due by February 19, 2019. The Department received written comments from the Applicant, the National Federation of Independent Business (NFIB), the Securities Industry and Financial Markets Association (SIFMA), and two members of the public. After considering the entire record developed in connection with the Applicant's exemption request, the Department has determined to grant the exemption, with revisions, as described below.

UBS QPAMs Comments

1. Effective Date and Notification Requirement

A. The UBS QPAMs have also requested that the Department issue an Advisory Opinion stating that an adverse judgment in the French First Instance Court would not constitute a conviction within the meaning of Section I(g) of PTE 84–14. The UBS QPAMs argue that if the Department determines that the French First Instance Court judgment does not constitute a conviction under Section I(g) of PTE 84–14 either because convictions in a foreign jurisdiction generally are not covered by Section I(g), or because the French First Instance Court's judgment, in particular, would not constitute a conviction under Section I(g), then the one year exemption will have been unnecessary as there would be no conviction for which an exemption is required. In that case, the UBS QPAMs state that the conditions of PTE 2017–07 should continue to be effective. The UBS QPAMs request that the Department revise the exemption to make clear that the exemption will expire automatically to the extent the Department issues an Advisory Opinion stating that the Potential 2019 French Judgment Against UBS/UBS France does not constitute a conviction for purposes of Section I(g) of PTE 84–14.

B. Additionally, the UBS QPAMs request that section I(k) of the exemption be revised so that the UBS QPAMs are not required to send notice within 60 days of the Potential 2019 French Judgment Against UBS/UBS France if the Department has not issued an Advisory Opinion within 60 days of the French First Instance Court's judgment.[3] The UBS QPAMs argue that the notice should be required by the later of 60 days from the date of judgment in the French First Instance Court or 30 days after an advisory opinion is issued by the Department that is adverse to the UBS QPAMs advisory opinion request. The UBS QPAMs argue this would avoid the necessity of requiring the UBS QPAMs to spend a significant amount of time and resources notifying plans of an exemption that would be inoperative and avoid disclosure of information that would ultimately be superseded by an advisory opinion and require correction. The UBS QPAMs also request similar revisions to the notice provision in Section I(j)(7).[4]

Department's Response to Comment A. The Department declines to revise the proposed exemption as requested by the UBS QPAMs. The Department has construed Section I(g) as extending to

[3] Proposed Section I(k) provides that: Within 60 days of the judgment against UBS or UBS France by the French First Instance Court, each UBS QPAM will provide a notice of the exemption, along with a separate summary describing the facts that led to the Convictions and the Potential 2019 French Judgment Against UBS/UBS France (the Summary), which have been submitted to the Department, and a prominently displayed statement (the Statement) (collectively, Initial Notice) that the Convictions and the Potential 2019 French Judgment Against UBS/UBS France, each separately result in a failure to meet a condition in PTE 84–14 and PTE 2017–07, to each sponsor and beneficial owner of a Covered Plan, or the sponsor of an investment fund in any case where a UBS QPAM acts as a sub-advisor to the investment fund in which such ERISA-covered plan and IRA invests. Effective as of the date that is 60 days after the Potential 2019 French Judgment Against UBS/UBS France Date, all Covered Plan clients that enter into a written asset or investment management agreement with a UBS QPAM after that date must receive a copy of the exemption, the Summary, and the Statement prior to, or contemporaneously with, the Covered Plan's receipt of a written asset management agreement from the UBS QPAM. Disclosures may be delivered electronically.

[4] Section I(j)(7) requires: Within six months of the date of the judgment against UBS or UBS France by the French First Instance Court, each UBS QPAM must provide a notice of its obligations under this Section I(j) to each Covered Plan. For prospective Covered Plans that enter into a written asset or investment management agreement with a UBS QPAM on or after the date of such a judgment, the UBS QPAM will agree to its obligations under this Section I(j) in an updated investment management agreement between the UBS QPAM and such clients or other written contractual agreement. This condition will be deemed met for each Covered Plan that received a notice pursuant to PTE 2016–17 and/or PTE 2017–07 that meets the terms of this condition. Notwithstanding the above, a UBS QPAM will not violate the condition solely because a Plan or IRA refuses to sign an updated investment management agreement.

foreign convictions [5] and granted new exemptions to convicted entities on the basis that foreign convictions were disqualifying under I(g).[6] In addition, although UBS asserts that the judgment of the French First Instance Court should not count as a conviction for purposes of Section I(g) until such time as all appeals have been exhausted, Section I(g) expressly provides that ''a person shall be deemed to have been 'convicted' from the date of the judgment of the trial court, regardless of whether that judgment remains under appeal.''

The Department notes, however, that if UBS/UBS France is ultimately exonerated on appeal, or if the Department were to reverse its view on the significance of the judgment of the French First Instance Court or on whether Section I(g) covers foreign convictions—the subject of the UBS QPAMs' advisory opinion request—the UBS QPAMs could continue to rely upon PTE 2017–07, irrespective of this separate exemption, assuming they meet the other conditions of PTE 2017–07, and there are no subsequent convictions. No change in exemption text is necessary for the UBS QPAMs in that circumstance.

Department's Response to Comment B. The Department declines to make the requested revision. Before granting an exemption under Section 408(a) of ERISA, the Department must conclude that its conditions are protective of affected plans and IRAs. The Department does not believe the exemption is sufficiently protective if UBS is permitted to delay required notification until after the Department resolved the pending advisory opinion request. In order to make informed decisions, Plans and IRAs with assets managed by UBS QPAMs should be aware and informed, at the soonest possible date, of the circumstances that caused UBS to submit its request for this exemption, along with the terms of this exemption.[7] Moreover, the sudden loss of an asset manager's status as a QPAM could, in some circumstances, be disruptive, harmful, and/or expensive for plans and IRAs with assets managed by the QPAM. Notice of the conviction, the new exemption, its terms, and duration, enable plans and IRAs to protect their interests and to plan for future contingencies.

Notwithstanding the foregoing, however, the Department recognizes that the UBS QPAMs do not agree that the French First Instance Judgment resulted in violation of Section I(g). Accordingly, the Department has modified Section I(k) so that the UBS QPAMs do not have to expressly acknowledge that the 2019 French Judgment Against UBS/UBS France resulted in a failure to meet a condition in PTE 84–14 and PTE 2017–07, but rather may simply recite that the Department of Labor has reached that conclusion

2. The Condition Making Future Foreign Convictions Disqualifying Should Be Omitted

Section I(l) of the Proposed Exemption provides that the exemption will ''immediately terminate'' in the event that ''an entity within the UBS corporate structure'' is ''convicted of a crime described in Section I(g) of PTE 84–14 . . . , *or* convicted *in a foreign jurisdiction* for a crime described in Section I(g) of PTE 84–14.'' (Emphases added.)

The Applicant requests the removal of the reference to foreign convictions in Section I(l). In support of its request the Applicant states the following:

(A) The Department has not included foreign convictions in any prior exemption, and should not do so for the first time in a short-term, temporary exemption at a time when an advisory opinion request has been made on the question of whether foreign convictions should be disqualifying under PTE 84–14;

(B) the inclusion of foreign convictions within Section I(l) is problematic and not administratively feasible, as it would require the Department to interpret and apply foreign law with which it is not familiar and has no expertise;

(C) the Department is exceeding its authority by imposing a *per se* disqualification that is more sweeping than the disqualification Congress enacted in Section 411 of ERISA; and

(D) there are superior alternatives available to the Department that are better suited to address concerns that may arise from a foreign conviction, including a case-by-case approach whereby the Department could assess whether to modify or revoke the exemption.

Department's Response to A. As noted above, it is the Department's view that Section I(g) of PTE 84–14 is not limited to crimes committed in the United States, and extends to crimes committed in foreign jurisdictions.[8] The quoted text in Section I(l) was merely intended to remove any doubt as to the effect of any future foreign conviction, not to cast doubt upon the Department's past application of Section I(g) to such convictions. After consideration of the comment, the Department has revised the condition to make it clear that the exemption will ''immediately terminate'' if ''an entity within the UBS corporate structure'' is ''convicted of a crime described in Section I(g) of PTE 84–14 . . . , including a conviction in a foreign jurisdiction.''

The Department stresses that a key purpose of Section I(g) is to ensure that a ''QPAM, and those who may be in a position to influence its policies, are expected to maintain a high standard of

[5] The purpose and intent of Section I(g) is explained in the Preamble to Proposed Prohibited Transaction Exemption 84–14, 47 FR 56945, 56947 (Dec. 21, 1982). That explanation provides: ''A QPAM, and those who may be in a position to influence its policies, are expected to maintain a high standard of integrity. Accordingly, the proposed exemption does not cover transactions if the QPAM or various affiliates have been convicted of various crimes (outlined in section I(g) of the proposal), that involve abuse or misuses of a position of trust, or felonies generally described in ERISA section 411.'' The Department notes that, in relevant part, neither the language nor the intent of the provision in Section I(g) changed between the proposed exemption and the final Prohibited Transaction Exemption 84–14.

[6] See, for example, the following exemptions issued by the Department, involving foreign convictions: Citigroup Inc., PTE 2012–08, 77 FR 19344 (March 30, 2012); Royal Bank of Canada, PTE 2016–10, 81 FR 75147 (October 28, 2016); Northern Trust Corporation, PTE 2016–11, 81 FR 75150 (October 28, 2016); Deutsche Bank, PTE 2015–15 80 FR 53574, (September 4, 2015).

[7] PTE 2015–15, for example, required each Deutsche Bank QPAM to provide a notice of the exemption, along with a separate summary describing the facts that led to the Convictions (the Summary), which were submitted to the Department, and a prominently displayed statement (the Statement) that each Conviction separately resulted in a failure to meet a condition in PTE 84–14, to each sponsor and beneficial owner of a Covered Plan that entered into a written asset or investment management agreement with a DB QPAM on or before June 16, 2018, or the sponsor of an investment fund in any case where a DB QPAM acts as a subadvisor to the investment fund in which such ERISA-covered plan and IRA invests. In that exemption, the ''term 'Convictions' means (1) the judgment of conviction against DB Group Services that was entered on April 18, 2017, in case number 3:15–cr–00062–RNC in the United States District Court for the District of Connecticut to a single count of wire fraud, in violation of 18 U.S.C. 1343 and (2) the judgment of conviction against DSK entered on January 25, 2016, in Seoul Central District Court, relating to charges filed against DSK under Articles 176, 443, and 448 of South Korea's Financial Investment Services and Capital Markets Act for spot/futures-linked market price manipulation. For all purposes under this exemption, 'conduct' of any person or entity that is the 'subject of [a] Conviction' encompasses the factual allegations described in Paragraph 13 of the Plea Agreement filed in the District Court in case number 3:15–cr–00062–RNC, and in the 'Criminal Acts' section pertaining to 'Defendant DSK' in the Decision of the Seoul Central District Court.''

[8] See, for example, the following exemptions issued by the Department, involving foreign convictions: Citigroup Inc., PTE 2012–08, 77 FR 19344 (March 30, 2012); Royal Bank of Canada, PTE 2016–10, 81 FR 75147 (October 28, 2016); Northern Trust Corporation, PTE 2016–11, 81 FR 75150 (October 28, 2016); Deutsche Bank, PTE 2015–15 80 FR 53574, (September 4, 2015).

integrity.'' [9] Particularly in light of the 2019 French Judgment Against UBS/UBS France, the Department believes it is important to make clear when the UBS QPAMs would not be permitted to continue to rely on this exemption if any entity in the QPAM corporate structure is convicted of another serious foreign crime. In that circumstance, the Department would have significant cause for concern about the QPAMs' standards of integrity. Accordingly, they would be expected to submit a new application for an exemption based on full disclosure of the relevant facts and the Department's full evaluation of the significance of those facts.

Department's Response to Comment B. The Department does not agree that a condition that requires the UBS QPAMs to avoid covered foreign convictions results in an exemption that is not administratively feasible for the Department to implement. Although foreign laws and legal structures can be complex, the Department can draw upon a variety of resources (including submissions by the applicant) to determine if a conviction falls within Section I(g), as well as to determine the weight that the Department should give the conviction in deciding whether to grant a new exemption and how to structure the exemption.

As noted above, the Department has previously granted exemptions following foreign convictions, without significant difficulty in administration. The question of whether a foreign conviction falls within such categories as a ''felony arising out of the conduct of the business of a broker, dealer, investment adviser, bank, insurance company, or fiduciary'' or ''income tax evasion'', within the meaning of the exemption, is not inherently more difficult or less administrable than many of the questions that the Department routinely considers in the exemption process (*e.g.,* questions relating to complex and unfamiliar financial transactions).

A service provider's conviction for a serious foreign crime is relevant to a fiduciary's analysis of whether to retain the service provider, and it is similarly relevant to the Department's determination of whether to grant the service provider relief from otherwise prohibited transactions.[10] The express reference to foreign convictions is necessary to safeguard the interests of plan participants and IRA owners.

Department's response to Comment C. Section 411 of ERISA enumerates specific crimes that disqualify convicted persons from acting as service providers and fiduciaries to ERISA-covered plans. The exemption condition, in contrast, conditions a QPAM's ability to engage in otherwise prohibited transactions on the QPAM's avoidance of serious criminal misconduct, so that the Department can have an appropriate level of confidence that the institution maintains a standard of high integrity.

In other words, Section 411 prohibits conduct that would otherwise be legal, while the exemption permits conduct that would otherwise be illegal. Section I(g) of the QPAM exemption has always covered crimes that are not expressly covered by Section 411 of ERISA; it serves a related, but different, purpose than Section 411.

Section 408(a) of ERISA requires the Department to limit the availability of administrative exemptions to transactions and arrangements that are protective of, and in the interest of, affected plans and IRAs, and administratively feasible. As discussed above, the condition on foreign convictions is critical to the Department's determination that the exemption at issue here meets the statutory test.

Department's Response to Comment D. The Department disagrees with the comment. Another serious foreign conviction would call into question the basis for permitting the UBS QPAMs to engage in prohibited transactions. If a trial court makes a determination of criminal misconduct, it would be appropriate to place the burden of seeking a new exemption on the UBS QPAMs. At that time, the Department would expect full disclosure of the wrongdoing that resulted in the conviction; the reasons (if any) that the Department should not be concerned about granting the QPAMs continued relief from ERISA's prohibited transaction provisions; and the basis for concluding that the UBS QPAMs will perform their fiduciary responsibilities with a high standard of integrity. The Department could then conduct a full analysis of whether and how to grant any further relief. This approach is both administrable and appropriately protective of the interests of plans, plan participants, and IRA owners.

Comment 3—Proposed Modifications to the Conditions in PTE 2017–07—Section I(a), I(b) and I(h)(2)

The UBS QPAMs state that the exemption should contain the same conditions as PTE 2017–07 and those conditions should not have been modified for purposes of this one-year exemption. In the UBS QPAMs' view, the Department should not impose additional conditions, without first resolving whether the adverse judgment in the French First Instance Court constitutes a conviction under Section I(g) of PTE 84–14. Additionally, the UBS QPAMs state that the modifications to the conditions of PTE 2017–07 do not take into account the UBS QPAMs' record of compliance with the terms of their prior exemptions.

Section I(a) of the proposed exemption provides in part that ''[t]he UBS QPAMs (including their officers, directors, agents other than UBS, UBS Securities Japan, and UBS France), and employees of such UBS QPAMs and any other party engaged on behalf of such UBS QPAMs who had responsibility for, or exercised authority in connection with the management of plan assets did not know of, did not have reason to know of, or participate in: (1) The FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the Potential 2019 French Judgment Against UBS/UBS France.'' Section I(b) of the proposed exemption provides that ''[t]he UBS QPAMs (including their officers, directors, agents other than UBS, UBS Securities Japan, and UBS France, and employees of such UBS QPAMs and any other parties engaged on behalf of such UBS QPAMs) did not receive direct compensation, or knowingly receive indirect compensation, in connection with (1) the FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the Potential 2019 French Judgment Against UBS/UBS France.''

The UBS QPAMs state that requiring these conditions to apply to third parties effectively conditions the exemption on facts regarding third parties that the UBS QPAMs are not in a position to know or confirm, and that the conditions, therefore, are not in the interest of participants and beneficiaries. The UBS QPAMs additionally claim that the Department previously had found that the conditions described in PTE 2017–07

[9] Preamble to Proposed Prohibited Transaction Exemption 84–14, 47 FR 56945, 56947 (Dec. 21, 1982).

[10] In this regard, when selecting or monitoring an asset manager, plan fiduciaries should not disregard foreign crimes committed by an entity within the asset manager's corporate structure, merely because the crimes may be complicated or difficult to interpret.

were sufficient to isolate the investment and compliance operations of the QPAMs from the influence of bad actors. The UBS QPAMs also argue that modifications to existing conditions that are specific to the conduct underlying prior convictions runs afoul of the Department's regulations at 29 CFR 2570.50. According to the UBS QPAMs, this regulation requires the Department notify the applicant of its proposed actions and reasons prior to publication of a notice proposing a modification or revocation. If the Department declines to delete the third party language entirely, the UBS QPAMs request that the language apply only to the Potential 2019 French Judgment Against UBS/UBS France.

Today the Department is granting a new exemption based on the application from the UBS QPAMs and is not modifying PTE 2017–07. The Department has determined to modify section I(a) and I(b) from the language of the proposed exemption to reflect that the language ''any other party engaged on behalf of such UBS QPAMs who had responsibility for, or exercised authority in connection with the management of plan assets'' will be applicable only for purposes of the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France.

Accordingly, Section I(a) is revised in part as follows: ''I(a) The UBS QPAMS (including their officers, directors, agents other than UBS, UBS Securities, Japan and UBS France, and the employees of such UBS QPAMs), did not have reason to know of, or participate in: (1) The FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France. Further, any other party engaged on behalf of such UBS QPAMs who had responsibility for, or exercised authority in connection with the management of plan assets did not know of, did not have reason to know of, or participate in the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France.'' Section I(b) is revised as follows: (b) The UBS QPAMs (including their officers, directors, agents other than UBS, UBS Securities Japan, and UBS France, and employees of such UBS QPAMs) did not receive direct compensation, or knowingly receive indirect compensation, in connection with the (1) the FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France. Further, any other party engaged on behalf of such UBS QPAMs who had responsibility for, or exercised authority in connection with the management of plan assets did not receive direct compensation, or knowingly receive indirect compensation, in connection with the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France.''

Section I(h)(2) of the proposed exemption provides that ''Any violation of, or failure to comply with an item in subparagraphs (h)(1)(ii) through (h)(1)(vi), is corrected as soon as reasonably possible upon discovery, or as soon after the QPAM reasonably should have known of the noncompliance (whichever is earlier), and any such violation or compliance failure not so corrected is reported, upon the discovery of such failure to so correct, in writing. Such report shall be made to the head of compliance and the General Counsel (or their functional equivalent) of the relevant UBS QPAM that engaged in the violation or failure, and, the independent auditor responsible for reviewing compliance with the Policies, and a fiduciary of any affected Covered Plan where such fiduciary is independent of UBS.''

The UBS QPAMs request that the language regarding reporting uncorrected policy violations or compliance failures to ''a fiduciary of any affected Covered Plan'' should be omitted from the exemption. The UBS QPAMs state that the Department previously proposed this requirement in other exemptions but omitted the requirement from the final exemptions due to the concerns of the applicants. The UBS QPAMs claim it will be problematic to comply with this requirement because: It is uncertain when the uncorrected violations or failures must be reported to the plan fiduciaries; due to a lack of materiality threshold, this requirement may prompt frequent reports of technical or insignificant violations requiring the expenditure of time and resources without any benefit to plans; and the condition is unclear on how many fiduciaries of a plan must receive the report. Moreover, the UBS QPAMs argue that requirement is unnecessary given the requirement that the independent auditor will evaluate any uncorrected violations or compliance failures and the violations will be addressed in audit reports which are publically available.

Given the requirement of the independent audit and the public availability of the audit report, the Department has determined not to include the additional requirement of separate notice to ''a fiduciary of any affected Covered Plan.'' The Department has modified section I(h)(2) accordingly.

Comment 4(a)—Definition of ''Conduct'' That Is the ''Subject Of'' an Adverse First Instance Judgment—Section II(b)

Section II(b) of the proposed exemption provides in part ''[f]or all purposes under this exemption, ''conduct'' of any person or entity that is the ''subject of the alleged criminal conduct that may be the subject of the Potential 2019 French Judgment Against UBS/UBS France'' encompasses any conduct of UBS, its affiliates, or UBS France and/or their personnel that is described in any such judgment.'' The UBS QPAMs argue that unlike in prior exemptions that used a similar formulation of ''conduct'', UBS does not know at this time the specific conduct that will be described in any adverse judgment by the French First Instance Court. The UBS QPAMs claim that under French criminal procedure the description of the conduct would not be finalized until after the date of the adverse judgment, and possibly months later. The UBS QPAMS state they have no reason to believe they will unable to satisfy conditions in the exemption to which the definition in Section II(b) would apply, but that they believe those conditions should only be operative after the written description of the judgment has been issued and the UBS QPAMs have opportunity to review the description. Therefore, the UBS QPAMS request that Section II(b) be revised to provide that any conditions based on the conduct described in any adverse First Instance Judgment only become effective 60 days after the final written description for the judgment is issued.

The Department is not making the requested revision to the definition in Section II(b). The Department believes that UBS has sufficient information of the conduct at issue to comply with the exemption condition. However, the Department has revised Section II(b) to provide more clarity. To make the required findings under section 408(a) of ERISA, the Department concludes that the conditions relating to criminal conduct should be applied as of the effective date of the exemption.

Comment 4(b)—Structure of UBS Compliance Function—Section I(m)(1)(ii)

The UBS QPAMs requested that Section I(m)(1)(ii) of the exemption be

modified to correctly reflect the current structure of UBS's compliance function. Accordingly, the Department has deleted the phrase ''the Global Head of C&ORC, who will report directly to UBS's Chief Risk Officer'' from Section I(m)(1)(ii).

National Federation of Independent Business

The Department received a comment from the National Federation of Independent Business (NFIB) stating the Department should afford interested persons a longer time period to view files with respect to proposed exemptions, and to comment on the exemptions. The NFIB states that longer time periods are necessary to afford them the notice and opportunity to be heard to which the law entitles them, and would give the Department the time necessary to make better-informed decisions. NFIB also claims that the Department should take greater care to ensure compliance with the procedural requirements set by statute for the grant of exemptions in order to avoid the risk of successful legal challenges to its exemptions.

In response to these assertions, the Department stresses that the comment period was appropriate under the circumstances of this particular proposed exemption. The period was necessarily limited because of the potential for an adverse judgment in the French First Instance Court on February 20, 2019, which could prevent the UBS QPAMs from continuing to rely upon the relief provided by PTE 84–14 and potentially cause harm to participants and beneficiaries. This exemption is for a temporary one-year period and if the UBS QPAMs apply for longer term exemptive relief, the Department will consider and afford a longer comment period for such relief, as appropriate.

SIFMA Comment

The Department received a comment from the Securities Industry and Financial Markets Association (SIFMA) urging the Department to issue an advisory opinion that section I(g) does not encompass foreign crimes. SIFMA states that if the Department does not issue the requested advisory opinion to SIFMA that section I(g) does not encompass foreign crimes, and declines to issue an advisory opinion to UBS on the effect of the French judgment on section I(g), and instead moves forward with this proposed temporary exemption application, it should delete the condition in section 1(l) that adds foreign convictions to the type of convictions that would cause the exemption to be immediately unavailable.

SIFMA argues that all the considerations described in *Small* v. *United States* [11] in support of the Court's construction of a statute are also relevant in determining whether exemption conditions based on foreign convictions meet the administratively feasible requirement of ERISA section 408(a). According to SIFMA, in order to make a determination that any foreign conviction should be disqualifying, the Department would have to understand and apply the criminal laws and criminal procedures of any one of hundreds of foreign countries, as well as the cases decided under those laws. In SIFMA's view, the reasons cited by the Supreme Court in Small as weighing against asking prosecutors or judges to ''refine'' these ''definitional distinctions'' on the facts of that case equally weigh against the Department's finding that an exemption referencing foreign convictions is administratively feasible within the meaning of ERISA section 408(a)(1). This is especially true, according to SIFMA, where the likelihood of ''getting it wrong'' is high, in light of the complexities and vagaries of foreign law.'' The Department's response to UBS's comments above, particularly UBS's comments on whether the exemption is administratively feasible, effectively address these points.

In light of the 2019 French Judgment Against UBS/UBS France, the Department believes it is important to make clear when the UBS QPAMs would not be permitted to continue to rely on this exemption if a member of the UBS corporate family is convicted of another serious foreign crime. In that circumstance, the Department would have still greater cause for concern about whether the UBS QPAMs and those in a position to influence their policies, maintain high standards of integrity and about the appropriateness of relief from the prohibited transaction provisions, which were enacted to protect plans, participants, and IRA owners from potentially abusive transactions. In that circumstance, the Department has concluded that it would be appropriate for the UBS QPAMs to seek a new exemption based upon a full consideration of the record and the misconduct at issue, rather than to rely upon an exemption that predates the new misconduct and the Department's consideration of that misconduct. The Applicants have also commented on the condition in section I(l) and the comment has been addressed above.

Comments From the Public

The Department received two comments from the public. One commenter stated that he thought the exemption was a ''good rule.'' A second commenter noted that he agreed with the Department that performance of the exemption audit on less than an annual basis will weaken an important plan protection. This commenter also stated that he agreed that an annual review by an independent auditor of a QPAM's written policies and procedures and a representative sample of plan transactions is necessary to address the lack of QPAM independence. Lastly, this commenter noted that he agreed with the Department's assessment of costs associated with the exemption audit and expressed approval for the ''proposed amendments.''

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) In accordance with section 408(a) of ERISA and section 4975(c)(2) of the Code, the Department makes the following determinations: The exemption is administratively feasible, the exemption is in the interests of affected plans and of their participants and beneficiaries, and the exemption is protective of the rights of participants and beneficiaries of such plans;

(3) The exemption is supplemental to, and not in derogation of, any other provisions of ERISA, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the

[11] See *Small* v. *United States*, 544 U.S. 385, 388–89 (2005).

transaction is in fact a prohibited transaction; and

(4) The availability of this exemption is subject to the express condition that the material facts and representations contained in the application accurately describe all material terms of the transaction which is the subject of the exemption.

Accordingly, the following exemption is granted under the authority of section 408(a) of ERISA and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011):

Exemption

Section I. Covered Transactions

Certain entities with specified relationships to UBS (hereinafter, the UBS QPAMs, as defined in Sections II(e)) will not be precluded from relying on the exemptive relief provided by Prohibited Transaction Class Exemption 84–14 (PTE 84–14 or the QPAM Exemption),[12] notwithstanding the 2013 Conviction of UBS Securities Japan Co., Ltd., the 2018 Conviction of UBS (collectively the Convictions, as defined in Section II(a)), and the 2019 French Judgment Against UBS/UBS France (as defined in Section II(b)) during the Exemption Period, provided that the following conditions are satisfied: [13]

(a) The UBS QPAMS (including their officers, directors, agents other than UBS, UBS Securities, Japan and UBS France, and the employees of such UBS QPAMs, did not have reason to know of, or participate in: (1) The FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France. Further, any other party engaged on behalf of such UBS QPAMs who had responsibility for, or exercised authority in connection with the management of plan assets did not know of, did not have reason to know of, or participate in the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France. For purposes of this exemption, ''participate in'' refers not only to active participation in the FX Misconduct, the misconduct underlying the Convictions, and the misconduct underlying the 2019 French Judgment Against UBS/UBS France, but also to knowing approval of that misconduct, or knowledge of such misconduct without taking active steps to prohibit such conduct, such as reporting the conduct to supervisors, including the Board of Directors;

(b) The UBS QPAMs (including their officers, directors, agents other than UBS, UBS Securities Japan, and UBS France, and employees of such UBS QPAMs) did not receive direct compensation, or knowingly receive indirect compensation, in connection with the (1) the FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France. Further, any other party engaged on behalf of such UBS QPAMs who had responsibility for, or exercised authority in connection with the management of plan assets did not receive direct compensation, or knowingly receive indirect compensation, in connection with the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France;

(c) The UBS QPAMs will not employ or knowingly engage any of the individuals who participated in: (1) The FX Misconduct; (2) the criminal conduct of UBS Securities Japan and UBS that is the subject of the Convictions; or (3) the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France;

(d) At all times during the Exemption Period, no UBS QPAM will use its authority or influence to direct an ''investment fund'' (as defined in Section VI(b) of PTE 84–14) that is subject to ERISA or the Code and managed by such UBS QPAM with respect to one or more Covered Plans (as defined in Section II(c)) to enter into any transaction with UBS, UBS Securities Japan, or UBS France or to engage UBS, UBS Securities Japan, or UBS France to provide any service to such investment fund, for a direct or indirect fee borne by such investment fund, regardless of whether such transaction or service may otherwise be within the scope of relief provided by an administrative or statutory exemption;

(e) Any failure of the UBS QPAMs to satisfy Section I(g) of PTE 84–14 arose solely from the Convictions and the 2019 French Judgment Against UBS/UBS France;

(f) A UBS QPAM did not exercise authority over the assets of any plan subject to Part 4 of Title I of ERISA (an ERISA-covered plan) or section 4975 of the Code (an IRA) in a manner that it knew or should have known would: Further the FX Misconduct, the criminal conduct that is the subject of the Convictions, or the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France; or cause the UBS QPAM or its affiliates to directly or indirectly profit from the FX Misconduct, the criminal conduct that is the subject of the Convictions, or the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France;

(g) Other than with respect to employee benefit plans maintained or sponsored for its own employees or the employees of an affiliate, UBS, UBS Securities Japan, and UBS France will not act as fiduciaries within the meaning of section 3(21)(A)(i) or (iii) of ERISA, or section 4975(e)(3)(A) and (C) of the Code, with respect to ERISA-covered plan and IRA assets; provided, however, that UBS, UBS Securities Japan, and UBS France will not be treated as violating the conditions of this exemption solely because it acted as an investment advice fiduciary within the meaning of section 3(21)(A)(ii) of ERISA or section 4975(e)(3)(B) of the Code;

(h)(1) Each UBS QPAM must continue to maintain, adjust (to the extent necessary), implement, and follow written policies and procedures (the Policies). The Policies must require, and must be reasonably designed to ensure that:

(i) The asset management decisions of the UBS QPAM are conducted independently of UBS's corporate management and business activities, including the corporate management and business activities of the Investment Bank division, UBS Securities Japan, and UBS France; this condition does not preclude a UBS QPAM from receiving publicly available research and other widely available information from a UBS affiliate;

(ii) The UBS QPAM fully complies with ERISA's fiduciary duties, and with ERISA and the Code's prohibited transaction provisions, in each case as applicable with respect to each Covered Plan, and does not knowingly participate in any violation of these duties and provisions with respect to Covered Plans;

[12] 49 FR 9494 (March 13, 1984), as corrected at 50 FR 41430, (October 10, 1985), as amended at 70 FR 49305(August 23, 2005), and as amended at 75 FR 38837 (July 6, 2010), hereinafter referred to as ''PTE 84–14'' or the ''QPAM Exemption.''

[13] Section I(g) of PTE 84–14 generally provides that ''[n]either the QPAM nor any affiliate thereof . . . nor any owner . . . of a 5 percent or more interest in the QPAM is a person who within the 10 years immediately preceding the transaction has been either convicted or released from imprisonment, whichever is later, as a result of'' certain criminal activity therein described.

(iii) The UBS QPAM does not knowingly participate in any other person's violation of ERISA or the Code with respect to Covered Plans;

(iv) Any filings or statements made by the UBS QPAM to regulators, including, but not limited to, the Department, the Department of the Treasury, the Department of Justice, and the Pension Benefit Guaranty Corporation, on behalf of or in relation to Covered Plans, are materially accurate and complete, to the best of such QPAM's knowledge at that time;

(v) To the best of the UBS QPAM's knowledge at that time, the UBS QPAM does not make material misrepresentations or omit material information in its communications with such regulators with respect to Covered Plans, or make material misrepresentations or omit material information in its communications with Covered Plans;

(vi) The UBS QPAM complies with the terms of this exemption;

(2) Any violation of, or failure to comply with an item in subparagraphs (h)(1)(ii) through (h)(1)(vi), is corrected as soon as reasonably possible upon discovery, or as soon after the QPAM reasonably should have known of the noncompliance (whichever is earlier), and any such violation or compliance failure not so corrected is reported, upon the discovery of such failure to so correct, in writing. Such report shall be made to the head of compliance and the General Counsel (or their functional equivalent) of the relevant UBS QPAM that engaged in the violation or failure, and the independent auditor responsible for reviewing compliance with the Policies. A UBS QPAM will not be treated as having failed to develop, implement, maintain, or follow the Policies, provided that it corrects any instance of noncompliance as soon as reasonably possible upon discovery, or as soon as reasonably possible after the QPAM reasonably should have known of the noncompliance (whichever is earlier), and provided that it adheres to the reporting requirements set forth in this subparagraph (vii);

(3) Each UBS QPAM will maintain, adjust (to the extent necessary) and implement a program of training during the Exemption Period, to be conducted during the Exemption Period, for all relevant UBS QPAM asset/portfolio management, trading, legal, compliance, and internal audit personnel. The Training must:

(i) At a minimum, cover the Policies, ERISA and Code compliance (including applicable fiduciary duties and the prohibited transaction provisions), ethical conduct, the consequences for not complying with the conditions of this exemption (including any loss of exemptive relief provided herein), and prompt reporting of wrongdoing; and

(ii) Be conducted by a professional who has been prudently selected and who has appropriate technical training and proficiency with ERISA and the Code;

(i)(1) Each UBS QPAM submits to an audit conducted by an independent auditor, who has been prudently selected and who has appropriate technical training and proficiency with ERISA and the Code, to evaluate the adequacy of, and each UBS QPAM's compliance with, the Policies and Training described herein. The audit requirement must be incorporated in the Policies. The audit must cover the Exemption Period and must be completed no later than six (6) months after the end of the exemption period. For time periods ending prior to the judgment against UBS or UBS France by the French First Instance Court and covered by the audit required pursuant to PTE 2017–07,[14] the audit requirements in Section I(i) of PTE 2017–07 will remain in effect. The audit under PTE 2017–07 covering the time period from January 10, 2018 until the date of the judgment against UBS or UBS France by the French First Instance Court must be completed within six (6) months of the date of any such judgment, and the corresponding certified Audit Report must be submitted to the Department no later than 45 days following the completion of such audit;[15]

(2) Within the scope of the audit and to the extent necessary for the auditor, in its sole opinion, to complete its audit and comply with the conditions for relief described herein, and only to the extent such disclosure is not prevented by state or federal statute, or involves communications subject to attorney client privilege, each UBS QPAM and, if applicable, UBS, will grant the auditor unconditional access to its business, including, but not limited to: Its computer systems; business records; transactional data; workplace locations; training materials; and personnel. Such access is limited to information relevant to the auditor's objectives as specified by the terms of this exemption;

(3) The auditor's engagement must specifically require the auditor to determine whether each UBS QPAM has developed, implemented, maintained, and followed the Policies in accordance with the conditions of this exemption, and has developed and implemented the Training, as required herein;

(4) The auditor's engagement must specifically require the auditor to test each UBS QPAM's operational compliance with the Policies and Training. In this regard, the auditor must test, for each UBS QPAM, a sample of such UBS QPAM's transactions involving Covered Plans, sufficient in size and nature to afford the auditor a reasonable basis to determine such UBS QPAM's operational compliance with the Policies and Training;

(5) For the audit, on or before the end of the relevant period described in Section I(i)(1) for completing the audit, the auditor must issue a written report (the Audit Report) to UBS and the UBS QPAM to which the audit applies that describes the procedures performed by the auditor in connection with its examination. The auditor, at its discretion, may issue a single consolidated Audit Report that covers all the UBS QPAMs. The Audit Report must include the auditor's specific determinations regarding:

(i) The adequacy of each UBS QPAM's Policies and Training; each UBS QPAM's compliance with the Policies and Training; the need, if any, to strengthen such Policies and Training; and any instance of the respective UBS QPAM's noncompliance with the written Policies and Training described in Section I(h) above. The UBS QPAM must promptly address any noncompliance. The UBS QPAM must promptly address or prepare a written plan of action to address any determination as to the adequacy of the Policies and Training and the auditor's recommendations (if any) with respect to strengthening the Policies and Training of the respective UBS QPAM. Any action taken or the plan of action to be taken by the respective UBS QPAM must be included in an addendum to the Audit Report (such addendum must be completed prior to the certification described in Section I(i)(7) below). In the event such a plan of action to address the auditor's recommendation regarding the adequacy of the Policies and Training is not completed by the time of

[14] 82 FR 61903 (December 29, 2017). PTE 2017–07 is an exemption that permits UBS QPAMs to rely on the exemptive relief provided by PTE 84–14, notwithstanding the 2013 and 2018 Convictions.

[15] Pursuant to PTE 2017–07, the initial audit period begins on January 10, 2018 and ends on March 9, 2019, and the corresponding Audit Report must be completed by September 9, 2019 and the Audit Report submitted to the Department within 45 days after completion. Accordingly, the last audit performed pursuant to PTE 2017–07 will cover the period beginning January 10, 2018 and ending on the date of judgment against UBS or UBS France by the French First Instance Court. The corresponding Audit Report must be completed within six months of the judgment and submitted to the Department within 45 days of completion.

submission of the Audit Report, the following period's Audit Report must state whether the plan was satisfactorily completed. Any determination by the auditor that a UBS QPAM has implemented, maintained, and followed sufficient Policies and Training must not be based solely or in substantial part on an absence of evidence indicating noncompliance. In this last regard, any finding that a UBS QPAM has complied with the requirements under this subparagraph must be based on evidence that the particular UBS QPAM has actually implemented, maintained, and followed the Policies and Training required by this exemption. Furthermore, the auditor must not solely rely on the Exemption Report created by the compliance officer (the Compliance Officer), as described in Section I(m) below, as the basis for the auditor's conclusions in lieu of independent determinations and testing performed by the auditor as required by Section I(i)(3) and (4) above; and

(ii) The adequacy of the Exemption Review described in Section I(m);

(6) The auditor must notify the respective UBS QPAM of any instance of noncompliance identified by the auditor within five (5) business days after such noncompliance is identified by the auditor, regardless of whether the audit has been completed as of that date;

(7) With respect to the Audit Report, the General Counsel, or one of the three most senior executive officers of the UBS QPAM to which the Audit Report applies, must certify in writing, under penalty of perjury, that the officer has reviewed the Audit Report and this exemption; that, to the best of such officer's knowledge at the time, such UBS QPAM has addressed, corrected, remedied any noncompliance and inadequacy or has an appropriate written plan to address any inadequacy regarding the Policies and Training identified in the Audit Report. Such certification must also include the signatory's determination, that, to the best of such officer's knowledge at the time, the Policies and Training in effect at the time of signing are adequate to ensure compliance with the conditions of this exemption and with the applicable provisions of ERISA and the Code;

(8) The Risk Committee of UBS's Board of Directors is provided a copy of the Audit Report; and a senior executive officer of UBS's Compliance and Operational Risk Control function must review the Audit Report for each UBS QPAM and must certify in writing, under penalty of perjury, that such officer has reviewed the Audit Report;

(9) Each UBS QPAM provides its certified Audit Report, by regular mail to: Office of Exemption Determinations (OED), 200 Constitution Avenue NW, Suite 400, Washington, DC 20210; or by private carrier to: 122 C Street NW, Suite 400, Washington, DC 20001–2109. This delivery must take place no later than 45 days following completion of the Audit Report. The Audit Report will be made part of the public record regarding this exemption. Furthermore, each UBS QPAM must make its Audit Report unconditionally available, electronically or otherwise, for examination upon request by any duly authorized employee or representative of the Department, other relevant regulators, and any fiduciary of a Covered Plan;

(10) Any engagement agreement with an auditor to perform the audit required under the terms of this exemption that is entered subsequent to the date of the judgment against UBS or UBS France by the French First Instance Court must be submitted to OED no later than two (2) months after the execution of such agreement;

(11) The auditor must provide the Department, upon request, for inspection and review, access to all the workpapers created and utilized in connection with the audit, provided such access and inspection is otherwise permitted by law; and

(12) UBS must notify the Department of a change in the independent auditor no later than two (2) months after the engagement of a substitute or subsequent auditor and must provide an explanation for the substitution or change including a description of any material disputes between the terminated auditor and UBS;

(j) As of the date of the judgment against UBS or UBS France by the French First Instance and throughout the Exemption Period, with respect to any arrangement, agreement, or contract between a UBS QPAM and a Covered Plan, the UBS QPAM agrees and warrants to Covered Plans:

(1) To comply with ERISA and the Code, as applicable with respect to such Covered Plan; to refrain from engaging in prohibited transactions that are not otherwise exempt (and to promptly correct any inadvertent prohibited transactions); and to comply with the standards of prudence and loyalty set forth in section 404 of ERISA with respect to each such ERISA-covered plan and IRA to the extent that section 404 is applicable;

(2) To indemnify and hold harmless the Covered Plan for any actual losses resulting directly from: A UBS QPAM's violation of ERISA's fiduciary duties, as applicable, and of the prohibited transaction provisions of ERISA and the Code, as applicable; a breach of contract by the QPAM; or any claim arising out of the failure of such UBS QPAM to qualify for the exemptive relief provided by PTE 84–14 as a result of a violation of Section I(g) of PTE 84–14 other than the Convictions and the 2019 French Judgment Against UBS/UBS France. This condition applies only to actual losses caused by the UBS QPAM's violations.

(3) Not to require (or otherwise cause) the Covered Plan to waive, limit, or qualify the liability of the UBS QPAM for violating ERISA or the Code or engaging in prohibited transactions;

(4) Not to restrict the ability of such Covered Plan to terminate or withdraw from its arrangement with the UBS QPAM with respect to any investment in a separately managed account or pooled fund subject to ERISA and managed by such QPAM, with the exception of reasonable restrictions, appropriately disclosed in advance, that are specifically designed to ensure equitable treatment of all investors in a pooled fund in the event such withdrawal or termination may have adverse consequences for all other investors. In connection with any such arrangements involving investments in pooled funds subject to ERISA entered into after the effective date of PTE 2017–07, the adverse consequences must relate to a lack of liquidity of the underlying assets, valuation issues, or regulatory reasons that prevent the fund from promptly redeeming an ERISA-covered plan's or IRA's investment, and such restrictions must be applicable to all such investors and be effective no longer than reasonably necessary to avoid the adverse consequences;

(5) Not to impose any fees, penalties, or charges for such termination or withdrawal with the exception of reasonable fees, appropriately disclosed in advance, that are specifically designed to prevent generally recognized abusive investment practices or specifically designed to ensure equitable treatment of all investors in a pooled fund in the event such withdrawal or termination may have adverse consequences for all other investors, provided that such fees are applied consistently and in like manner to all such investors; and

(6) Not to include exculpatory provisions disclaiming or otherwise limiting liability of the UBS QPAM for a violation of such agreement's terms. To the extent consistent with Section 410 of ERISA, however, this provision does not prohibit disclaimers for liability caused by an error,

misrepresentation, or misconduct of a plan fiduciary or other party hired by the plan fiduciary who is independent of UBS and its affiliates, or damages arising from acts outside the control of the UBS QPAM;

(7) Within six months of the date of the judgment against UBS or UBS France by the French First Instance Court, each UBS QPAM must provide a notice of its obligations under this Section I(j) to each Covered Plan. For prospective Covered Plans that enter into a written asset or investment management agreement with a UBS QPAM on or after the date of the judgment, the UBS QPAM will agree to its obligations under this Section I(j) in an updated investment management agreement between the UBS QPAM and such clients or other written contractual agreement. This condition will be deemed met for each Covered Plan that received a notice pursuant to PTE 2016–17 and/or PTE 2017–07 that meets the terms of this condition. Notwithstanding the above, a UBS QPAM will not violate the condition solely because a Plan or IRA refuses to sign an updated investment management agreement.

(k) Within 60 days of the judgment against UBS or UBS France by the French First Instance Court, each UBS QPAM will provide a notice of the exemption, along with a separate summary describing the facts that led to the Convictions and the 2019 French Judgment Against UBS/UBS France (the Summary), which have been submitted to the Department, and a prominently displayed statement (the Statement) (collectively, Initial Notice) that the Convictions and, in the Department's view, the 2019 French Judgment Against UBS/UBS France, each separately result in a failure to meet a condition in PTE 84–14 and PTE 2017–07, to each sponsor and beneficial owner of a Covered Plan, or the sponsor of an investment fund in any case where a UBS QPAM acts as a sub-advisor to the investment fund in which such ERISA-covered plan and IRA invests. Effective as of the date that is 60 days after the 2019 French Judgment Against UBS/UBS France Date, all Covered Plan clients that enter into a written asset or investment management agreement with a UBS QPAM after that date must receive a copy of the exemption, the Summary, and the Statement prior to, or contemporaneously with, the Covered Plan's receipt of a written asset management agreement from the UBS QPAM. Disclosures may be delivered electronically;

(l) The UBS QPAMs must comply with each condition of PTE 84–14, as amended, with the sole exception of the violations of Section I(g) of PTE 84–14 that are attributable to the Convictions and the 2019 French Judgment Against UBS/UBS France. If, during the Exemption Period, an entity within the UBS corporate structure is convicted of a crime described in Section I(g) of PTE 84–14, (other than the 2013 Conviction, 2018 Conviction, and the 2019 French Judgment Against UBS/UBS France), including a conviction in a foreign jurisdiction for a crime described in Section I(g) of PTE 84–14, relief in this exemption would terminate immediately;

(m)(1) UBS continues to designate a senior compliance officer (the Compliance Officer) who will be responsible for compliance with the Policies and Training requirements described herein. The Compliance Officer must conduct a review for the Exemption Period (the Exemption Review),[16] to determine the adequacy and effectiveness of the implementation of the Policies and Training. With respect to the Compliance Officer, the following conditions must be met:

(i) The Compliance Officer must be a professional who has extensive experience with, and knowledge of, the regulation of financial services and products, including under ERISA and the Code; and

(ii) The Compliance Officer must have a reporting line within UBS's Compliance and Operational Risk Control (C&ORC) function to the Head of Compliance and Operational Risk Control, Asset Management. The C&ORC function is organizationally independent of UBS's business divisions—including Asset Management, the Investment Bank, and Global Wealth Management—and is led by the head of Group Compliance, Regulatory and Governance, or another appropriate member of the Group Executive Board;

(2) With respect to the Exemption Review, the following conditions must be met:

(i) The Exemption Review includes a review of the UBS QPAMs' compliance with and effectiveness of the Policies and Training and of the following: Any compliance matter related to the Policies or Training that was identified by, or reported to, the Compliance Officer or others within the C&ORC function during the previous year; the most recent Audit Report issued pursuant to this exemption or PTE 2017–07; any material change in the relevant business activities of the UBS QPAMs; and any change to ERISA, the Code, or regulations related to fiduciary duties and the prohibited transaction provisions that may be applicable to the activities of the UBS QPAMs;

(ii) The Compliance Officer prepares a written report for the Exemption Review (an Exemption Report) that (A) summarizes his or her material activities during the Exemption Period; (B) sets forth any instance of noncompliance discovered during the Exemption Period, and any related corrective action; (C) details any change to the Policies or Training to guard against any similar instance of noncompliance occurring again; and (D) makes recommendations, as necessary, for additional training, procedures, monitoring, or additional and/or changed processes or systems, and management's actions on such recommendations;

(iii) In the Exemption Report, the Compliance Officer must certify in writing that to the best of his or her knowledge at the time: (A) The report is accurate; (B) the Policies and Training are working in a manner which is reasonably designed to ensure that the Policies and Training requirements described herein are met; (C) any known instance of noncompliance during the Exemption Period and any related correction taken to date have been identified in the Exemption Report; and (D) the UBS QPAMs have complied with the Policies and Training, and/or corrected (or are correcting) any known instances of noncompliance in accordance with Section I(h) above;

(iv) The Exemption Report must be provided to appropriate corporate officers of UBS and each UBS QPAM to which such report relates, and to the head of compliance and the General Counsel (or their functional equivalent) of the relevant UBS QPAM; and the report must be made unconditionally available to the independent auditor described in Section I(i) above;

(v) The Exemption Review, including the Compliance Officer's written Exemption Report, must be completed within three (3) months following the end of the period to which it relates;

(n) UBS imposes its internal procedures, controls, and protocols on UBS Securities Japan to: (1) Reduce the

[16] Pursuant to PTE 2017–07 the Compliance Officer must conduct an exemption review (annual review) for each period corresponding to the audit periods set forth in Section I(i)(1) of PTE 2017–07 and the Compliance officer's written report submitted to the Department within three (3) months of the end of the period to which it relates. Accordingly, the final exemption review pursuant to PTE 2017–07 must cover the period January 10, 2018 through the date of the judgment against UBS or UBS France by the French First Instance Court, and the corresponding Compliance Officer's written report must be submitted within three (3) months of the judgment.

likelihood of any recurrence of conduct that that is the subject of the 2013 Conviction, and (2) comply in all material respects with the Business Improvement Order, dated December 16, 2011, issued by the Japanese Financial Services Authority;

(o) UBS complies in all material respects with the audit and monitoring procedures imposed on UBS by the U.S. Commodity Futures Trading Commission Order, dated December 19, 2012;

(p) Each UBS QPAM will maintain records necessary to demonstrate that the conditions of this exemption have been met, for six (6) years following the date of any transaction for which such UBS QPAM relies upon the relief in the exemption;

(q) During the Exemption Period, UBS must: (1) Immediately disclose to the Department any Deferred Prosecution Agreement (a DPA) or Non-Prosecution Agreement (an NPA) with the U.S. Department of Justice, entered into by UBS or any of its affiliates (as defined in Section VI(d) of PTE 84–14) in connection with conduct described in Section I(g) of PTE 84–14 or section 411 of ERISA; and (2) immediately provides the Department any information requested by the Department, as permitted by law, regarding the agreement and/or conduct and allegations that led to the agreement;

(r) Within six months from the date of the judgment against UBS or UBS France by the French First Instance Court, each UBS QPAM, in its agreements with, or in other written disclosures provided to Covered Plans, will clearly and prominently inform Covered Plan clients of their right to obtain a copy of the Policies or a description (Summary Policies) which accurately summarizes key components of the UBS QPAM's written Policies developed in connection with this exemption. If the Policies are thereafter changed, each Covered Plan client must receive a new disclosure within six (6) months following the end of the calendar year during which the Policies were changed.[17] With respect to this requirement, the description may be continuously maintained on a website, provided that such website link to the Policies or Summary Policies is clearly and prominently disclosed to each Covered Plan; and

(s) A UBS QPAM will not fail to meet the terms of this exemption, solely because a different UBS QPAM fails to satisfy a condition for relief described in Sections I(c), (d), (h), (i), (j), (k), (l), (p), or (r); or if the independent auditor described in Section I(i) fails a provision of the exemption other than the requirement described in Section I(i)(11), provided that such failure did not result from any actions or inactions of UBS or its affiliates.

Section II. Definitions

(a) The term ''Convictions'' means the 2013 Conviction and the 2017 Conviction. The term ''2013 Conviction'' means the judgment of conviction against UBS Securities Japan Co. Ltd. in case number 3:12–cr–00268–RNC in the U.S. District Court for the District of Connecticut for one count of wire fraud in violation of Title 18, United States Code, sections 1343 and 2 in connection with submission of YEN London Interbank Offered Rates and other benchmark interest rates. The term ''2018 Conviction'' means the judgment of conviction against UBS in case number 3:15–cr–00076–RNC in the U.S. District Court for the District of Connecticut for one count of wire fraud in violation of Title 18, United States Code, Sections 1343 and 2 in connection with UBS's submission of Yen London Interbank Offered Rates and other benchmark interest rates between 2001 and 2010. For all purposes under this exemption, ''conduct'' of any person or entity that is the ''subject of the Convictions'' encompasses any conduct of UBS and/or their personnel, that is described in (i) Exhibit 3 to the Plea Agreement entered into between UBS and the Department of Justice Criminal Division, on May 20, 2015, in connection with case number 3:15–cr–00076–RNC, and (ii) Exhibits 3 and 4 to the Plea Agreement entered into between UBS Securities Japan and the Department of Justice Criminal Division, on December 19, 2012, in connection with case number 3:12–cr–00268–RNC;

(b) The term ''2019 French Judgment Against UBS/UBS France'' includes any adverse judgment against UBS or UBS France regarding case Number 1105592033. For all purposes under this exemption, ''conduct'' of any person or entity that is the ''criminal conduct that is the subject of the 2019 French Judgment Against UBS/UBS France'', includes any conduct of UBS, its affiliates, or UBS France and/or their personnel that is described in any such judgment;

(c) The term ''Covered Plan'' means a plan subject to Part IV of Title I of ERISA (an ''ERISA-covered plan'') or a plan subject to section 4975 of the Code (an ''IRA''), in each case, with respect to which a UBS QPAM relies on PTE 84–14, or with respect to which a UBS QPAM (or any UBS affiliate) has expressly represented that the manager qualifies as a QPAM or relies on the QPAM class exemption (PTE 84–14). A Covered Plan does not include an ERISA-covered plan or IRA to the extent the UBS QPAM has expressly disclaimed reliance on QPAM status or PTE 84–14 in entering into a contract, arrangement, or agreement with the ERISA-covered plan or IRA.

(d) The term ''FX Misconduct'' means the conduct engaged in by UBS personnel described in Exhibit 1 of the Plea Agreement (Factual Basis for Breach) entered into between UBS and the Department of Justice Criminal Division, on May 20, 2015 in connection with Case Number 3:15–cr–00076–RNC filed in the U.S. District Court for the District of Connecticut.

(e) The term ''UBS QPAM'' means UBS Asset Management (Americas) Inc., UBS Realty Investors LLC, UBS Hedge Fund Solutions LLC, UBS O'Connor LLC, and any future entity within the Asset Management or the Global Wealth Management Americas U.S. divisions of UBS that qualifies as a ''qualified professional asset manager'' (as defined in Section VI(a) of PTE 84–14) [18] and that relies on the relief provided by PTE 84–14, and with respect to which UBS is an ''affiliate'' (as defined in Part VI(d) of PTE 84–14). The term ''UBS QPAM'' excludes UBS securities Japan, the entity implicated in the criminal conduct that is the subject of the 2013 Conviction, UBS, the entity implicated in the criminal conduct that is the subject of the 2018 Conviction and implicated in the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France, and UBS France, the entity implicated in the criminal conduct of UBS and UBS France that is the subject of the 2019 French Judgment Against UBS/UBS France.

(f) The term ''UBS'' means UBS AG.

(g) The term ''UBS France'' means ''UBS (France) S.A.,'' a wholly-owned subsidiary of UBS incorporated under the laws of France.

(h) The term ''UBS Securities Japan'' means UBS Securities Japan Co. Ltd, a wholly-owned subsidiary of UBS incorporated under the laws of Japan.

[17] In the event the Applicant meets this disclosure requirement through Summary Policies, changes to the Policies shall not result in the requirement for a new disclosure unless, as a result of changes to the Policies, the Summary Policies are no longer accurate.

[18] In general terms, a QPAM is an independent fiduciary that is a bank, savings and loan association, insurance company, or investment adviser that meets certain equity or net worth requirements and other licensure requirements and that has acknowledged in a written management agreement that it is a fiduciary with respect to each plan that has retained the QPAM.

(i) All references to ''the date of the judgment by the French First Instance Court'' refer to any judgment against UBS or UBS France in case number 1105592033;

(j) The term ''Exemption Period'' means one year beginning on the date of the French First Instance judgment against UBS or UBS France regarding case Number 1105592033;

(k) The term ''Plea Agreement'' means the Plea Agreement (including Exhibits 1 and 3 attached thereto) entered into between UBS and the Department of Justice Criminal Division, on May 20, 2015 in connection with Case Number 3:15–cr–00076–RNC filed in the US District Court for the District of Connecticut.

Effective Date: This exemption will be in effect for one year from the date of the judgment in the French First Instance Court against UBS and/or UBS France in case number 1105592033.

Signed at Washington, DC, this 21st day of February, 2019.

Lyssa Hall,

Director, Office of Exemption Determinations Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2019–03339 Filed 2–22–19; 11:15 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's), Employment and Training Administration is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by April 29, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Timothy Theberge, Office of Trade Adjustment Assistance, Room N–5428, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. Telephone number: 202–693–3401 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD). Fax: 202–693–3584. Email: *theberge.timothy@dol.gov*. A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed above.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Section 221(a) of Title II, Chapter 2 of the Trade Act of 1974, as amended by the Trade Adjustment Assistance Reauthorization Act of 2015, authorizes the Secretary of Labor and the Governor of each state to accept petitions for certification of eligibility to apply for adjustment assistance. The petitions may be filed by a group of workers, their certified or recognized union or duly authorized representative, employers of such workers, one-stop operators, or one-stop partners. ETA Form 9042, Petition for Trade Adjustment Assistance, and its Spanish translation, ETA Form 9042A, Solicitud De Asistencia Para Ajuste, establish a format that may be used for filing such petitions.

Sections 222, 223, and 249 of the Trade Act of 1974, as amended, require the Secretary of Labor to issue a determination for groups of workers as to their eligibility to apply for adjustment assistance. After reviewing all of the information obtained for each petition for Trade Adjustment Assistance filed with the Department, a determination is issued as to whether the statutory criteria for certification are met. The information collected via the following forms will be used by the Secretary to determine to what extent, if any, increased imports or shifts in either service or production have impacted the petitioning worker group:

- ETA Form 9043a, Business Data Request—Article
- ETA Form 9043b, Business Data Request—Service
- ETA Form 9118, Business Information Request
- ETA Form 8562a, Business Customer Survey
- ETA Form 8562a1, Business Second Tier Customer Survey
- ETA Form 8562b, Business Bid Survey

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0342.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the

use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended.

Form(s): ETA 9042A, Petition for Trade Adjustment Assistance, and its Spanish translation ETA 9042A; ETA 9043a, Business Data Request—Article; ETA 9043b, Business Data Request—Service; ETA 8562a, Business Customer Survey; ETA 85622a–1, Business Second Tier Customer Survey; ETA–8562b, Business Bid Survey; and ETA 9118, Business Information Request.

OMB Control Number: 1205–0342.

Affected Public: Individuals or Households, Businesses, State Governments.

Estimated Number of Respondents: 5,280.

Frequency: Once.

Total Estimated Annual Responses: 5,460.

Estimated Average Time per Response: 2.0805 Hours.

Estimated Total Annual Burden Hours: 11,360.

Total Estimated Annual Other Cost Burden: $0.00.

Molly E. Conway,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2019–03209 Filed 2–25–19; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Meeting of the Labor Advisory Committee for Trade Negotiation and Trade Policy

AGENCY: Bureau of International Labor Affairs, U.S. Department of Labor, and Office of the United States Trade Representative.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given of a meeting of the Labor Advisory Committee for Trade Negotiation and Trade Policy.

DATES: March 25, 2019, 10:30 a.m. to 12:00 p.m.; U.S. Department of Labor, Secretary's Conference Room, 200 Constitution Ave. NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Anne M. Zollner, Chief, Trade Policy and Negotiations Division, Bureau of International Labor Affairs, U.S. Department of Labor; Phone: (202) 693–4890.

SUPPLEMENTARY INFORMATION: The U.S. Department of Labor and the Office of the U.S. Trade Representative are co-sponsors of this Federal Advisory Committee. The meeting will include a review and discussion of current issues which influence U.S. trade policy. Potential U.S. negotiating objectives and bargaining positions in current and anticipated trade negotiations will be discussed. Pursuant to 19 U.S.C. 2155(f)(2)(A), it has been determined that the meeting will be concerned with matters the disclosure of which would seriously compromise the Government's negotiating objectives or bargaining positions. Therefore, the meeting is exempt from the requirements of subsections (a) and (b) of sections 10 and 11 of the Federal Advisory Committee Act (relating to open meetings, public notice, public participation, and public availability of documents). 5 U.S.C. app. Accordingly, the meeting will be closed to the public.

Signed at Washington, DC.

Martha E. Newton,

Deputy Undersecretary, Bureau of International Labor Affairs.

[FR Doc. 2019–03307 Filed 2–25–19; 8:45 am]

BILLING CODE 4510–28–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30 a.m., Tuesday, March 12, 2019.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW, Washington, DC 20594.

STATUS: The one item is open to the public.

MATTERS TO BE CONSIDERED: 58039 Aircraft Accident Report—Departure From Controlled Flight Trans-Pacific Air Charter, LLC Learjet 35A, N452DA, Teterboro, New Jersey, May 15, 2017.

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle McCallister at (202) 314–6305 or by email at *Rochelle.McCallister@ntsb.gov* by Wednesday, March 6, 2019.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov.*

Schedule updates, including weather-related cancellations, are also available at *www.ntsb.gov.*

FOR MORE INFORMATION CONTACT: Candi Bing at (202) 314–6403 or by email at *bingc@ntsb.gov.*

FOR MEDIA INFORMATION CONTACT: Keith Holloway at (202) 314–6100 or by email at *keith.holloway@ntsb.gov.*

Dated: February 22, 2019.

LaSean McCray,

Assistant Federal Register Liaison Officer.

[FR Doc. 2019–03456 Filed 2–22–19; 4:15 pm]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–8907; NRC–2019–0026]

United Nuclear Corporation (UNC) Church Rock Project; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Intent to prepare an environmental impact statement (EIS) and conduct a scoping process; request for comment; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on February 8, 2019, regarding UNC's request to amend its license (SUA–1475) to excavate approximately 1 million cubic yards of mine spoil from the Northeast Church Rock Mine Site and dispose of it at the existing mill site in Church Rock, New Mexico. This action is necessary to correct a document that was referenced in the Background and Availability of Documents section as ''ADAMS Package Accession No. ML18360A424 (Package)'' to read ''ADAMS Accession No. ML19007A126.''

DATES: February 26, 2019.

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–2019–0026. Address questions about Docket IDs in *Regulations.gov* to Krupskaya Castellon; telephone: 301–287–9221; email: *Krupskaya.Castellon@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

• *Email comments to: UNC-ChurchRockEIS.resource@nrc.gov*

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: Ashley Waldron, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7317; email: *Ashley.Waldron@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the FR on February 8, 2019, in FR Doc. 2019–01642, on page 2935, in the third column, under the last paragraph, last line in Section II, ''Background,'' correct ''ADAMS Package Accession No. ML18360A424'' to read ''ADAMS Accession No. ML19007A126.'' The document is also referenced in the last line of the Document table in Section VII, Availability of Documents, correct ''ML18360A424 (Package)'' to read ''ML19007A126.''

Dated at Rockville, Maryland, on February 21, 2019.

For the U.S. Nuclear Regulatory Commission.

Michael F. King,

Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2019–03300 Filed 2–25–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0058]

Biweekly Notice; Applications and Amendments To Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from January 29, 2019, to February 11, 2019. The last biweekly notice was published on February 12, 2019.

DATES: Comments must be filed by March 28, 2019. A request for a hearing must be filed by April 29, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received 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 INSERT: NRC–2019–0058. Address questions about Docket IDs in *Regulations.gov* to Krupskaya Castellon; telephone: 301–287–9221; email: *Krupskaya.Castellon@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1927, email: *Lynn.Ronewicz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID INSERT: NRC–2019–0058, facility name, unit number(s), plant docket number, application date, and subject 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 INSERT: NRC–2019–0058.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0058, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding

the pendency before the Commission of a request for a hearing from any person.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the

standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''Cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection

in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Duke Energy Progress, LLC, Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of amendment request: December 14, 2018. A publicly-available version is in ADAMS under Accession No. ML18353A951.

Description of amendment request: The amendments would modify requirements for repetitive verification of the status of locked, sealed, or secured components to allow the verification to be done by use of administrative means consistent with Technical Specifications Task Force (TSTF) Traveler 269, Revision 2, ''Allow Administrative Means of Position Verification for Locked or Sealed Valves.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change modifies Technical Specification (TS) 3.6.1.3, ''Primary Containment Isolation Valves (PCIVs)'' and TS 3.6.4.2, ''Secondary Containment Isolation Dampers (SCIDs).'' These specifications require penetration flow paths with inoperable isolation devices be isolated and periodically verified to be isolated. Consistent with TSTF–269–A, Revision 2, notes are proposed to be added to TS 3.6.1.3, Required Actions A.2 and C.2, and TS 3.6.4.2, Required Action A.2, to allow isolation devices that are locked, sealed, or otherwise secured to be verified using administrative means.

The proposed change does not affect any plant equipment, test methods, or plant operation, and is not an initiator of any analyzed accident sequence. The inoperable containment penetrations will continue to be isolated, and hence perform their isolation function. Operation in accordance with the proposed TSs will ensure that all analyzed accidents will continue to be mitigated as previously analyzed. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a physical alteration to the plant (*i.e.,* no new or different type of equipment will be installed) or a change to the methods governing normal plant operation. Furthermore, the change does not alter the assumptions made in the safety analysis. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change will not affect operation of plant equipment or the function of any equipment assumed in the accident analysis. Affected containment penetrations will continue to be isolated as required by the existing TSs. Therefore, the proposed change does not involve a significant reduction in safety margin.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn B. Nolan, Deputy General Counsel, Duke Energy Corporation, 550 South Tryon Street, Mail Code DEC45A, Charlotte, NC 28202.

Entergy Operations, Inc., Docket No. 50–313, Arkansas Nuclear One, Unit 1 (ANO–1), Pope County, Arkansas

Date of amendment request: December 19, 2018. A publicly-available version is in ADAMS under Accession No. ML18353B044.

Description of amendment request: The amendment would revise the ANO–1 Technical Specifications (TSs) to adopt Technical Specifications Task Force (TSTF) Traveler TSTF–567, Revision 1, ''Add Containment Sump TS to Address GSI [Generic Safety Issue]–191 Issues.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change adds a new specification to the TS for the reactor building sump. An existing SR [surveillance requirement] on the reactor building sump is moved to the new specification and a duplicative requirement to perform the SR in TS 3.5.3 is removed. The new specification retains the existing requirements on the reactor building sump and the actions to be taken when the reactor building sump is inoperable with the exception of adding new actions to be taken when the reactor building sump is inoperable due to reactor building accident generated and transported debris exceeding the analyzed limits. The new action provides time to evaluate and correct the condition instead of requiring an immediate plant shutdown.

The reactor building sump is not an initiator of any accident previously evaluated. The reactor building sump is a passive component and the proposed change does not increase the likelihood of the malfunction. As a result, the probability of an accident is unaffected by the proposed change.

The reactor building sump is used to mitigate accidents previously evaluated by providing a borated water source for the Emergency Core Cooling System (ECCS) and Reactor Building Spray (RBS) System. The design of the reactor building sump and the capability of the reactor building sump assumed in the accident analysis is not changed. The proposed action requires implementation of mitigating actions while the reactor building sump is inoperable and more frequent monitoring of reactor coolant leakage to detect any increased potential for an accident that would require the reactor building sump. The consequences of an accident during the proposed action are no different than the current consequences of an accident if the reactor building sump is inoperable.

The proposed change clarifies the SFDP [Safety Function Determination Program] when a supported system is made inoperable by the inoperability of a single TS support system. The SFDP directs the appropriate use of TS actions and the proposed change does not alter the current intent of the TS. The actions taken when a system is inoperable are not an assumption in the initiation or mitigation of any previously evaluated accident.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change adds a new specification to the TS for the reactor building sump. An existing SR on the reactor building sump is moved to the new specification and a duplicative requirement to perform the SR in TS 3.5.3 is removed. The new specification retains the existing requirements on the reactor building sump and the actions to be taken when the reactor building sump is inoperable with the exception of adding new actions to be taken when the reactor building sump is inoperable due to reactor building accident generated and transported debris exceeding the analyzed limits. The new action provides time to evaluate and correct the condition instead of requiring an immediate plant shutdown.

The proposed change does not alter the design or design function of the reactor

building sump or the plant. No new systems are installed or removed as part of the proposed change. The reactor building sump is a passive component and cannot initiate a malfunction or accident. No new credible accident is created that is not encompassed by the existing accident analyses that assume the function of the reactor building sump.

The proposed change clarifies the SFDP when a supported system is made inoperable by the inoperability of a single TS support system. The SFDP directs the appropriate use of TS actions and the proposed change does not alter the current intent of the TS. The proposed change to the Safety Function Determination Program will not result in any change to the design or design function of the reactor building sump or a method of operation of the plant.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change adds a new specification to the TS for the reactor building sump. An existing SR on the reactor building sump is moved to the new specification and a duplicative requirement to perform the SR in TS 3.5.3 is removed. The new specification retains the existing requirements on the reactor building sump and the actions to be taken when the reactor building sump is inoperable with the exception of adding new actions to be taken when the reactor building sump is inoperable due to reactor building accident generated and transported debris exceeding the analyzed limits. The new action provides time to evaluate and correct the condition instead of requiring an immediate plant shutdown.

The proposed change does not affect the controlling values of parameters used to avoid exceeding regulatory or licensing limits. No Safety Limits are affected by the proposed change. The proposed change does not affect any assumptions in the accident analyses that demonstrate compliance with regulatory and licensing requirements.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Anna Vinson Jones, Senior Counsel, Entergy Services, Inc., 101 Constitution Avenue NW, Suite 200 East, L–ENT–WDC, Washington, DC 20001.

NRC Branch Chief: Robert J. Pascarelli.

Susquehanna Nuclear, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2, Luzerne County, Pennsylvania

Date of amendment request: January 9, 2019. A publicly-available version is in ADAMS under Accession No. ML19009A431.

Description of amendment request: The amendments would temporarily change Technical Specification (TS) TS 3.7.1, ''Residual Heat Removal Service Water (RHRSW) System and the Ultimate Heat Sink (UHS),'' and TS 3.7.2, ''Emergency Service Water (ESW) System,'' to allow one division of the ESW and RHRSW systems to be inoperable for a total of 14 days to address piping degradation. The amendments would also remove the Table of Contents (TOC) from the TSs and place it under licensee control.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change is to permit a temporary extension to existing TS Completion Times to allow for ESW system piping replacement. The division of the ESW and RHRSW systems that are not being worked on will remain fully OPERABLE during the 14 day Completion Time. Although it would not be able to be restored to a fully OPERABLE status, the impacted division of ESW and RHRSW will be capable of being restored to perform its safety function within the limiting 72 hour Completion Time. The ESW and RHRSW systems and their supported equipment function as accident mitigators. Removing one division from service for a limited period of time does not affect any accident initiator and, therefore, cannot change the probability of an accident. The proposed changes and the ESW repair evolution have been evaluated to assess their impact on the systems affected and ensure design basis safety functions are preserved. There is a slight increase in risk associated with having the ESW and RHRSW systems and their supported systems out of service for longer than currently allowed by the SSES [Susquehanna] TS. However, Susquehanna will maintain the non-impacted division of ESW and RHRSW fully OPERABLE throughout the repair evolution and will protect required equipment in accordance with its protected equipment program. The non-impacted division is capable of serving 100 percent of the heat loads for both the online and outage units during an accident. As such, there is no impact on consequence mitigation for any transient or accident.

Additionally, Susquehanna proposes an administrative change to remove the TOC from the TS and place it under licensee control. This has no impact on the design or operation of the plant and cannot impact the probability of an accident in any way.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change is to permit a temporary extension to existing TS Completion Times to allow for ESW system piping replacement. The change does not involve a physical alteration of the plant (*i.e.,* no different equipment will be installed) or a change in the methods governing normal plant operations. The proposed change does not alter assumptions made in the safety analysis. During the replacement evolution, one division of the ESW and RHRSW systems will not be capable of performing their safety function. However, the other division of ESW and RHRSW are capable of providing the necessary cooling in the event of an accident. Furthermore, the ability to perform the safety function for the impacted division can always be recovered within the existing TS Completion Times and the systems will be fully restored to OPERABLE status following the pipe replacement. The proposed change does not introduce new failure mechanisms, malfunctions, or accident initiators not considered in the design and licensing basis.

Additionally, Susquehanna proposes an administrative change to remove the TOC from the TS and place it under licensee control. This has no impact on the design or operation of the plant and cannot create a new or different kind of accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change is to permit a temporary extension to existing TS Completion Times to allow for ESW system piping replacement. The proposed change does not alter the manner in which safety limits, limiting safety settings, or limiting conditions for operation are determined. The safety analysis assumptions and acceptance criteria are not affected by this change. The change will ultimately result in an increase in a margin of safety due to installation of the new piping.

Additionally, Susquehanna proposes an administrative change to remove the TOC from the TS and place it under licensee control. This has no impact on the design or operation of the plant and cannot impact any safety margins.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this

review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Damon D. Obie, Associate General Counsel, Talen Energy Supply, LLC, 835 Hamilton St., Suite 150, Allentown, PA 18101.

NRC Branch Chief: James G. Danna.

IV. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: September 5, 2018.

Brief description of amendments: The amendments revised the Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Technical Specification 5.5.15, ''Battery Monitoring and Maintenance Program,'' to align with the latest Institute of Electrical and Electronics Engineers (IEEE) Standard (Std.) for maintenance and testing of the safety-related batteries. Specifically, the amendments replaced all the references of the IEEE Std. 450–1995, ''IEEE Recommended Practice for Maintenance, Testing, and Replacement of Vented Lead-Acid Batteries for Stationary Applications,'' with the updated IEEE Std. 450–2010, as endorsed, with certain regulatory positions, in Regulatory Guide 1.129, Revision 3, ''Seismic Design Classification.''

Date of issuance: February 5, 2019.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 343 (Unit No. 1) and 325 (Unit No. 2). A publicly-available version is in ADAMS under Accession No. ML18346A358; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–58 and DPR–74: The amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

*Date of initial notice in **Federal Register:*** November 6, 2018 (83 FR 55574).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated February 5, 2019.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia

Date of amendment request: July 20, 2018, as supplemented by letter dated December 3, 2018.

Brief description of amendments: The amendments consisted of changes to Combined License Appendix A, Technical Specifications (TSs), and revised operability requirements for the Engineered Safety Feature Actuation System Spent Fuel Pool Level—Low 2 and In-Containment Refueling Water Storage Tank Wide Range Level—Low instrumentation functions for Refueling Cavity and Spent Fuel Pool Cooling System (SFS) Isolation. Additional changes added TS operability requirements for the SFS containment isolation valves in MODES 5 and 6.

Date of issuance: January 15, 2019.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 150 (Unit 3) and 149 (Unit 4). A publicly-available version is in ADAMS under Package Accession No. ML18351A189; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Combined License Nos. NPF–91 and NPF–92: The amendments revised the facility Combined Licenses.

*Date of initial notice in **Federal Register:*** September 11, 2018 (83 FR 45986). The supplement dated December 3, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 15, 2019.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Burke County, Georgia

Date of amendment request: August 10, 2018.

Brief description of amendments: The amendments consisted of changes to Combined License Appendix A, Technical Specifications (TSs), and revised TS Limiting Condition for Operation (LCO) 3.1.8, ''Physics Tests Exception—Mode 2,'' to include Function 4 as one of the LCO 3.3.1, ''Reactor Trip System (RTS) Instrumentation,'' functions where the number of required channels may be reduced to three during the performance of physics tests. Additionally, LCO 3.8.3, ''Inverters—Operating,'' was revised to make an editorial nomenclature change from ''constant voltage source transformer'' to ''voltage regulating transformer.''

Date of issuance: January 30, 2019.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 153 (Unit 3) and 152 (Unit 4). A publicly-available version is in ADAMS under Package Accession No. ML18354B207; documents related to these amendments

are listed in the Safety Evaluation enclosed with the amendments.

Facility Combined Licenses Nos. NPF–91 and NPF–92: The amendments revised the facility Combined Licenses.

Date of initial notice in ***Federal Register:*** September 25, 2018 (83 FR 48467).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 30, 2019.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket Nos. 50–390 and 50–391, Watts Bar Nuclear Plant, Units 1 and 2 (Watts Bar), Rhea County, Tennessee

Date of amendment request: January 5, 2018.

Brief description of amendments: The amendments revised Technical Specification (TS) 3.6.3, ''Containment Isolation Valves,'' and Surveillance Requirement 3.6.3.5 to change the frequency in accordance with the Watts Bar Containment Leakage Rate Testing Program, which is described in TS 5.7.2.19. The changes allow leak rate testing of the containment purge system containment isolation valves to be performed at least once every 30 months, as prescribed in Regulatory Guide 1.163, ''Performance-Based Containment Leak-Test Program.''

Date of issuance: January 28, 2019.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 123 (Unit 1) and 24 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18327A005; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–90 and NPF–96: The amendments revised the Facility Operating Licenses and TSs.

Date of initial notice in ***Federal Register:*** March 13, 2018 (83 FR 10924).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 28, 2019.

No significant hazards consideration comments received: No.

V. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed no significant hazards consideration determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) The application for amendment, (2) the amendment to Facility Operating License or Combined License, as applicable, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Northern States Power Company—Minnesota, Docket No. 50–306, Prairie Island Nuclear Generating Plant, Unit 2, Goodhue County, Minnesota

Date of amendment request: January 29, 2019.

Description of amendment: The amendment revised Technical Specification 3.8.1, Condition E, to allow a one-time extension to the completion time for two diesel generators out of service.

Date of issuance: January 29, 2019.

Effective date: January 29, 2019.

Amendment No: 213. A publicly-available version is in ADAMS under Accession No. ML19029A094;

documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–60: The amendment revised the Renewed Facility Operating License and Technical Specifications.

Public comments requested as to proposed no significant hazards consideration: No.

The Commission's related evaluation of the amendment, finding of emergency circumstances, State consultation, and final no significant hazards consideration determination are contained in a Safety Evaluation dated January 29, 2019.

Attorney for licensee: Peter M. Glass, Assistant General Counsel, Xcel Energy Services, Inc., 414 Nicollet Mall, Minneapolis, MN 55401.

NRC Branch Chief: David J. Wrona.

Dated at Rockville, Maryland, this 15th day of February, 2019.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–02934 Filed 2–25–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of February 25, March 4, 11, 18, 25, April 1, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of February 18, 2019

There are no meetings scheduled for the week of February 18, 2019.

Week of February 25, 2019—Tentative

There are no meetings scheduled for the week of February 25, 2019.

Week of March 4, 2019—Tentative

Tuesday, March 5, 2019

10:00 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

Week of March 11, 2019—Tentative

There are no meetings scheduled for the week of March 11, 2019.

Week of March 18, 2019—Tentative

Wednesday, March 20, 2019

10:00 a.m. Meeting with the Organization of Agreement States and the Conference of Radiation Control Program Directors (Public), (Contact: Paul Michalak: 301–415–5804)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of March 25, 2019—Tentative

Thursday, March 28, 2019

9:00 a.m. Transformation at the NRC: Innovation (Public Meeting), (Contact: June Cai: 301–415–1771)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of April 1, 2019—Tentative

Thursday, April 4, 2019

10:00 a.m. Meeting with the Advisory Committee on the Medical Uses of Isotopes (Public Meeting), (Contact: Kellee Jamerson: 301–415–7408)

Additional Information: The meeting scheduled on March 28, 2019 at 9:00 a.m., Transformation at the NRC: Innovation, was postponed from the originally scheduled date of January 31, 2019.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* Braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, (301–415–1969), or by email at *Wendy.Moore@nrc.gov.*

Dated at Rockville, Maryland, this 21st day of February, 2019.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2019–03337 Filed 2–22–19; 11:15 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting

DATES AND TIMES: Monday, March 4, 2019, at 9:30 a.m.

PLACE: Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Monday, March 4, 2019, at 9:30 a.m.

1. Strategic Items.
2. Administrative Matters.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Acting Secretary.

[FR Doc. 2019–03460 Filed 2–22–19; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33379; 812–14881]

Monteagle Funds and Nashville Capital Corporation

February 21, 2019.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements''). The requested

exemption would permit an investment adviser to hire and replace certain subadvisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the subadvisers.

Applicants: Monteagle Funds (the ''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company, and Nashville Capital Corporation (the ''Adviser''), a Tennessee corporation registered as an investment adviser under the Investment Advisers Act of 1940 (collectively with the Trust, the ''Applicants'').

Filing Dates: The application was filed on February 27, 2018 and amended on June 11, 2018, October 23, 2018, and December 21, 2018.

Hearing or Notification of Hearing: An order granting the application 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 March 18, 2019, and should be accompanied by proof of service on the 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: Monteagle Funds, 8000 Town Centre Drive, Suite 400, Broadview Heights, OH 44147; Nashville Capital Corporation, 2506 Winford Avenue, Nashville, TN 37211.

FOR FURTHER INFORMATION CONTACT: Zeena Abdul-Rahman, Senior Counsel, at (202) 551–4099, or Andrea Ottomanelli Magovern, 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.

Summary of the Application

1. The Adviser will serve as the investment adviser to the Funds pursuant to an investment advisory agreement with the Trust (the ''Advisory Agreement'').[1] The Adviser will provide each Fund with overall investment management services and will continuously review, supervise and administer each Fund's investment program, subject to the supervision of, and policies established by, each Fund's board of trustees (''Board''). The Advisory Agreement permits the Adviser, subject to the approval of the Board, to delegate to one or more subadvisers (each, a ''Subadviser'' and collectively, the ''Subadvisers'') the responsibility to provide the day-to-day portfolio investment management of each Fund, subject to the supervision and direction of the Adviser.[2] The primary responsibility for managing the Funds will remain vested in the Adviser. The Adviser will hire, evaluate, allocate assets to and oversee the Subadvisers, including determining whether a Subadviser should be terminated, at all times subject to the authority of the Board.

2. Applicants request an exemption to permit the Adviser, subject to Board approval, to hire certain Subadvisers pursuant to subadvisory agreements and materially amend existing subadvisory agreements without obtaining the shareholder approval required under section 15(a) of the Act and rule 18f–2 under the Act.[3] Applicants also seek an exemption from the Disclosure Requirements to permit a Fund to disclose (as both a dollar amount and a percentage of the Fund's net assets): (a) The aggregate fees paid to the Adviser and any Affiliated Subadviser; and (b) the aggregate fees paid to Subadvisers other than Affiliated Subadvisers. For any Fund that employs an Affiliated Subadviser, the Fund will provide separate disclosure of any fees paid to the Affiliated Subadviser.

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Fund shareholders and notification about subadvisory changes and enhanced Board oversight to protect the interests of the Funds' shareholders.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the application, the Advisory Agreements will remain subject to shareholder approval while the role of the Subadvisers is substantially similar to that of individual portfolio managers, so that requiring shareholder approval of subadvisory agreements would impose unnecessary delays and expenses on the Funds. Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Adviser's ability to negotiate fees paid to the Subadvisers that are more advantageous for the Funds.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03311 Filed 2–25–19; 8:45 am]

BILLING CODE 8011–01–P

[1] Applicants request relief with respect to any existing or future series of the Trust or any other registered open-end management company that: (a) Is advised by the Adviser, or any person controlling, controlled by or under common control with the Adviser or its successors (each, an ''Adviser''); (b) uses the manager of managers structure described in the application; and (c) complies with the terms and conditions of the requested order (any such series, a ''Fund'' and collectively, the ''Funds''). For purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] The Trust currently has six series. The Adviser has hired a Subadviser for each of these Funds in compliance with section 15(a) of the Act.

[3] The requested relief will not extend to any Subadviser that is an affiliated person, as defined in section 2(a)(3) of the Act, of the Trust, a Fund, or the Adviser, other than solely by reason of serving as a Subadviser to one or more of the Funds, or as an adviser or subadviser to any series of the Trust other than the Funds (''Affiliated Subadviser'').

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33380; 812–14954]

Acquirers Funds, LLC, et al.

February 21, 2019.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an

exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) index-based series of certain open-end management investment companies (''Funds'') to issue shares redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value (''NAV''); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds (''Funds of Funds'') to acquire shares of the Funds.

Applicants: Acquirers Funds, LLC (the ''Initial Adviser''), a California limited liability company that is registered as an investment adviser under the Investment Advisers Act of 1940, ETF Series Solutions (the ''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series, and Quasar Distributors, LLC, a Delaware limited liability company and broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act'').

Filing Dates: The application was filed on September 17, 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 March 18, 2019 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, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090; Applicants: Acquirers Funds, LLC, 415 North Camden Drive, Suite 223, Beverly Hills, CA 90210; ETF Series Solutions, 615 East Michigan Street, Milwaukee, Wisconsin 53202; Quasar Distributors, LLC, 777 East Wisconsin Avenue, 6th Floor, Milwaukee, Wisconsin 53202.

FOR FURTHER INFORMATION CONTACT: Christine Y. Greenlees, Senior Counsel, at (202) 551–6990, or Andrea Ottomanelli Magovern, 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 for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds (''ETFs'').[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an ''Authorized Participant'', which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond generally to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act (''Affiliated Person''), or an affiliated person of an Affiliated Person (''Second-Tier Affiliate''), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the Distributor will compile, create, sponsor or maintain the Underlying Index.[2]

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (''Deposit Instruments''), and shareholders redeeming their shares will receive specified instruments (''Redemption Instruments''). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation

[1] Applicants request that the order apply to The Acquirers Fund (the ''Initial Fund''), a new series of the Trust, and any additional series of the Trust, and any other open-end management investment company or series thereof (''Future Funds'' and together with the Initial Fund, ''Funds''), each of which will operate as an ETF and will track a specified index comprised of domestic and/or foreign equity securities and/or domestic and/or foreign fixed income securities (each, an ''Underlying Index''). Each Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each such entity and any successor thereto, an ''Adviser'') and (b) comply with the terms and conditions of the application. For purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Each Self-Indexing Fund will post on its website the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second-Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[3] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision 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. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03310 Filed 2–25–19; 8:45 am]

BILLING CODE 8011–01–P

[3] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33378; 812–14939]

Toroso Investments, LLC and Tidal ETF Trust

February 21, 2019

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) index-based series of certain open-end management investment companies (''Funds'') to issue shares redeemable in large aggregations (''Creation Units''); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value (''NAV''); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds (''Funds of Funds'') to acquire shares of the Funds; and (f) certain Funds to issue Shares in less than Creation Unit size to investors participating in a distribution reinvestment program.

Applicants: Tidal ETF Trust (the ''Trust''), a Delaware statutory trust, which will register with the Commission as a series open-end management investment company, and Toroso Investments, LLC (the ''Initial Adviser''), a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940.

Filing Dates: The application was filed on August 9, 2018 and amended on December 4, 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 March 18, 2019 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, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090; Applicants: The Trust and the Initial Adviser, 898 N Broadway, Suite 2, Massapequa, New York 11758.

FOR FURTHER INFORMATION CONTACT: Benjamin Kalish, Attorney-Adviser, at

(202) 551–7361, or Parisa Haghshenas, Branch Chief, at (202) 551–6723 (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 for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds (''ETFs'').[1] Fund shares will be purchased and redeemed at their NAV in Creation Units (other than pursuant to a distribution reinvestment program, as described in the application). All orders to purchase Creation Units and all redemption requests will be placed by or through an ''Authorized Participant,'' which will have signed a participant agreement with the distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond closely to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act (''Affiliated Person''), or an affiliated person of an Affiliated Person (''Second-Tier Affiliate''), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the distributor will compile, create, sponsor or maintain the Underlying Index.[2]

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis, or issued in less than Creation Unit size to investors participating in a distribution reinvestment program. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (''Deposit Instruments''), and shareholders redeeming their shares will receive specified instruments (''Redemption Instruments''). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units (other than pursuant to a distribution reinvestment program).

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions, and Deposit Instruments and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[3] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the

[1] Applicants request that the order apply to the Initial Fund and any additional series of the Trust, and any other existing or future open-end management investment company or existing or future series thereof (each, included in the term ''Fund''), each of which will operate as an ETF and will track a specified index comprised of domestic and/or foreign equity securities and/or domestic and/or foreign fixed income securities (each, an ''Underlying Index''). Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each of the foregoing and any successor thereto, an ''Adviser'') and (b) comply with the terms and conditions of the application. For purposes of the requested order, a ''successor'' is limited to an entity or entities that result from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Each Self-Indexing Fund will post on its website the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

[3] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

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. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03312 Filed 2–25–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85168; File No. SR–NYSEAMER–2019–01]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31E Relating to the Minimum Trade Size Modifier

February 20, 2019.

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 February 11, 2019, NYSE American LLC (the ''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31E relating to the Minimum Trade Size Modifier. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31E relating to the Minimum Trade Size (''MTS'') Modifier.

The MTS Modifier is currently available for Limit IOC Orders,[4] Midpoint-Liquidity (''MPL'') Orders,[5] Tracking Orders,[6] Non-Displayed Primary Pegged Orders,[7] and Discretionary Pegged Orders.[8] As such, the MTS Modifier is currently available only for orders that are not displayed and do not route. On arrival, Limit IOC Orders, MPL Orders, Non-Displayed Primary Pegged Orders, and Discretionary Pegged Orders with an MTS Modifier will trade against contra-side orders in the Exchange Book that in the aggregate or individually, meet the MTS.[9] Once resting, MPL Orders, Tracking Orders, Non-Displayed Primary Pegged Orders, and Discretionary Pegged Orders with an MTS Modifier function similarly: If a contra-side order does not meet the MTS, the incoming order will not trade with and may trade through the resting order with the MTS Modifier. In addition, MPL Orders, Tracking Orders, Non-Displayed Primary Pegged Orders, and Discretionary Pegged Orders with an MTS Modifier will be cancelled if such orders are traded in part or reduced in size and the remaining quantity is less than the MTS.

First, the Exchange proposes to amend its rules to make MTS Modifier functionality available for an additional non-displayed order that does not route, *i.e.,* Non-Displayed Limit Orders.[10] This proposed change is based on the rules of both the Nasdaq Stock Market LLC (''Nasdaq'') and Investors Exchange LLC (''IEX''), which both offer minimum trade size functionality for orders that are not displayed and that do not route.[11]

Second, the Exchange proposes to allow ETP Holder to elect that Limit IOC Orders with an MTS Modifier trade on arrival against contra-side orders in the Exchange Book that individually meet such order's MTS. Rule 7.31E(i)(3)(B) requires an ETP Holder to specify whether an order with an MTS Modifier would trade on arrival against contra-side orders in the Exchange Book that in the aggregate or individually meet such order's MTS. Currently, an ETP Holder cannot elect that a Limit IOC Order with an MTS Modifier trade only with

[4] *See* Rule 7.31E(b)(2)(A). In sum, a Limit Order designated IOC is to be traded in whole or in part on the Exchange as soon as such order is received, and the quantity not so traded is cancelled. *Id.*

[5] *See* Rule 7.31E(d)(3). In sum, an MPL Order is a ''Limit Order that is not displayed and does not route, with a working price at the midpoint of the PBBO.'' *Id.*

[6] *See* Rule 7.31E(d)(4). In sum, a Tracking Order is an order to buy (sell) with a limit price that is not displayed, does not route, must be entered in round lots and designated Day, and will trade only with an order to sell (buy) that is eligible to route.

[7] *See* Rule 7.31E(h)(2). In sum, a Non-Displayed Pegged Order is a Pegged Order to buy (sell) with a working price that is pegged to the PBB (PBO), with no offset allowed. All Pegged Orders are not displayed and do not route. *See* Rule 7.31E(h).

[8] *See* Rule 7.31E(h)(3). In sum, a Discretionary Pegged Order is a Pegged Order to buy (sell) that upon entry to the Exchange is assigned a working price equal to the lower (higher) of the midpoint of the PBBO (''Midpoint Price'') or the limit price of the order. All Pegged Orders are not displayed and do not route. *See* Rule 7.31E(h).

[9] Tracking Orders, including Tracking Orders with an MTS Modifier, are passive orders that do not trade on arrival.

[10] *See* Rule 7.31E(d)(2). In sum, a Non-Displayed Limit Order is a Limit Order that is not displayed and does not route. *Id.* The Exchange understands that its affiliated exchanges, the New York Stock Exchange, Inc. (''NYSE''), NYSE National, Inc. (''NYSE National''), and NYSE Arca, Inc. (''NYSE Arca'', together with the Exchange, NYSE National and NYSE, the ''Affiliate SROs'') have either filed or intend to file similar proposes rule changes with the Commission to extend the availability of their respective MTS Modifiers to Non-Displayed Limit Orders. *See* SR–NYSE–2019–01 (filed for immediate effectiveness on January 28, 2019) *and* SR–NYSEArca–2019–03 (filed for immediate effectiveness on January 28, 2019).

[11] *See* Nasdaq Rule 4703(e) (Nasdaq's ''Minimum Quantity Order'' may not be displayed and will be rejected if it includes an instruction to route) and IEX Rule 11.190(b)(11)(A) (IEX's ''Minimum Quantity Order'' or ''MQTY'' is a non-displayed, non-routable order'').

individual order(s) in the Exchange Book that each meets such order's MTS. The Exchange proposes to remove this restriction from Rule 7.31E(i)(3)(B)(ii).

* * * * *

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. The Exchange anticipates that the implementation date will be in the second quarter of 2019.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[12] in general, and furthers the objectives of Section 6(b)(5),[13] in particular, because 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.

The Exchange believes that the proposal to expand the availability of the Exchange's existing MTS Modifier to an additional non-displayed, non-routable order, *e.g.,* Non-Displayed Limit Orders, would 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, because the proposed rule change is based on similar minimum trade size functionality on Nasdaq and IEX, which both similarly make minimum trade size functionality available to non-displayed, non-routable orders.[14]

The Exchange also believes that the proposal to allow ETP Holder to elect that Limit IOC Orders with an MTS Modifier trade on arrival against contra-side orders in the Exchange Book that individually meet such order's MTS would 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, because the proposed rule change would provide ETP Holders greater control over the execution of their Limit IOC Orders. The Exchange did not previously support functionality that permitted Limit IOC Orders with an MTS Modifier to trade against individual orders that each meet such order's MTS. The Exchange has since made the necessary technology changes and, therefore, proposes to remove this restriction from Rule 7.31E(i)(3)(B)(ii) as it is no longer necessary. Furthermore, the Exchange's affiliates, NYSE and NYSE Arca recently filed proposed rule changes with the Commission to modify their respective MTS Modifiers to align with that of NYSE American and allow orders with an MTS Modifier to execute against individual orders that each meet the incoming order's MTS and the NYSE and NYSE Arca proposals did not include a similar restriction on Limit IOC Orders.[15] The Exchange notes that similar minimum trade size functionality on Nasdaq and IEX does not prohibit Limit IOC Orders with an MTS Modifier from being able to execute only against individual orders that meet the order's MTS.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change is designed to increase competition by making available on the Exchange functionality that is already available on Nasdaq and IEX. The Exchange also believes that the proposed rule change would promote competition by providing market participants with an additional venue to which to route non-displayed, non-routable orders with an MTS Modifier.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[18]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[19] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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–NYSEAMER–2019–01 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–NYSEAMER–2019–01. 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

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 11.

[15] *See supra* note 10.

[16] 15 U.S.C. 78s(b)(3)(A)(iii).

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 15 U.S.C. 78s(b)(2)(B).

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–NYSEAMER–2019–01 and should be submitted on or before March 19, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03218 Filed 2–25–19; 8:45 am]

BILLING CODE 8011–01–P

[20] 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 April 29, 2019.

ADDRESSES: Send all comments to Joseph Eitel, Director, Office of Personnel Security, Small Business Administration, 721 19th Street, Room 392, Denver, CO 80202.

FOR FURTHER INFORMATION CONTACT: Joseph Eitel, Director, Office of Personnel Security, *joseph.eitel@sba.gov*, 303–844–7750, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Small Business Administration SBA Form 912 is used to collect information needed to make character determinations with respect to applicants for monetary loan assistance or applicants for participation in SBA programs. The information collected is used as the basis for conducting name checks at national Federal Bureau of Investigation (FBI) and local levels.

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: Statement of Personal History.

Description of Respondents: Applicants participating in SBA programs.

Form Number: SBA Form 912.

Total Estimated Annual Responses: 142,000.

Total Estimated Annual Hour Burden: 35,500.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–03230 Filed 2–25–19; 8:45 am]

BILLING CODE 8025–01–P

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 April 29, 2019.

ADDRESSES: Send all comments to Jermanne Perry, Management Analyst, Office of Surety Guarantee, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Jermanne Perry, Management Analyst, Office of Surety Guarantee, *Jermanne.perry@sba.gov* 202–401–8275, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Small Business Administration (SBA) Surety Bond Guarantee Program was created to encourage surety companies to provide bonding for small contractors. The information collected on this form from small businesses and surety companies will be used to evaluate the eligibility of applicants for contracts up to $250,000.

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: Quick Bond Guarantee Application and Agreement.

Description of Respondents: Surety Companies.

Form Number: SBA Form 990A.

Total Estimated Annual Responses: 21,046.

Total Estimated Annual Hour Burden: 3,065.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–03229 Filed 2–25–19; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2019–0005]

Agreement on Social Security Between the United States and Iceland; Entry Into Force

AGENCY: Social Security Administration.

ACTION: Notice.

SUMMARY: We are giving notice that an agreement coordinating the United States (U.S.) and Icelandic social security programs will go into force effective on March 1, 2019. The

Agreement with Iceland, which was signed on September 27, 2016, is similar to U.S. social security agreements already in force with 29 other countries—Australia, Austria, Belgium, Brazil, Canada, Chile, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Korea (South), Luxembourg, the Netherlands, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the United Kingdom, and Uruguay. Section 233 of the Social Security Act authorizes agreements of this type.

SUPPLEMENTARY INFORMATION: Like the other agreements, the U.S.-Icelandic Agreement eliminates dual social security coverage. This situation exists when a worker from one country works in the other country and has coverage under the social security systems of both countries for the same work. Without such agreements in force, when dual coverage occurs, the worker, the worker's employer, or both may be required to pay social security contributions to the two countries simultaneously. Under the U.S.-Icelandic Agreement, a worker who is sent by an employer in one country to work in the other country for 5 or fewer years remains covered only by the sending country. The Agreement includes additional rules that eliminate dual U.S. and Icelandic coverage in other work situations.

The Agreement also helps eliminate situations where workers suffer a loss of benefit rights because they have divided their careers between the two countries. Under the Agreement, workers may qualify for partial U.S. benefits or partial Icelandic benefits based on combined (totalized) work credits from both countries.

Persons who wish to receive copies of the Agreement or who want more information about its provisions may write to the Social Security Administration, Office of Data Exchange, Policy Publications, and International Negotiations, 4700 Annex Building, 6401 Security Boulevard, Baltimore, MD 21235, or visit the Social Security website at *www.socialsecurity.gov/international.* The full text of the Agreement and its accompanying Administrative Arrangement are available at *https://www.ssa.gov/international/Agreement_Texts/iceland.html.*

Nancy A. Berryhill,

Acting Commissioner of Social Security.

[FR Doc. 2019–03271 Filed 2–25–19; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 10673]

30-Day Notice of Proposed Information Collection: Local U.S. Citizen Skills/Resources Survey

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to March 28, 2019.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), U.S. Department of State, 2201 C St. NW, Washington, DC 20522, who may be reached at *RiversDA@state.gov* and 202–485–6332.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Local U.S. Citizen Skills/Resources Survey.
- *OMB Control Number:* OMB No. 1405–0188.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS–5506.
- *Respondents:* United States Citizens.
- *Estimated Number of Respondents:* 2,400.
- *Estimated Number of Responses:* 2,400.
- *Average Time per Response:* 15 minutes.
- *Total Estimated Burden Time:* 600 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Local U.S. Citizen Skills/Resources Survey is a systematic method of gathering information about skills and resources from U.S. citizens that will assist in improving the well-being of other U.S. citizens affected or potentially affected by a crisis.

Methodology

This information collection can be completed by the respondent electronically or manually. The information will be collected on-site at a U.S. Embassy/Consulate, by mail, fax, or email.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Department of State.

[FR Doc. 2019–03274 Filed 2–25–19; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 10672]

30-Day Notice of Proposed Information Collection: Request for Entry Into Children's Passport Issuance Alert Program

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection

described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to March 28, 2019.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), U.S. Department of State, 2201 C. St. NW, Washington, DC 20522, who may be reached at mailto: *RiversDA@state.gov* and 202–485–6332.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Request for Entry into Children's Passport Issuance Alert Program.
- *OMB Control Number:* 1405–0169.
- *Type of Request:* Revision of a previously approved information collection.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS–3077.
- *Respondents:* Concerned parents or their agents, institutions, or courts.
- *Estimated Number of Respondents:* 4,000.
- *Estimated Number of Responses:* 4,000.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 2,000 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The information requested will be used to support entry of the name of a minor (an unmarried, unemancipated person under 18 years of age) into the Children's Passport Issuance Alert Program (CPIAP). CPIAP provides a mechanism for parents or other persons with legal custody of a minor to obtain information regarding whether the Department has received a passport application for the minor. This program was developed as a means to prevent international parental child abduction and to help prevent other travel of a minor without the consent of a parent or legal guardian. If a minor's name and other identifying information has been entered into the CPIAP, when the Department receives an application for a new, replacement, or renewed passport for the minor, the application may be placed on hold for up to 90 days and the Office of Children's Issues may attempt to notify the requestor of receipt of the application. Form DS–3077 will be primarily submitted by a parent or legal guardian of a minor. This collection is authorized by 22 CFR 51.28, which is the regulation that implements the statutory two-parent consent requirement and prescribes the bases for an exception to the requirement.

Methodology

The completed Form DS–3077 can be filled out online and printed or completed by hand. The form must be manually signed and submitted to the Office of Children's Issues by email, fax or mail with supporting documentation.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Department of State.

[FR Doc. 2019–03272 Filed 2–25–19; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Air Carrier Contract Maintenance Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on December 20, 2018. The information to be collected is necessary because the FAA needs accurate and up to date data indicating who is performing maintenance on behalf of air carriers, what type of maintenance is being performed, and where the maintenance is being performed. This collected information will be used by the FAA to adequately target its inspection resources for surveillance and make accurate risk assessments.

DATES: Written comments should be submitted by March 28, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Hall at (940) 594–5913, or by email at: *Barbara.L.Hall@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0766.

Title: Air Carrier Contract Maintenance Requirements.

Form Numbers: There are no forms associated with this collection.

Type of Review: This is a renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on December 20, 2018 (83 FR 65391). Air carrier maintenance has evolved from mostly an ''in-house'' operation to an extended network of maintenance providers that fulfill contracts with air carriers to perform their aircraft maintenance. Any person performing maintenance for an air carrier must follow the air carrier's maintenance manual.

The FAA has found that, although an air carrier is required to list its maintenance providers and a general description of the work to be done in its maintenance manual, these lists are not always kept up to date, are not always complete, and are not always in a format that is readily useful for FAA oversight and analysis purposes. Without accurate and complete information on the work being performed for air carriers, the FAA cannot adequately target its inspection resources for surveillance and make accurate risk assessments.

This collection of information supports regulatory requirements necessary under 14 CFR part 121 and part 135 to ensure safety of flight by requiring air carriers to provide a list to the FAA of all persons with whom they contract their maintenance. The list must be updated with any changes, including additions or deletions, and the updated list provided to the FAA in a format acceptable to the FAA by the last day of each calendar month.

This collection also supports the FAA's strategic goal to provide to the next level of safety, by achieving the lowest possible accident rate and always improving safety, so all users of our aviation system can arrive safely at their destinations.

Respondents: 312 air carriers (110 large air carriers and 202 small air carriers).

Frequency: Monthly.

Estimated Average Burden per Response: 6 hours.

Estimated Total Annual Burden: 22,464 hours.

Barbara Hall,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2019–03228 Filed 2–25–19; 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 that are final. The actions relate to a proposed highway project on State Route 91 (Post Miles 16.9–19.8) and on Interstate 605 (Post Miles 5.0–5.8) in the Cities of Cerritos and Artesia, in the County of Los Angeles, 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 subject to 23 U.S.C. 139(*l*)(1). 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 July 26, 2019. 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: Jinous Saleh, Senior Environmental Planner, Caltrans District 7, 100 South Main Street, Suite MS 16A, Los Angeles, California, 90012, (213) 897–0683, *Jinous.Saleh@dot.ca.gov.* For FHWA, Larry Vinzant at (916) 498–5040 or email *larry.vinzant@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans and the FHWA have taken final agency actions subject to U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The Westbound State Route 91 Improvement Project will widen and improve approximately 4 miles (mi) of freeway along westbound State Route 91 (SR–91) between approximately Shoemaker Avenue and the Interstate 605 (I–605) interchange, and at the I–605 northbound exit to Alondra Boulevard. Caltrans approved the construction of the Build Alternative with Design Option 1 (Reduced Lane/Shoulder Width) and Design Option 3 (Pioneer Boulevard Westbound Ramps/168th Alignment). Also, as part of the project, the Gridley Road Overcrossing will be improved to a two-lane road with standard shoulders and sidewalks on both sides. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment/Finding of No Significant Impact (EA/FONSI) for the project, approved on January 17, 2019, and in other documents in Caltrans project records. The EA/FONSI and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans EA/FONSI can be viewed and downloaded from the project website at *http://www.dot.ca.gov/d7/env-docs/.*

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. General: National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4351)
2. Clean Air Act (42 U.S.C. 7401–7671(q))
3. Migratory Bird Treaty Act (16 U.S.C. 703–712)
4. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470(f) *et seq.*)
5. Clean Water Act (Section 401) (33 U.S.C. 1251–1377)
6. Federal Endangered Species Act of 1973 (16 U.S.C. 1531–1543)
7. Executive Order 11990—Protection of Wetlands
8. Department of Transportation Act of 1966, Section 4(f) (49 U.S.C. 303)
9. Executive Order 13112—Invasive Species

(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).

Tashia J. Clemons,

Director, Planning and Environment, Federal Highway Administration, Sacramento, California.

[FR Doc. 2019–03250 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2009–0078]

Petition for Waiver of Compliance

Under part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that on January 31, 2019, the American Short Line and Regional Railroad Association (ASLRRA) petitioned the Federal Railroad Administration (FRA) for an amended waiver of compliance from certain provisions of the Federal hours of service laws contained at 49 U.S.C. 21103(a)(4), which, in part, require a train employee to receive 48 hours off duty after initiating an on-duty period for 6 consecutive days. FRA assigned the petition Docket Number FRA–2009–0078.

Specifically, ASLRRA seeks to amend its existing waiver to add seven member railroads that did not participate in the original waiver, but in the fourth quarter of 2018 determined that they now wish to participate. ASLRRA states the following railroads expressed a desire to participate in the waiver, and maintain at their headquarters supporting documentation of employee support as required:

- Camp Chase Railway, LLC
- Chesapeake and Indiana Railroad Company
- D&I Railroad
- Foster Townsend Rail Logistics (FTRL)
- San Pedro Valley Railroad
- Vermillion Valley Railroad Co, Inc.
- Youngstown & Southeastern Railroad Company, Inc.

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 April 12, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2019–03244 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0013]

Petition for Waiver of Compliance

Under part 211 of Title 49 of the Code of Federal Regulations (CFR), this document provides the public notice that by a document dated January 25, 2019, the Logansport and Eel River Railroad Short Line, Inc. (LERR) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 234. FRA assigned the petition Docket Number FRA–2019–0013.

Specifically, LERR seeks relief from the Emergency Notification System regulations in 49 CFR part 234, subpart E, *Requirements for Emergency Notification for Telephonic Reporting of Unsafe Condition at Highway-Rail and Pathway Grade Crossings.* LERR explains that the trackage involved is currently out of service and that they are in the process of selling the trackage to the Indiana Transportation Museum.

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 Department of Transportation's Docket Operations Facility, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 12, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to 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.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2019–03245 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Department of Transportation Advisory Committee on Human Trafficking; Notice of Public Meeting

AGENCY: Office of the Secretary of Transportation, Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the Department of Transportation Advisory Committee on Human Trafficking.

DATES: The meeting will be held on March 12, 2019, from 10:00 a.m. to 4:30 p.m. EDT.

ADDRESSES: The meeting will be held at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Individuals wishing for audio participation, and any person requiring accessibility accommodations, should contact the Official listed in the next section.

FOR FURTHER INFORMATION CONTACT: Nicole L. Bambas, Senior Advisor, Office of International Transportation and Trade, U.S. Department of Transportation, at *trafficking@dot.gov* or (202) 366–5058. Also visit the ACHT internet website at *https://www.transportation.gov/stophumantrafficking/acht.*

SUPPLEMENTARY INFORMATION:

I. Background

The Advisory Committee on Human Trafficking (ACHT) was created in accordance with Section 5 of the *Combating Human Trafficking in Commercial Vehicles Act* (Pub. L. 115–99) to make recommendations to the Secretary of Transportation on actions the Department can take to help combat human trafficking, and to develop recommended best practices for States and State and local transportation stakeholders in combatting human trafficking.

II. Agenda

At the March 12, 2019, meeting, the agenda will cover the following topics:

- Welcome
- Subcommittee Reports
- Discussion and Deliberation
- Public Participation
- Next Steps and Closing

A final agenda will be posted on the ACHT internet website at *https://www.transportation.gov/stophumantrafficking/acht* at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public on a first-come, first served basis, as space is limited. Members of the public who wish to attend in-person are asked to register via email by submitting their name and affiliation to *trafficking@dot.gov* by February 26, 2019. Individuals requesting accessibility accommodations, such as sign language, interpretation, or other ancillary aids, may do so by submitting their request via email to *trafficking@dot.gov* by February 26, 2019.

There will be 30 minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for each commenter may be limited. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name, address, and organizational affiliation of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the Office of the Secretary may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EST on February 26, 2019, for inclusion in the meeting records and for circulation to ACHT members. All prepared remarks submitted on time will be accepted and considered as part of the record.

Persons who wish to submit written comments for consideration by ACHT during the meeting must submit them no later than 5:00 p.m. EST on February 26, 2019, to ensure transmission to ACHT members prior to the meeting. Comments received after that date and time will be distributed to the members but may not be reviewed prior to the meeting.

Copies of the meeting minutes will be available on the ACHT internet website at *https://www.transportation.gov/stophumantrafficking/acht.*

* * * * *

Dated: February 8, 2019.

Joel Szabat,

Assistant Secretary, Office for Aviation and International Affairs.

[FR Doc. 2019–03280 Filed 2–25–19; 8:45 am]

BILLING CODE 4910–9x–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On February 20, 2019, OFAC determined that the property and

interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. HAKIMZADA, Jasmeet (a.k.a. SINGH, Jasmeet), Flat 17, 2nd FL Atlas Tower, Jamal Abdud Nasir Rd., Sharjah, United Arab Emirates; DOB 26 Jun 1979; nationality India; Gender Male; Passport Z2030393 (India) (individual) [SDNTK]. Identified as a significant foreign narcotics trafficker pursuant to section 805(b)(1) of the Foreign Narcotics Kingpin Designation Act, 21 U.S.C. 1904(b)(1) (Kingpin Act).

2. HAKIMZADA, Harmohan Singh (a.k.a. SING, Har Mohan), Flat 17, 2nd FL Atlas Tower, Jamal Abdud Nasir Rd., Sharjah, United Arab Emirates; DOB 23 Jun 1953; nationality India; Gender Male; Passport 1850327 (India); alt. Passport Z1432933 (India) (individual) [SDNTK] (Linked To: HAKIMZADA, Jasmeet) Designated pursuant to section 805(b)(2) of the Kingpin Act, for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act; also designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of, Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act.

3. KAUR, Eljeet (a.k.a. HAKIMZADA KAUR, Eljeet), Flat 17, 2nd FL Atlas Tower, Jamal Abdud Nasir Rd., Sharjah, United Arab Emirates; DOB 03 May 1959; nationality India; Gender Female; Passport Z2525822 (India) (individual) [SDNTK] (Linked To: HAKIMZADA, Jasmeet). Designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of, Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act, and Harmohan HAKIMZADA, a foreign person designated by the Secretary of the Treasury pursuant to the Kingpin Act.

Entities

1. MAIWAND GENERAL TRADING CO LLC, API Building, 2nd Floor, Suite 202, Deira, Dubai, United Arab Emirates; Business Registration Number 229172 (United Arab Emirates) [SDNTK] (Linked To: HAKIMZADA, Jasmeet; Linked To: HAKIMZADA, Harmohan). Designated pursuant to section 805(b)(2) of the Kingpin Act for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of the Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act, and Harmohan HAKIMZADA, a foreign person designated by the Secretary of the Treasury pursuant to the Kingpin Act; also designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of, Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Foreign Narcotics Kingpin Designation Act, and Harmohan HAKIMZADA, a foreign person designated by the Secretary of the Treasury pursuant to the Foreign Narcotics Kingpin Designation Act.

2. MAIWAND EXIM PRIVATE LIMITED, F–1129, Chitranjan Park, New Delhi 110019, India; Company Number U51909DL2006PTC14620 (India); alt. Company Number U51909DL2006PTC146202 (India) [SDNTK] (Linked To: HAKIMZADA, Jasmeet; Linked To: HAKIMZADA, Harmohan). Designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act, and Harmohan HAKIMZADA, a foreign person designated by the Secretary of the Treasury pursuant to the Kingpin Act.

3. MAIWAND TOBACCO LIMITED, E–70 1st Floor Greater Kailash Part II, New Delhi 110048, India; Company Number Ul6003DL2005PLC140650 (India); alt. Company Number U16003DL200PLC140650 (India) [SDNTK] (Linked To: HAKIMZADA, Jasmeet; Linked To: HAKIMZADA, Harmohan). Designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act, and Harmohan HAKIMZADA, a foreign person designated by the Secretary of the Treasury pursuant to the Kingpin Act.

4. MAIWAND BEVERAGES LIMITED, S–439, Greater Kailash Part II, New Delhi 110048, India; Company Number U51900DL2012PLC23061 (India); alt. Company Number U51900DL2012PLC230619 (India) [SDNTK] (Linked To: HAKIMZADA, Jasmeet; Linked To: HAKIMZADA, Harmohan). Designated pursuant to section 805(b)(3) of the Kingpin Act for being owned, controlled, or directed by, or acting for or on behalf of Jasmeet HAKIMZADA, a significant foreign narcotics trafficker designated by the Secretary of the Treasury pursuant to the Kingpin Act, and Harmohan HAKIMZADA, a foreign person designated by the Secretary of the Treasury pursuant to the Kingpin Act.

Dated: February 20, 2019.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–03314 Filed 2–25–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Information Collection; Comment Request

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.

DATES: Written comments should be received on or before April 29, 2019 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. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: To obtain additional information, or copies of the information collection and instructions, or copies of any comments received, contact LaNita Van Dyke, at (202) 317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments will become a matter of public record. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether the collection of information is necessary for the proper performance of the agency's functions, including whether the information has 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 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 the requested information.

Currently, the IRS is seeking comments concerning the following form, and reporting and record-keeping requirements:

1. *Title:* Notification of Distribution From a Generation-Skipping Trust.

OMB Number: 1545–1143.

Form Number: 706–GS(D–1).

Abstract: Form 706–GS(D–1) is used by trustees to provide information to the IRS and to distributees regarding generation-skipping distributions from trusts. The information is needed by distributees to compute the generation-skipping tax imposed by Internal Revenue Code section 2601. The IRS uses the information to verify that the tax has been properly computed.

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: 80,000.

Estimated Time per Respondent: 4 hours, 22 minutes.

Estimated Total Annual Burden Hours: 348,800.

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 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.

Approved: February 19, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03216 Filed 2–25–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8582–CR

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. Currently, the IRS is soliciting comments concerning Form 8582–CR, Passive Activity Credit Limitations.

DATES: Written comments should be received on or before April 29, 2019. 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 LaNita Van Dyke, at (202)317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Passive Activity Credit Limitations.

OMB Number: 1545–1034.

Form Number: 8582–CR.

Abstract: Under Internal Revenue Code section 469, credits from passive activities, to the extent they do not exceed the tax attributable to net passive income, are not allowed, Form 8582–CR is used to figure the passive activity credit allowed and the amount of credit to be reported on the tax return.

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, business or other for-profit organizations, and farms.

Estimated Number of Respondents: 300,000.

Estimated Time per Respondent: 7 hr., 53 min.

Estimated Total Annual Burden Hours: 2,370,600.

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: February 19, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03219 Filed 2–25–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection: Comment Request for Form 4669

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. Currently, the IRS is soliciting comments concerning Form 4669, Statement of Payments Received.

DATES: Written comments should be received on or before April 29, 2019. 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 LaNita Van Dyke, at (202) 317–6009 at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Statement of Payments Received.

OMB Number: 1545–0364.

Form Number: 4669.

Abstract: Form 4669 is used by payors in specific situations to request relief from payment of certain required taxes. A payor who fails to withhold certain required taxes from a payee may be entitled to relief, under sections 3402(d), 3102(f)(3), 1463 or Regulations section 1.1474–4. To apply for relief, a payor must show that the payee reported the payments and paid the corresponding tax. To secure relief as described above, a payor must obtain a separate, completed Form 4669 from each payee for each year relief is requested.

Current Actions There are no changes being made to the Omnibus Survey at this time.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 85,000.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 21,250.

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: February 19, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03220 Filed 2–25–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for TD 8656

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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning final regulation TD 8656, Imposition of the Accuracy-Related Penalty.

DATES: Written comments should be received on or before April 29, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to L. 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 Sara Covington, (202) 317–6038, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *sara.l.covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Section 6662—Imposition of the Accuracy-Related Penalty.

OMB Number: 1545–1426.

Regulation Project Number: TD 8656.

Abstract: These regulations provide guidance on the accuracy-related penalty imposed on underpayments of tax caused by substantial and gross valuation misstatements as defined in Internal Revenue Code sections 6662(e) and 6662(h). Under section 1.6662–6(d) of the regulations, an amount is excluded from the penalty if certain requirements are met and a taxpayer maintains documentation of how a transfer price was determined for a transaction subject to Code section 482.

Current Actions: There is no changes in the paperwork burden previously approved by OMB.

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: 8 hours, 3 minutes.

Estimated Total Annual Burden Hours: 20,125.

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: February 20, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03213 Filed 2–25–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 5306

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. Currently, the IRS is soliciting comments concerning Form 5306, Application for Approval of Prototype or Employer Sponsored Individual Retirement Account.

DATES: Written comments should be received on or before April 29, 2019] 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 LaNita Van Dyke, at (202) 317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Approval of Prototype or Employer Sponsored Individual Retirement Account (IRA).

OMB Number: 1545–0390.

Form Number: 5306.

Abstract: This application is used by employers who want to establish an individual retirement account trust to be used by their employees. The application is also used by banks and insurance companies that want to establish approved prototype individual retirement accounts or annuities. The data collected is used to determine if the individual retirement account trust or annuity contract meets the requirements of Code section 408(a), 408(b), or 408(c) so that the IRS may issue an approval letter.

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: Business or other for-profit organizations.

Estimated Number of Respondents: 600.

Estimated Time Per Respondent: 13 hr., 45 min.

Estimated Total Annual Burden Hours: 8,244.

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: February 19, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03222 Filed 2–25–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Ruling 2000–35

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. Currently, the IRS is soliciting comments concerning Revenue Ruling 2000–35, Automatic Enrollment in Section 403(b) Plans.

DATES: Written comments should be received on or before April 29, 2019 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 LaNita Van Dyke, at (202) 317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Automatic Enrollment in Section 403(b) Plans.

OMB Number: 1545–1694.

Form Number: Revenue Ruling 2000–35.

Abstract: Revenue Ruling 2000–35 describes certain criteria that must be met before an employee's compensation can be reduced and contributed to an employee's section 403(b) plan in the absence of an affirmative election by the employee.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Not-for-profit institutions, and state, local or tribal governments.

Estimated Number of Respondents: 200.

Estimated Time per Respondent: 53 minutes.

Estimated Total Annual Burden Hours: 175.

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: February 20, 2019

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03214 Filed 2–25–19; 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 taxable distributions received from cooperatives.

DATES: Written comments should be received on or before April 29, 2019 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: Taxable Distributions Received From Cooperatives.

OMB Number: 1545–0118.

Form Number: 1099–PATR.

Abstract: Form 1099–PATR is used to report patronage dividends paid by cooperatives in accordance with Internal Revenue Code section 6044. The information is used by IRS to verify reporting compliance on the part of the recipient.

Current Actions: There have been no changes to the form that would affect burden. However, the agency has updated the estimated number of responses based on its most recent filing data.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,820,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 455,000.

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: February 20, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03221 Filed 2–25–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 706–GS(T)

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 Generation-Skipping Transfer Tax Return For Terminations.

DATES: Written comments should be received on or before April 29, 2019 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 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: Generation-Skipping Transfer Tax Return For Terminations.

OMB Number: 1545–1145.

Form Number: 706–GS(T).

Abstract: Form 706–GS(T) is used by trustees to compute and report the tax due on generation-skipping transfers

that result from the termination of interests in a trust. The IRS uses the information to verify that the tax has been properly computed.

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: 500.

Estimated Number of Responses: 1 hour, 22 minutes.

Estimated Total Annual Burden Hours: 684.

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. Comments will be 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 has 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 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: February 19, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03212 Filed 2–25–19; 8:45 am]

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 310, 347, et al.

Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 310, 347, and 352

[Docket No. FDA–1978–N–0018] (Formerly Docket No. FDA–1978–N–0038)

RIN 0910–AF43

Sunscreen Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this proposed rule to put into effect a final monograph for nonprescription, over-the-counter (OTC) sunscreen drug products. This proposed rule describes the conditions under which FDA proposes that OTC sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded. It is being published as part of the ongoing review of OTC drug products conducted by FDA. It is also being published to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Sunscreen Innovation Act (SIA).

DATES: Submit either electronic or written comments. on the proposed rule by May 28, 2019. Electronic comments must be submitted on or before May 28, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 28, 2019. See section XII for proposed effective and compliance dates of a final rule based on this document.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. 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 the closing date.

Please be advised that safety and effectiveness data that are not available to the public cannot be relied on to establish conditions under which the OTC drugs described in this document of proposed rulemaking are generally recognized as safe and effective. Accordingly, you should not submit, and FDA generally does not intend to rely on, any evidence of safety and effectiveness that bears a confidential mark unless you include a statement that the information may be released to the public. Similarly, if your submission includes safety and effectiveness data or information marked as confidential by a third party (such as a contract research organization or consultant), you should either include a statement that you are authorized to make the information publicly available or include an authorization from the third party permitting the information to be publicly disclosed. If you submit data without confidential markings in response to this document and such data includes studies or other information that were previously submitted confidentially (*e.g.,* as part of a new drug application), FDA intends to presume that you intend to make such data publicly available.

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–1978–N–0018 (formerly Docket No. FDA–1978–N–0038) for ''Sunscreen Drug Products for Over-the-Counter Human Use.'' 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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) in the following ways:

• Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with

the title, ''Sunscreen Drug Products for Over-the-Counter Human Use.''

The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket No. FDA–1978–N–0018), along with their comments on other parts of the proposed rule.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993, 240–402–4246.

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I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

The Food and Drug Administration (FDA or Agency) is publishing this proposed rule as part of the regulatory proceeding to put into effect a final monograph [1] for nonprescription, OTC sunscreen drug products under the OTC Drug Review. In 2011, FDA announced that ''we are considering certain active ingredient safety issues further . . . In a forthcoming rulemaking, we intend to request additional data regarding the safety of the individual sunscreen active ingredients.'' (''Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use'' (Max SPF PR), 76 FR 35672 at 35673, June 17, 2011). As described in further detail below, changed conditions in the nearly 20 years since publication of the final rule ''Sunscreen Drug Products for Over the Counter Human Use'' (64 FR 27666, May 21, 1999) (now stayed) (Stayed 1999 Final Monograph) have meant that additional safety data are now needed to establish that certain of the active ingredients listed in the Stayed 1999 Final Monograph are GRASE for use in sunscreen products.[2]

As detailed below, we emphasize that this proposed rule does not represent a conclusion by FDA that the sunscreen active ingredients included in the Stayed 1999 Final Monograph but proposed here as Category III are unsafe for use in sunscreens. Rather, we are requesting additional information on these ingredients so that we can evaluate their GRASE status in light of changed conditions, including substantially increased sunscreen usage and exposure and evolving information about the potential risks associated with these products since they were originally evaluated. While these additional data are being developed and reviewed, FDA generally intends to follow the enforcement approach discussed in section III.B with regard to sunscreen products that contain those sunscreen active ingredients included in the Stayed 1999 Final Monograph.

This proposed rule is also being published to comply with section 586E of the FD&C Act (21 U.S.C. 360fff–5), as amended by the SIA (21 U.S.C. ch. 9, sub. 5, part I, enacted November 26, 2014). The SIA calls for FDA to issue a final OTC sunscreen monograph to be effective within 5 years of enactment of the SIA, or by November 26, 2019 (section 586E(a) of the FD&C Act). If the final OTC sunscreen monograph does not include provisions related to the effectiveness of various sun protection factor (SPF) levels and address all dosage forms known to FDA to be used in sunscreens marketed in the United States without approved new drug applications (NDAs), the SIA requires FDA, among other things, to submit a report to Congress explaining these omissions (section 586E(b) of the FD&C Act). As explained in section I.B, in this proposed rule, FDA is addressing multiple conditions of use applicable to sunscreen monograph products, including both the effectiveness of various SPF values and all marketed sunscreen dosage forms (and intends to do so in the final rule as well).

This proposed rule does not address the sunscreen active ingredients that were originally submitted under the procedures established in FDA's time and extent application (TEA) regulation (§ 330.14 (21 CFR 330.14)) (67 FR 3074, January 23, 2002), and are now being addressed through a process set forth in the SIA.

B. Summary of the Major Provisions of the Proposed Rule

1. Proposed GRASE Status of Active Ingredients Listed in the Stayed 1999 Final Monograph

a. Framework for evaluation of safety data. As previously noted, changed conditions in the time since issuance of the Stayed 1999 Final Monograph have meant that additional safety data are now needed to establish that certain of the active ingredients listed in the Stayed 1999 Final Monograph are GRASE for use in sunscreen products in accordance with the standards established in § 330.10(a)(4) (21 CFR

[1] An OTC monograph establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are generally recognized as safe and effective (GRASE) and not misbranded. The proposed rule classifies active ingredients and other conditions as Category I (proposed to be GRASE and not misbranded), Category II (proposed to be not GRASE or to be misbranded), or Category III (additional data needed).

[2] Unless otherwise noted, references in this proposed rule to sunscreen active ingredients and/or sunscreen products are to sunscreen active ingredients or products marketed pursuant to the OTC monograph system and subject to 21 CFR 201.327. Unless specifically noted, references to sunscreen active ingredients and/or sunscreen products in this notice do not refer to those marketed pursuant to a new drug application (NDA) or an abbreviated new drug application (ANDA). They also do not refer to sunscreen active ingredients being evaluated under the new procedures set out in the SIA (21 U.S.C. 360fff *et seq*).

330.10(a)(4)). FDA's approach to the clinical safety evaluation of OTC sunscreen active ingredients is based on our current scientific understanding regarding the safety evaluation of topical drug products for chronic use, and is therefore generally consistent with the safety data needed to meet the requirements for approval of an NDA for a chronic-use topical drug product (*e.g.,* topical safety studies (irritation, sensitization, and photosafety); bioavailability (absorption); and evaluation of adverse events observed in clinical studies). Postmarketing safety information is also relevant to our safety evaluation.

Our current approach to the nonclinical safety evaluation of these active ingredients takes into account their lengthy marketing history in the United States. Unlike the nonclinical data required to meet the standard for approval of chronic-use topical NDA products (which include comprehensive nonclinical pharmacology and toxicology safety testing), the approach to nonclinical safety testing reflected in this proposed rule is largely focused on potential long-term adverse effects or effects not otherwise readily detected from human use (*i.e.,* carcinogenicity and reproductive toxicity).

b. Existing safety data for ingredients listed in Stayed 1999 Final Monograph. In section VIII, we discuss our review of the scientific literature, submissions to the sunscreen monograph docket, and adverse event reports submitted to FDA's Adverse Event Reporting System (FAERS) for the ingredients listed in the Stayed 1999 Final Monograph and identify any existing gaps. Because our review of this evidence has produced sufficient safety data on both zinc oxide and titanium dioxide to support a proposal that sunscreen products containing these ingredients (at concentrations of up to 25 percent) would be GRASE, we are proposing that these ingredients are Category I. Our evaluation of the available safety data for aminobenzoic acid (PABA) and trolamine salicylate, however, has caused us to conclude that the risks associated with use of these active ingredients in sunscreen products outweigh their benefits. In the case of trolamine salicylate, these risks include the potential for serious detrimental health effects (including bleeding) caused by the anti-coagulation effects of salicylic acid and increased risk of salicylate toxicity when this ingredient is used in sunscreens. For PABA, the risks include significant rates of allergic and photoallergic skin reactions, as well as cross-sensitization with structurally similar compounds. Accordingly, we are proposing that these two ingredients are Category II.

Because the public record does not currently contain sufficient data to support positive GRASE determinations for cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, or avobenzone, we are proposing that these ingredients are Category III. For example, the available literature includes studies indicating that oxybenzone is absorbed through the skin to a greater extent than previously understood and can lead to significant systemic exposure, as well as data showing the presence of oxybenzone in human breast milk, amniotic fluid, urine, and blood plasma. The significant systemic availability of oxybenzone, coupled with a lack of data evaluating the full extent of its absorption potential, is a concern, among other reasons, because of questions raised in the published literature regarding the potential for endocrine activity in connection with systemic oxybenzone exposure. Nearly all of these sunscreen active ingredients also have limited or no data characterizing their absorption.

2. Proposed Requirements Related to Dosage Forms

In 2011, FDA published an Advance Notice of Proposed Rulemaking (ANPR) that identified sunscreen dosage forms considered either eligible or ineligible for inclusion in the sunscreen monograph, and specifically requested comments on the safety and efficacy of spray sunscreens. After considering comments received in response (and other available data), we are proposing the following dosage forms as Category I: Oils, lotions, creams, gels, butters, pastes, ointments, and sticks. We are also proposing Category I status for spray sunscreens, subject to testing necessary to minimize potential risks from unintended inhalation (particle size restrictions) and flammability (flammability and drying time testing), together with related labeling requirements. We are proposing to add sunscreen powders to the list of those eligible for inclusion in the monograph and proposing that this dosage form is Category III; we expect that powders would also be subject to particle size restrictions if found to be GRASE in the final monograph. Finally, we are proposing that sunscreens in all other dosage forms—including wipes, towelettes, body washes, and shampoos—are new drugs because we did not receive data showing that they were marketed prior to 1972, as required for inclusion in the monograph.

3. Proposed Maximum Sun Protection Factor and Broad Spectrum Requirements

In the Stayed 1999 Final Monograph, FDA established SPF 30+ as the maximum labeled SPF value for sunscreen monograph products, and subsequently proposed (in 2011) to raise this value to SPF 50+. Because of evidence showing additional meaningful clinical benefit associated with broad spectrum sunscreen products with an SPF of 60, we are now proposing to raise the maximum labeled SPF value to SPF 60+. Given the lack of data showing that sunscreens with SPF values *above* 60 provide additional meaningful clinical benefit, we are proposing not to allow labeled SPF values higher than 60+.

While our proposed cap for SPF labeling is SPF 60+, we are proposing to permit the marketing of sunscreen products formulated with SPF values up to 80. This formulation margin is intended to provide manufacturers with formulation flexibility that we hope will: (1) Help facilitate the development of products with greater Ultraviolet A (UVA) protection and (2) more fully account for the range of variability in SPF test results (discussed further in sections IX.B.4.b–c) for sunscreen products labeled SPF 60+. We are proposing not to allow the marketing (without an approved NDA) of sunscreen products with SPF values above SPF 80.

In addition, since publication of the 2011 ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use'' (L&E Final Rule) (76 FR 35620, June 17, 2011) and Max SPF PR, the body of scientific evidence linking UVA exposure to skin cancers and other harms has grown significantly. This evidence raises concerns about the potential for inadequate UVA protection in marketed sunscreen products—particularly in high SPF sunscreen products that either do not pass the current broad spectrum test or (though they pass our current broad spectrum test) have inadequate uniformity in their UVA protection. Consumers using these products may, while successfully preventing sunburn, accumulate excessively large doses of UVA radiation—thereby exposing themselves to additional risks related to skin cancer and early skin aging.

To address these concerns, we are making a number of proposals designed to couple a greater magnitude of UVA protection to increases in SPF values. We are proposing to require that all sunscreen products with SPF values of 15 and above satisfy broad spectrum

requirements. Among other things, this proposal eliminates the potential confusion permitted by the current labeling regime, in which a higher numbered product (for example, one labeled SPF 30) may provide inferior protection against UVA radiation than a lower numbered product (for example, one labeled broad spectrum SPF 15). We are also proposing to add to the current broad spectrum test a requirement that broad spectrum products meet a UVA I/UV ratio of 0.7 or higher. Given how much of the UVA portion of the ultraviolet (UV) spectrum is composed of UVA I radiation, and given what we now know about the skin cancer risks associated with UVA exposure, ensuring that sunscreen products provide adequate protection in the UVA I portion of the spectrum is critical.[3] Because sunscreens with SPF 2 to 14 have not been demonstrated to help reduce the risk of skin cancer and early skin aging caused by the sun, whether or not they provide protection against UVA radiation as well as ultraviolet B (UVB) radiation, we are not proposing to require that they pass the revised broad spectrum test. However, we seek comment on whether these low SPF products should remain in the market.

Finally, we are proposing to require that sunscreen products with SPF values of 15 or above be labeled with an SPF number corresponding to the lowest number in a range of tested SPF results. For example, sunscreens testing at SPF 15–19 would be labeled ''SPF 15''; those testing at 40–49 would be labeled ''SPF 40.'' We are making this proposal because new evidence has caused us to reexamine the variability inherent in the SPF test (which relies on visual assessments of erythema in human subjects). The data we reviewed suggests that the clinical evaluation undertaken during SPF testing creates variability that justifies the use of SPF ranges. As explained further in sections IX.B.4.b–c, because this variability is exacerbated at high SPFs, we are proposing that sunscreens testing at SPF 30 or more be labeled in increments of 10 (*i.e.,* SPF 30, SPF 40, SPF 50, with a proposed maximum of SPF 60+), that sunscreens testing at SPF 15 to 29 be labeled in increments of 5 (*i.e.,* SPF 15, SPF 20, SPF 25), and that the requirement that labeled SPF values correspond to ranges (rather than precise numerical values) is not necessary below SPF 15.

4. Proposed PDP Labeling Requirements

We are also proposing to partially revise the current requirements for information that must appear on the principal display panel (PDP) of sunscreen products. The PDP is the part of a product label that is most likely to be viewed or examined when the product is displayed for retail sale. A major feature of the PDP is the statement of identity (SOI). We are proposing that the SOI consist of an alphabetical listing of the sunscreen active ingredients in the product, followed by ''Sunscreen'' and the product's dosage form (such as lotion or spray). This information would supplement other important elements of the PDP (*e.g.,* SPF, broad spectrum, and water resistance information) to provide a succinct summary of the product's key characteristics on the front of the package or container, permitting consumers to more readily compare products and either select or avoid a given product accordingly. For sunscreen products that have not been shown to help prevent skin cancer or early skin aging caused by the sun, the SPF statement would be followed by an asterisk (*) directing consumers to see the ''Skin Cancer/Skin Aging alert'' elsewhere on the label. Finally, to prevent required information from being obscured or overwhelmed by other labeling features, we are revising the format requirements for the SPF, broad spectrum, and water resistance statements on the PDP.

5. Proposed Requirements Related to Final Formulation Testing Processes and Recordkeeping

To ensure that FDA can assess compliance with our regulations, we are proposing to require records of required final formulation testing of sunscreen products to be maintained for 1 year after the product expiration date, or, if the product is exempt from expiration dating (as most sunscreens are), for 3 years after distribution of the last lot labeled in reliance on that testing. In addition, we are proposing to require responsible persons (defined in section IX.D.2.b) to keep records of sunscreen formulation testing, and clarifying that required records would be subject to FDA inspection. We are also proposing a number of revisions to our labeling and testing regulations designed to clarify FDA expectations about clinical final formulation testing processes and to ensure that the testing of marketed sunscreen products is conducted in a manner that both protects human subjects and produces reliable results.

6. Proposed Status of Sunscreen-Insect Repellent Combination Products

The proposed rule also addresses sunscreen-insect repellent products, which are jointly regulated by FDA as sunscreen drugs and by the Environmental Protection Agency (EPA) as pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In 2007, FDA and EPA both issued ANPRs requesting comment on the appropriate regulatory status of these products. We are proposing to classify these products as Category II because incompatibilities between FDA and EPA labeling requirements prevent these products from being labeled in a manner that sufficiently ensures safe and effective use of the sunscreen component and provides adequate directions for use. In addition, there are data suggesting that combining some sunscreen active ingredients with the insecticide DEET may increase absorption of either or both components.

7. Proposed Actions To Effectuate Lifting of Stay and Harmonize Impacted Regulations

Finally, we are proposing to lift the stay on the 1999 Final Monograph (subject to the revisions to parts 201, 310, 347, and 352 (21 CFR parts 201,[4] 310, 347, and 352) described in this document), and have proposed revisions to these regulations necessary to effectuate the lifting of the stay and to harmonize any impacted regulations.

C. Legal Authority

We are issuing this proposed rule under sections 201, 301, 501, 502, 503, 505, 510, 586E, 701, 702, 703, 704, and 721 of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360fff–5, 371, 372, 373, 374, and 379e) and under section 351 of the Public Health Service Act (42 U.S.C. 262).

D. Costs and Benefits

If finalized, the proposed rule would update and make effective regulations to ensure the safety and effectiveness of sunscreen products marketed under the OTC drug monograph. The rule would update sunscreen product labeling standards, address the safety of sunscreen active ingredients, revise and

[3] We note that because our proposal to raise the maximum labeled SPF value to 60+ is based on studies that all used broad spectrum sunscreens, the additional clinical benefit we are proposing to recognize in sunscreen products with SPF values greater than 50 cannot be decoupled from the broad spectrum protection provided by those products. As a result, our proposal to raise the maximum labeled SPF value to SPF 60+ is both consistent with and dependent upon our proposal to require that all sunscreen monograph products with SPF values of 15 and above satisfy our broad spectrum requirements.

[4] We note that, for ease of comprehension, we have included in this document the current provisions of 21 CFR 201.327 that we are not proposing to revise along with the provisions of that regulation that we are proposing to revise.

clarify our expectations for testing and recordkeeping by entities that conduct sunscreen testing, and address other sunscreen safety or efficacy concerns, like combination sunscreen-insect repellents and alternative dosage forms.

Consumers would benefit from less exposure to sunscreen products containing active ingredients about which safety questions remain, less exposure to sunscreen products labeled with potentially misleading sun protection information, increased consumption of products with better UVA protection, less exposure to flammable spray sunscreens, and less exposure to spray and powder sunscreen products posing inhalation risks. Consumers would also experience transaction cost savings. The costs of the rule to sunscreen manufacturers include administrative costs, costs to fill data gaps for active ingredients and powder dosage forms, product formulation testing costs, and costs to reformulate and relabel sunscreen products. Finally, testing entities would incur recordkeeping costs if they do not already maintain adequate records of testing equipment, methods, and observations in final formulation testing.

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

Abbreviation/acronym	What it means
ANDA	Abbreviated new drug application.
ANPR	Advance notice of proposed rulemaking.
CFR	Code of Federal Regulations.
DART	Developmental and reproductive toxicity.
DEET	N,N-Diethyl-meta-toluamide.
EPA	Environmental Protection Agency.
FAERS	FDA's Adverse Event Reporting System.
FDA or Agency	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act.
FR	Federal Register.
GRASE	Generally recognized as safe and effective (or general recognition of safety and effectiveness).
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
IND	Investigational new drug application.
IRB	Institutional Review Board.
mL	Milliliter.
MUsT	Maximal usage trial.
NDA	New drug application.
NDAC	Nonprescription Drugs Advisory Committee.
Ng	Nanogram.
Nm	Nanometer.
NOAEL	No observed adverse effect level.
NPIC	National Pesticide Information Center.
NTP	National Toxicology Program of the National Institutes of Health.
OMB	Office of Management and Budget.
OTC	Over-the-counter.
PABA	Aminobenzoic acid.
ROS	Reactive oxygen species.
SIA	Sunscreen Innovation Act.
SPF	Sun protection factor.
TEA	Time and extent application.
TFM	Tentative final monograph.
U.S.C.	United States Code.
USP	United States Pharmacopeia.
UVA	Ultraviolet A.
UVB	Ultraviolet B.

III. Background

A. FDA's Current Regulatory Framework

In the following sections, we provide a brief description of terminology used in the OTC Drug Review regulations as well as an overview of OTC sunscreen products, their intended uses, and FDA's regulation of them.

1. Terminology

a. OTC drug review. The OTC Drug Review is the process established by FDA to evaluate the safety and effectiveness of OTC drug products marketed in the United States before May 11, 1972, and to establish the conditions under which they are considered to be GRASE and not misbranded. As described further below, the OTC Drug Review is generally conducted via a multiphase public rulemaking process (each phase requiring a **Federal Register** publication), resulting in the establishment of a monograph for an OTC therapeutic drug category.

b. Generally recognized as safe and effective (GRASE). An OTC drug is ''generally recognized as safe and effective'' if it meets each of the conditions contained in an applicable OTC final monograph, the conditions contained in part 330 (21 CFR part 330), and any other applicable regulatory and statutory requirements for OTC drugs, including the labeling requirements in part 201.

c. Proposed, tentative final, and final monographs. The *proposed monograph,* which is typically published in the form of an ANPR, is the end product of the first phase of the rulemaking process described above. After reviewing the report and recommendations of an expert advisory review panel responsible for initially reviewing the safety, effectiveness, and labeling of products in a given therapeutic category, FDA publishes a proposed monograph (together with the report and recommendations of the expert review panel) (see § 330.10(a)(6)). After a period of public comment, FDA publishes a *tentative final monograph* (TFM) (in the form of a proposed rule, proposing conditions under which OTC drugs in the therapeutic class being considered are GRASE and not misbranded (see § 330.10(a)(7)). Following public comment on the TFM, FDA publishes a *final monograph* in FDA's regulations (see 21 CFR chapter I, subchapter D) codifying the conditions under which products in the OTC therapeutic drug category are GRASE and not misbranded (see § 330.10(a)(9)). An OTC drug may be legally marketed without an approved NDA or abbreviated new drug application (ANDA) if it meets each of the conditions contained in an applicable final monograph, the conditions contained in part 330, and any other applicable regulatory and statutory requirements for OTC drugs, including the labeling requirements in part 201.

d. Category I, II, and III classifications. In the course of establishing an OTC monograph, active ingredients and other OTC drug conditions are classified in one of three categories: Category I (conditions under which a nonprescription drug in the therapeutic category would be GRASE and not misbranded), Category II (conditions that would result in the drug being classified as not GRASE and/or misbranded) and Category III (conditions proposed to be excluded from the final monograph because available data are insufficient to classify them as either Category I or Category II) (see § 330.10(a)(6)).

2. OTC Sunscreen Products Regulated Under the OTC Drug Review and Their Intended Uses

OTC sunscreen drugs regulated under the OTC Drug Review are topically applied products indicated to help prevent sunburn; some are also indicated to decrease the risk of skin cancer and early skin aging caused by exposure to the sun's UV radiation (when used as directed with other sun protection measures) (see § 201.327(c)). The active ingredients in sunscreen products achieve these protective effects by absorbing, reflecting, and/or scattering radiation in the UV range (from 290 to 400 nanometers (nm)) (see section 586(10) of the FD&C Act (21 U.S.C. 360fff(10)); see also § 352.3(c) (21 CFR 352.3(c)), stayed).

Sunscreen products must be labeled with an SPF value calculated using a standardized SPF testing procedure set forth in FDA regulations (in § 201.327(i)). As discussed in further detail in section IX.B.1, the SPF test

measures the amount of UV radiation exposure it takes to cause sunburn when a person is using a sunscreen when compared with how much UV exposure it takes to cause sunburn when the person is not using a sunscreen. Because SPF values represent a sunscreen's level of sunburn protection, they are primarily (though not exclusively) an indicator of expected protection from UVB radiation (see section IX.B.1 for a discussion of both UVB and UVA radiation).

To pass FDA's current test for the inclusion of the term ''broad spectrum'' in labeling (which was established in the 2011 L&E Final Rule), sunscreen products must demonstrate that, in addition to UVB protection, they also provide UVA protection. Further, only products that have been demonstrated both to provide broad spectrum protection and to have a minimum SPF value of 15 have been shown to reduce the risk of skin cancer and early skin aging caused by the sun (when used as directed with other sun protection measures). By contrast, sunscreens that have *not* been demonstrated to provide both broad spectrum protection and an SPF value of at least 15 have only been demonstrated to help prevent sunburn.[5] Thus, under the 2011 L&E Final Rule, passing the broad spectrum test in § 201.327(j) (21 CFR 201.327(j)) is necessary, but not itself sufficient, to support inclusion of a skin cancer indication in labeling, although any product that passes the broad spectrum test may be labeled with the term ''Broad Spectrum'' in conjunction with its SPF value.

B. History of This Rulemaking

1. The OTC Sunscreen Drug Review and FDA's Regulation of OTC Sunscreen Drug Products

Our initial call for safety and efficacy data for sunscreen products was issued in 1972 (37 FR 26456, December 12, 1972). The resulting data submissions were reviewed by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Products, whose panel report and recommended monograph were published as an ANPR in 1978 (43 FR 38206, August 25, 1978). The ANPR contained a list of the 21 sunscreen active ingredients[6] that the panel recommended for classification as GRASE when used under the conditions described in the panel's report (43 FR 38206 at 38219). In 1993, having reviewed the panel's report and related public comments, FDA published a TFM (58 FR 28194, May 12, 1993) which (with one exception—padimate A) proposed as GRASE all of the active ingredients that had been included in the ANPR. The TFM also included specified maximum concentrations at which the proposed ingredients would be considered GRASE for use in sunscreens.

In the years following the publication of the 1993 TFM, FDA removed several additional ingredients from the TFM (see 59 FR 29706, June 8, 1994), as described at 64 FR 27666 at 27681, and proposed the inclusion of two more.[7] In 1999, FDA published a final sunscreen monograph, which included the following 16 sunscreen active ingredients along with the conditions (including maximum concentrations) under which these ingredients would be considered GRASE for use in sunscreens:[8]

TABLE 1—SUNSCREEN ACTIVE INGREDIENTS INCLUDED IN THE STAYED 1999 FINAL MONOGRAPH

Active ingredient	Maximum concentration (%)
Aminobenzoic acid (PABA)	15
Avobenzone	3
Cinoxate	3
Dioxybenzone	3
Ensulizole	4
Homosalate	15
Meradimate	5
Octinoxate	7.5
Octisalate	5
Octocrylene	10
Oxybenzone	6
Padimate O	8
Sulisobenzone	10
Titanium dioxide	25
Trolamine salicylate	12
Zinc oxide	25

Among other things, the Stayed 1999 Final Monograph established a minimum SPF value of 2, and an SPF of 30+ as the maximum labeled SPF value (64 FR 27666). FDA concluded that the above-listed ingredients (at the listed concentrations) could also be used in combination, with limited exceptions, provided that each active ingredient contributed a minimum SPF of 2 to the finished product (64 FR 27666).[9]

The effective date for complying with the Stayed 1999 Final Monograph was May 21, 2001. This deadline was extended (65 FR 36319, June 8, 2000) and then stayed until further notice (66 FR 67485, December 31, 2001) to provide additional time to resolve various outstanding issues, such as the labeling and testing of finished OTC sunscreen products. As a result, the

[5] As described in further detail in section IXB.2, in the time since the L&E Final Rule was issued in 2011, the body of evidence about the role of UVA radiation in the development of skin cancer has grown. As a result, FDA is making a number of proposals designed (among other things) to couple a greater magnitude of UVA protection to increases in SPF values.

[6] The ingredients were: Aminobenzoic acid, digalloyl trioleate, 2-ethylhexyl 2-cyano-3,3-diphenylacrylate, glyceryl aminobenzoate, menthyl anthranilate, padimate O, sulisobenzone, cinoxate, dioxybenzone, ethylhexyl *p*-methoxycinnamate, homosalate, oxybenzone, 2-phenylbenzimidazole-5-sulfonic acid, titanium dioxide, diethanoloamine *p*-methoxycinnamate, ethyl 4-[bis (hydroxylpropyl)] aminobenzoate, 2-ethylhexyl salicylate, lawsone with dihydroxyacetone, padimate A, red petrolatum, and triethanolamine salicylate.

[7] In 61 FR 48645 (September 16, 1996) (proposing that avobenzone is GRASE up to 3 percent alone and 2 to 3 percent when in combination with cinoxate, diethanolamine methoxycinnamate, dioxybenzone, homosolate, octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone, sulisobenzone, and/or trolamine salicylate) and 63 FR 56584 (October 22, 1998) (proposing that zinc oxide is GRASE alone or in combination with any previously proposed GRASE active ingredient except avobenzone). The list of active ingredients was (and would continue to be) modified because of, among other things, a lack of interest in developing United States Pharmacopeia (USP) compendial monographs for certain of the active ingredients originally proposed (see 64 FR 27666 at 27681).

[8] See § 352.10, now stayed; 64 FR 27666. The active ingredient names used in that regulation, as originally published, differ from those used in table 1, which are the current established names for these active ingredients. We note that subsequent to the publication of the Stayed 1999 Final Monograph, we issued another final rule in 2002 amending the names used for four of those ingredients to make them consistent with the renaming of those ingredients in the corresponding USP monographs (67 FR 41821 at 41823, June 20, 2002). Under section 502(e) of the FD&C Act, drug labels are required to bear the established name of each active ingredient, and if FDA has not designated an official name under section 508 of the FD&C Act (21 U.S.C. 358), the compendial name is the established name. To comply with section 502(e) of the FD&C Act, sunscreen drug products must therefore bear the current compendial names for their active ingredients, and the current compendial names are used throughout this document. Because the 2002 final rule that changed those names was published after part 352 was stayed, however, those amendments have not yet been incorporated into the published monograph regulation.

[9] An exception to this rule involving avobenzone was retained from the TFM: The Stayed 1999 Final Monograph stated that avobenzone may not be combined with PABA, phenylbenzimidazole sulfonic acid, menthyl anthranilate, padimate O, titanium dioxide, or zinc oxide. In 2007, we proposed to include in the monograph a condition permitting the marketing of sunscreens containing avobenzone in combination with either zinc oxide or ensulizole based on safety and effectiveness data about these combinations provided to the docket (''Sunscreen Drug Products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph'', 72 FR 49070 at 49074, August 27, 2007). As described in section VII.A, we now anticipate finalizing a monograph that would permit all listed active ingredients to be combined without limitation. This approach is consistent with the approach to sunscreen combinations generally taken throughout the OTC Drug Review for sunscreens.

Stayed 1999 Final Monograph has never been in effect.

In 2011, FDA published a draft guidance for industry, ''Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application,'' addressing the circumstances under which FDA intended to exercise its enforcement discretion with respect to certain marketed OTC sunscreen products in the period until a final OTC sunscreen monograph becomes effective. This guidance was finalized in May 2018 (2018 Final Guidance) (Ref. 1). Unless the failure to pursue regulatory action poses a potential health hazard to the consumer, FDA generally does not intend to object to the marketing of OTC sunscreen products that do not have an approved NDA or ANDA provided that they: (1) Contain as sunscreen active ingredients only the active ingredients or combinations of active ingredients listed in 21 CFR 352.10 and 352.20 (both currently stayed); (2) do not make claims addressed in §§ 201.327(c)(3) and (g) and 310.545(a)(29)(ii); (3) comply with the requirements for OTC drugs set forth in part 201 and § 330.1 (21 CFR 330.1), the requirements for adverse event reporting for OTC drugs set forth in the FD&C Act (see section 760 (21 U.S.C. 379aa)), and the provisions of the FD&C Act addressing adulteration; and (4) follow applicable labeling and testing requirements for OTC sunscreens set forth in § 201.327.

2. Recent Significant Rulemakings Relevant to This Proposed Rule

Since publishing the Stayed 1999 Final Monograph, FDA has issued a number of **Federal Register** notices relating to OTC sunscreens. Major notices pertinent to today's proposed rule are summarized briefly in table 2 below:

TABLE 2—RECENT SIGNIFICANT **Federal Register** NOTICES PERTINENT TO THIS RULE

Federal Register notice	Information in notice
Insect Repellent-Sunscreen Drug Products for Over-the-Counter Human Use: Request for Information and Comments; 72 FR 7941, February 22, 2007.	We issued a notice stating that we were considering amending the Stayed 1999 Final Monograph to include conditions for marketing insect repellent-sunscreen drug products and requested information to form a regulatory position on these products. The Environmental Protection Agency, which regulates the insect repellent component of insect repellent-sunscreen combinations, published a similar notice concurrently with ours, also seeking information and comment on these products.
Sunscreen Drug Products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph; 72 FR 49070, August 27, 2007.	We proposed to amend the Stayed 1999 Final Monograph to address, among other things, formulation, labeling, and testing requirements for both UVA and UVB radiation protection.
Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use (L&E Final Rule); 76 FR 35620, June 17, 2011.	We issued a final rule establishing labeling and testing requirements for sunscreen products. Among other things, the L&E Final Rule established optional broad spectrum labeling, created an optional indication relating to decreasing the risk of skin cancer and early skin aging for broad spectrum products with an SPF of 15 or higher, and required a labeling warning for sunscreens that did not both satisfy the broad spectrum test and provide an SPF of at least 15.
2011 Proposed Rule: Revised Effectiveness Determination (Max SPF PR); 76 FR 35672, June 17, 2011.	We proposed to raise the limit on the maximum permissible labeled SPF value for sunscreen products to ''50+.'' Among other things, we sought comment on the appropriateness of a formulation cap for sunscreen products.
2011 ANPR and Request for Data and Information on Certain Dosage Forms; 76 FR 35669, June 17, 2011.	We issued an ANPR describing the sunscreen dosage forms that we considered to be part of the OTC Drug Review and thus eligible for potential inclusion in a sunscreen monograph, as well as those dosage forms that we did not consider eligible. We requested data to enable us to ensure that the administrative record would be adequate to support GRASE determinations for the eligible sunscreen dosage forms. In particular, we emphasized that additional safety and efficacy data would be needed to support final monograph status for spray dosage forms. We also announced that we were issuing a draft guidance document (discussed above) explaining the Agency's intended enforcement policy for sunscreens marketed pursuant to the monograph system, including with respect to dosage forms. The Agency's approach to enforcement of spray sunscreens is now described in the 2018 Final Guidance.

IV. Scope of This Rulemaking

Eligibility for inclusion in an OTC monograph was originally limited to active ingredients and other conditions that had been used in drugs marketed in the United States prior to the inception of the OTC Drug Review in 1972. After publication of the final sunscreen monograph in 1999, FDA published its TEA regulation (§ 330.14), (67 FR 3060 at 3074, January 23, 2002), which sets forth criteria and procedures by which OTC drugs initially marketed in the United States *after* the OTC Drug Review began and OTC drugs without any U.S. marketing experience can be considered for inclusion in the OTC drug monograph system. Congress later passed the SIA, which, among other things, supplements FDA's TEA regulations for OTC sunscreen drug products (21 U.S.C. 360fff through 360fff–7) (2014).

This proposed rule addresses the GRASE status (and conditions of use applicable to) sunscreen drug products containing active ingredients listed in the Stayed 1999 Final Monograph. It does not address the pending sunscreen active ingredients that were originally submitted under the procedures established in the TEA regulation and are now being addressed through the SIA process.[10] As discussed further in section VII, however, the safety data we described as necessary to evaluate the safety and effectiveness of sunscreen products containing those active ingredients are the same as what we are now describing as needed to establish that the active ingredients listed in the Stayed 1999 Final Monograph are GRASE for use in sunscreen products. We are not revisiting the contribution that the active ingredients listed in the Stayed 1999 Final Monograph make to the effectiveness of sunscreens. The Agency has not received information suggesting that it is necessary to revisit its prior decision about the effectiveness of the active ingredients at this time.

[10] FDA's proposed sunscreen orders on each of these ingredients can be found at *https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm434843.htm.*

V. Legal Authority

We are issuing this proposed rule under sections 201, 301, 501, 502, 503, 505, 510, 586E, 701, 702, 703, 704, and 721 of the FD&C Act and under section 351 of the Public Health Service Act (42 U.S.C. 262).

VI. Need for Additional Safety Information

A. Increased Consumer Exposure to Sunscreen Active Ingredients

Consumer exposure to sunscreen active ingredients has increased dramatically since FDA began its initial safety evaluations of the sunscreen active ingredients at issue in this proposed rule. Many factors have influenced this increase, including the following:

- Significant increases in the number and types of consumers using sunscreen products (Refs. 2 and 3)
- Sunscreen products containing a greater number of active ingredients at greater concentrations (Ref. 4)
- Increased awareness of the risks of sun exposure and encouragement of routine sunscreen use by medical and public health authorities (see, *e.g.,* Ref. 5)
- Evolving directions for use on sunscreen products instructing consumers to use greater amounts of sunscreen per application and to reapply sunscreen products more frequently (76 FR 35672 at 35678), codified as § 201.327)
- Expanding availability and use of many different types of sunscreen products, including daily-use products such as facial makeup, moisturizing creams, and lipstick

Relatively few sunscreen products were in use when the U.S. Army initially funded research into the development of effective sunscreen products for use by military personnel on aircraft carriers (and others routinely exposed to long periods of intense sunlight) during World War II (Ref. 2). The reach of sunscreen products began to broaden when they were later marketed for use specifically by consumers who sunburned readily (*i.e.,* fair-skinned individuals) in situations of intentional sun exposure, such as sunbathing on a beach (Ref. 6). Sunscreen products are now routinely used by a much broader range of consumers for protection against many types of sun-induced skin damage, not just sunburn. Accumulating data demonstrate that increased sun exposure increases the risk of developing skin cancers and premature skin aging (Ref. 2). To help reduce the risk of these types of sun-induced skin damage, public health organizations (including FDA) have for years urged consumers to use sunscreen products along with other sun-protective behaviors like limiting time in the sun and wearing protective clothing (Refs. 7, 8, and 9).

Another factor driving increased consumer exposure to sunscreen active ingredients has been the introduction and widespread adoption of sunscreen products with higher labeled SPF values. The maximum SPF value proposed for sunscreen labeling has progressively increased from SPF 15 in the 1978 panel report, to SPF 30+ in the Stayed 1999 Final Monograph, to SPF 50+ in the 2011 Max SPF PR. To achieve these higher SPFs, many currently marketed products are formulated with more active ingredients combined together in higher concentrations than were generally combined in products when FDA's review of OTC sunscreens began. Increased knowledge about the role of UVA radiation in causing skin damage has also encouraged the formulation of broad spectrum products with combinations of active ingredients designed to achieve protection against both UVA and UVB radiation. In addition, other widely used products, such as facial makeup, moisturizing creams, and lipsticks, have had sunscreen active ingredients added to their formulations. These trends are reflected in the evolution of the current labeling provisions for sunscreen products regulated under the OTC monograph system.

Changes in the instructions for using these sunscreen products have also contributed to increased use of, and exposure to, sunscreen active ingredients. The labeling recommended by the advisory panel in 1978 simply instructed consumers to apply sunscreen products liberally and to reapply after swimming or excess perspiration (43 FR 38206 at 38215). The labeling currently required, by contrast, encourages consumers to always use a broad spectrum SPF 15 or higher product, to use sunscreen products regularly, and to apply them generously/liberally 15 minutes before sun exposure and at least every 2 hours or more frequently when swimming or sweating (§ 201.327(e)).

B. Emerging Safety Concerns

In recent years, a growing body of data has suggested that the transdermal absorption of some sunscreen active ingredients is greater than previously thought, and thus may raise previously unevaluated safety concerns, including the potential for reproductive, developmental, or carcinogenic effects. As discussed in further detail in section VIII.C.1.a, newly available information suggests, for example, that there is the potential for toxicity associated with the transdermal absorption and systemic availability of oxybenzone. This new information about absorption and potential safety risks is inadequate, by itself, to support an affirmative conclusion that products containing the active ingredients at issue are not safe. Coupled with the lack of clinical pharmacology and nonclinical safety data for certain sunscreen active ingredients, however, it leads us to conclude that, for some sunscreen active ingredients, the current record does not include adequate evidence of safety to satisfy the applicable legal standards for general recognition of safety and effectiveness as set forth in § 330.10.

VII. Framework for Evaluation of Safety Data

In light of these safety concerns, FDA held a meeting of its Nonprescription Drugs Advisory Committee (NDAC) on September 4 and 5, 2014, to discuss the scope of safety testing that should be conducted to support general recognition of safety and effectiveness for active ingredients for use in nonprescription sunscreen products. FDA proposed the following safety testing paradigm:

Clinical data:
- Dermal irritation and sensitization testing
- Phototoxicity and photoallergenicity testing
- Human maximal use bioavailability studies
- Postmarketing adverse event reports

Nonclinical (toxicology) data:
- Dermal carcinogenicity
- Systemic carcinogenicity
- Developmental and reproductive toxicity (DART)
- Toxicokinetics
- Additional testing when data suggest a concern about other long-term effects, such as endocrine effects

There was consensus among the committee members that FDA's proposed framework was a good starting point (Ref. 10). In November 2015, FDA published a draft guidance for industry, ''Over-the-Counter Sunscreens: Safety and Effectiveness Data'' (Draft Safety and Effectiveness Data Guidance) (see 80 FR 72975, November 23, 2015), which described and requested comment on the safety and effectiveness data necessary to determine whether an OTC sunscreen active ingredient or combination of active ingredients evaluated under the SIA was GRASE when used under specified conditions. FDA finalized this guidance in November 2016, after considering public comment on its draft recommendations (Ref. 11).[11] The recommendations in this guidance reflect FDA's scientific expertise, existing technical guidance, experience from reviewing safety and efficacy data submitted for GRASE review of sunscreen active ingredients under the OTC Drug Review, and input from and

[11] FDA's recommendations regarding the safety and effectiveness data necessary to determine whether an OTC sunscreen active ingredient (or combination of ingredients) evaluated under the SIA was GRASE when used under specified conditions generally remained unchanged in the final guidance.

concurrence by outside scientific experts.

All sunscreens marketed without an NDA are subject to the same standard: General recognition of safety and effectiveness. Accordingly, as noted previously, the data that we expect to be necessary to evaluate the safety and effectiveness of the sunscreen monograph active ingredients are the same as those we recommended as necessary to evaluate the safety and effectiveness of sunscreen active ingredients previously considered under the procedures established in the TEA regulation and now being considered pursuant to the framework established by the SIA (see Safety and Effectiveness Data Guidance (Ref. 11)).

The studies described in this section are generally needed for FDA to determine that a sunscreen active ingredient is GRASE for use in nonprescription sunscreens. Specific data gaps for individual active ingredients depend on the quality and quantity of available safety data, and are identified in section VIII. As described in that section, those active ingredients for which the existing public record contains sufficient data to support a positive GRASE finding are proposed as Category I. Those for which additional data are necessary are proposed as Category III. In addition, in evaluating the existing safety data for the active ingredients listed in the Stayed 1999 Final Monograph, FDA determined that the risks associated with two of these ingredients outweigh their benefits. As discussed in further detail in section VIII.B, FDA is therefore proposing that these two ingredients are Category II because sunscreens containing these ingredients would not be GRASE.

A. General

FDA's OTC drug regulations identify the general types of safety information that should be submitted as evidence that an OTC drug is GRASE for use as labeled (§ 330.10(a)(2)) and the standard by which safety is to be judged (§ 330.10(a)(4)(i)). When applying these regulations to each drug, FDA uses its scientific expertise to determine what constitutes ''adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use'' (§ 330.10(a)(4)(i)).

FDA recognizes the contribution that broad spectrum sunscreens with an SPF value of 15 or higher can make to decreasing the risk of skin cancer and early skin aging caused by the sun if used as directed with other sun protection measures. To protect the public health, however, it is also important for FDA to balance the potential benefits of these sunscreen products to consumers against their potential risks. Providing an adequate safety margin for OTC sunscreen active ingredients and finished sunscreen products is a key element of FDA's risk assessment. A *safety margin* calculation takes the highest animal NOAEL and estimates a maximum safe level of exposure for humans. Because animal studies do not always predict effects in humans, the actual threshold for an effect in humans may be different (*i.e.,* higher or lower) than in the species tested. The human sensitivity to a drug is often unknown. To account for this, the predicted safe exposure level in humans that is reflected in the safety margin is well below where toxicities were seen in animals.

In determining the specific testing and other data needed to adequately demonstrate that an OTC sunscreen active ingredient is safe, FDA considers both the circumstances under which OTC sunscreen products are intended to be used by consumers (*i.e.,* the conditions of use) and current scientific knowledge and assessment technology. FDA's approach to the clinical safety evaluation of OTC sunscreen active ingredients is based on our current scientific understanding regarding safety evaluation of topical drug products for chronic use, and thus is generally consistent with the safety data requirements that would apply to an NDA for a chronic-use topical drug product (*i.e.,* topical safety studies (irritation, sensitization, and photosafety); bioavailability (absorption); and evaluation of adverse events observed in clinical studies).[12] In addition, the evaluation of adverse events reported during the commercial marketing of sunscreen products containing the ingredient and other postmarketing safety information is also relevant to safety.

FDA's approach to the nonclinical safety evaluation of these active ingredients takes into account their lengthy marketing history in the United States. In contrast to nonclinical data requirements for a chronic-use topical drug product NDA, which include results from comprehensive nonclinical pharmacology and toxicology safety testing, the approach to nonclinical safety testing in this proposed rule is largely focused on potential long-term adverse effects or effects not otherwise readily detected from human use (*i.e.,* carcinogenicity and reproductive toxicity). Additional testing beyond what is described below may be recommended for active ingredients for which data suggest a concern about other long-term effects, such as hormonal disruption.

In addition, although sunscreen products are typically formulated with two or more active ingredients, the framework described below contemplates that testing will be performed using formulations that include one active ingredient. Generally, unless data suggest that there may be a safety or efficacy concern with a particular combination of active ingredients, we anticipate that an active ingredient that is found to be GRASE for use in sunscreens could be combined with other active ingredients that are also GRASE for use in sunscreens. If data suggest that there may be a safety or efficacy concern with a particular combination of active ingredients (or active and inactive ingredients), additional data may be necessary to support a positive GRASE determination for sunscreens containing that combination.

The following sections describe the specific safety data that FDA expects the Agency will need to determine whether an active ingredient is GRASE for use in sunscreens.

B. Clinical Safety Testing

1. Human Dermal Safety Studies

Human dermal safety studies for topical products in which exposure to light after application is anticipated generally consist of two sets of studies—those conducted without specific exposure to light and those conducted to assess reactions after UV exposure (photosafety studies) (Ref. 12). The studies usually consist of dermal irritation patch testing, dermal sensitization patch testing, dermal phototoxicity testing, and dermal photoallergenicity testing.

Because marketed sunscreen products typically contain a combination of active ingredients, and product formulations frequently change, it is difficult to determine causal links between individual active ingredients and reported irritation and hypersensitivity adverse events associated with a particular product. Therefore, FDA generally expects to use data from human dermal irritation studies, human dermal sensitization studies, and human dermal photosafety studies, in conjunction with postmarketing adverse event data, to inform GRASE determinations and labeling. Nonetheless, in some cases, it may be reasonable to omit human

[12] *Chronic use* is defined as continuous or intermittent use for at least 6 months during the course of a lifetime.

dermal irritation studies, human dermal sensitization studies, and/or human dermal photosafety studies, depending on the rigor of available postmarketing safety information. For example, if FDA concludes that there is a positive risk-benefit profile for a sunscreen active ingredient, but that it is known to be a sensitizer, it may be possible to develop safety labeling to address this risk without data generated in the human dermal safety studies described below (see, *e.g.,* section VIII.C.1.a).

a. Human dermal irritation and sensitization studies. Studies of dermal irritation and sensitization, using the repeat insult patch test or other relevant tests, are elements in the safety evaluation of topical drug products that, like sunscreens, are applied to the skin repeatedly over long periods of time. Designed to detect the potential for local dermatologic events with fewer subjects than might be observed in larger clinical trials, these tests often employ product application that is more frequent and/or for longer duration than proposed clinical dosing. In dermal irritation studies, a test substance is applied to a small pad (patch) and affixed to the test subject's skin, usually on the back, to determine whether the ingredient causes direct skin toxicity. Dermal sensitization studies are conducted similarly but are designed to detect immunologically mediated reactions, which require prior exposure to the allergen.

Nonprescription sunscreens regulated under the OTC monograph system may be used in many product formulations, including those yet unknown. Therefore, cumulative irritation studies that evaluate the sunscreen active ingredient at the highest concentration for which a GRASE determination is sought should be conducted using the ingredient in an appropriate vehicle, using the vehicle alone, and using both negative and positive controls. The evaluation should include scoring of erythema, edema, and a papular response or skin erosion.

Dermal sensitization studies, conducted to detect immunologically mediated reactions, should be conducted in three phases: (1) The induction phase (3 weekly applications for 3 weeks); (2) the rest phase (no product application for 10 to 14 days); and (3) the challenge phase (patch applications to new sites for 48 hours with a confirmatory rechallenge to exclude false positives).

Although FDA recommends separate dermal irritation and sensitization studies, it may be appropriate to combine irritation and sensitization studies in the same study as long as a sufficient number of subjects are included for sensitization evaluation.

b. Human photosafety studies. Topically applied dermatologic drug products should be tested for photosafety if they absorb light in the UVA, UVB, or visible spectra. Photosafety evaluations of sunscreen active ingredients that absorb light should consist of skin photoallergenicity and skin phototoxicity testing. *Photoallergy* is an immunologically mediated reaction to a chemical, initiated by the formation of photoproducts (*e.g.,* protein adducts) following a photochemical reaction. Similar to dermal sensitivity testing described above, photoallergy tests use an induction/rest/challenge/rechallenge multiphase design to assess erythema, edema, and vesiculation. *Phototoxicity* (or photoirritation) is an acute light-induced tissue response to a photoreactive chemical. Phototoxicity testing typically includes a test patch, a vehicle patch, and a sham patch application for 24 hours, followed by UV light exposure of the test area. A second set of patch application areas not irradiated with light serves as a control. FDA expects that, to support a GRASE finding, photosafety studies of sunscreen active ingredients that absorb light will need to be conducted using the active ingredient at the highest concentration for which a GRASE determination is sought in an appropriate vehicle, using the vehicle alone, and with a negative control.

2. Human Absorption Studies/Maximal Usage Trial

Because nonprescription sunscreens are topically applied, a critical safety consideration is whether dermal application results in skin penetration and systemic exposure to their active ingredients and, if so, to what extent. This information helps identify potential safety concerns and helps determine whether an adequate safety margin exists within which an active ingredient is GRASE for use in sunscreens.

The principal barrier to topical drug product penetration is the multilayered, lipid-rich stratum corneum. The passage of any drug product through this layer is influenced by many factors, including the drug product's physicochemical features, molecular weight, and vehicle/formulation properties. Vehicle/formulation properties are particularly important because the choice of vehicle can markedly affect the permeation potential of a drug product. Effects can range from simple hydration of the stratum corneum by occlusive vehicles/formulations to direct permeation enhancement by solvent effects on the lipids in the stratum corneum. Products absorbed through the skin have the potential to cause systemic adverse effects, affecting the safety assessment. Because sunscreens are intended to work at the skin's surface, systemic absorption may also lower efficacy, affecting the efficacy assessment. Such considerations ultimately weigh into the risk-benefit calculus FDA uses to determine whether an OTC sunscreen containing a given active ingredient is GRASE.

Since the mid-1990s, topical product NDAs have included a Maximal Usage Trial (MUsT) as part of the clinical pharmacology/bioavailability assessment. A MUsT is designed to capture the effect of *maximal use* on absorption into the blood with standard pharmacokinetic assessments (*e.g.,* C_{max}, T_{max},[13] area under the curve, half-life, clearance, and volume of distribution) (for further information about conduct of a MUsT, see Ref. 13). For a topical product NDA, the MUsT is usually conducted in subjects with the disease of interest, where disrupted skin is a feature. In situations where disrupted skin is not a feature of the condition being treated or the topical product is intended for prevention of disease (*e.g.,* sunscreens), the MUsT for a topical product NDA should be conducted in subjects with healthy, intact skin. The MUsT for a topical product NDA is conducted with the specific product formulation for which approval is sought applied at the upper limit of surface area involvement that is studied in the phase 3 clinical trials and is proposed for labeling. For example, if the proposed labeling of an acne product permits the product to be used on up to 30 percent of body surface area, that would be the coverage evaluated in the MUsT.

We expect that data from a MUsT will be needed to support an adequate assessment of safety for most sunscreen active ingredients (Ref. 10). Because sunscreen products regulated pursuant to the OTC monograph system may include active ingredients in a variety of formulations, FDA recommends that a MUsT be conducted under maximal use conditions employing a minimum of four formulations, containing the sunscreen active ingredient as the only active ingredient.[14] These formulations

[13] C_{max} is the peak plasma concentration and T_{max} is the time to peak plasma concentration.

[14] We note, however, as described in section VIII.C.1.b, that because of avobenzone's potential for photodegradation, we recommend that a MUsT for avobenzone evaluate avobenzone in combination with a photostabilizer. In some cases,

Continued

should be prepared using vehicle/formulation systems that are appropriate for sunscreen topical products (*e.g.,* they are deployable and spreadable) that represent real-world marketed formulations, and that are expected to produce the highest in vivo absorption. Justification for the formulations chosen, including results of in vitro testing using a human cadaver skin permeation system (*e.g.,* static cell, also known as vertical diffusion cell) (Refs. 14 and 15), should be included in the study protocol. The protocol should contain sufficient detail for others to reproduce the formulations and manufacturing process.[15]

FDA anticipates that the use of multiple formulations will help identify the overall absorption potential of the sunscreen active ingredient of interest. The MUsT should be conducted in subjects with healthy, intact skin [16] at the highest concentration of the ingredient for which a GRASE determination is sought. Based on recommended sunscreen use on all exposed skin, the exposed area should include at least 75 percent of the body surface area. Data from the formulation that produces the highest in vivo absorption would then be used to determine the safety margin.

The assay used in the MUsT should be properly validated according to current good laboratory practices (21 CFR part 58). Additionally, the Agency's most current guidance on bioanalytical method validation may be found by searching at *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.* The assay's limit of quantitation-limit of detection should be sufficiently low to allow a signal-to-noise ratio that ensures confidence in detection of a concentration of 0.5 nanogram (ng)/milliliter (mL) for the compound of interest in the receptor fluid.

An important consideration for designing a MUsT is that it should include testing for a duration that allows for the attainment of steady state levels to ensure that maximum penetration of the ingredient has taken place and to optimize the chances of the ingredient being detected. Thus, for sunscreen active ingredients, FDA expects that single application studies would be inadequate. Because the subjects in a MUsT represent an enriched dataset in the upper range of exposures, safety-related data (such as vital signs, adverse events) from the study's regularly scheduled physical examinations should also be collected. We strongly encourage consultation with FDA about MUsT protocols before beginning the trial.

Finally, as discussed further in section VIII.D, if the sunscreen active ingredient is determined to be GRASE for use in sunscreens, the sunscreen monograph, when finalized, must set out the conditions under which any future sunscreen containing that active ingredient will be GRASE and not misbranded. As such a condition, FDA is considering certain final formulation testing to address the potential for transdermal absorption and its impact on safety. FDA anticipates that the formulation that produces the highest in vivo absorption in the MUsT would be appropriate to designate as a standard control formulation for future in vitro human cadaver skin permeation system testing (*e.g.,* a static or vertical diffusion cell) of each final sunscreen formulation that includes that active ingredient. If such testing were included as a condition in a final sunscreen monograph, and if in vitro permeation of the sunscreen active ingredient in the final product formulation were equal to or less than the value from in vitro testing of the standard control formulation (that was shown by the MUsT to have the highest degree of systemic absorption), FDA anticipates that the safety margin previously calculated would be considered adequate to support the safety of the finished formulation.

3. Pediatric Considerations

Young children have a larger ratio of skin surface to body volume than adults, which can increase a child's systemic exposure to topically applied drug products. In addition, growing children have greater potential to experience deleterious developmental effects from drug exposure. If the calculated safety margin for an active ingredient (based on nonclinical results and human MUsT) is relatively small, FDA will exercise its scientific judgment to determine whether a sunscreen active ingredient MUsT in young children or other studies are warranted to ensure that the safety margin for marketed products containing the ingredient is within an acceptable range for this population.

C. Nonclinical Safety Testing

1. Carcinogenicity Studies: Dermal and Systemic

FDA generally recommends carcinogenicity studies for any pharmaceutical with an expected clinical use (either intermittent or continuous) of at least 6 months (Ref. 17). The animal carcinogenicity studies help characterize the potential tumor risks associated with use of a sunscreen active ingredient in human beings by identifying any observed tumors by type, the level of exposure at which tumors occur, and the highest level of exposure at which no adverse effects occur, referred to as the NOAEL. As noted earlier, FDA intends to use the NOAEL in determining the safety margin for human exposure to sunscreens containing the active ingredient. In addition to detecting carcinogenic potential, carcinogenicity studies in animals can also help to identify other systemic or organ toxicities that may be associated with the sunscreen active ingredient.

FDA expects that a dermal carcinogenicity study involving application of the test article to the skin of mice or rats for 2 years will thus need to be conducted to support a GRASE finding for the active ingredient unless the ingredient has been demonstrated not to reach the viable layers of the skin where it could impact skin tumor development. FDA also considers it important to study the effects of systemic exposure if human bioavailability data show that dermal application of a particular formulation results in skin penetration and systemic exposure to the active ingredient. Therefore, we expect that a second carcinogenicity study by a route that produces systemic exposure will also be needed to support the safety of a sunscreen active ingredient, if systemic exposure is observed in the bioavailability data. This can be a 2-year study or a shorter (usually 6 months) alternative carcinogenicity model, and it should be conducted in a species different from that used in the dermal carcinogenicity study. FDA notes that the absence of a carcinogenicity signal from an alternative transgenic carcinogenicity study (*e.g.,* TgRasH2 mouse) would likely support the safety of a sunscreen active ingredient. If a carcinogenicity signal were observed in such a study, however, the study could not be used to support the safety of a sunscreen active ingredient because there would be no basis for calculating

sunscreen active ingredients (*e.g.,* octocrylene) can serve as photostabilizers. In such cases, we expect that the MUsT could include such ingredients.

[15] FDA has issued draft guidance with recommendations for the conduct of MUsT studies to support the safety of active ingredients that are candidates for inclusion in a topical drug product under an OTC Drug monograph (Ref. 16). When finalized, this guidance will represent FDA's current thinking on this topic. FDA also encourages persons who are interested in conducting a MUsT to support the safety of an active ingredient to discuss proposed protocols with the Agency.

[16] As discussed *infra,* the MUsT should be conducted on healthy, intact skin because sunscreens are intended for prevention rather than treatment.

a safety margin with this study (Ref. 18). All carcinogenicity studies, regardless of route, should assess a full panel of tissues.[17]

FDA expects that a systemic carcinogenicity study would not be needed to support a GRASE determination for a sunscreen active ingredient if an adequately conducted human pharmacokinetic MUsT resulted in a steady state blood level less than 0.5 ng/mL, and an adequately conducted toxicology program did not reveal any other safety signals for the ingredient or any known structurally similar compound indicating the potential for adverse effects at lower levels. The threshold value of 0.5 ng/mL is based on the assessment that the level would approximate the highest plasma level below which the carcinogenic risk of any unknown compound would be less than 1 in 100,000 after a single dose. This threshold value is consistent with the Threshold of Toxicological Concern concept, which was applied to impurities in the ICH guidance for industry ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk'' (Ref. 19). FDA expects that the 0.5 ng/mL concentration will be sufficiently above the assay's limit of quantitation—limit of detection to allow a signal-to-noise ratio that ensures confidence in either the derived concentrations (in the case of ''exaggerated'' values) or lack of concentrations.

2. Developmental and Reproductive Toxicity Studies

FDA expects that DART studies will need to be conducted to evaluate the potential effects that exposure to the sunscreen active ingredient may have on developing offspring throughout gestation and postnatally until sexual maturation, as well as on the reproductive competence of sexually mature male and female animals (Ref. 20). As with systemic carcinogenicity studies, we expect that studies to assess fertility and early embryonic development, and pre- or postnatal toxicity in rats will not be needed if an adequately conducted human MUsT shows a steady state blood level less than 0.5 ng/mL, and an adequately conducted toxicology program produces no signals indicating that the ingredient (including its clinically relevant metabolites) or any known structurally similar compound interacts with related pathways.[18] We expect that effects on embryofetal development will need to be assessed in rats and rabbits in all cases.

Gestational and neonatal stages of development may be particularly sensitive to active ingredients with hormonal activity (endocrine disruption). For this reason, these studies should include assessments of endpoints such as vaginal patency, preputial separation, anogenital distance, and nipple retention, which can be incorporated into traditional DART study designs to assess potential hormonal effects on the developing offspring. Behavioral assessments (*e.g.,* mating behavior) of offspring, which may detect neuroendocrine effects, should also be performed (Ref. 21).

3. Toxicokinetics (Ref. 22)

Animal toxicokinetic data should also be collected for sunscreen active ingredients, as these data provide an important bridge between toxic levels seen in animal studies and any potential human adverse events associated with systemic exposure to the sunscreen's active ingredient. Toxicokinetic measurements are usually obtained during the course of ongoing nonclinical toxicity studies, such as carcinogenicity or DART studies, rather than through separate studies.

D. Postmarketing Safety Data

In addition to the active ingredient safety data already described, FDA's GRASE evaluation also takes into consideration publicly available information about serious adverse drug experiences and known or expected adverse effects associated with commercially marketed products that contain the active ingredient(s) under consideration.

E. Sunscreens Containing Nanomaterials

We note that FDA is not proposing to categorically classify sunscreen products manufactured using nanotechnology (or containing nanomaterials) as GRASE or not GRASE solely based on this characteristic. Nanotechnology is used to create, explore, or manipulate materials measured in nanometers (nm) (billionths of a meter), and has applications in a wide range of products, including OTC sunscreens. Such materials generally have dimensions between approximately 1 and 100 nm (Ref. 23). Materials at such small sizes can have different chemical or physical properties or biological effects compared to larger-scale counterparts, making possible a variety of functional effects, and also potentially affecting the safety, effectiveness, or regulatory status of FDA-regulated products.

FDA has not established regulatory definitions of *nanotechnology, nanomaterial, nanoscale,* or other related terms. As described in FDA's guidance for industry ''Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology'' (Nanotechnology Considerations Guidance) (Ref. 24), at this time, when considering whether an FDA-regulated product involves the application of nanotechnology, FDA asks

(1) Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm).

In addition, because materials or end products can also exhibit related properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm that are relevant to evaluations of safety, effectiveness, performance, quality, public health impact, or regulatory status of products, we will also ask:

(2) Whether a material or end-product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to 1 micrometer (μm) (1,000 nm).

We will apply these considerations broadly to all FDA-regulated products, including sunscreen products. For the purpose of this proposed rule, we use the term ''nanomaterial'' generally to refer to materials falling within either point 1 or 2 above. The use of this term in this manner is consistent with its use in FDA's nanotechnology-related guidances, including FDA's Nanotechnology Considerations Guidance.

Nanomaterial forms of the active ingredients zinc oxide and titanium dioxide have been used in marketed OTC sunscreens. In addition to nanomaterial forms of zinc oxide and titanium dioxide, other nanomaterials are also reported to have been used, or promoted or studied for possible use, in sunscreen products (Ref. 25).

[17] FDA recommends submitting the carcinogenicity study protocol(s) for review by FDA's Center for Drug Evaluation and Research's (CDER's) Executive Carcinogenicity Assessment Committee before initiating the studies. For further guidance regarding carcinogenicity studies, see the FDA guidance for industry ''Carcinogenicity Study Protocol Submissions,'' May 2002 (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm078924.pdf*).

[18] Examples of such pathways could include endocrine function and signaling pathways related to growth and development.

As discussed in further detail in section VIII.A, having examined the scientific information in the record, including for nanomaterial forms of zinc oxide and titanium dioxide, FDA is not now proposing conditions of use for these two active ingredients under the sunscreen monograph that distinguish nanomaterials from other forms of these ingredients. As indicated above, FDA also does not propose to categorically classify sunscreen products that are manufactured using nanotechnology or contain nanomaterials as GRASE or not, solely on that basis. Manufacturers of products containing nanomaterials marketed under the OTC sunscreen monograph remain responsible for ensuring that the product satisfies all applicable legal requirements. FDA encourages manufacturers of such products to consult with FDA to facilitate a mutual understanding of specific scientific or regulatory issues relevant to their product.

FDA invites comment on the following topics:

- Specific nanomaterials or types of nanomaterials that have been used or proposed for use in OTC sunscreen products
- Concerns about sunscreen product safety, effectiveness, or quality associated with the use of nanomaterials in OTC sunscreen products, with supporting data
- Need for, and proposals of, specifications or limitations for particular nanomaterials for use in OTC sunscreen products
- Any particular nanomaterials that you believe should not be permitted for use in OTC sunscreen products, along with supporting scientific information
- FDA's proposed regulatory approach and/or alternative regulatory approaches to the use of nanomaterials in OTC sunscreen products

VIII. Existing Safety Data for Sunscreen Active Ingredients

In the remainder of this section, we discuss the existing data and data gaps for each of the sunscreen monograph active ingredients and explain why we propose that these active ingredients are GRASE or not GRASE for use in sunscreens. Those ingredients for which the existing data are sufficient to support a positive GRASE determination are proposed as Category I. Those ingredients for which additional data are necessary before a GRASE determination can be made are proposed as Category III. In cases where FDA's evaluation of the existing safety data caused us to determine that the risks associated with the ingredients outweigh their benefits, the ingredients are proposed as Category II.

A. Ingredients Proposed as Category I

Based on our review of the publicly available data for these ingredients, both zinc oxide and titanium dioxide are proposed as Category I.

1. Zinc Oxide

Our review of the scientific literature, submissions to the sunscreen monograph docket, and adverse event reports submitted to FAERS has produced sufficient safety data on zinc oxide to support a proposal that a sunscreen containing up to 25 percent zinc oxide would be GRASE under the conditions proposed in this rulemaking and the general conditions required in part 330. This proposal is based in significant part on the existing, substantial evidence that zinc oxide (including particles on the nanoscale, *i.e.,* approximately 1 to 100 nm) does not penetrate into or through human skin to any great extent and, to the extent any de minimis penetration occurs, does not result in adverse health effects, given the high levels of endogenous zinc in the human system.

a. Background. Zinc oxide is an inorganic, mineral compound. Because of its ability to reflect UVA wavelengths, zinc oxide is frequently used in sunscreens to help establish broad spectrum protection (Ref. 26). While larger particles of zinc oxide used in sunscreens (greater than approximately 100 nm) may impart an opaque, white color to the product, zinc oxide is also manufactured in smaller particle sizes (less than approximately 100 nm) to reduce this white/opaque appearance (Refs. 27 and 28). In addition to its use in sunscreens, zinc oxide is also used in non-sunscreen ointments, pastes, and lotions for various skin disorders because of its protective, astringent, and antiseptic properties (Ref. 29).

b. Discussion. Zinc oxide is insoluble in water and largely insoluble in biological fluids.[19] This insolubility precludes the possibility of its systemic absorption from topical application of sunscreen products beyond a de minimis amount, even if zinc oxide is included at its maximum eligible concentration of 25 percent and regardless of the formulation of the product. The available studies on the dermal penetration of zinc oxide, further discussed below, confirm that its penetration—regardless of particle size—is primarily limited to the upper layers of the non-living stratum corneum, with most penetration occurring only into skin folds and furrows or hair follicles. These studies show that zinc oxide particles do not penetrate down into the viable dermis to any significant extent. Any de minimis transdermal penetration that may occur does not result in adverse health effects, because the tiny amount of zinc oxide particles that achieve transdermal absorption, if any, would dissociate into zinc and oxygen ions, both of which are naturally occurring elements in the human body (Ref. 30). Zinc is the 14th most common element in the human body and is essential for all living things; the average human body contains about 2.0 to 2.5 grams of zinc, and normal dietary intake of zinc is about 15 milligram (mg) per day (Refs. 30 and 31). Homeostatic mechanisms in the body regulate zinc's absorption, distribution, cellular uptake, and excretion (Ref. 31). Similarly, any oxygen absorbed through the skin is nonharmful, as oxygen is plentiful in the human body and essential for life.

Our search of the literature on zinc oxide revealed four recent studies about zinc oxide's penetration into human skin, which confirm our expectations based on the physical properties of this compound. The first two studies (conducted by Leite-Silva et al. and Darvin et al.) examined the penetration of zinc oxide into the skin using multiphoton tomography (Refs. 32 and 33). Both studies showed a lack of overall permeation of zinc oxide beyond a few cell layers, except in the case of furrows and wrinkles (Refs. 32 and 33). The second two studies—a pilot and subsequent full trial conducted by Gulson et al.—evaluated the penetration of nanoscale zinc oxide into the skin and the bloodstream using a stable isotope tracing method (Refs. 34 and 35). Although the Gulson studies found that a minimal amount of topically applied zinc was absorbed, the absorption observed was at levels that are orders of magnitude less than daily nutritional intake and well below what would be of concern for a naturally occurring element in the body subject to homeostatic mechanisms (Ref. 36). An additional porcine study found (as discussed in our 2012 response to a citizen petition submitted by the International Center for Technology Assessment and others (Docket No. FDA–2006–P–0213–0003) (ICTA Petition Response)), that although sunburn caused by UVB rays increased the penetration of zinc oxide into the

[19] We note that nanoscale zinc oxide can be solubilized to a small extent in the presence of phosphate and lecithin at pH's that are achievable on the skin. Even under these conditions, however, the amount potentially absorbed is de minimis and far lower than daily nutritional intake of zinc.

non-living stratum corneum, there remained minimal penetration of zinc oxide into the epidermal and dermal layers of the skin (Ref. 37). Because topically applied zinc oxide particles do not enter systemic circulation to any meaningful extent, we do not consider a MUsT to be necessary to support the safety of this ingredient.

In addition to the studies described above, we also located two studies evaluating the clinical safety of topically applied zinc oxide in which zinc oxide (25 percent) was used as a medicated occlusive dressing on the lower arms of healthy volunteers (Refs. 38 and 39). In these studies (which were designed to maximize potential absorption and identify any resulting adverse events), even with the increased dermal or epidermal zinc levels resulting from occlusion, there still were no adverse skin events. Our review of the available human dermal safety studies on zinc oxide [20] also identified data showing that test material containing up to 25 percent zinc oxide did not induce human irritant, photoirritant, allergic, or photoallergic reactions. No human pathological phototoxicity or significant human photosensitization reaction indicative of skin irritation were noted either. The literature supporting the safety of skin protectant drug products containing zinc oxide [21] reinforce these clinical safety findings. Our review in this area is also consistent with the conclusion of the European Commission's Scientific Committee on Consumer Safety that the use of nanoscale zinc oxide in sunscreens at a concentration of up to 25 percent does not pose a risk of adverse effects in humans after topical application (Ref. 40).

A very small number of rash and hypersensitivity reports for sunscreens containing zinc oxide were located in FAERS. With a single exception, the sunscreens involved contained two or more active ingredients, making it difficult to attribute causation to a specific active ingredient. Unlike other sunscreen ingredients with a known hypersensitivity risk, we did not identify any reports in FAERS or in the literature with features suggestive of a causative link, such as skin test results positive for zinc oxide. In addition, there is an extremely large safety database of zinc oxide use in other topical products, including for the treatment of diaper rash in infants. This corroborates the negative results in human studies for irritation, photoirritation, allergy, and photoallergy that support our proposed finding regarding the safety of sunscreens containing this ingredient under the conditions proposed. Reports of non-hypersensitivity-related clinical safety issues with zinc oxide were infrequent and not serious. For these reasons, we do not consider additional clinical studies (including photosafety, irritation, or sensitization studies) to be necessary for this ingredient.

Dermal carcinogenicity studies have not been conducted for zinc oxide. In general, as discussed in section VII.C.1, adequate tests for safety of an active ingredient for use in topical products for chronic use (such as a sunscreen) would need to include dermal carcinogenicity studies if the active ingredient reaches the viable layers of skin where it could have a biological effect. Given the minimal penetration of zinc oxide below the non-living stratum corneum, there is no plausible mechanism by which zinc oxide could have an effect on skin tumor development. We are therefore proposing to find that zinc oxide is GRASE for use in sunscreens despite the lack of dermal carcinogenicity studies studying this ingredient.

Based on the minimal systemic exposure resulting from dermally applied zinc oxide, in particular when compared to endogenous zinc levels, we see no need for further nonclinical studies to support the safety of sunscreens containing zinc oxide, including systemic carcinogenicity studies, developmental and reproductive toxicity studies, or toxicokinetic studies.[22]

c. Conclusion. Our review of the available data from both animal and human studies and data on physical properties such as solubility leads us to conclude that the transdermal absorption of zinc oxide—regardless of particle size—from any topically applied sunscreen formulation is extremely unlikely, and that any de minimis absorption that may occur would not result in adverse health effects, given the high levels of endogenous zinc. The very low likelihood of any systemic absorption of zinc oxide in turn indicates that the safety margin for zinc oxide is large; accordingly, consistent with our approach to pediatric studies discussed in section VII.B.5, we do not consider pediatric studies to be needed for this ingredient. We propose to find that the currently available safety data provide sufficient evidence to demonstrate the minimal absorption, low dermal irritation, low allergenic sensitization and photoallergenicity, and low phototoxic potential of zinc oxide—regardless of particle size—up to 25 percent, and that these data support a finding that zinc oxide up to 25 percent is GRASE for use in sunscreens under the proposed conditions. Accordingly, we propose that zinc oxide is a Category I active ingredient.

2. Titanium Dioxide

For similar reasons, we propose that titanium dioxide is also a Category I active ingredient. Our review of information publicly available in the scientific literature, submissions to the sunscreen monograph docket, and FAERS has produced sufficient information to support a proposal that a sunscreen product containing up to 25 percent titanium dioxide would be GRASE under the conditions proposed in this rulemaking and the general conditions required in part 330.

a. Background. Titanium dioxide is an inorganic mineral compound consisting of small, crystalline-structured or amorphous particles. It is widely used as an excipient and is currently listed as an inactive ingredient in more than 60 approved drug products (including topical, oral, and inhalation products, among others) (Ref. 46). Titanium dioxide particles can be manufactured to have a variety of different dimensions, shapes (such as spheres or rods), and crystal polymorphs (such as anatase or rutile). Titanium dioxide (typically with particle dimensions ranging from 200 to 300 nm) is manufactured as a white powder for use as a white color pigment in pharmaceuticals. Manufacturers have also introduced processes that produce

[20] This literature included three clinical safety studies conducted by Hill Top Research, Inc. for Procter & Gamble regarding (a) human sensitization (Study Reports 96–6635–76a and 96–6635–76b); (b) human photoirritation/phototoxicity (Study Report 96–6634–76); and (c) human photoallergenicity (Study Report 96–6633–76). See Citizen Petition submitted by Proctor & Gamble, June 24, 1997 (FDA–1978–N–0018–0639) and the ''Opinion concerning Zinc Oxide'' drafted by the European Commission, Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP), which included five summaries of human clinical safety studies, all evaluating zinc oxide 25 percent (Ref. 40).

[21] See, *e.g.,* Beeckman et al. (Ref. 41); 43 FR 34628 at 34641(August 4, 1978) (discussing use of zinc oxide 1 percent to 25 percent as a skin protectant active ingredient: ''Zinc oxide is widely recognized as a skin protectant'' and ''No reports of topical toxicity were found in the literature'' on zinc oxide).

[22] Our review of the available nonclinical safety literature on zinc oxide included references for a 90-day dermal toxicity study, genotoxicity, and limited developmental and reproductive toxicity information. The review of this literature suggests that genotoxicity, findings for zinc oxide are mixed, and that there is minimal dermal toxicity in rodents after 90 days. (See Refs. 42 and 43.) Oral rat embryofetal toxicity studies showed some adverse maternal and fetal effects, but only at very high doses (≤200 mg/kg/day) significantly higher than what is at issue here (Refs. 44 and 45).

titanium dioxide with particle dimensions ranging from 15 to 50 nm to reduce its white/opaque appearance. Titanium dioxide particles used in sunscreens are also now often treated with chemical coatings (such as silicones, metal oxides, or organic acids) that are bonded to the exterior surface of the particles to, among other things, improve the aesthetic characteristics of the final formulation.

b. Discussion. Titanium dioxide is essentially insoluble in water and in biologic fluids (Ref. 47). As with zinc oxide, this lack of solubility prevents the transdermal absorption of more than a de minimis amount of titanium dioxide, regardless of either the concentration of titanium dioxide or the formulation of the product (Refs. 48 and 49). Further, unlike zinc oxide, which, if dissolved, would dissociate into zinc and oxygen (Ref. 50), the chemical stability of titanium dioxide is such that it does not dissociate under the conditions that exist in (or on) the human body (Ref. 51). Even if titanium dioxide were to dissociate into titanium and oxygen, titanium is unreactive in physiologic conditions, and (for this, among other, reasons) is frequently used in medical devices and structures implanted in the human body (Refs. 51 and 52).

The available studies on the transdermal absorption of titanium dioxide confirm that the skin is an effective barrier to the penetration of titanium dioxide, regardless of particle size—including those on the nanoscale (Refs. 53, 54, and 55). In our 2012 response to the ICTA Petition mentioned earlier, we described the then available information about the absorption of titanium dioxide nanomaterials and concluded that the ''currently available literature indicates that insoluble nanomaterials of titanium dioxide used in sunscreens do not penetrate into or through human skin to produce adverse health effects when applied topically'' (ICTA Petition Response at 26). Since that time, our search of the available literature has not revealed anything that would change this conclusion. Because topically applied titanium dioxide particles do not enter systemic circulation to any meaningful extent, we do not consider a MUsT to be necessary for this ingredient.

Given the lack of transdermal absorption of titanium dioxide beyond a de minims amount and, as a result, the very low likelihood of any systemic effects, we also do not consider additional nonclinical studies (including systemic carcinogenicity, developmental and reproductive toxicity, or toxicokinetic) to be necessary to support the safety of this ingredient.[23] Because titanium dioxide penetration beyond the non-living stratum corneum and into the viable layers of the skin is also minimal, as with zinc oxide, we do not consider dermal carcinogenicity studies to be needed for titanium dioxide either.

The inability of more than an extremely minimal amount of titanium dioxide to reach viable tissues that could have an immunologic reaction also prevents dermal irritation, sensitization reactions, and photosafety issues for this ingredient. Our search of the available literature on titanium dioxide identified nonclinical data reinforcing this, showing that dermal toxicity after dermal application of titanium dioxide in rodents is minimal (Refs. 57 to 60). Accordingly, we do not consider additional clinical photosafety, irritation, or sensitization studies to be necessary to support the safety of this ingredient. We note that the available studies on titanium dioxide evaluate products with titanium dioxide concentrations up to 10 percent. Given that the physical properties of titanium dioxide both preclude its penetration into or through the human skin regardless of concentration and make it unlikely that there would be dermal photosafety, irritation, or sensitization associated with titanium dioxide exposure (and that there is no data to suggest such photosafety, irritation, or sensitization would exist at higher concentrations), we propose that titanium dioxide—regardless of particle size—is GRASE for use in sunscreens at concentrations up to 25 percent, consistent with the level set in the Stayed 1999 Final Monograph.

In evaluating whether titanium dioxide is GRASE for use in sunscreen products, we have considered published literature indicating that nanoscale titanium dioxide can exhibit photocatalytic properties (Ref. 61). The literature indicates that the crystalline structure of titanium dioxide particles plays a role in this photocatalytic activity, and that the anatase crystalline polymorph is associated with greater photocatalytic activity than the rutile polymorph (Ref. 61). The European Commission has established limitations on the percentage of anatase crystalline polymorph in titanium dioxide to minimize photocatalytic activity.[24] Coating titanium dioxide particles has also been shown to minimize photocatalytic activity (and to limit particle clumping, which can have an impact on how products blend).[25]

In theory, if photocatalytic activity occurred when sunscreen products containing nanoscale titanium dioxide were exposed to light, it could result in the breakdown of other sunscreen active ingredients in these products. We have no evidence, however, that this in fact occurs in sunscreen products containing titanium dioxide or that there are any other negative impacts resulting from such photocatalytic activity. Accordingly, its potential for photocatalytic activity does not undermine our conclusion that titanium dioxide is GRASE for use in sunscreen products. Nonetheless, we invite comment (including supporting data) on whether sunscreens containing titanium dioxide are negatively impacted by the potential photocatalytic effects of that ingredient and, if so, to what extent; and on additional regulatory conditions, if any, that are necessary to address this potential issue.

We note, as well, that it is the responsibility of manufacturers to ensure that any inactive ingredients used in a drug product marketed pursuant to the OTC Drug Review, including coatings used to address photocatalytic activity or for other purposes, are safe and suitable for their intended use (see § 330.1(e)). FDA encourages manufacturers to contact the Agency regarding any specific coatings that they are considering for use in a topical sunscreen.

c. Conclusion. Given the chemical properties of titanium dioxide as insoluble and unreactive under physiologic conditions and the available studies showing that titanium dioxide does not penetrate into the skin or enter into systemic circulation to any meaningful extent, we consider the available safety data adequate to support a proposal that titanium dioxide is GRASE for use in sunscreens. As with zinc oxide, our proposal rests in significant part on the data showing that absorption of titanium dioxide into or through the skin is very unlikely and

[23] We note that the available literature also includes data showing that oral administration of relatively high doses of titanium dioxide did not produce adverse fetal effects in rats. (See Ref. 56.)

[24] In a July 2013 opinion addressing the safe use of titanium dioxide in sunscreen products, the European Commission's Scientific Committee on Consumer Safety gave its opinion that titanium dioxide particles consisting, among other things, of up to 5 percent anatase crystal ''can be considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin'' (Ref. 62). In 2016, this physicochemical parameter was incorporated by the European Commission into its Regulation on Cosmetic Products (Regulation (EC) No. 1223/2009 11/30/2009) permitting the use of titanium dioxide as a UV filter or as a colorant in cosmetics. See Regulation (EC) No 1143/2016 July 13, 2016.

[25] Id.

that any de minimis absorption that could theoretically occur would not result in adverse health effects. As a result, the safety margin here is large, and consistent with our approach to pediatric studies discussed in section VII.B.5, we therefore consider pediatric studies to be unnecessary for this ingredient.

B. Ingredients Proposed as Category II

FDA's review of the available safety data for PABA and trolamine salicylate have caused us to conclude that the risks associated with use of these ingredients in sunscreen products outweigh their benefits. Accordingly, we are proposing that these two ingredients are Category II.

1. Para-Aminobenzoic Acid

PABA use has decreased significantly in recent years because of, among other things, its adverse effects on skin and its discoloring and staining effect on clothing. Our review of more than 700 sunscreen brands sold in the United States (Ref. 63) indicates that PABA is in fact no longer being marketed in the United States.

A search of the scientific literature, submissions to the sunscreen monograph docket, drug approval documents from FDA and the European Medicines Agency, adverse event reports submitted to FAERS, and FDA Advisory Committee meeting reports (among other sources) has produced clinical safety data on PABA that supports a conclusion that a sunscreen containing PABA would not be GRASE. The available clinical information includes significant numbers of reports of allergic and photoallergic skin reactions to PABA, with rates of PABA-induced skin reactions potentially 8 percent or higher (Refs. 64 to 67). An 8 percent incidence is a serious concern: By comparison, only 34 hypersensitivity reactions associated with sunscreen products have been identified in FAERS since 1969.[26]

Further, PABA has the ability to cause cross-sensitization to structurally similar aromatic amines and nitro compounds (*i.e.,* it can cause individuals exposed to it to develop sensitivity reactions to similar compounds) (Ref. 69). The list of compounds at issue includes a variety of widely used products, such as sulfonamide antibiotics (commonly used to treat a variety of infections, from urinary tract infections to certain types of pneumonia), thiazide diuretics (the number one recommended treatment for hypertension for certain communities), certain local anesthetics (such as benzocaine and procaine), and dyes (including para-phenylenediamine (a hair dye) and aniline dyes (used in medical products)) (Refs. 70, 71, and 72). Cross-sensitization to these products is a serious concern, as widespread PABA use could result in a significant increase in cross-reactivity with these agents and the incidence of allergic and photoallergic dermatitis, some of which are likely to be severe.

These safety issues alone are reason enough to find PABA not GRASE for use in sunscreens. In addition, however, data obtained from the urine samples of human subjects receiving topical PABA application shows that PABA also penetrates the skin and enters systemic circulation (Ref. 73). Because full MUsT studies for PABA have not been done, it is unclear to what degree such transdermal absorption takes place. However, one article in the published literature suggests that there is an association between autoimmune disorder and PABA use (Ref. 71), and we found one report each of hepatotoxicity (Ref. 74) and chronic interstitial nephritis (Ref. 75) after oral PABA administration. Although it is difficult to determine causality on the basis of such single reports, if a MUsT were to show absorption of PABA, these reports could represent an additional safety concern.

In addition, genotoxicity findings with PABA use have been largely negative in the absence of UV irradiation. Adequate assessments of the dermal carcinogenicity potential of PABA are unavailable, as are DART studies. If a MUsT were to show absorption of PABA, therefore, necessary studies would include dermal and systemic carcinogenicity studies, DART studies, and toxicokinetic studies. However, given that the above-described safety concerns associated with PABA are significant enough to place PABA in Category II, conducting such testing is neither appropriate nor ethical. We propose that PABA is not GRASE for use in sunscreens.

2. Trolamine Salicylate

We also propose that trolamine salicylate is not GRASE for use in sunscreens, and is, like PABA, a Category II active ingredient. As described in further detail below, there are significant safety concerns associated with the use of trolamine salicylate in sunscreen products. We propose that these concerns are sufficient to support a conclusion that a sunscreen containing trolamine salicylate would not be GRASE. We note that, as with PABA, our review of more than 700 sunscreen brands sold in the United States suggests that trolamine salicylate is no longer being marketed in sunscreens sold in the United States (Ref. 63).

a. Background. Trolamine salicylate is comprised of trolamine and salicylic acid. Salicylic acid is a non-steroidal anti-inflammatory drug (NSAID); it is the active moiety in aspirin, and has been widely used as an analgesic (*i.e.,* pain relieving), anti-pyretic (*i.e.,* fever reducing), and anti-inflammatory agent. In addition to these properties, salicylic acid inhibits platelet aggregation, which in turn inhibits blood coagulation. For this reason, some salicylic acid-containing products (such as aspirin) are used by consumers to help reduce cardiovascular adverse events, including myocardial infarction, stent thrombosis, and transient ischemic attacks.

Trolamine salicylate was included in the Stayed 1999 Final Monograph for sunscreens at a concentration of up to 12 percent. It was also proposed as a Category III active ingredient in the tentative final monograph for OTC external analgesic drug products (External Analgesic TFM) (''External Analgesic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph,'' 48 FR 5852 at 5855 (February 8, 1983)). The mechanisms of action for trolamine salicylate for these two drug categories are very different; to be effective as an external analgesic, trolamine salicylate must penetrate the skin and reach the relevant sites of action. The available evidence clearly establishes that trolamine salicylate is transdermally absorbed (Refs. 76 and 77). To be effective as a sunscreen, however, trolamine salicylate must be present on the surface of the skin so that it can reflect, scatter, or absorb UV radiation.

The directions for use for the two product categories differ significantly as well. The current requirements for sunscreen labeling include directions that the product should be applied to all skin exposed to the sun, that it should be used ''regularly'' to decrease the risk of skin cancer and early skin aging,[27] and that it should be reapplied at least every 2 hours (21 CFR 201.327). In contrast, currently marketed external analgesic products containing trolamine salicylate include directions for use stating that they should be applied to ''affected areas,'' that they should be reapplied no more than three to four

[26] Total sunscreen sales since 1969 are not readily available. However, in 2016 a total of 161,882,779 sunscreen units were sold in the United States (Ref. 68).

[27] This direction applies to sunscreens with an SPF of 15 or greater that are also broad spectrum.

times a day, and that use should be discontinued after 7 days.[28]

b. Significant safety concerns associated with use of trolamine salicylate as a sunscreen. FDA is concerned that use of trolamine salicylate as an active ingredient in sunscreens could cause serious detrimental health effects due to the anti-coagulation effects of salicylic acid. FDA located two case reports of serious coagulation-related adverse events associated with liberal dermal application of trolamine salicylate. The first case involved a surgical patient who experienced coagulopathy (impairment of the blood's ability to coagulate) at surgical sites in connection with use of topical trolamine salicylate (Ref. 76). Although the patient discontinued aspirin use 2 weeks before surgery per her doctor's instructions, she was unaware that use of a topical cream containing trolamine salicylate should have been stopped as well, and continued liberal application of the product to her knees for arthritis pain in the period leading up to her surgery. Four hours after surgery, the patient returned to the operating room bleeding profusely from all surfaces that had been operated on and experiencing massive bilateral hematomas. She lost more than 900 mL of blood.

In the second case, a patient taking warfarin (an anticoagulant) for atrial fibrillation and stroke prevention experienced a considerable increase in prothrombin time (*i.e.,* the time it takes for blood to coagulate) after liberal application of trolamine salicylate to his neck and shoulders for pain relief (Ref. 78). The patient's prothrombin time had previously been in the therapeutic range of 1.3 to 1.5 times the control, but increased to 2.5 times the control during trolamine salicylate use. When trolamine salicylate use was discontinued, the patient's prothrombin time returned to 1.3 times the control.

FDA is also concerned that sunscreens containing trolamine salicylate could lead to other adverse effects associated with salicylic acid exposure. These include gastrointestinal distress and hemorrhage, ototoxic effects (*i.e.,* impacts on hearing), hypersensitivity reactions, asthma exacerbations, acid-base imbalance, salt and water retention, liver injury, and Reye's Syndrome (in children). At high doses, acute salicylate toxicity (salicylism) may occur. Early symptoms of salicylism include tinnitus, vertigo, nausea, vomiting, and diarrhea; subsequent symptoms suggesting a more severe intoxication include altered mental status (ranging from agitation to lethargy), hyperpyrexia, noncardiac pulmonary edema, and coma.[29]

If trolamine salicylate were to be applied to all skin exposed to the sun and reapplied every 2 hours as directed in sunscreen labeling, the potential for transdermal absorption and systemic availability of substantial amounts of salicylic acid raises significant concerns about the potential for increased occurrence of the above-described adverse events. This is a particular concern given the widespread use of other OTC NSAID products with anti-inflammatory, analgesic, or anti-pyretic effects, which, combined with the use of sunscreens containing trolamine salicylate, may raise the anti-platelet effects experienced by consumers to problematic levels. Concerns relating to transdermal absorption may be especially acute for children, who have a higher surface-area-to-body-weight ratio than adults. FDA proposes that the above-described safety concerns are enough, by themselves, to support a finding that trolamine salicylate is not GRASE for use in sunscreens, and therefore, is a Category II active ingredient.

c. Data gaps. In addition, there are several categories of data about trolamine salicylate that FDA expects would be necessary to support a positive GRASE determination for its use in sunscreen products that are currently missing from the public record. For example, there is insufficient clinical dermal sensitization, irritation, and photosafety data for trolamine salicylate. Although the transdermal absorption of trolamine salicylate is well established, the record currently lacks a MUsT that would allow us to evaluate the extent of exposure to this ingredient when it is used as a sunscreen. Such data is important because it would allow FDA to interpret systemic toxicity findings in animal toxicology studies in the context of the amount likely to be absorbed from sunscreen use. Given the FDA recommendation that a MUsT for sunscreen use include application to a majority (75 percent at a minimum) of the body surface of each test subject, the above described safety concerns (including the potential for salicylism associated with exposure to high doses of trolamine salicylate) would raise significant ethical concerns about the conduct of a MUsT in these circumstances. Were it possible to ethically conduct a MUsT for this ingredient, and if such a MUsT showed significant transdermal absorption of trolamine salicylate, this would raise questions about whether enough of this ingredient remains present on the surface of the skin for it to function effectively as a sunscreen. As we noted in section VII.B.4, such considerations ultimately weigh into the risk-benefit calculus FDA uses to determine whether an active ingredient would be GRASE for use in sunscreens.

Although we have data addressing the toxicology profile of salicylate, adequately detailed nonclinical DART studies for trolamine and toxicokinetic data to interpret DART studies were also not found in the public record. Adequate DART information, if it were available, might reveal additional data needs (for example, to address any potential hormonal effects that may be identified). Dermal carcinogenicity data are available from the National Toxicology Program for trolamine in acetone and trolamine alone (applied neat).[30] In the absence of toxicokinetic data to interpret existing carcinogenicity studies, we cannot determine how the exposure in the animal studies relates to human exposure to trolamine from the use of trolamine salicylate as a sunscreen active ingredient.

d. Conclusion. For the reasons described above, FDA proposes that trolamine salicylate is not GRASE for use in sunscreens. The safety concerns associated with the use of trolamine salicylate as an active ingredient in sunscreens are significant enough to support classification of trolamine salicylate as a Category II ingredient. In particular, the potential for transdermal absorption and systemic availability of substantial amounts of salicylic acid in connection with the exposure resulting from the use of trolamine salicylate in sunscreens raises concerns about increased occurrence of the above-described serious adverse events (including salicylism and serious coagulation-related issues). The record also contains several significant data gaps that would need to be addressed to support a positive GRASE determination for trolamine salicylate.

[28] Based on an evaluation of product labeling available at *https://labels.fda.gov* (accessed April 4, 2018). See also External Analgesic TFM.

[29] The symptoms associated with both acute and chronic salicylate toxicity are well established. Descriptions are available from many sources, including: National Library of Medicine's Toxicology Data Network (ToxNet), ''Salicylic Acid,'' September 2008, available at *https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+672* (accessed March 27, 2018). FDA also included a comprehensive summary of salicylism in 21 CFR 343.80.

[30] In mice, liver tumors were identified, providing evidence of systemic absorption of trolamine, but the suspected mechanism of action is likely not relevant to humans (Refs. 79 and 80). A causal link between the proposed mechanism and tumor formation in mice is lacking.

Given the safety concerns described above, however, conducting the clinical absorption testing recommended to address these gaps for use as a sunscreen raises ethical concerns.

C. Ingredients Proposed as Category III

The public record does not contain sufficient data to support a positive GRASE determination for cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone or avobenzone at this time. Accordingly, these ingredients are being proposed as Category III. In the sections that follow, we discuss our review of the available safety evidence for these ingredients and identify the existing data gaps.

1. Ingredients for Which the Record Contains Significant Data Gaps: Cinoxate, Dioxybenzone, Ensulizole, Homosalate, Meradimate, Octinoxate, Octisalate, Octocrylene, Padimate O, and Sulisobenzone

The most significant gaps in the administrative record exist for the following active ingredients: Cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, and sulisobenzone. We expect that data from all the types of studies described in section VII will need to be submitted to support general recognition of safety and effectiveness for each of these ingredients.

Only three of these active ingredients (homosalate (Ref. 81)), octinoxate (Refs. 81 to 84), and octisalate (Ref. 81), for example, appear to have been evaluated in human absorption studies, and most of the available absorption studies for these three ingredients had significant limitations. For example, the studies use a limited number of subjects or are based on only a single application of the sunscreen active ingredient to a limited area of the body. Even with this limited sunscreen exposure, some of these studies showed systemic availability of the active ingredient (octinoxate (Refs. 83 and 84)). None of these 10 ingredients has been studied in an adequate and well-controlled MUsT that would determine the amount of systemic exposure to the active ingredients under conditions of maximal use.

We note that a recent publication examining the relationship between melting point, molecular weight, and the transdermal delivery rates of the active ingredients in approved drug products shows that products containing active ingredients with melting points and molecular weights similar to many of these 10 sunscreen active ingredients are among those successfully delivered transdermally—and therefore available systemically (Ref. 85). This reinforces the potential for transdermal absorption of and systemic exposure to these sunscreen ingredients. The potential for such systemic exposure is a concern because the available data are inadequate to determine either the level of systemic exposure to these active ingredients or the potential unintended consequences of such exposure. Given the lack of chronic exposure toxicology data for these 10 ingredients—which makes an evaluation of the dermal and systemic effects of chronic use impossible—this is especially concerning. A number of these active ingredients have also shown hormonal effects in mammalian assays (homosalate (Refs. 86 to 92)) and padimate O (64 FR 27666 at 27671) and in in vitro and in vivo assays (homosalate (Refs. 86 to 92), octinoxate (Refs. 93 and 94),and octocrylene (Ref. 95). Although these findings are only preliminary, we do not have adequate DART studies to enable us to assess the impact of these potential hormonal effects on development and reproduction.

In addition, several of these 10 ingredients (homosalate (Refs. 81 and 84), octinoxate (Refs. 81 and 96 to 101), octisalate (Refs. 81, 84, and 101 to 105),octocrylene (Refs. 95 and 106), padimate O (Ref. 100), and sulisobenzone (Refs. 107 and 108)) have been studied in dermal penetration studies, which show (in general, with the exception of homosalate) that these ingredients permeate into the epidermis and/or dermis. The studies show that there are several factors (including vehicle composition and the presence of other active ingredients) that can influence, and potentially increase, the permeation and/or penetration of these ingredients.

Because the record does not currently contain sufficient data to support their safety, we are proposing that cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, and sulisobenzone are Category III ingredients. As previously noted, we expect that data from all the types of studies described in section VII will be needed to support general recognition of safety and effectiveness for these ingredients.

2. Ingredients for Which the Record Contains Fewer Data Gaps: Oxybenzone and Avobenzone

While the record does not currently contain sufficient data to support positive GRASE findings for oxybenzone and avobenzone, we have significantly more data for these two ingredients than for the ingredients discussed in the preceding section. To help facilitate submission of the remaining data, we describe the data gaps for these two ingredients in greater detail below.

a. Oxybenzone data. Although we located substantially more data on oxybenzone than on the ingredients discussed in section VIII.C.1, our review of the scientific literature, submissions to the sunscreen monograph docket, and postmarket safety data publicly available through FAERS revealed significant gaps in the data we expect to be necessary to support a positive GRASE finding for use of oxybenzone at a concentration of up to 6 percent in sunscreen products. The available literature includes studies indicating that oxybenzone is absorbed through the skin and can lead to significant systemic exposure, as well as data showing the presence of oxybenzone in human breast milk, amniotic fluid, urine, and blood plasma. The significant systemic availability of oxybenzone (and, as discussed further below, the lack of data evaluating the full extent of its absorption potential) is a concern, among other reasons, because of questions raised in the published literature regarding the potential for endocrine activity with systemic oxybenzone exposure. Accordingly, we expect that a positive GRASE finding for oxybenzone-containing sunscreens would require, among other things, both a MUsT showing the degree of oxybenzone absorption under maximal usage conditions and DART studies that fully investigate its potential endocrine-disrupting effects. We found neither in the existing record.

The record also lacks systemic and dermal carcinogenicity studies for oxybenzone; these (and toxicokinetic data) should also be provided to support a positive GRASE finding for this ingredient. Finally, the available literature also raises questions about the safety of use of oxybenzone-containing sunscreens in young children because of the potential for higher absorption and bioaccumulation of oxybenzone in this population. As discussed in further detail in the sections that follow, we invite input and comment on appropriate studies and/or age restrictions to address these pediatric issues.

b. Background of oxybenzone. Unlike zinc oxide and titanium dioxide, both of which are inorganic (or physical) UV filters consisting of metal oxides that primarily reflect or scatter UV radiation,

oxybenzone is an organic (or chemical) filter, which absorbs UV radiation. It belongs to a class of aromatic ketones known as benzophenones and has a UV absorption profile covering both UVA and UVB wavelengths (Ref. 109). Because of its superior UVA coverage, oxybenzone was increasingly used through the early 1990s and ultimately replaced PABA in sunscreen products (Ref. 110). Use of oxybenzone in sunscreens increased when ''PABA-free'' sunscreens were introduced into the market because of recognition that PABA and its esters induced contact and photocontact allergic reactions (Ref. 110). As discussed below, however, evidence shows that oxybenzone also has contact allergenic and photoallergenic potential (Ref. 111). In addition to its use as a sunscreen active ingredient, oxybenzone is used in, among other things, perfumes, lipsticks, hair sprays, and conditioners as a photostabilizer and/or fragrance enhancer (Refs. 112 to 114).

c. Data showing transdermal absorption and significant systemic availability of oxybenzone. Data that have become available since publication of the Stayed 1999 Final Monograph suggest that the transdermal absorption of oxybenzone is high (Refs. 82, 115, and 116). One study involving sampling of plasma and urine following topical application of an oxybenzone-containing formulation showed absorption and significant systemic availability of oxybenzone (Ref. 82). In this study, 15 men and 17 women were dosed once daily, applying a 10 percent oxybenzone cream formulation to approximately 90 percent of the body's surface area for 4 days. The figures below illustrate the plasma and urine levels observed.

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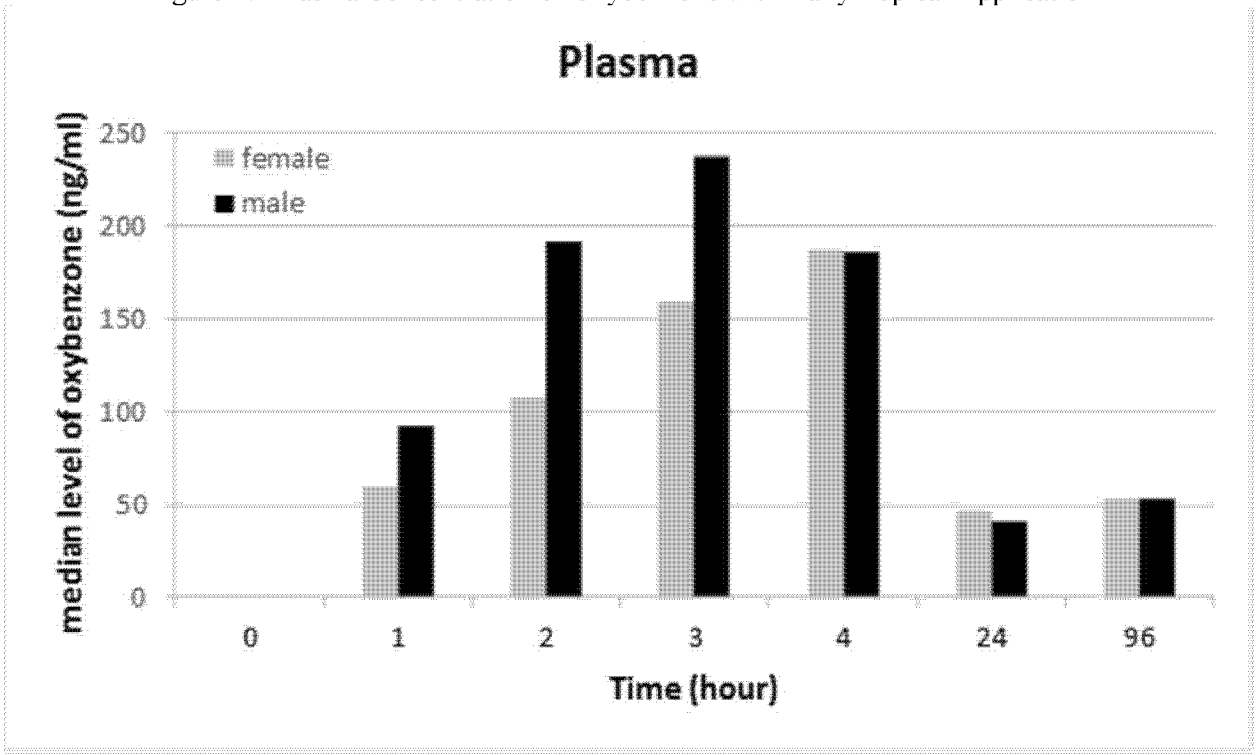
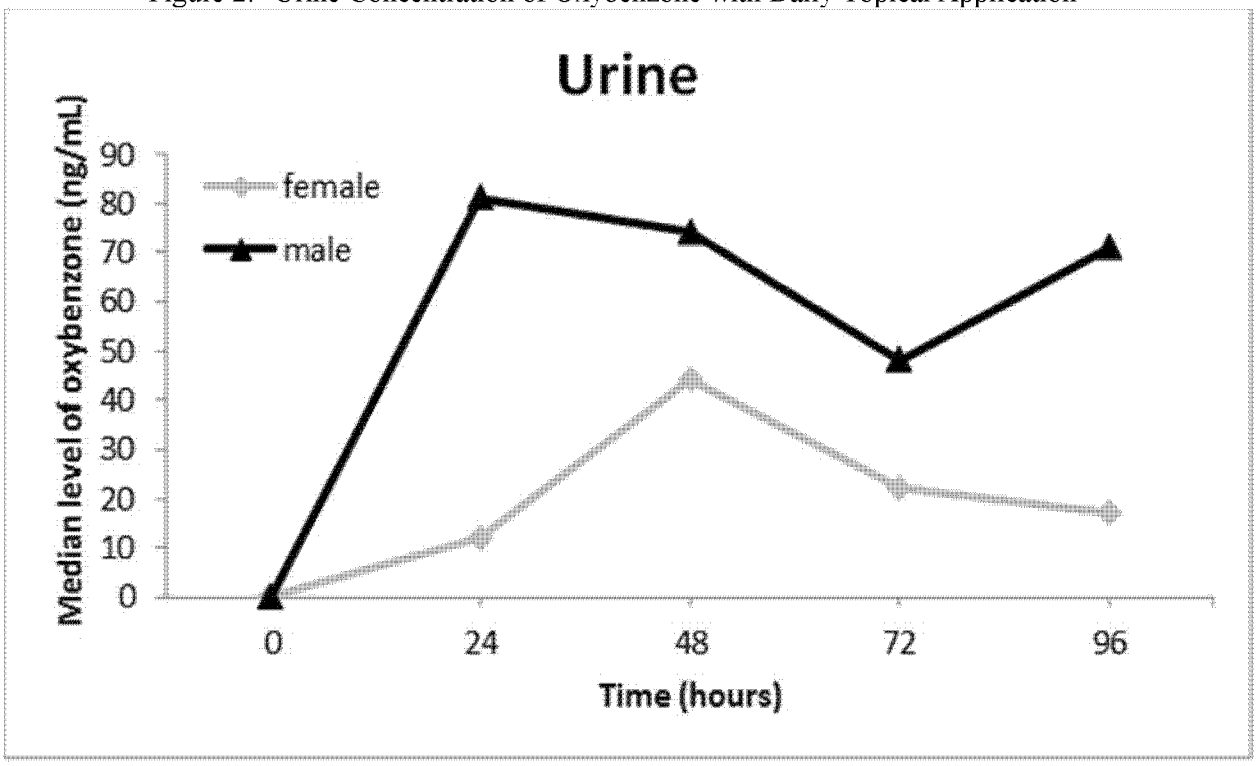
Figure 1.--Plasma Concentration of Oxybenzone with Daily Topical Application



Source: Data adapted from Janjua et al., 2008 (Ref. 82).

BILLING CODE 4164–01–C

Figure 2.--Urine Concentration of Oxybenzone with Daily Topical Application



Source: Data adapted from Janjua et al., 2008 (Ref. 82).

BILLING CODE 4164–01–C

Although this study provides important information about the significant absorption potential of oxybenzone, it does not obviate the need for a MUsT. Among other things, once-daily application may result in substantially lower systemic exposure than application at least every 2 hours (as sunscreen labeling directs). This difference in application frequency is a particular concern given that the data show oxybenzone levels would still be increasing at the time of reapplication if a 2-hour application window were observed. Additionally, the cream formulation used in the study was not formulated as a sunscreen product and may have contained ingredients not typically used in sunscreen formulations, and/or lacked other ingredients typically present. Because the formulation can have an impact on absorption, the absorption results produced by the study may not reflect absorption levels that would result from actual use of oxybenzone-containing sunscreen products.

Another study, which evaluated the transdermal absorption of a marketed sunscreen containing 4 percent oxybenzone in 16 women and 9 men, showed prolonged systemic availability of oxybenzone following topical exposure (Ref. 116). In this study, which was designed to evaluate the effects of UV radiation on oxybenzone absorption, the sunscreen was applied to study subjects twice daily for 5 days. Although the study concluded that UV exposure did not significantly affect the urinary excretion of oxybenzone, it provided further evidence of the systemic availability of oxybenzone following topical application and showed that renal excretion of oxybenzone continued for 5 days after the last application of the sunscreen. Although the use of a commercial sunscreen formulation, and twice- rather than once-daily sunscreen application are improvements over the formulation and application frequency used in the previous study, twice-daily application remains insufficient to approximate the recommended application frequency of sunscreen products in real-world use. Furthermore, because the study used a sunscreen with 4 percent rather than the full 6 percent concentration of oxybenzone eligible for the sunscreen monograph, its results may not fully reflect the absorption that would result from use of a 6 percent oxybenzone-containing product. To properly characterize the potential for absorption of oxybenzone in sunscreen products and to determine a margin of safety for use of oxybenzone at up to 6 percent in sunscreen products, we expect that a MUsT will be needed.

d. Inadequate data on oxybenzone's developmental and reproductive toxicity. The significant systemic availability of oxybenzone following topical application and the lack of data fully characterizing its absorption levels are concerns, among other reasons, because of literature suggesting that oxybenzone may have endocrine activity (see, *e.g.,* Refs. 88, 92, and 117). Dermal exposure to oxybenzone (in acetone) in rats and mice and oral feeding of oxybenzone to rats and mice resulted in reduced sperm density in males in 13-week general toxicity studies conducted by the National Toxicology Program (NTP) (Ref. 118). In female rats and mice, increased estrous cycle length was observed in 13-week oral feeding studies.[31] Importantly, the actual effects of oxybenzone on female fertility were not evaluated. In a preliminary dose range-finding pre- and postnatal development study in rats, findings in male offspring indicated that cells in the testes undergoing programmed cell death were increased in all oxybenzone-exposed animals and that numbers of spermatocytes in the testes were markedly reduced after oral feeding at oxybenzone (Ref. 119). Although these findings are notable, they are all derived from dermal studies

[31] These changes could potentially be addressed with historical control data (Ref. 88).

with oxybenzone in acetone and oral feeding studies of oxybenzone; these methods of exposure could potentially lead to higher levels of systemic exposure to oxybenzone than with sunscreen use. Accordingly, a MUsT and toxicokinetic data are needed to determine the relevance of these findings to human use of oxybenzone as a sunscreen active ingredient.

In humans, the endocrine effects of oxybenzone have been studied with inconclusive results (see, *e.g.,* Refs. 83, 120, and 121). In biomonitoring studies of pregnant and lactating women, oxybenzone has been detected in breast milk, amniotic fluid, and urine samples (Ref. 83, 120, and 121). High levels of oxybenzone in the urine of mothers have been associated with: (1) Decreased birth weight in girls and (2) increased birth weight and head circumference in boys, both of which can be indications of endocrine effects (Ref. 83). This association is particularly concerning given the widespread exposure of the U.S. population to oxybenzone. Estimates suggest that oxybenzone (from all sources) is present in the urine of 97 percent of the U.S. population, and that oxybenzone concentrations are higher in women than in men (possibly because women are more likely to use sunscreen and other personal care products containing oxybenzone, leading to greater cumulative exposure) (Ref. 83 and 115).

Because current data suggest that oxybenzone may affect the human endocrine system, FDA believes that a positive GRASE determination for oxybenzone would require that its potential toxicities have been fully explored, including through DART studies (fertility and early embryonic studies in rodents, embryofetal development studies in rodent and nonrodent species, and pre- and postnatal development studies in rodents). In addition, as noted below, toxicokinetic data are needed to interpret these studies. We note that, if the results of DART studies do not resolve the concerns raised in the literature relating to potential endocrine disruption, it may still be possible to resolve these concerns through additional testing.[32] In addition, because of the potential risk posed by metabolites of oxybenzone (existing reports suggest that some oxybenzone metabolites are more hormonally active than the parent drug (Ref. 109)), we recommend that the analytical method used in the MUsT be validated for both the parent and the metabolites of interest (Ref. 115) to support a positive GRASE finding for this ingredient. The results from the metabolite study will inform whether additional nonclinical studies assessing oxybenzone's metabolites should be conducted to support its safety. We note that the NTP is currently conducting additional DART studies on oxybenzone (although their embryofetal studies do not appear to include an assessment in a nonrodent species) (Ref. 122).[33]

e. Inadequate carcinogenicity and toxicokinetic data for oxybenzone. High population exposure to oxybenzone, coupled with a lack of carcinogenicity testing for this ingredient, caused the National Cancer Institute to nominate oxybenzone for toxicology testing in 1979 (Ref. 123). The NTP reports that 2-year oral (dosed feed) carcinogenicity studies in rats and mice are in a draft report stage, but results are not yet publicly available (Ref. 122). In addition, no reports of either ongoing or planned dermal carcinogenicity studies for oxybenzone have been published. To support a positive GRASE finding for oxybenzone, carcinogenicity data from well-conducted dermal and systemic carcinogenicity studies should be provided. Toxicokinetic data in rodents (oral and dermal) and rabbits (oral) are also recommended; these data could be obtained from either stand-alone studies or as part of DART and dermal carcinogenicity studies.

Our search of the available literature also revealed information suggesting that oxybenzone may generate reactive oxygen species (ROS)[34] in the presence of UV light, but that this issue, and the harms associated with it, have not been fully explored (Ref. 124). We invite comment and input on the extent to which ROS generation is a concern for sunscreens containing oxybenzone and whether additional data on this topic are needed.

f. Dermal safety of oxybenzone. The available data indicate that oxybenzone (at concentrations up to 6 percent) has a favorable safety profile with respect to irritation and sensitization potential. For example, the North American Contact Dermatitis Group conducted an analysis of patients who were patch tested for allergies between 2001 and 2010 (see, *e.g.,* Ref. 125). From 2001 to 2008, oxybenzone was tested at 3 percent; from 2009 to 2010, the concentration used for the test was increased to 10 percent. Of the 23,908 patients patch tested, only 82 patients (0.34 percent) had positive test patch results with oxybenzone. In addition, a search of FAERS for case reports of hypersensitivity reactions to oxybenzone-containing sunscreen products resulted in only 31 cases (4 with anaphylaxis) between 1988 and 2011. Because sufficient data exist to make a determination, we do not consider additional dermal irritation or sensitization studies to be necessary to support a positive GRASE finding for oxybenzone up to 6 percent. As is customary in clinical trials, however, we recommend that dermal safety data for oxybenzone be collected during MUsT studies.

Nevertheless, the overwhelming majority of results from available studies (see, *e.g.,* Refs. 125 to 136) addressing allergic contact dermatitis for oxybenzone show that oxybenzone is an allergen for persons with preexisting skin conditions. Because the evidence establishing oxybenzone as a photoallergen in individuals with photosensitivity is clear, no further dermal photosafety studies to characterize this risk are needed. However, if we were to receive adequate data to support a positive GRASE finding for oxybenzone, we would consider requiring labeling language to address the risk of allergic reactions associated with oxybenzone use. We invite comment on whether such labeling should be required for sunscreens containing oxybenzone and, if so, what that labeling should entail.

g. Safety questions regarding use of oxybenzone in pediatric populations. Sunscreens are currently labeled for use in children as young as 6 months old. The available literature, however, includes several publications that raise concerns about the use of sunscreens containing oxybenzone in young children. Among these publications is a 2006 report from the Swedish Research Council noting that children under the age of 2 years old have not fully developed the enzymes believed to metabolize oxybenzone (Ref. 137), which suggests, in theory, that small children may not be able to eliminate oxybenzone as easily as adults. The possibility for bioaccumulation in children, taken together with the potential increased absorption of oxybenzone in young children (due to their greater body surface-area-to-weight ratio) and the potential harms associated with absorption discussed above,

[32] For examples of the type of studies that could be explored at that juncture see Ref. 21.

[33] As a reminder, such data must be generally available to be considered as part of this rulemaking process. Once available, FDA intends to review such data to determine whether it resolves particular data concerns we have in this area.

[34] *Reactive oxygen species* are ''a type of unstable molecule that contains oxygen and that easily reacts with other molecules in a cell. A buildup of ROS in cells may cause damage to DNA, RNA, and proteins, and may cause cell death.'' *https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=687227.*

militates in favor of caution when using oxybenzone products in young children. Accordingly, we are seeking any existing pediatric data on the safety of oxybenzone use in children under 2 years old. We are also requesting input on: (1) Whether additional data on the safety of oxybenzone use in young children is necessary to support the use of oxybenzone-containing sunscreens in children under 2 years of age (taking into consideration the practical hurdles involved in conducting studies in children of this age) or (2) whether sunscreen products containing oxybenzone should instead be contraindicated for use in children younger than 2 years (given, among other things, the availability for use as sunscreen active ingredients of physical UV filters like titanium dioxide and zinc oxide, which do not raise the same questions about safe use in young children).

h. Conclusion. Given the available data showing significant transdermal absorption and systemic availability of oxybenzone, as well as the potential for endocrine activity, we propose that oxybenzone is not GRASE for use in sunscreens without further data. As described above, a MUsT should be conducted to fully characterize the absorption of oxybenzone and to calculate a margin of safety for human use. As part of the MUsT, we believe that a study of oxybenzone's metabolites in humans is also necessary; the results of this study will inform whether additional nonclinical studies with metabolites are needed to address potential endocrine effects. Given that oxybenzone demonstrates significant systemic absorption, FDA believes that data on carcinogenicity (both systemic and dermal) and developmental/reproductive toxicity are likely to be needed to support the safety of this ingredient, as are toxicokinetic data to bridge between animal and human data. We seek any existing data on the pediatric safety of oxybenzone. We also seek comment on whether additional safety data are needed to support the use of sunscreens containing oxybenzone on children under 2 years of age, as well as comment on whether these sunscreens should be contraindicated for use in this population. We note that, because of the risk of allergic reactions associated with oxybenzone use, if we receive adequate data to support a positive GRASE finding for oxybenzone, we may require labeling to address this risk. We seek comment on whether such labeling should be required for sunscreens containing oxybenzone and, if so, what such labeling language should entail.

In summary, table 3 shows the additional studies that FDA anticipates would be necessary to support a positive GRASE finding for sunscreens containing oxybenzone.

TABLE 3—SUMMARY OF RECOMMENDATIONS: STUDIES FOR OXYBENZONE UP TO 6 PERCENT

Safety studies FDA proposes are necessary to support a GRASE determination	Additional studies or data necessary?
Pharmacological Studies:	
Human absorption (MUsT) (including metabolite study in humans)	Yes.
Nonclinical Safety Studies:	
Toxicokinetics	Yes.
Dermal Carcinogenicity	Yes.
Systemic Carcinogenicity	Yes.
DART: [1]	Yes.
Fertility and early embryonic development.	
Embryofetal development in two species (rodent and non-rodent).	
Prenatal and postnatal development.	
Clinical Safety Testing:	
Skin irritation and sensitization	No.
Skin photoallergenicity and phototoxicity	No.
Pediatric studies	Seeking input on whether additional studies or contraindication are necessary to support the safety of sunscreens containing oxybenzone for children under 2 years of age.

[1] As noted above, if DART studies do not resolve the concerns raised in the literature relating to potential endocrine disruption, it may be possible to resolve these concerns through additional testing.

i. Avobenzone data. Our review of the available scientific literature, submissions to the sunscreen monograph docket, and publicly available FAERS data also revealed significant gaps in the data we expect to be necessary to support a finding that avobenzone (at up to either 3 percent or 5 percent, as discussed below) is GRASE for use in sunscreens. Most critically, we encountered no studies examining the absorption of avobenzone in vivo, and those in vitro studies we located had several weaknesses that limit their usefulness in assessing the potential absorption of avobenzone from formulated sunscreen products. This is a concern given that, as explained in further detail below, certain of avobenzone's chemical properties suggest that sunscreen products containing avobenzone have a potential for absorption. There are also other gaps in the record, including (as discussed below) dermal carcinogenicity data, toxicokinetic data, and—potentially, depending on the outcome of MUsT studies assessing the absorption of avobenzone—systemic carcinogenicity and additional DART studies. Accordingly, we propose to find that avobenzone is Category III.

j. Background of avobenzone. Avobenzone, like oxybenzone, is an organic (chemical) UV filter. Because avobenzone primarily absorbs radiation in the UVA portion of the UV spectrum, it is typically combined with another sunscreen active ingredient that provides protection in the UVB range. Avobenzone exhibits greater photoinstability than other UV absorbers; the available evidence shows that avobenzone degrades quickly upon exposure to sunlight, which can cause its efficacy to be decreased by between 50 and 90 percent after 60 minutes of exposure to sunlight (Refs. 138 and 139).[35] To address this, avobenzone is typically combined with a photostabilizer to prevent rapid photodegradation (Refs. 138 and 139).

[35] Avobenzone's photodegradation also results in the formation of free radicals, which could, in theory, create sensitization and irritation responses and increase long-term risk of skin cancers and photoaging (Ref. 139).

k. Potential for absorption of avobenzone. Although avobenzone is not soluble to any great extent in water, it is soluble in organic solvents. These include oils (which are present on human skin), alcohols, and other substances regularly included in sunscreen product formulations. Although this solubility is not enough, by itself, to determine whether transdermal absorption will take place, it is a necessary precondition (Ref. 140). In addition, like the 10 active ingredients described in section VIII.C.1, avobenzone's melting point and molecular weight are similar to those of active ingredients in approved drug products that are successfully delivered transdermally and therefore available systemically (Ref. 85). As with the 10 sunscreen active ingredients previously discussed, this suggests a potential for transdermal absorption of avobenzone.

l. Lack of adequate data on transdermal absorption of avobenzone. Nevertheless, our review of the available literature on avobenzone failed to produce any studies evaluating the in vivo absorption of avobenzone at 3 percent or higher under (or even approaching) maximal usage conditions. While we were able to locate a few studies evaluating avobenzone's absorption in vitro, these studies had a number of weaknesses that significantly limited the conclusions that could be drawn from them.

The first in vitro study we located evaluated the penetration—through excised human skin—of five sunscreen ingredients (including avobenzone) that had been diluted in mineral oil and water (Ref. 100). The study used a static cell technique. As discussed in section VIII.D, in a static cell study, the test product (here, a sunscreen/mineral oil/water formulation) is placed on the upper side of a membrane (here, the excised skin) in the open donor chamber of a static cell, and a sampling fluid is placed on the other side of the membrane in a receptor cell. Diffusion of the ingredient (here the avobenzone) from the topically applied product to and across the membrane is monitored by examining sequentially collected samples of the receptor fluid. To ensure that all transdermal penetration of the ingredient that takes place is fully reflected in the receptor fluid, the receptor fluid must be optimized for absorption (in other words, *sink* conditions must be created in the fluid).

In this study, the use of skin as the membrane in the system allowed for an evaluation of the presence and depth of permeation via *skin stripping*—the sequential application and removal of adhesive tape to the skin samples. However, it is unclear whether the receptor phase of the study created adequate sink conditions. In addition, the formulations used in the study (which, as noted previously, consisted of only water, mineral oil, and the sunscreen ingredient) did not contain any of the other types of excipients (such as emollients, stabilizers, or solubilizers) that can also function as permeation/absorption enhancers and that are typically present in sunscreen product formulations. The study results showed that there was avobenzone present in the stratum corneum, the epidermis, and the viable dermis of the skin used as the membrane, but not in the receptor fluid. Although the lack of avobenzone in the receptor fluid is encouraging, the other characteristics of the study limit its value in assessing the actual absorption potential of avobenzone used in sunscreen products.

The second in vitro study (Ref. 141) we located suffered from similar limitations. This study assessed the avobenzone permeation observed using a static cell (as generally described above), and then took the skin from the static cell and subjected it to multiple rounds of tape stripping to assess the presence of avobenzone at various levels of the skin. Following tape stripping, the skin was subjected to digestion (*i.e.,* the skin sample was subjected to a chemical treatment that breaks down the cell membranes to release any sunscreen that might be either bound to proteins or bound up in the cells).

The study results showed significant retention of avobenzone in the stratum corneum, a lesser amount in the epidermis, and none in the dermis or receptor fluid. Like the previous study, however, the test material used in this study did not include any of the permeation enhancers typically included in commercial sunscreen formulations. It is also unclear whether sink conditions existed in the receptor phase of the study.

The final in vitro study used a static cell to evaluate the transdermal penetration of six sunscreen formulations collected from a health spa that marketed its own line of skin care products (Ref. 96). This study improved on the design of the previous two studies in several respects. First, the receptor fluid contained ethanol, a permeation enhancer often used in sunscreen products, which produced sink conditions in the receptor phase. Secondly, to create favorable conditions for absorption, the products were applied at a thickness of 20 mg/square centimeters (cm^2) on the skin's surface (*i.e.,* 10 times the skin loading typically expected (Refs. 142 and 143)). In addition, the study's use of commercially marketed sunscreen formulations (which, as discussed above, typically contain multiple permeation/absorption-enhancing excipients) more accurately reflects the absorption potential of marketed sunscreen products.

Despite these improvements, the usefulness of the study was limited by its use of an analytical method that prevented the detection of any avobenzone absorption below 100 ng/mL. This level of absorption is hundreds of times higher than what is relevant for our considerations in assessing the acceptable absorption level from a topically applied product. The concentration of avobenzone used in the study (ranging from 0.2 percent to 1 percent) is also significantly lower than what is relevant for our current consideration of maximum concentration of this ingredient. Although avobenzone was only absorbed to a very small extent (between 3 percent and 3.96 percent) under these study conditions, these weaknesses in the study's design significantly limit the conclusions that can be reached from its results.

Given that avobenzone's chemical properties suggest that it has a potential for transdermal absorption in sunscreen products, the lack of adequate data assessing its absorption in realistic sunscreen formulations is a concern. We therefore expect that a MUsT demonstrating the degree of absorption of avobenzone into the human body under maximal use conditions will be needed to support a positive GRASE determination for sunscreens containing avobenzone. Further, in light of the above-described data showing avobenzone's photoinstability, we also expect that, if sufficient data are provided to support the safety of avobenzone, any future sunscreen monograph including avobenzone as an active ingredient will include the limitation that avobenzone is not GRASE for use in sunscreen products unless it has been photostabilized (via use of a photostabilizing UV filter or other photostabilizing ingredient/mechanism) to prevent its photodegradation and (among other concerns) the attendant reduction in avobenzone efficacy.

Because photodegradation can reduce the amount of avobenzone absorbed transdermally, we also expect that a MUsT sufficient to support the general recognition of safety of avobenzone for sunscreen use would need to test formulations of avobenzone that include a photostabilizer. Including

photostabilizers in MUsT formulations will allow for accurate assessment of absorption levels in final formulated sunscreen products containing avobenzone. This proposal is consistent with our general recommendation that materials evaluated under the MUsT paradigm represent real-world sunscreen formulations, rather than overly simplified solutions that fail to replicate the absorption potential of marketed formulations. As noted in section VII.B.4, we encourage sunscreen manufacturers to discuss their MUsT protocol with FDA before beginning the trial.

m. Data supporting dermal safety of avobenzone. The available clinical dermal studies indicate that avobenzone at concentrations up to 5 percent have a favorable safety profile with respect to potential irritation, sensitization, and photosafety. In 2009, in conjunction with a citizen petition [36] (L'Oreal Petition, Docket No. FDA–1978–N–0018–0675) asking FDA to take action to permit the marketing of sunscreen products containing avobenzone up to 5 percent, L'Oreal USA Products, Inc. (L'Oreal) submitted nine human repeat insult patch, phototoxicity, and photoallergy studies with six different sunscreen formulations containing avobenzone (3.4 percent, 4 percent, or 5 percent). The studies showed that the formulations were well tolerated for topical use (*i.e.,* essentially non-allergenic, non-irritating, and non-sensitizing, with mild to moderate reactions occurring only rarely) (L'Oreal Petition).[37] A separate search of the available scientific literature on the clinical safety of avobenzone did not reveal anything to undermine these findings. Although the available literature included a small number of reports of contact irritation and photosensitization in connection with avobenzone-containing products, details about the composition of the formulations at issue (and the concentrations of avobenzone) were frequently missing from the literature, making it difficult to determine the cause of these responses. A small number of serious hypersensitivity reports for sunscreens containing avobenzone were also located in FAERS. Because the sunscreens at issue usually contained three or more active ingredients, however, it is difficult to determine what caused the reaction. Because sufficient data exist to make a determination, we do not consider additional dermal clinical studies (including photosafety, irritation, or sensitization studies) to be necessary to support the safety of this ingredient for sunscreen use at up to 5 percent. As is customary in clinical trials, however, we recommend that dermal safety data for avobenzone be collected during MUsT studies.

n. Other nonclinical safety studies for avobenzone. Dermal carcinogenicity studies have not been conducted for avobenzone. The available data on the permeation of avobenzone suggest that it may permeate into at least the dermis and epidermis, which means that it is possible for avobenzone to impact skin tumor development. We therefore expect that dermal carcinogenicity studies will be necessary to support a positive GRASE finding for sunscreens containing this ingredient. Available embryofetal development studies in rats and rabbits did not reveal any findings of concern. However, our review of the nonclinical data for avobenzone [38] also revealed that toxicokinetic data following repeat-dose exposure will be needed to interpret pivotal nonclinical safety studies (including the embryofetal development studies in rats and rabbits) once the MUsT data become available. (As explained in section VII.B.4, these data are used to compare drug levels achieved in animal studies with those observed in humans under maximal exposure conditions.) In addition, if results of a MUsT demonstrate that there is significant systemic absorption of avobenzone, additional fertility and early embryonic development and prenatal and postnatal development studies in rats will be needed to support a positive GRASE finding. Depending on the results of the MUsT, systemic carcinogenicity studies may also be needed.

o. Avobenzone in combination with other sunscreen active ingredients. As noted in section III.B, our finding in the Stayed 1999 Final Monograph that avobenzone was GRASE for use in sunscreens would have allowed its combination only with certain other sunscreen active ingredients (64 FR 27666 at 27688) because we did not have targeted evidence to support the safety and effectiveness of avobenzone when combined with the remaining active ingredients. We believe this limitation was inconsistent with the approach to evaluating sunscreen combinations that the Agency has generally taken throughout the OTC Drug Review for sunscreens. For this reason, unless evidence is submitted to suggest that there is a safety or efficacy concern associated with the combination of avobenzone with another active ingredient, we expect to conclude that a positive GRASE determination for avobenzone will support its use in sunscreens either alone or in combination with all other sunscreen active ingredients.

p. L'Oreal request to increase concentration of avobenzone to 5 percent. Avobenzone is currently listed in the Stayed 1999 Final Monograph at concentrations up to 3 percent. As described earlier, in 2009 FDA received a citizen petition from L'Oreal requesting, among other things, that we amend the sunscreen monograph to increase the allowable level of avobenzone to 5 percent (L'Oreal Petition at 1). In the Stayed 1999 Final Monograph, the Agency determined that avobenzone at concentrations up to 3 percent is an effective sunscreen active ingredient. We now likewise conclude that the record contains sufficient information to satisfy the effectiveness prong of the GRASE standard for sunscreens containing avobenzone at concentrations up to 5 percent.

As described above, data submitted with that L'Oreal Petition were sufficient to establish that avobenzone at a concentration of up to 5 percent has a favorable safety profile with respect to potential irritation, sensitization, and photosafety. To support a finding that avobenzone at concentrations up to 5 percent is GRASE for use in sunscreens, however, FDA expects that a MUsT evaluating the transdermal absorption of avobenzone up to 5 percent, as well as dermal carcinogenicity studies and toxicokinetic data for avobenzone at a concentration of at least 5 percent, will also be needed. Depending on the outcome of the MUsT, we may also need systemic carcinogenicity data and additional DART studies, including fertility and early embryonic development, and pre- and postnatal development studies in rats for avobenzone at 5 percent. The record does not currently include any of these data. However, if FDA were to receive sufficient data to support a positive GRASE finding for avobenzone up to 5 percent, we would expect to include

[36] FDA–1978–N–0018–0675, two volume submission (February 20, 2009) (L'Oreal Petition).

[37] Id., volume I, pp. 5–8.

[38] The available nonclinical data for avobenzone include acute oral and dermal toxicity studies in rats; a 13-week oral toxicity study in rats; a 28-day dermal toxicity study in rats; a 21-day dermal toxicity study in rabbits; several in vitro genotoxicity tests; an in vivo micronucleus test in mice, as well as a sensitization test in guinea pigs; a primary skin irritation test in rabbits; an ocular irritation test in rabbits; a phototoxicity study in guinea pigs; a photoallergenicity study in guinea pigs; and embryofetal development studies in rats and rabbits (Givaudan-Roure Petition, Docket No. FDA–1978–N–0018–0751). Importantly, (except for the embryofetal development studies) these studies are not sufficient to resolve safety concerns for a chronically used product.

avobenzone at this percentage in a final sunscreen monograph.

q. Conclusion. Given that: (1) Avobenzone's organic solubility, molecular weight, and melting point suggest it has a potential for transdermal absorption; (2) there is a lack of available data on the transdermal absorption of avobenzone in vivo (including under maximal use conditions); and (3) there are limitations in the available in vitro studies assessing avobenzone absorption, we expect that a properly designed MUsT will be necessary to support a positive GRASE finding for avobenzone use in sunscreens. We expect that, to be GRASE for sunscreen use, avobenzone will need to be photostabilized to address its potential for degradation, and we therefore expect that any future sunscreen monograph including avobenzone as an active ingredient will include the limitation that avobenzone is not GRASE for use in sunscreen products unless it has been photostabilized to prevent its photodegradation. In addition, we believe that an adequate MUsT evaluating the absorption potential of avobenzone will need to include a photostabilizer to ensure that the potential transdermal absorption of avobenzone from avobenzone-containing sunscreens is accurately assessed.

We also expect that dermal carcinogenicity and toxicokinetic data will be necessary to support a positive GRASE finding for sunscreens containing avobenzone. Depending on the outcome of a MUsT assessing the absorption of avobenzone, systemic carcinogenicity testing and additional DART studies, including fertility and early embryonic development and pre- and postnatal development studies in rats may be needed as well. We will also determine the extent to which additional DART studies may be needed based on the results of the MUsT. Depending on the results of the nonclinical and pharmacology studies for this ingredient and the safety margin that is calculated from these results, pediatric studies for avobenzone may also be needed to support the use of sunscreens containing avobenzone in pediatric populations.

TABLE 4—SUMMARY OF RECOMMENDATIONS: STUDIES FOR AVOBENZONE UP TO 3 (OR 5) PERCENT

Safety studies FDA proposes are necessary to support a GRASE determination	Additional studies or data necessary?
Pharmacological Studies:	
Human absorption (MUsT) (including metabolite study in humans)	Yes.
Nonclinical Safety Studies:	
Toxicokinetics	Yes.
Dermal Carcinogenicity	Yes.
Systemic Carcinogenicity	Dependent on results of the MUsT.
DART:	
Fertility and early embryonic development	Dependent on results of the MUsT.
Embryofetal development in two species (rodent and non-rodent)	No.
Prenatal and postnatal development	Dependent on results of the MUsT.
Clinical Safety Testing:	
Skin irritation and sensitization	No.
Skin photoallergenicity and phototoxicity	No.
Pediatric studies	Pediatric studies may be required depending on the outcome of the MUsT.

D. Anticipated Final Formulation In Vitro Permeation Testing

As noted earlier, a final sunscreen monograph will need to set out the conditions under which any product marketed pursuant to it would be GRASE and not misbranded. Variations among individual sunscreen product formulations—in particular, characteristics of the specific vehicle (*e.g.,* the cream, lotion, or oil) in which active ingredients are delivered—can affect the transdermal absorption of sunscreens, and thus, have an impact on their safety and effectiveness. To address this, FDA currently requires final formulation testing of OTC sunscreen products to support labeled claims regarding their effectiveness—namely, testing for SPF value as well as broad spectrum protection and water resistance where those attributes are claimed in product labels.[39] For purposes of this proposed rule, we use the term *final formulation testing* to refer to testing conducted on the sunscreen product formulation to be marketed. Our expectation is that final formulation testing would also generally be necessary to ensure that the active ingredient in any given sunscreen formulation permitted under the monograph would not be systemically absorbed beyond the amount FDA determined to be safe.

The discussion that follows provides FDA's thinking about such testing of final formulations, which we anticipate requiring in the future for sunscreen products marketed under the sunscreen monograph (unless FDA determines that the ingredient or ingredients contained in the product are unlikely to be absorbed through the skin). Because this testing would not be required for sunscreens containing only those active ingredients proposed here as Category I (zinc oxide and titanium dioxide), FDA has not yet reached a final determination as to the particular parameters that might be required for such final formulation testing. We anticipate that we may specify final formulation testing requirements in the monograph in the future, however, as active ingredients that we are now proposing as Category III may be included in the monograph in the future if FDA receives data supporting their GRASE status. Final formulation testing requirements applicable to such ingredients would be established on an ingredient-specific basis, taking into consideration the data provided to

[39] See § 201.327 for the current labeling requirements, and underlying testing, for OTC sunscreens containing one or more of the 16 active ingredients that are addressed in this rulemaking, for use in products marketed without approved NDAs. OTC sunscreens marketed under NDAs provide similar information in their product-specific applications to substantiate their labeling. For proposed changes to § 201.327, see codified section of this document. The Stayed 1999 Final Monograph also required SPF testing of final formulations as a GRASE condition. Elsewhere in this proposed rule, we propose to establish monograph conditions in 21 CFR part 352 that ensure that all sunscreens are tested for SPF in accordance with § 201.327(i) and achieve a minimum SPF of 2, and that certain sunscreens pass the broad spectrum test in § 201.327(j).

support a positive GRASE determination for the specific ingredient (for example, whether any safety signals are detected in well-conducted nonclinical carcinogenicity and DART studies). We encourage interested parties to provide information and comment for each sunscreen active ingredient that is relevant to establishing this kind of final formulation testing for each active ingredient.

FDA's expectation is that this testing would not generally call for an in vivo study. Instead, FDA expects that the conditions of marketing specified for sunscreens containing a given active ingredient would require manufacturers to perform in vitro permeation testing before marketing each sunscreen formulation containing that ingredient. Consistent with the approach for SPF and broad spectrum final formulation testing set forth in § 201.327 (for proposed changes to § 201.327, see codified section of this document), FDA anticipates that it would not review the results of the in vitro permeation testing before product marketing. Rather, FDA expects that any future conditions pertaining to final formulation in vitro permeation testing in the sunscreen monograph would include a requirement that manufacturers maintain records of this testing, and that those records be available for FDA inspection upon request.

FDA anticipates establishing a standard control formulation for each sunscreen active ingredient to be used in the in vitro permeation testing of products containing that ingredient. The standard control formulation would be the formulation that produces the highest in vivo absorption in the MUsT. The results of in vitro permeation testing using this control formulation would then be used as a bridge to a corresponding level of in vivo absorption from the MUsT that is used to establish the safety margin for the ingredient. Then, FDA anticipates establishing conditions to ensure that final formulation in vitro permeation testing would be conducted for each formulation intended to be marketed, using the specified vertical diffusion cell described below. The results of the in vitro permeation testing of each final formulation would be compared to the absorption found in the standard control formulation for the active ingredient it contains.

In vitro permeation testing is a methodology that has been used in dermal formulation development for over 30 years and, as used here, specifically refers to use of the ''Vertical Diffusion Cell'' (Ref. 144). A vertical diffusion cell is comprised of three major units: (1) An upper chamber (into which the sunscreen formulation is placed); (2) the rate-limiting membrane (the prepared human skin); (3) and the lower chamber/fluid channel (containing a receptor fluid that is evaluated to determine how much of the sunscreen it ''receives'') (Refs. 145 to 147). The vertical diffusion cell system has been commercialized and is available as both single and multiple unit models that can be automated.

Other relevant parameters FDA expects to consider in establishing future requirements for in vitro permeation testing include (among other things) the thickness and integrity of collected skin, storage conditions used for collected skin, receptor fluid composition, skin and receptor fluid temperature, the number of skin samples (and donors) used, study duration, sampling period, application method, and number of experimenters.

We note that if a final sunscreen formulation contains a combination of sunscreen active ingredients, FDA anticipates requiring that this final formulation be tested against the standard control formulations for each of the sunscreen active ingredients it contains. As noted above, a standard control formulation might not be specified for (and final formulation in vitro permeation testing might not be necessary to establish safety for) a sunscreen containing a particular active ingredient if FDA determines that the ingredient is unlikely to be absorbed through the skin. As mentioned above, we therefore do not propose to require final formulation in vitro permeation testing for sunscreen formulations containing only zinc oxide and/or titanium dioxide.

In cases in which such testing is required, FDA anticipates that if the in vitro permeation of each sunscreen active ingredient in the final formulated product is equal to or less than the value obtained from in vitro permeation testing of the standard control formulation for that active ingredient, the product's safety margin would be considered to fall within the parameters judged to be GRASE, and thus to support marketing of the formulation. However, if the in vitro permeation of the active ingredient from the specific final formulation is greater than the value obtained from in vitro permeation testing of the standard control formulation for that active ingredient, FDA anticipates that the drug product(s) using that formulation would not be considered GRASE. In that situation, the sponsor would have the option to either: (1) Reformulate the product and conduct in vitro permeation testing to establish that the reformulated product satisfies the final formulation in vitro permeation testing requirements set out in the sunscreen monograph or (2) seek NDA approval for the new formulation.

IX. Additional Proposed Conditions of Use

A. Proposed Requirements Related to Dosage Form

OTC sunscreens have been marketed in a variety of dosage forms over the years. Responding in part to the growing market acceptance of spray sunscreens, on June 17, 2011, FDA issued an ANPR addressing sunscreen dosage forms (Dosage Forms ANPR) (76 FR 35669, June 17, 2011). The ANPR identified dosage forms considered eligible or ineligible for review and potential inclusion in the OTC sunscreen monograph, based on FDA's knowledge, at that time, of their history of marketing before the OTC Drug Review began in 1972. It also solicited specific information about the safety, effectiveness, and directions for use of spray sunscreens.

1. Summary of Eligible and Ineligible Dosage Forms

In this proposed rule, FDA is confirming that the following dosage forms identified in the Dosage Forms ANPR are eligible for review and potential inclusion in the OTC sunscreen monograph based on their history of sunscreen marketing before 1972: Oil, lotion, cream, gel, butter, paste, ointment, stick, spray, and powder. With the exception of powder, FDA proposes that sunscreens in these dosage forms are GRASE subject to certain conditions described below and elsewhere in this proposed rule. We note that sunscreen powders were classified as ineligible for review in the Dosage Forms ANPR because, at that time, we were unable to identify any sunscreen products in powder form that were marketed before the OTC Drug Review began. Based on marketing data submitted to the ANPR docket and in a related citizen petition (Docket No. 1978–N–0018–0741), we have determined that the powder dosage form is eligible to be considered for inclusion in the OTC sunscreen monograph. However, as described in section IX.A.4, we tentatively conclude that additional safety and efficacy data will be necessary to classify sunscreens in the powder dosage form as GRASE and include them in the final monograph. We are proposing that sunscreens in all dosage forms other than those identified as eligible for consideration above—

including wipes, towelettes, body washes, and shampoos—are new drugs because we did not receive data showing that they were marketed prior to 1972.

2. Overview of Comments on the Dosage Forms ANPR

FDA received a total of 14 comments on the Dosage Forms ANPR. Six of the comments provided no new data, but generally supported the advantages of spray sunscreens, agreed with the need to address concerns about spray sunscreens' performance and/or safety (especially when used on children), opined that existing SPF methods would not need to be modified for sprays, or (in most cases) agreed with FDA's suggested directions for use. Other comments argued for the inclusion of additional dosage forms identified as ineligible in the Dosage Forms ANPR, but failed to provide supporting marketing data. One comment contained marketing information showing that sunscreen products in powder form, which we had previously identified as ineligible for the monograph, had been marketed in the United States before 1972. The remaining comments (all from industry) provided data and information that directly or indirectly addressed questions raised in the Dosage Forms ANPR concerning the safety, effectiveness, and labeling of spray sunscreens. These comments are discussed in sections IX.A.3 and IX.A.4 below.

3. Safety and Effectiveness of Spray Sunscreens

As we recognized in the Dosage Forms ANPR, compared to traditional lotions, oils, and the like, spray sunscreens raise potential concerns of both safety and efficacy that FDA must consider in determining whether sunscreens in the spray dosage form would be GRASE. With respect to efficacy, FDA must consider factors such as whether spraying sunscreen rather than applying it by hand provides effective coverage on exposed skin, how consumers use spray products, and whether current test methods for SPF and broad spectrum protection can be relied on for adequate labeling of spray products. With respect to safety, spray sunscreens raise the question of potential harm from inhalation of sunscreen components as well as potential flammability risks.

a. Characteristics of sunscreen spray products. Spray sunscreens use varying technologies to package and deliver a sunscreen formulation as an aerosol spray, *i.e.,* an airborne suspension of fine droplets or particles. In some spray products, the sunscreen formulation is mixed in a canister with a liquefied gas propellant that supplies the force to generate an aerosol containing both dissolved sunscreen formulation and propellant upon activation of a valve system. There are also pump spray sunscreen products that are not packaged under pressure but generate spray by applied mechanical force without the need for a propellant. Many currently marketed spray sunscreen products use a delivery technology referred to as a bag-on-valve system, in which the sunscreen formulation is contained in a bag with an attached valve inside a canister filled with propellant, so as not to mix the sunscreen formulation and propellant ingredients. For purposes of this document, a spray sunscreen product is one discharged from either a pressurized or nonpressurized container, with the understanding that the degree of atomization will likely vary according to the formulation, the container system used, and the design of the spray actuator, among other factors.

b. Spray sunscreen performance and effectiveness. The Dosage Form ANPR asked a series of questions relating to the performance and effectiveness of spray sunscreens, including questions about the amount of spray sunscreen typically applied by consumers, uniformity of coverage, how frequently consumers reapply spray sunscreens, whether consumers rub spray sunscreens into the skin when directed to do so and the resulting effect on effectiveness, and whether—and if so, how—the SPF and/or broad spectrum tests need to be modified to address sunscreen sprays. The Dosage Forms ANPR also solicited studies comparing spray sunscreens to other eligible dosage forms to see whether the dosage forms are comparable.

Four comments provided data from multiple studies examining and comparing the performance of spray and lotion sunscreens on a variety of parameters, including amounts applied, uniformity of coverage as measured with UV filter photography, comparative SPF results, and consumer ratings of ease and effectiveness of application, among others. FDA's evaluation of the information submitted indicated that key questions asked in the Dosage Forms ANPR were directly or indirectly addressed by these studies. These studies indicated that consumers like the convenience of spray sunscreens and adapt their use of these products to achieve effective coverage. Data provided on application uniformity lacked study reports and were difficult to compare directly, but—taken together—they suggest a high degree of uniformity between sprays and lotions in coverage of exposed skin, as well as between different spray application scenarios such as spraying directly on skin or spraying followed by rubbing. Information submitted indicated that the amount of spray sunscreen dispensed is higher than the amount dispensed for sunscreen lotions, and that consumers are more likely to reapply sprays than lotions. There was no response from any stakeholder regarding consumers' compliance with directions to rub a spray sunscreen into the skin. However, data was provided suggesting that rubbing spray sunscreens into the skin did not enhance effectiveness. Based on these comments and the available data, we are not proposing to require that labeling provide instructions to rub spray sunscreens into the skin.

Comments on the Dosage Forms ANPR also agreed, and we concur, that the current FDA-required SPF and broad spectrum tests are appropriate for evaluating the efficacy of sunscreens in spray dosage forms. SPF testing requires application of a set amount of sunscreen (2 mg/cm^2 on each test subject), which can readily be done for spray sunscreen formulations. For example, comments on the Dosage Form ANPR stated that the SPF testing of sunscreen spray products can be conducted following the method described in the current rule by weighing out the liquid form and applying it to the skin. This premise is supported by data from SPF testing submitted in the comments. For example, one comment submitted five SPF testing reports conducted on sprays using the FDA-required methods, in which the expected SPF values for the test formulations were almost identical to the SPF testing results. The same logic applies to broad spectrum testing, which also uses a defined amount of sunscreen by weight. Based on this information, we conclude that the current and proposed SPF and broad spectrum testing methods are also appropriate for spray dosage forms.

c. Spray sunscreen safety. FDA has identified two primary safety concerns specific to spray sunscreen dosage forms: (1) The potential risk of respiratory harm from inhaling sunscreen ingredients and (2) the potential flammability risk when consumers are exposed to flame or heat before spray solvents have completely dried. For the reasons described below, we believe that both potential risks can be acceptably mitigated by proposed formulation limitations, labeling requirements, and adequate testing, and

thus propose to establish these as additional conditions in the monograph to ensure that sunscreen products in a spray dosage form would be GRASE.

d. Inhalational toxicity. Broadly speaking, the human respiratory system consists of the upper respiratory tract (*i.e.,* the airways of the nose to the larynx) and lower respiratory tract (the trachea and branching airways of the lung, including bronchi, bronchioles, and alveoli) (see generally Refs. 148 and 149). Much of the respiratory system is lined with a layer consisting of mucus cells and cilia that mechanically propel inhaled particles out of the lower respiratory tract toward the mouth, where they may be swallowed or expectorated (Refs. 148 and 149). The most significant concern associated with any product that may be accidentally inhaled is the potential risk of adverse effects associated with deep lung deposition, which occurs when particles in an aerosol (*i.e.,* a suspension of airborne particles such as a sunscreen spray) reach the unciliated airways in the lung. Particles that can reach the unciliated airways of the deep lung are described as respirable and may be associated with serious adverse effects such as asthma, emphysema, bronchospasm, or chronic obstructive pulmonary disease; particles that do not reach the deep lung may be associated with less harmful adverse events such as local irritation of the upper airway, coughing, or sneezing (Refs. 149 to 151). The potential health risk associated with inhalation of hazardous aerosols depends on how much of a toxic substance is deposited in a given region of the respiratory tract and how much remains after physiological clearance occurs through mechanisms such as coughing, sneezing, mechanical transport, or, in the deep lung, engulfment by specialized cells or other protective action (Refs. 148 and 152).

The pathogenic potential of inhaled aerosols depends on where in the respiratory tract a particle is deposited (Ref. 152). Whether spray particles that enter the body through inhalation at the nose or mouth will be deposited in the lung depends largely on their physical characteristics: Most notably particle size, with the likelihood of respirability increasing as particle size decreases (Refs. 148 to 153). The effects of particle size on respirability of inhaled particles is well studied. There is general agreement that particles greater than 10 micrometers (μm) in diameter may enter the mouth and the airway up to the larynx. Approximately 50 percent of particles up to 10 μm in diameter can penetrate beyond the larynx to the thoracic region of the respiratory tract, while only particles smaller than 4 μm reach the unciliated airways and alveolar region of the lungs (see generally Refs. 148 to 153). Thus, although there are little or no data on the potential inhalation toxicity of particular spray sunscreen ingredients, we are proposing that exposure to harmful levels of such ingredients can effectively be minimized by imposing particle size limitations on spray sunscreen products.

Several comments on the Dosage Forms ANPR submitted results of particle size distribution testing using available methods and apparatus, with the aim of showing that exposure to inhaled sunscreen products or ingredients would be minimal and thus unlikely to cause adverse effects. The data submitted were similar and in some cases overlapping. In an analysis of pooled particle size distribution data from all submissions, representing 50 U.S.-marketed spray sunscreen products, 32 had particles smaller than 4 μm in diameter and thus within the respirable portion of the total particle size distribution. However, the great majority of the particle sizes observed were nonrespirable. The highest percentage that any product had of particles smaller than 4 μm in diameter was 0.43 percent and the mean was 0.22 percent, which is extremely low.

In addition to reviewing information from comments on the Dosage Forms ANPR, FDA conducted its own analysis of particle size distribution for 14 marketed spray sunscreens. In those tests, no sunscreen had more than 10 percent of particles in sizes less than 10 μm in diameter and only three had particles smaller than 5 μm (Ref. 154).

To limit the risks of unintentional exposure and potential associated adverse events to respirable particles in spray sunscreens, we are proposing limits on the size of particles dispensed from the consumer container for finished spray sunscreens in order for those products to be GRASE. We propose that 90 percent of the particles dispensed from the consumer container must be at least 10 μm or greater in order to limit exposure beyond the larynx, and to prevent deposition in the deep lung, the minimum particle size dispensed from the consumer container must be no less than 5 μm. This limit was chosen because it is the lowest whole number above the generally accepted threshold (4 μm) at which particles enter the unciliated airway and because it allows for experimental error that may be inherent in particle size measurements. Sunscreen products that do not meet both limitations would not be GRASE because there is not sufficient information in the record to support a positive finding about their safety. We believe that, taken together, these two limitations would significantly reduce inhalation risk from spray sunscreens by reducing particle exposure to the larynx and deeper lung tissues. The particle size data submitted in response to the Dosage Forms ANPR also suggest that these limitations would be readily achievable without unduly burdening sunscreen spray manufacturers.

With the establishment of these two limits, FDA believes that the risks of adverse events related to unintentional inhalation of spray sunscreens will be minimal. Stakeholders asserted that the risk of inhalation toxicity is already low, primarily based on particle size of marketed sprays. Limited data on adverse event reports and animal toxicity studies were also submitted in a few comments on the Dosage Forms ANPR, but were inadequate to support the safety of spray sunscreens in the absence of particle size limitations. If the particle size limitations proposed here are adopted, however, we do not believe that additional animal toxicity or other safety data need to be provided to support a GRASE finding for spray sunscreens.

We are proposing that particle size testing to demonstrate compliance with the proposed limitations must be conducted on spray products as they are dispensed from the consumer container as part of the lot release testing that would be routinely completed as part of current good manufacturing practice (CGMP) compliance under part 211 (21 CFR part 211). It is necessary to test the size of particles dispensed from the consumer container to ensure that particle size requirements are met under conditions of use by consumers.

For purposes of these proposed particle size requirements, we are using the term *particle size* broadly to mean the discrete unit emitted from the spray container that is available for inhalation by a consumer when the product is applied. If the *particle* dispensed from the consumer container is a droplet that meets the size requirements, the consumer will not accidentally inhale it into the deep lung. However, if that same droplet breaks apart into smaller fractions when it is dispensed from the consumer container, those fractions would be the *particles* that must meet the size requirement to ensure that consumers will not inadvertently inhale them past the larynx.

We are not proposing a specific test methodology for spray sunscreen particle size. Rather, sunscreen manufacturers would be obligated to ensure that particle size testing for their

sunscreen sprays would be conducted on each lot of the final product as dispensed from the consumer container in accordance with adequate written specifications. USP General Chapter 601 part B provides methodology and requirements for sprays, aerosols, and powders that include methodology to determine droplet/particle size distribution, and we expect to consider testing done in accordance with the USP as adequate to meet this proposed requirement (Ref. 155).

We note that several comments on the Dosage Forms ANPR expressed concern about the potential inhalation risk from exposure to spray sunscreens that contain nanomaterials (as both active and inactive ingredients). One comment also recommended that FDA require the presence of such ingredients to be disclosed on spray sunscreen labels. FDA's approach to nanotechnology and nanomaterials in sunscreen products is discussed in section VII.E. FDA is not now proposing conditions of use, including labeling, for spray sunscreens that distinguish based on the presence of nanomaterials because we are proposing that any sunscreen spray that contains any particles smaller than 5 µm when it is dispensed from the consumer container would not be GRASE. With respect to nanomaterials in spray sunscreens, we note that the primary determinant of inhalation risk is the size of the particles in emitted sprays, which may be larger than individual formulation components. Nanoscale ingredients would not pass the particle size limitations for spray sunscreens; therefore, if they were to be detected when sprayed from the consumer container during particle size testing, the sunscreen could not be marketed under the OTC monograph.

In addition to the proposed limitations on particle size for sunscreen sprays and related testing, we are proposing to require that the following labeling be included in the directions for sunscreen sprays to minimize unintended inhalation:

- Hold container 4 to 6 inches from skin to apply.
- Do not spray directly into face. Spray on hands then apply to face.
- Do not apply in windy conditions.
- Use in a well-ventilated area and avoid inhalation.

This language is the same as that published in the Dosage Forms ANPR. Its adoption was supported by comments on the Dosage Forms ANPR, and the language is widely used on currently marketed spray sunscreens consistent with the 2018 Final Guidance.

e. Flammability risk. In July 2013, FDA issued a Consumer Update regarding persons catching on fire while wearing spray sunscreen products near an open flame:

> The Food and Drug Administration (FDA) has become aware of five separate incidents in which people wearing sunscreen spray near sources of flame suffered significant burns that required medical treatment. The specific products reported to have been used in these cases were voluntarily recalled from the market, so should no longer be on store shelves. . . . In the five incidents reported to FDA, however, the burns occurred after the sunscreen spray had been applied. The ignition sources were varied and involved lighting a cigarette, standing too close to a lit citronella candle, approaching a grill, and in one case, doing some welding (Ref. 156).

These cases all involved a single manufacturer's product that has since been voluntarily recalled. Review of adverse event reports since the voluntary recall of this product indicates that no additional cases involving spray sunscreens have been reported. However, sunscreens are often used in very hot outdoor environments with high ambient air temperatures. Sunscreens are also frequently used around sources of flame or sparks, such as grills, bonfires, smoking, or other ignition sources. To ensure safe use of spray sunscreens and to better inform consumers about potential flammability risks, we are proposing to limit the flammability and require flammability labeling of spray sunscreens under the OTC sunscreen monograph.

FDA's general labeling regulations for OTC drugs provide for OTC monographs to require flammability labeling in suitable cases (§ 201.66(c)(5)(ii)(C)) (21 CFR 201.66(c)(5)(ii)(C))), and we have done so for products such as topical antitussives (21 CFR 341.74) and wart removers (21 CFR 358.150). As we did for those products, we are proposing to require each spray sunscreen formulation to be labeled for flammability in accordance with the testing methodology described in a regulatory provision issued by the Consumer Product Safety Commission (CPSC) (see 16 CFR 1500.43a). We have proposed to incorporate this flash point testing methodology to address our concern regarding the flammability of sunscreen in the spray dosage form after it has been dispensed onto the skin. We therefore propose that all batches of sunscreen spray products be tested for flammability in accordance with 16 CFR 1500.43a as part of batch release testing conducted in accordance with CGMP requirements.

We are also proposing to define three flammability categories for use in regulating and labeling sunscreens: (1) Extremely flammable, (2) flammable, and (3) combustible. These definitions refer to flash point testing to be performed using the method described in 16 CFR 1500.43a. These definitions are analogous to certain CPSC definitions located at 16 CFR 1500.3. Given the conditions under which sunscreens may be used, we are proposing that spray sunscreens found to meet the definition of extremely flammable in proposed § 352.3(f) are not GRASE and may not be marketed under the OTC sunscreen monograph. Products found to meet the definition of flammable or combustible in proposed § 352.3(g) or (h) would be required to include the following language in the ''Warnings'' section of the drug facts labeling: [bullet] ''Flammable'' or ''Combustible'' [as applicable] followed by a colon and the statement ''Keep away from fire or flame''.

A further concern related to flammability is the time required for volatile solvents in a spray product to dry on the skin before a consumer can safely approach a source of heat or flame or can smoke without danger of fire. Typical sunscreen spray formulations contain 50 to 80 percent of a volatile carrier, most commonly ethyl alcohol. These volatile solvents are necessary to the formulation to allow the product to be sprayed onto the skin. After spraying, the solvents are intended to rapidly evaporate leaving a film of UV filters on the skin surface as the product dries. Once a spray product is dry, the solvent is no longer present so the flammability risk is low. However, prior to this point, the flammability risk would be higher.

We think that consumers should be warned to stay away from sources of flame while a flammable or combustible sunscreen spray dries. For this reason, we propose to require that each batch of a sunscreen spray product that meets the definition of flammable or combustible at § 352.3(g) or (h) be tested for drying time in accordance with written specifications. If the drying time is less than 5 minutes, we propose to require that the labeling state, ''Wait 5 minutes after application before approaching a source of heat or flame, or before smoking.'' If the drying time is at least 5 minutes but less than 10 minutes, we propose that the labeling would state, ''Wait 10 minutes after application before approaching a source of heat or flame, or before smoking.'' We propose that a sunscreen spray that is flammable or combustible and that takes 10 minutes or more to dry would not be GRASE because of the possibility of consumers approaching sources of fire

during such an extended drying period. We invite comment on this approach.

4. Powder Dosage Forms

Although we have found powder sunscreens to be eligible for consideration in the OTC sunscreen rulemaking, we have tentatively determined that additional data as outlined below will be needed to support a conclusion that sunscreens in this dosage form are GRASE and to support consideration of appropriate labeling. Also, like sprays, powder sunscreens pose the potential for unintended inhalation, and for this reason, if admitted to the sunscreen monograph, the same limitations as to particle size here proposed for sprays would be expected to apply. For powder sunscreens that meet the particle size limitations proposed for sprays, we do not expect that additional toxicology data would be needed to address the potential health risks associated with inhalation.

One comment on the Dosage Forms ANPR provided data on SPF and broad spectrum performance of five powder formulations, as well as data from repeated insult patch tests and photosensitivity studies that were asserted not to show any safety issues. FDA has conducted particle distribution testing on five powder sunscreens. The powder sunscreens tested had a larger proportion of relatively small particles compared to the sprays. Only one of the five powder sunscreens would have complied with the requirement we are considering that no more than 10 percent of the particles could be smaller than 10 µm in diameter, and that product was also the only one that would have met the prospective limitation of no particles smaller than 5 µm in diameter (Refs. 153 and 154). Based on the data submitted, we believe that (current and proposed) SPF and broad spectrum test methods are appropriate for use with powder sunscreens, and we are not requesting additional respiratory safety information for powders that meet the same particle size limitations proposed for spray sunscreens.

FDA invites comments and data on the following topics related to powder sunscreens:

- What amounts of powder sunscreens do consumers typically dispense?
- What amounts of powder sunscreens are effectively transferred to the skin?
- How uniform is the sunscreen application across the sun-exposed area of the skin?
- How frequently do consumers reapply the product?
- Does rubbing a powder into the skin change sunscreen effectiveness?
- Are powder dosage forms water-resistant? If they are not water-resistant, is a direction to reapply every 2 hours sufficient to assure their safe and effective use?
- Can the powder dosage form be used safely and effectively over all areas of skin exposed to the sun, or should this dosage form be limited to the face?
- What factors, if any, should FDA consider in connection with particle size limitations or test methods for sunscreen powders?
- Are there important differences among powder types (*e.g.,* loose, compact) or applicators that would affect particle size testing?

FDA will evaluate data and information submitted in response to these questions, as well as any other submitted or available data, to determine whether additional data are needed to support a final GRASE determination for this dosage form.

B. Proposed Maximum SPF and Broad Spectrum Requirements

In the Stayed 1999 Final Monograph, FDA established SPF 30+ as the maximum labeled SPF value for sunscreen monograph products, and required that each sunscreen monograph active ingredient contribute a minimum SPF of 2 to finished sunscreen products (64 FR 27666 at 27672, 27674 and 27675). The final monograph did not include any broad spectrum protection provisions. In its 2001 decision to stay the final monograph, however, FDA indicated that it was issuing the stay because the Agency intended to amend the sunscreen monograph to address requirements for both UVA and UVB radiation protection (66 FR 67485). FDA later addressed these issues in the 2011 L&E Final Rule, which, among other things: (1) Established optional broad spectrum labeling based on satisfaction of a critical wavelength test, (2) created an optional indication relating to skin cancer and early skin aging risk reduction for broad spectrum products with an SPF of 15 or higher, and (3) required a labeling warning for sunscreens that did not both satisfy the broad spectrum test and provide an SPF of at least 15 (76 FR 35620 at 35626–35628) (L&E Final Rule). Concurrently with publication of the L&E Final Rule, FDA issued a proposed rule to raise the maximum labeled SPF value for sunscreen products containing sunscreen monograph active ingredients to SPF 50+ (76 FR 35672, June 17, 2011).

In the time since these 2011 publications, the body of evidence in the published literature on UVA radiation (particularly UVA I radiation) and its role in the development of skin cancer has grown. This new data about the harms of UVA exposure is a significant concern given, among other things, that with currently available sunscreens, consumers may unknowingly accumulate excessively large UVA doses by using sunscreens with high SPF values that either: (1) Do not pass FDA's current critical wavelength-based broad spectrum test or (2) have inadequate uniformity in their UVA protection. Because of these concerns, we are making a number of proposals designed, among other things, to couple a greater magnitude of UVA protection to increases in SPF values.

1. Background

UV radiation includes both UVA and UVB rays. UVB rays (*i.e.,* those with wavelengths from 290 to 320 nm) are higher energy, are much more effective at producing sunburn, and produce greater amounts of cellular damage (including DNA lesions, which can result in gene mutations linked to skin cancers) (Refs. 157 and 158). UVA rays (*i.e.,* those with wavelengths from 320 to 400 nm) are lower energy and less effective at producing sunburn, but make up the majority of UV radiation, and penetrate much deeper into the skin, potentially causing oxidative damage (through formation of ROS) to skin pigment cells (Ref. 159). UVA rays also contribute to photo-aging (Ref. 157 and 160). Although the current scientific literature attributes UV-signature DNA lesions primarily to UVB wavelengths, UVA wavelengths can also produce DNA lesions. Although UVA wavelengths produce DNA lesions to a significantly lesser degree than UVB wavelengths do, DNA lesions produced by UVA rays have been reported to have slower repair rates (Ref. 157). UVA rays are comprised of UVA I rays (340 to 400 nm) and UVA II rays (320 to 340 nm). As discussed below, until recently, UVA I rays were generally not considered to contribute significantly to the harms associated with UV exposure.

Sunscreen products must be labeled with an SPF value calculated using a standardized SPF testing procedure set forth in FDA regulations (see § 201.327(i)). ISO 17166 CIE S 007/E was approved for incorporation by reference into § 201.327(i) as of June 18, 2012 (76 FR 35619, June 17, 2011). The SPF test measures the amount of UV radiation exposure it takes to cause

sunburn when a person is using a sunscreen compared with how much UV exposure it takes to cause sunburn when the person is not using a sunscreen. Sunscreens with increasing SPF values (up to a certain point) have been demonstrated to provide increased sunburn protection. Because SPF values represent a sunscreen's level of sunburn protection, they are primarily (though not exclusively) an indicator of expected protection from UVB radiation. To pass FDA's current test for broad spectrum labeling (§ 201.327(j)), however, sunscreens must demonstrate that, in addition to UVB protection, they also provide some UVA protection.

Only products that have been determined to have a minimum SPF value of 15 *and* to pass our broad spectrum test may include statements in their labeling indicating that they decrease the risk of skin cancer and early skin aging caused by the sun when used as directed with other sun protection measures (§ 201.327(c)(2)). In contrast, sunscreens that have not been determined to provide both broad spectrum protection and an SPF value of at least 15 must include a skin cancer/skin aging alert warning to consumers that ''[s]pending time in the sun increases your risk of skin cancer and early skin aging'' and that ''[t]his product has been shown only to help prevent sunburn, not skin cancer or early skin aging'' (§ 201.327(d)(2)).

2. Increased Evidence of Harms Associated With Exposure to UVA Radiation

Since publication of the 2011 L&E Final Rule and Max SPF PR, the strength of scientific evidence linking UVA exposure to skin cancers and other harms has increased. This evidence suggests that UVA wavelengths continue generating DNA lesions hours after UV exposure (Ref. 161) and that if left unrepaired, these DNA lesions can form UV-induced mutations in many genes that have been detected in both melanoma and nonmelanoma skin cancers (Refs. 162 to 165). Further, unlike UVB-induced DNA lesions, which attenuate with skin depth, recent evidence indicates that DNA lesions induced by UVA I exposure show the opposite pattern, with both increased DNA lesions in the basal layer of the epidermis (where melanocytes and proliferating keratinocytes reside) and less efficient DNA lesion repair in the basal layer (Refs. 166 and 167).

Damage to cells in the basal layer (if left unrepaired or if inefficiently repaired) can lead to mutations in critical genes that increase the possibility that normal cells will transform into cancer cells. While inefficient DNA repair is a concern for all individuals exposed to UV radiation, this concern is particularly acute in those with xeroderma pigmentosum (a disease caused by a disorder of the DNA repair system), who have extreme sensitivity to UV radiation, and who develop both nonmelanoma skin cancer and melanoma with a high frequency and very early in life (Ref. 168). In addition to the skin cancer-related risks associated with UVA exposure, increasing evidence shows that UVA I radiation also produces immunosuppression (Refs. 169 and 170). This, too, is a general concern for all individuals, but is especially dangerous for certain at-risk populations (such as organ transplant recipients and others on immunosuppressive drugs).

Given the above-described evidence, we are concerned about the existing potential for inadequate UVA protection in marketed sunscreen products. This is a particular concern with respect to high SPF sunscreen products that do not pass FDA's current critical wavelength-based broad spectrum test or that (though they pass our current broad spectrum test) have inadequate uniformity in their UVA protection. Consumers using these products may, while successfully preventing sunburn, accumulate excessively large doses of UVA radiation, thereby exposing themselves to additional risks related to skin cancer and early skin aging. The International Agency for Research on Cancer has found that high SPF sunscreen products are associated with longer intentional UV exposures (Ref. 171), raising the concern that use of these products may result in significant doses of UVA radiation. We note that concerns relating to inadequate UVA protection came up in several comments we received in response to the 2011 Max SPF PR, and that these comments raised particular concerns about inadequate UVA protection in high SPF products. This concern has also grown over time in the published literature (Refs. 172 to 175).

For all of these reasons, we are proposing a number of steps designed to couple a greater magnitude of UVA protection to increases in SPF values. As discussed in further detail below, we are also making proposals designed to address evidence of variability in SPF values and evidence showing additional clinical benefits associated with SPF 60 sunscreens.

3. Broad Spectrum Proposals

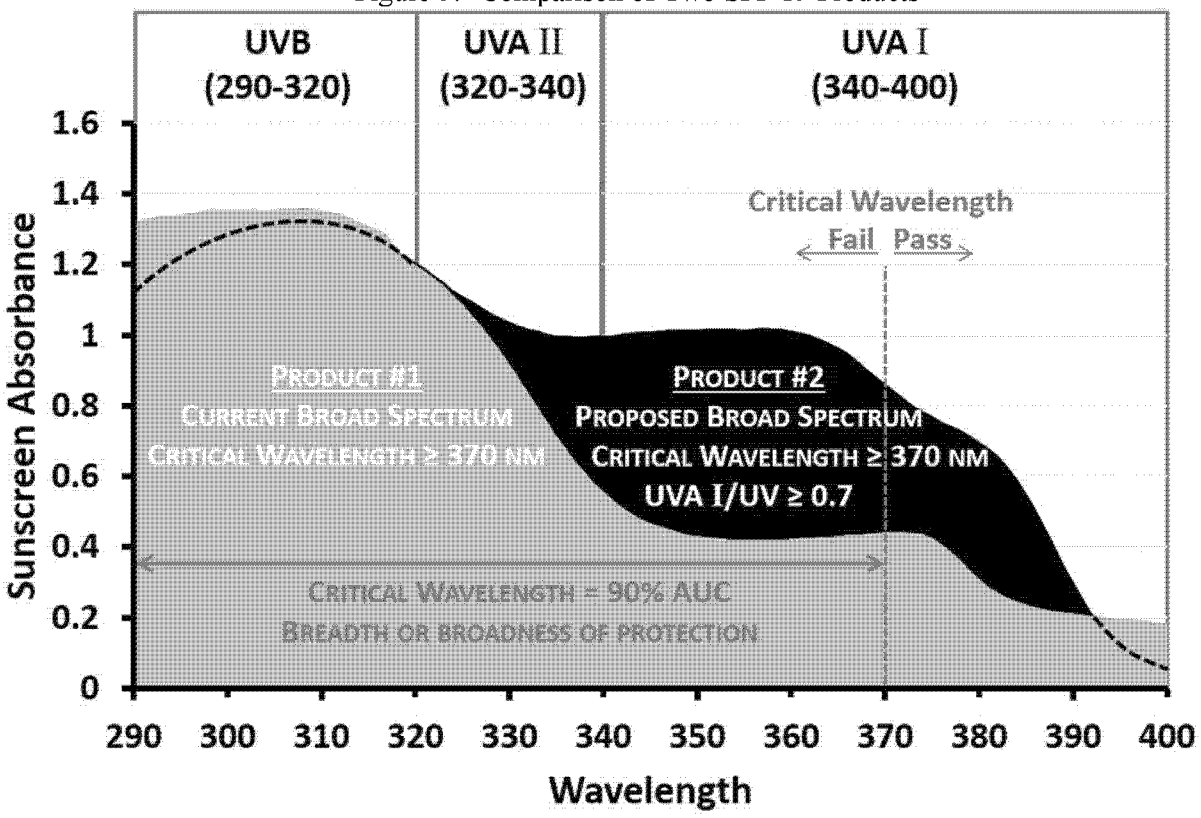
a. UVA I/UV ratio required to pass the broad spectrum test. We are proposing certain changes to the requirements to pass the broad spectrum test. Specifically, we are proposing to add to the current broad spectrum test a requirement that products meet a UVA I/UV ratio of 0.7 or higher. We note that the current broad spectrum test procedure would remain unchanged [40] and that this new ratio would be calculated using data from the existing test, which should help minimize burden on manufacturers.

The current labeling regulation requires that sunscreens labeled as broad spectrum achieve a critical wavelength of 370 nm or greater (§ 201.327(j)). A sunscreen product's UV protection is often displayed as a curve on a graph showing the amount of UV absorbance the product provides at each wavelength in the UV spectrum (*i.e.,* from 290 to 400 nm). The ''critical wavelength'' of the product is the wavelength corresponding to 90 percent of the area under this curve. Higher critical wavelengths, therefore, illustrate greater breadths of UV protection across the 290 to 400 nm spectrum.

Most sunscreen products—even if they achieve a critical wavelength of 370 nm or greater and therefore meet the current criteria for broad spectrum labeling—have historically covered the UVB and UVA II ranges preferentially. Given how much of the UVA portion of the UV spectrum is composed of UVA I radiation (see Figure 3 below) and given what we now know about the risks associated with UVA exposure, and with UVA I exposure in particular, ensuring that sunscreen products provide adequate protection in the UVA I portion of the spectrum is critical.

[40] We note that, as described in section IX.D.2.i, we are proposing a minor revision in equipment specifications for the broad spectrum test to respond to feedback that FDA received on this issue and proposing some minor revisions to current language to make clear our existing expectations.

Figure 3.--Comparison of Two SPF 15 Products[1]



[1] Product 1 satisfies the current broad spectrum requirement of achieving a critical wavelength of 370 nm or greater; product 2 meets both components of the proposed broad spectrum requirement (achieving both a critical wavelength of 370 nm or greater and a UVA I/UV ratio of 0.7 or greater).

We are therefore proposing to require that in order to pass the broad spectrum test, a product must demonstrate that it provides a UVA I/UV ratio of 0.7 or higher, indicating that the product provides a minimum measure of UVA I radiation absorbance relative to total UV radiation (*i.e.,* UVB + UVA) absorbance, in addition satisfying to the 370 nm critical wavelength requirement. Requiring a UVA I/UV ratio of 0.7 or higher for broad spectrum products would mean that these products would have a more uniform amount of radiation protection across the UVA I, UVA II, and UVB ranges. This improved fidelity across the UV spectrum is especially important for high SPF products which, as discussed above, are associated with longer intentional sun exposure, which in turn can result in significant doses of UVA radiation. This proposed UVA I/UV ratio would also help eliminate the current potential for a product labeled as broad spectrum that has a higher SPF value to provide (unbeknownst to the consumer) poorer broad spectrum protection than a product labeled as broad spectrum with a lower SPF value (depending on the particular combination of active ingredients used in the product and which parts of the UV spectrum they absorb). For example, under the current testing regime, a sunscreen that is labeled ''broad spectrum SPF 30'' could provide less UVA protection than a sunscreen labeled ''broad spectrum SPF 15.''

We note that FDA first raised concerns relating to the adequacy of UVA protection in sunscreen products in 2007 (see 72 FR 49070 at 49104 to 49107). At that time, we proposed a similar ratio to the one we are proposing today as part of a different, more complex proposal for testing and labeling to address broad spectrum protection that, among other things, included both in vitro (spectrophotometric) and in vivo (clinical) testing for UVA radiation, as well as a four-tier UVA star rating labeling system. In response to comments describing purported disadvantages of that proposal, including general comments that the proposal was overcomplicated, specific comments on the proposed in vitro testing method, and comments indicating that ''[t]he proposed ratio places too much emphasis on the UVA I region, which is not generally considered to contribute significantly to the harmful effects of exposure to UV radiation'' (76 FR 35620 at 35650), we made a number of changes to our 2007 proposal in the 2011 L&E Final Rule. Those changes included elimination of the UVA I/UV ratio and adoption of the above-described critical wavelength test for establishing broad spectrum protection instead. As we noted in the preamble to the L&E Final Rule, our decision not to require the UVA I/UV ratio at that time was based, in part, on our agreement with comments stating that the scientific evidence available at that time indicated that UVA I exposure did not pose sufficient risk of harm to justify the emphasis placed on it by the ratio, and that the critical wavelength test provided a superior measure of broad spectrum protection (id. at 35650).

As described above, in the time since issuance of the L&E Final Rule, the body of evidence showing the harms of UVA exposure, and of UVA I exposure, in particular, has grown significantly (Refs.

159, 161, 162, 166, 167, and 169). It is now clear that in addition to producing the immunosuppression described above, UVA I exposure also results in increasing DNA damage with increasing skin depth (in contrast to UVB-induced DNA damage, which is reduced as skin depth increases). In addition, given that UVA I is the predominant portion of UVA radiation, new evidence (discussed in section IX.B.2) strengthening the link between UVA radiation and skin cancer development raises our concerns about the potential for inadequate protection in the UVA I portion of the UV spectrum. Accordingly, we no longer agree with the earlier comments suggesting that UVA I does not contribute significantly to the harmful effects of exposure to UV radiation, or with our 2011 conclusion that a UVA I/UV ratio requirement would therefore place too much emphasis on this portion of the UV spectrum.

We emphasize that we are not proposing to replace the existing critical wavelength test, and that the proposed ratio would supplement (and be calculated using data from) the existing broad spectrum test. We also note that the UVA I/UV ratio we are proposing would result in a level of UVA protection similar to what is achieved via the European Union's recommended minimum UVA protection factor of ⅓ of the labeled SPF and via the United Kingdom's Boots 3-star rating (the United Kingdom has for decades used a tiered star rating system based on an alternative ratio method) (Refs. 173 and 174). We note that data collected in 2009 about 330 sunscreen products commercially available in the United States showed that, at that time, more than half of these products already satisfied the broad spectrum test we are now proposing (see Comment, Docket No. FDA–1978–N–0018–0690).

b. Broad spectrum requirement for all products that are ≥SPF 15. We are also proposing to require that all sunscreen products with SPF values of 15 and above demonstrate that they provide more uniform protection across the UVA I, UVA II, and UVB ranges of the UV spectrum by satisfying FDA's revised broad spectrum test. This proposal is designed to link increases in SPF value not only to increases in UVB protection, but to increases in the magnitude of UVA protection as well. We note that a consumer using a sunscreen that provides robust protection against sunburn but that does *not* pass FDA's revised broad spectrum test—and therefore provides inadequate UVA protection—may fail to get out of the sun, thereby exposing themselves to higher levels of UVA radiation than if they had not been protected from sunburn. Given the increasing evidence of major health risks associated with UVA exposure, we propose to find that such products (those with SPF values of 15 and greater that do not provide sufficient protection across the UV spectrum (as demonstrated by satisfying FDA's revised broad spectrum requirement)) are not GRASE. At the same time, we conclude that the evidence described above regarding the contribution of UVA I to skin carcinogenesis, coupled with the evidence reviewed in the 2011 L&E Final Rule (see 76 FR 35620 at 35630–35634), supports the proposal to include sunscreen products that have an SPF of 15 or higher and also pass the revised broad spectrum test in the sunscreen monograph with indications both for use to help prevent sunburn and for use, as directed with other sun protection measures, to reduce the risk of skin cancer and early skin aging caused by the sun. As we indicated in the L&E Final Rule, the whole range of UV radiation, and not specific wavelengths, is a human carcinogen, and the exact wavelengths most responsible for these harmful effects are not known (see id. at 35631, 35633). To assure that a clinically meaningful reduction in the risks of skin cancer and early skin aging is achieved, then, a product must contribute to substantially limiting overall UVB and UVA exposure (see id. at 35630, 35631–35632), as will be assured by our proposal to couple the enhanced breadth of protection across the UVA spectrum provided by the revised pass criteria for the broad spectrum test with the magnitude of protection assured by requiring a minimum SPF of 15.

By requiring that all sunscreens with SPF values of 15 or more satisfy the (new) broad spectrum standard (including the new ratio requiring proportionate protection), this proposal will also enable consumers to select a product primarily by numerical (SPF) value on the label, having assurance that, when used as directed, a product labeled with a higher numerical SPF value provides proportionately more protection not only against sunburn, but also against skin cancer and skin aging than lower numbered products [41] (provided that the product provides an SPF of at least 15). In doing so, this proposal also eliminates another source of potential confusion permitted by the current labeling regime, in which a higher numbered product (for example, one labeled SPF 30) may provide inferior protection against UVA radiation than a lower numbered product (for example, one labeled Broad Spectrum SPF 15).

c. Sunscreen products with SPFs <15. As noted above and in section III.A.2, sunscreen products with SPF values below 15 have not been shown to reduce the risk of skin cancer or early skin aging caused by the sun, whether or not they provide broad spectrum protection. Because of this limitation, we considered proposing to remove from the monograph sunscreen products with SPF values lower than 15. However, as the Surgeon General has acknowledged (Ref. 5), some consumers may seek intentional sun exposure because (for example) they associate tanned skin with attractiveness and health. These consumers may seek some protection from sunburns and therefore, select a low SPF product (*i.e.,* one with an SPF value below 15). If such products are removed from the market, these consumers may choose not to use a sunscreen product at all rather than use a broad spectrum product with an SPF of 15 or above.

Although the benefits of sunscreen products with SPFs below 15 (which are not indicated to reduce the risk of skin cancer or early skin aging) are limited, FDA believes that the use of such products is preferable to the use of no sunscreen at all. Thus, to provide sunburn protection for these consumers, FDA is proposing that sunscreens with SPF 2 to 14 that bear prominent labeling regarding their limited use for sunburn prevention and the risks associated with spending time in the sun (see sections IX.B.1 and IX.C) may remain on the market without approved NDAs. Because products with SPFs below 15 have not been demonstrated to reduce the risk of skin cancer, FDA is not proposing to require products with SPF values under 15 to pass the broad spectrum test. However, we seek comment on whether the limited benefits such sunscreen products confer outweigh the risks of sunscreen drug exposure and the potential false sense of security provided regarding UV protection (*i.e.,* whether such sunburn-only sunscreen products are GRASE and should remain on the market without approved NDAs).

4. Maximum SPF Value Proposals

a. Maximum labeled SPF value would be SPF 60+. In conjunction with the broad spectrum proposals described above, we are also proposing to raise the maximum labeled SPF value for

[41] As noted in section III.A.2, only those broad spectrum sunscreen products that have an SPF of 15 or higher have been shown to help prevent skin cancer and early skin aging.

products containing sunscreen monograph active ingredients to SPF 60+. Under this proposal, sunscreen products with SPF values of 60 or greater would be labeled ''SPF 60+.''

FDA has proposed to raise the maximum SPF value that sunscreens marketed pursuant to the OTC Monograph System can display on their labeling several times. In the 1978 notice of proposed rulemaking, we proposed that such sunscreens be labeled with a maximum SPF value of 15 (43 FR 38206 at 38213 to 38214). In the 1999 final monograph, we determined that that cap should be increased to SPF 30+ (64 FR 27666 at 27675). In 2007 (72 FR 49070 at 49085 to 49087) and then in 2011 (Max SPF PR), we tentatively concluded that data existed to show that sunscreens with labeled SPF values of up to 50+ provide additional clinical benefit to consumers. Our proposal today to increase the maximum labeled SPF value to 60+ is similarly based on data showing the additional clinical benefit provided by SPF 60 sunscreen products when those products also provide broad spectrum protection.

In the 2011 Max SPF PR proposing an SPF 50+ cap, we noted that the record, at that time, lacked adequate data demonstrating that sunscreen products with SPF values above 50 provided additional meaningful clinical benefit over and above what was provided by SPF 50 protection (76 FR 35672 at 35672 to 35674). We requested data showing that such clinical benefits existed (id.). In response to both the 2007 and 2011 proposals, we received comments providing citations to data showing the additional meaningful clinical benefit provided by sunscreen products with SPF values of 60 for certain at-risk populations when those sunscreens also included broad spectrum protection. (See, *e.g.,* Ulrich et al. (showing statistically significant protection of organ transplant recipients, who are highly susceptible to nonmelanoma skin cancer, from squamous cell carcinoma with use of broad spectrum SPF 60 sunscreen) (Ref. 176); see also Comment FDA–1978–N–0018–0710, August 31, 2011, citing Kuhn et al. (showing statistically significant prevention of skin lesions in topical lupus erythematosus patients with use of broad spectrum SPF 60 sunscreen after exposure to either UVA I source or UVA II/UVB source) (Ref. 177); Faurschou et al. (showing prevention of urticarial reaction in subjects with idiopathic solar urticaria with use of broad spectrum SPF 60 sunscreen) (Ref. 178); Fourtanier et al. (showing lower levels of polymorphous light eruption in subjects using broad spectrum SPF 60 versus SPF 50 products (Ref. 179)). Based on the additional meaningful clinical benefit provided by broad spectrum SPF 60 sunscreens shown in these studies, we are proposing to raise the maximum labeled SPF value to SPF 60+.

Because the studies demonstrating the additional meaningful clinical benefit provided by SPF 60 sunscreens all used sunscreens that also provided broad spectrum protection, however, the additional clinical benefit shown to exist at SPF 60 cannot be decoupled from the broad spectrum protection provided by those products. That is, the additional meaningful clinical benefit shown in these studies may have been the result of the sunscreens' protection against rays in the UVB range or in the UVA range, or both. For this reason, our proposal to recognize the additional meaningful clinical benefit provided by sunscreens with SPF values above 50 is consistent with, and dependent upon, our proposal that all sunscreen products with SPF values of 15 and above be required to provide broad spectrum protection.

Given the lack of data showing that sunscreens with SPF values *above* 60 provide additional meaningful clinical benefit, however, we are proposing not to allow labeled SPF values higher than 60+. Labeling sunscreen products with SPF values higher than what has been shown to provide additional meaningful clinical benefit could have unintended negative consequences. For example, as discussed above, such products may inadvertently promote extended solar exposures because consumers feel protected and assume that the higher SPF value implies that greater UV exposure is safe (see, *e.g.,* Autier, et al., 2007 (Ref. 171)).

b. Formulation cap for sunscreen products of SPF 80. Although we are proposing that the maximum labeled SPF value will be SPF 60+, we are proposing to permit the marketing of sunscreen products formulated with determined [42] SPF values up to 80. We are proposing to permit this additional formulation margin in part because of the inherent variability in SPF test results. A sunscreen product's SPF value is calculated from measurements that are based on an investigator's visual evaluation of an individual test subject's erythema response to a series of UV doses administered in successive sites on the subject's back. Because the administered UV dose series for the final minimal erythema dose (MED) [43] of a sunscreen with an expected SPF of 60 increases by 15 percent with each successive dose (see § 201.327(i)(5)(iii)), a difference in judgment of one site in opposing directions would result in up to approximately 30 percent variability in the assessment of the amount of exposure that resulted in the erythema.[44]

Allowing the marketing of sunscreen monograph products with determined SPF test results up to 80 would, therefore, more fully account for the range of variability in SPF test results for sunscreen products labeled SPF 60+. We are also proposing this formulation margin to provide manufacturers with additional formulation flexibility that we hope will help facilitate the development of products with greater UVA protection, given our expectation that active ingredients added for the primary purpose of increasing UVA protection would contribute to a sunscreen's determined SPF value as well. We seek comment on whether SPF 80 is the appropriate formulation cap to accomplish these objectives.

We are proposing not to allow the marketing (without an approved NDA) of sunscreen products with determined SPF values above SPF 80. This proposal follows from the principle that if the addition of ingredients to a drug does not provide additional clinical benefit but potentially increases the risk associated with the drug, this shifts the benefit-risk calculation and renders the drug not GRASE (see, *e.g.,* 76 FR 35673 at 35675). In light of this principle, we solicited comments in 2011 on the appropriateness of a formulation cap for sunscreen products (id.).

Some of the comments that we received in response to the 2011 Max SPF PR expressed concerns (in general) about the safety of unnecessary exposure to sunscreen active ingredients. We received only one comment, however, directly addressing the question of an SPF formulation cap. That comment emphasized that there was no formulation limit in other countries using an SPF labeling cap, and

[42] As used in this preamble, the determined SPF value is the SPF value that equals the largest whole number less than $\overline{SPF} - (t*SE)$, determined for a sunscreen product in accordance with § 201.327(i). See also section IX.D.2.b, where we propose to define this term in the regulation.

[43] The minimal erythema dose (MED) is the smallest UV dose that produces perceptible redness of the skin (erythema) with clearly defined borders at 16 to 24 hours after UV exposure (§ 201.327(i)(5)(i)).

[44] The determination of SPF for each subject is calculated via a ratio of the MED of protected skin over the final MED of unprotected skin. In a scenario in which the final MED of unprotected skin is underestimated by 15 percent and the MED of protected skin is overestimated by 15 percent, this would present approximately 30 percent variability for the individual subject.

that the list of permitted active ingredients in the monograph itself establishes an SPF ceiling for the formulation as a whole. FDA rejects the premise that the list of permitted active ingredients establishes an adequate SPF cap for sunscreen formulations, as this theory does not take into account the potential addition of new GRASE ingredients to the list of active ingredients under the monograph. This comment also appears to imply that the maximum concentration of each active ingredient correlates specifically to a particular numerical contribution to the total SPF value of the product. This has not been established (see 64 FR 27666 at 27674 and 27675 (noting that formulation techniques may enable increases in SPF without use of higher concentrations of active ingredients)). In addition, as mentioned in 2011 in the Max SPF PR (76 FR 35672 at 35674), the theoretical increase in protection implied by higher SPF values generated in a laboratory does not necessarily correspond to meaningful additional sunburn protection for consumers in actual use conditions. Given that a solar simulator in a lab can produce much higher UV doses than a consumer would receive from the sun (even in the most extreme situations), it is unlikely that a consumer could ever actually reach the theoretical ceiling created by the list of permitted active ingredients.

Given the lack of demonstrated clinical benefit for sunscreens with determined SPF values above SPF 60, and the potential for risks—discussed elsewhere in this document—associated with exposure to sunscreen active ingredients, we propose not to permit the marketing (without an approved NDA) of sunscreen products with determined SPF values above SPF 80 (which reflects a formulation margin intended both to give full effect to the SPF 60 limit and to enable formulation flexibility).

c. Proposal for ≥SPF 15 labeling. Finally, we are proposing to require that sunscreen monograph products with determined SPF values of 15 or above be labeled with an SPF number corresponding to the lowest number in a range of tested SPF results, as shown in table 5.[45] For example, sunscreens testing at SPF 15 to 19 would be labeled ''SPF 15''; those testing at 40 to 49 would be labeled ''SPF 40.''[46]

This proposal is designed to avoid misleading consumers about the relative efficacy of sunscreen products, given the lack of clinical data showing meaningful efficacy differences between closely grouped SPF values. We note that in the 2011 L&E Final Rule, FDA declined a request that SPF be labeled in multiples of five, stating that there was no mathematical or statistical basis for this labeling approach because SPF values could generally be determined with a precision that allowed for SPF values to be labeled in intervals of less than five units. New data showing variability both between tested SPF values for individual study subjects and for determined SPF results achieved across multiple labs testing the same sunscreen formulation (*i.e.,* variability inherent in a clinical test that relies on visual assessments) (FDA–1978–N–0018–0740, 2011; Ref. 182), however, has caused us to reexamine this issue.

As described above, the clinical SPF test is conducted using a solar simulator to administer several specified doses of UV radiation that increase by 15 to 25 percent with each successive dose to a human subject's back in both sunscreen-treated and untreated areas (with the specific UV doses being derived from the expected SPF of the product and a determination of the individual subject's UV sensitivity). The clinical investigator then visually evaluates both the sunscreen-treated and untreated areas of the subject's back to identify the areas with perceptible skin redness (erythema) that has clearly defined borders. Determining which of several areas on a single subject's back should be considered to meet this ''clearly defined borders'' criteria is an exercise of clinical judgment. Once the investigator has made this judgment, he or she then records the smallest dose of UV radiation it took to create an area with the observed skin reaction of erythema with clearly defined borders. After assessing multiple individual test subjects this way, the resulting UV exposure information is used in calculating the determined SPF value of the sunscreen being tested. The data we reviewed suggest that the clinical evaluation undertaken during this process creates variability that justifies the use of SPF ranges.

For example, in a study using panels of five subjects, the mean SPF values observed across multiple labs ranged from 54 to 82 for a target SPF 80 (FDA–1978–N–0018–0740, 2011). This same study also evaluated a scenario where a lab was not told the target SPF, but was rather given a range of SPF 20 to 100 for a product with an expected SPF of 100. The results showed that it was extremely difficult for labs to reproduce the labeled SPF 100, with mean SPF values ranging from 37 to 75. In a second study with multiple panels of 25 subjects that was controlled and randomized, the determined SPF of two sunscreen formulations tested across four labs ranged from 63 to 69 for a target SPF 70 and from 82 to 89 for a target SPF 90 (Ref. 182). Although the magnitude of the differences observed in this second study were not statistically significant, the fact that multiple labs determined different specific numerical values for a single formulation suggests that the use of labeled values representing ranges more accurately represents the sun protection provided by a product, and therefore is appropriate to avoid misleading consumers.

We note that variability in SPF values is exacerbated at high SPFs. For example, individual test results with 30 percent variability from a determined SPF value of 20 would range from SPF 14 to SPF 26; individual test results with 30 percent variability from a determined SPF value of 50 would range from SPF 35 to SPF 65. Accordingly, as shown in table 5, we propose that the range of tested values reflected in the labeled SPF number should be wider at higher SPF values and narrower at lower ones, and that the requirement that labeled SPF values correspond to ranges rather than precise numerical values is not necessary below SPF 15.

TABLE 5—PROPOSED SPF LABELING RANGES

Range of determined SPF values	Associated labeled SPF value
60–80	60+.
50–59	50.
40–49	40.
30–39	30.
25–29	25.
20–24	20.
15–19	15.
2–14	Determined SPF Value.

C. Proposed PDP Labeling Requirements

We are also proposing some revisions to the principal display panel (PDP) for sunscreen products (the PDP is the portion of an OTC drug product label that is most evident when the product is displayed for retail sale (§ 201.60)). In addition to satisfying general OTC drug labeling requirements found in part 201,

[45] We note that the use of ranges to represent SPF values on product labeling is already in use in Australia and the European Union (Refs. 180 and 181).

[46] The proposed labeled values are expressed in increments of 5 for products with determined SPF results of 15 to 29.9 (*i.e.,* SPF 15, SPF 20, SPF 25), but for determined SPF results of 30 or more, the proposed labeled values are expressed in increments of 10 (*i.e.,* SPF 30, SPF 40, SPF 50, with a proposed maximum of SPF 60+.).

sunscreen product PDPs are currently required to satisfy specific labeling requirements in § 201.327. We are proposing to amend these requirements for sunscreen PDP labeling (currently codified in § 201.327(a) and (b), and (for the statement of identity of products that also include skin protectants) in § 201.327(h)) to help consumers better understand, evaluate, and compare sunscreen products by providing additional information on the PDP, and by ensuring the prominence and readability of information required to appear on the front of the container or package. We are also proposing to renumber and consolidate provisions on PDP labeling and the statement of identity (SOI) in § 201.327(b) to incorporate new proposed provisions in § 201.327(a), as described in section IX.D.2.b of this preamble. In addition, we are proposing that labeling a sunscreen product in accordance with proposed § 201.327(b) would be a condition for marketing a sunscreen under the OTC sunscreen monograph in part 352.

We are proposing to revise the current SOI, which is required to appear on the PDP by both current and proposed § 201.327. Currently, the SOI for sunscreens under this regulation contains ''the established name of the drug, if any'' and identifies the product as a ''sunscreen.'' The revised SOI would consist of an alphabetical listing of all sunscreen active ingredients in the product using the names shown in § 201.327, followed by ''Sunscreen'' and the product's dosage form (such as lotion or spray). In light of these proposed changes to the SOI for sunscreens, we are also proposing harmonizing changes to the provisions that address the SOI for products that combine sunscreen and skin protectant active ingredients (proposed § 201.327(h) and cross-referenced in the sunscreen monograph in § 352.60 (21 CFR 352.60) and in the skin protectant monograph in § 347.60 (21 CFR 347.60)).

The proposal to list all active ingredients as part of the SOI is generally consistent with SOI labeling of other OTC and prescription drugs. Providing information about a product's active ingredients and dosage form would supplement other important elements of the PDP (SPF, broad spectrum, and water resistance information) to provide a succinct summary of the product's key characteristics on the front of the package or container. We expect that this approach would enable consumers to more readily compare differing products and either select or avoid a given product accordingly. As an indication that consumers value information about a sunscreen's active ingredients, an analysis of top-rated sunscreen product reviews on *Amazon.com* found that product ingredients were listed as a positive factor in 17 percent of responses, and a negative factor in 10 percent of responses (Ref. 183).

Based on a review of marketed sunscreen product labels, FDA is concerned that the SOI may currently be obscured by the inclusion and prominence of other printed or graphic information on the PDP. For this reason, we also propose to require the SOI to appear in direct conjunction with the most prominent display of the proprietary name, in a boldface font at least one-fourth the size of the most prominent printed matter on the PDP, and displayed so that the text is generally parallel to the base of the packaging. We propose that the entire SOI appear in the same font style, size, and color with the same background color, and as continuous text with no intervening text or graphic material other than text provided in accordance with the requirements for the SOI for a product that also includes a skin protectant, where applicable. These requirements would supplement, and not replace, the general requirements regarding the PDP and SOI for all nonprescription products in §§ 201.60 and 201.61.

Proposed § 201.327(b) would incorporate the ''Broad Spectrum SPF,'' ''SPF,'' and ''Water Resistant'' statements that already must appear on the PDP as described in current § 201.327(a). Additionally, for all products with SPF values below 15, we propose to require that the SPF statement be followed by an asterisk (*) directing the consumer to the statement ''*See Skin Cancer/Skin Aging Alert.'' We propose that the quoted statement must appear in the bottom 30 percent of the PDP. This statement is intended to draw the consumer's attention to the Skin Cancer/Skin Aging Alert that would continue to be required for these products as part of the ''Warnings'' in the Drug Facts portion of the label (§ 301.327(d)), because there is evidence that some sunscreen consumers are not reading this information in its current location (Refs. 184 and 185).

Under the current regulation, the entirety of the ''Broad Spectrum SPF'' or ''SPF'' statement, as applicable, must appear on the sunscreen PDP in the same font style, size, and color and with the same background color, and, if used, the ''Broad Spectrum SPF'' statement must also appear as continuous text with no intervening text or graphic. To further ensure the prominence and readability of information that is important for consumers to evaluate and compare sunscreen products, we propose that these statements must also appear in bold typeface at least one-fourth the size of the most prominent printed matter on the PDP, and as text generally parallel to the base of the packaging.

The proposed new ''*See Skin Cancer/Skin Aging Alert'' statement would also be required to appear in bold typeface at least one-fourth the size of the most prominent printed matter on the PDP, and as text generally parallel to the base of the packaging. In addition, the entire statement would appear in the same font style, size, and color with the same background color, and as continuous text with no intervening text or graphic.

Finally, because water resistance is also an important characteristic for consumers when choosing a sunscreen, we also propose to apply comparable format requirements to the current ''Water Resistant'' statement. The statement would also be required to appear in bold typeface at least one-fourth the size of the most prominent printed matter on the PDP, and displayed so that the text is generally parallel to the base of the packaging. In addition, the entire statement would appear in the same font style, size, and color with the same background color, and as continuous text with no intervening text or graphic.

D. Proposed Requirements Related to Final Formulation Testing and Recordkeeping

We are also proposing a number of revisions in § 201.327: (1) To ensure that efficacy testing of the sunscreen formulation to be marketed is conducted in a way that protects human subjects and produces reliable results and (2) to enable FDA to assess compliance with this section's provisions going forward. We also propose to make compliance with these requirements a monograph condition in part 352.

1. General Approach to Final Formulation Testing

Current § 201.327 includes technical instructions for conducting the final formulation testing required to support the SPF values, water resistance statements, and broad spectrum statements shown in sunscreen product labeling. However, the current regulation does not explicitly address important broader considerations that are essential to ensure that final formulation testing is conducted and

documented in a way that verifiably provides for protection of human subjects in SPF and water resistance testing, as well as ensuring the reliability of all the testing data that underlies sunscreen labeling. We expect that persons responsible for conducting final formulation testing should already be following best practices in their current testing programs. However, we are concerned that many entities may not uniformly observe such practices and/or may not maintain the records needed to document compliance with the final formulation testing procedures set forth in § 201.327. FDA's experience in conducting inspections and other actions to verify testing under the current provisions of § 201.327 have suggested latent problems in these areas. Although limited, this experience reinforces FDA's belief that further clarification of regulatory expectations is necessary given the public health importance of ensuring that sunscreen products are effective and accurately labeled, and the broad range of entities that may be involved in bringing sunscreen products to market. Thus, we are proposing to incorporate FDA's current expectations more explicitly in the revised provisions. The proposed provisions are broadly consistent with current best practices for efficacy testing conducted in human subjects, and are not expected to require significant changes by reputable and experienced testing establishments. Key areas of concern that are addressed by the proposed revisions include the following.

a. Protection of human subjects and oversight of clinical final formulation testing. Ensuring that clinical final formulation testing is both designed and conducted in a manner that will yield reliable results is critical, as is ensuring the protection of the human subjects on whom SPF and water resistance testing are conducted. Existing provisions within the SPF test in § 201.327(i)(3)(iv) require that informed consent be obtained, but do not otherwise specify what this should involve or how clinical final formulation testing should be overseen. Across disciplines, testing involving human subjects is ordinarily conducted under institutional review board (IRB) oversight as a means of ensuring that informed consent and other human subject protections are provided and ensuring the integrity of study design and execution. FDA likewise expects that IRB review is already routinely being obtained by many establishments for SPF and water resistance testing.

Nonetheless, our experience in conducting inspections and other actions to verify the reliability of final formulation testing under the current provisions of § 201.327 have raised some questions about current practices. For example, FDA's observations have raised questions about whether and how entities conducting final formulation testing have put in place protocols and IRB oversight to ensure that test subjects do not repeat participation in testing with a frequency that could both compromise the ability to distinguish erythemic reactions to the test article and raise other questions about human subject protection. We are concerned that the lack of explicit requirements with regard to IRB oversight, as well as the cursory nature of the informed consent requirement in the current sunscreen labeling regulation, may result in inconsistent practices in the conduct of SPF testing that would compromise the reliability of results. Among other things, IRB review is critical to verify the adequacy of informed consent and to ensure that study protocols incorporate appropriate inclusion/exclusion criteria for subject selection (both to protect test subjects and to ensure the accuracy of results).

b. Qualifications of study personnel. In some instances, it may not be clear upon inspection whether all aspects of a study were conducted by appropriately qualified personnel. For example, FDA would not consider it adequate for a technician, rather than an appropriately trained medical professional (such as, for example, a nurse or dermatologist), to perform a physical examination for potential nevi, moles, or other dermal lesions. As with all clinical and nonclinical testing done to support labeling, the use of properly trained and appropriately qualified personnel is essential to ensure the reliability and accuracy of test results. Documentation of the qualifications and training of personnel is also necessary to enable FDA's efficient enforcement of the FD&C Act.

c. Documentation of equipment maintenance, study methods, and observations. Failure to maintain adequate records of testing equipment, methods, and observations can raise broad questions about the reliability of final formulation testing. In FDA's experience since the promulgation of current § 201.327, there has been a lack of uniformity in testing entities' approaches to recordkeeping for final formulation testing, raising concerns about the adequacy of recordkeeping procedures. Failure of testing entities to keep adequate records to support final formulation testing may leave FDA unable to verify that the UV doses provided in SPF and water resistance test reports are accurate and valid. This is also true with respect to documentation of emission spectrum, the percentage of erythema-effective radiation contribution, and changes to solar simulator components and the UV meter/dose controller system. Failure to accurately calibrate and maintain equipment at one testing entity may affect data across multiple clinical SPF testing studies and/or broad spectrum testing for multiple different final formulations that are ultimately sold under different labels. Inadequate recordkeeping may interfere with efficient enforcement. We propose to address these concerns and align the regulation with our existing expectations through revised regulatory provisions that are described further in the following sections.

2. Specific Regulatory Proposals

a. Consequences of failure to observe best practices. We propose to clarify in the introductory paragraph of § 201.327 that a product is deemed misbranded if its labeling relies on the results of final formulation testing that was not conducted in compliance with all of the applicable provisions of § 201.327. Unless testing is conducted in compliance with all applicable provisions of § 201.327, FDA does not have adequate assurance that the labeling reliably reflects the properties of the sunscreen product. Therefore, if final formulation testing is not properly conducted in accordance with this section, labeling a sunscreen with an SPF value or representation of water resistance or broad spectrum properties based on that testing is a misrepresentation to the consumer that the labeling reliably states the product's properties, which should also be consistent with a system of standardized sunscreen labeling that can be used to make cross-product comparisons. We propose to incorporate the provisions of § 201.327(a) through (*l*) into part 352 as conditions under which a sunscreen is GRASE and not misbranded. If these provisions are finalized, failure to comply with these conditions would make a drug subject to regulatory action as misbranded and an unapproved new drug.

b. General obligations of responsible persons. We are aware that many different business relationships involving numerous entities are commonly used in the manufacturing, testing, and labeling of nonprescription sunscreen drug products. To clarify the locus of responsibility for ensuring that adequate final formulation testing procedures are in place, and to clearly delineate responsibility for

recordkeeping related to final formulation testing, FDA proposes a new defined term, *responsible person.*

We propose to define the term *responsible person* in a way that is consistent with FDA's treatment of regulatory responsibilities for other OTC drug products and that is in alignment with requirements for adverse event reporting for over-the-counter drug products, in section 760(b)(1) of the FD&C Act. The proposed definition for *responsible person* is ''the manufacturer, packer, or distributor whose name appears on the labeling of a sunscreen product covered by this section.'' Defining *responsible person* in this way will enable FDA to better assess compliance with § 201.327 because it creates a chain of responsibility that is immediately apparent from the product's labeling. The responsible person, as identified on the labeling, is ultimately responsible for ensuring that the product bearing its name is labeled in accordance with the requirements of § 201.327.

The proposed revision of § 201.327(a) would broadly set forth the general obligations of responsible persons with respect to final formulation testing under § 201.327(i) and (j), and it would make clear that the responsible person is charged with ensuring that sunscreen products are appropriately tested. The obligations of responsible persons as enumerated in § 201.327 are modeled after those of investigational new drug application (IND) sponsors under part 312 (21 CFR part 312), but are somewhat modified to accommodate unique aspects of clinical and nonclinical sunscreen formulation testing. Because final formulation testing under § 201.327(i) and (j) is intended to verify the claimed properties of a final formulation, and because this purpose is narrower in scope and duration than most clinical testing performed under FDA's IND regulations in part 312, a responsible person under proposed § 201.327 would have responsibilities that incorporate some of the traditional responsibilities of investigators as well as those of sponsors under part 312. For example, FDA proposes to clarify that responsible persons must select appropriately qualified personnel to conduct testing, ensure compliance with the requirements for IRB review and obtaining informed consent, and monitor the compliance of personnel with investigators' statements.

This proposed approach accounts for situations in which investigators and other personnel conducting final formulation testing are employees of the responsible person. We also propose to clarify that the responsible person must ensure that investigators and other personnel conducting investigations under § 201.327(i) comply with requirements related to human subject protection and the appropriate conduct of clinical testing. We believe that this better reflects the employer/employee relationships that are more common in connection with final formulation testing rather than with clinical testing conducted under an IND. These proposed provisions regarding selection of personnel are also consistent with the existing obligations of manufacturers under parts 210 and 211 (21 CFR parts 210 and 211), both of which govern compliance with CGMPs.

The proposed revision of § 201.327(a)(1) permits a responsible person to transfer some or all of its obligations to another entity, consistent with current industry practice, except for obligations with respect to recordkeeping. The recordkeeping proposal is discussed in section IX.D. Failure of an entity to comply with provisions of this part governing responsibilities it has assumed would subject that entity to the same regulatory action as if it were a responsible person who had failed to comply with those obligations. This provision is analogous to the provision in FDA's regulations at part 312 allowing for transfer of obligations of IND sponsors.

c. Adequate clinical testing procedures and conditions. Although current § 201.327 requires ''legally effective written informed consent from all test subjects'' (§ 201.327(i)(3)(iv)), it does not address broader underlying requirements for conducting clinical testing. In light of the concerns we identified regarding current clinical testing procedures and conditions, we propose to amend § 201.327 by adding paragraph (i)(1), ''Adequate Clinical Testing Procedures and Conditions.'' We expect that final formulation testing conducted in compliance with the proposals in this paragraph will be more likely to ensure protection of human subjects while also more reliably determining the SPF value and water resistance properties of the final formulations being tested. Unless appropriate clinical testing procedures and conditions are adhered to, FDA cannot have confidence in the resulting labeled SPF and water resistance properties of the product.

Proposed § 201.327(i)1(B) and (C) have been added to make clear that FDA's regulations governing informed consent (part 50 (21 CFR part 50)) and IRB approval of research (part 56 (21 CFR part 56)) apply to clinical final formulation testing that is conducted under § 201.327(i). In our view, as a matter of good clinical practice, IRB approval should already be routinely currently obtained for clinical final formulation testing under current § 201.327 because it is essential to producing results that are scientifically sound and ethically appropriate. Because clinical final formulation testing required to support labeling under current § 201.327 is not conducted under an IND or in support of a GRASE determination in the OTC sunscreen monograph, it was not previously included explicitly in the scope of testing covered by parts 50 and 56. We propose to rectify this omission by explicitly cross-referencing parts 50 and 56 in revised § 201.327(i). This will clarify that both of these parts apply to clinical final formulation testing and will resolve any inconsistency in current practice.

The proposed reference to part 50 clarifies FDA's position that legally effective written informed consent to participate in clinical final formulation testing should share the same properties as informed consent required for all other clinical testing covered by FDA's regulations in part 50. Similarly, by referencing part 56, the proposal ensures that final formulation testing is held to the same standards for IRB review as other clinical testing covered by FDA's regulations. In reviewing clinical protocols, IRBs have the ability to determine whether the protocol is adequately designed to study the endpoints sought, and to ensure that protocol elements, such as enrollment criteria, adequately protect both human subjects and the scientific rigor of the experiment.

d. Control of personnel. We propose to place responsibility on the responsible person to ensure that investigators and other personnel conducting clinical final formulation testing adhere to the investigational plan, the signed investigator statement, and all applicable regulations. We also propose to place responsibility on the responsible person for ensuring human subjects' protection, including through appropriately reporting changes in the testing to IRBs, and by appropriately seeking prior IRB approval for any changes to the testing, except where necessary to eliminate apparent immediate hazards to human subjects. Under the proposed rule, responsible persons are also expected to obtain from each investigator, and retain for their records, a signed investigator statement. This is similar to what is required of sponsors of INDs, and it helps to ensure that the investigator is qualified, understands his or her obligations, and will comply with the requirements of

this paragraph and with the protocol. It also enables better oversight of clinical investigations by FDA because it creates a record of the investigator's relevant experience and qualifications.

e. Research monitoring. A number of changes in § 201.327(i)(1) are being proposed to ensure adequate monitoring of clinical final formulation testing. Revised § 201.327(i)(1) would require that responsible parties inform all investigators testing a formulation if there are new observations about the drug, particularly with regard to adverse events or safe use. This is necessary to ensure proper communication between study personnel and protection of human subjects. Responsible persons must also monitor the conduct of investigations to ensure that clinical testing is being conducted in accordance with the protocol and with applicable regulations. If a responsible person discovers noncompliance by study personnel, then the responsible person must either secure compliance or remove the noncompliant personnel from conducting testing.

Finally, we propose to require that investigators report adverse events and/or safety concerns to the responsible person, and that investigators also provide responsible persons with final reports at the conclusion of testing. We believe that this will ensure there is appropriate documentation and communication of adverse events and/or safety concerns that arise during testing. It will also ensure there is a record of SPF testing conducted under § 201.327(i) that can be relied upon should questions related to a particular formulation arise when the sunscreen formulation is marketed. The proposed requirements are consistent with reporting required in the IND context, although, because of the short duration of the clinical final formulation testing conducted under § 201.327(i), we are not proposing to require annual reporting.

f. Test subject selection. We propose additional language regarding the selection of test subjects in § 201.327(i)(4). This is an area in which FDA's inspections of testing entities have suggested a lack of consistency. We are particularly concerned that inclusion/exclusion criteria provide for adequate time between study and enrollment and prior UV exposure, such as from participation in a previous SPF test, sunbathing, or sunlamp use. Erythemal responses can remain for days after sunbathing, and it is known that pigmentation development takes up to a week after initial exposure and remains for weeks to months (Ref. 186). SPF clinical studies should not include individuals who have participated in sunbathing, tanning bed use, or another SPF clinical study for at least the past 4 weeks or perhaps longer if UV-induced responses remain. The proposed clarification regarding conduct of physical examinations of test subjects reflects this consideration, and our additional proposal for IRB review, addressed elsewhere, will help ensure it is appropriately acted on.

g. Applicability of registration and CGMP requirements. Proposed § 201.327(k) reflects FDA's existing view that final formulation testing conducted under § 201.327 constitutes the ''manufacture'' of a drug. As such, this testing must be conducted in an establishment registered in accordance with part 207 (21 CFR part 207) and section 510 of the FD&C Act. This interpretation is consistent with the definition of *manufacture* in part 207, which includes ''each step in the manufacture, preparation, propagation, compounding, or processing of a drug . . . .'' (§ 207.1). The definition of *manufacture* as used in part 207 also ''includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs for another registered establishment's drug'' (id). Accordingly, a sunscreen product labeled in reliance on final formulation testing done in an unregistered establishment is misbranded under section 502(o) of the FD&C Act. This interpretation is also consistent with FDA's regulations in § 330.1, which require that OTC monograph drug products be manufactured in a registered establishment in order to be generally recognized as safe and effective and not misbranded. The incorporation of this provision in § 201.327, therefore, is intended to clarify an existing requirement for facilities performing this type of testing.

We also propose to clarify that, as a manufacturing activity, final formulation testing conducted under this paragraph is expected to be done in accordance with CGMPs as set forth in parts 210 and 211 (see § 210.3(b)(12), indicating that for the purposes of parts 210 and 211, ''Manufacture, processing, packing or holding of a drug product includes packaging and labeling operations, testing, and quality control of drug products''). This is consistent with FDA's regulations in § 330.1, which require compliance with CGMPs as a condition for OTC drug products to be GRASE and not misbranded when otherwise marketed consistent with conditions in a final monograph. Adherence to CGMP requirements in parts 210 and 211 includes compliance with the requirements to keep certain records and to have appropriately trained and qualified personnel. Failure to comply with CGMPs results in a product being adulterated under section 501(a)(2)(B) of the FD&C Act.

h. Recordkeeping. To enable FDA to better monitor compliance with the requirements of § 201.327, we propose to include specific recordkeeping requirements for final formulation testing. Accordingly, proposed § 201.327(*l*) clarifies what records of testing performed under this section must be kept, by whom, and for how long. This provision also allocates responsibility for records maintenance and specifies what records must be made available to FDA for inspection. Recordkeeping is essential for FDA to evaluate whether required testing of final formulations is being conducted in accordance with § 201.327(i) and (j), and to enable the Agency to investigate postmarketing product failures or adverse events. Appropriate recordkeeping also enables FDA to conduct better and more efficient inspections of entities conducting final formulation testing.

These recordkeeping requirements are in alignment with what is required for other types of manufacturing under CGMPs as set forth in parts 210 and 211. The proposed provisions are intended to clarify how, and for how long, records must be kept to substantiate required final formulation testing. We are proposing that records of testing must be kept by the responsible person (as newly defined in § 201.327(a), discussed previously), as well as by any other entity that actually performs testing (under a transfer of obligations per § 201.327(a)(1) or otherwise). Requiring that records be kept by both the responsible person and the testing entity (if different) will enable FDA to more easily identify records supporting the labeling of any given final formulation even when the product is labeled with the responsible person's information, but testing and manufacturing was completed by a third party.

The proposed recordkeeping requirements reflect FDA's experience in interacting with regulated industry. By requiring that records be kept by both the responsible person and any other entity that performs final formulation testing, the proposed rule will enable more efficient enforcement of the FD&C Act by, for example, allowing FDA to identify the source of formulation failures or apparent inconsistencies between the product labeling and consumer experience. The proposed recordkeeping requirements

will also assist FDA when it is conducting inspections of entities that perform final formulation testing for a number of different responsible persons and products, as we believe is the norm in this industry. Having ready access to records reflecting the overall conduct of final formulation testing during an inspection of such an entity is important because it will enable FDA to identify potential systemic problems in final formulation testing that may have an impact on the reliability of results supporting the labeling of multiple different sunscreen products marketed by a variety of responsible persons. We note that these recordkeeping requirements should not be understood to mandate duplicative records within the files of a single testing entity or single responsible party. For example, if one investigator is responsible for testing multiple final formulations, one copy of the signed investigator statement and Curriculum Vitae (CV) would be sufficient to support all formulations tested by that investigator.

Consistent with FDA's view that final formulation testing is manufacturing, and thus is subject to CGMPs, equipment maintenance records and other records documenting compliance with CGMPs are expected to be maintained as required by parts 210 and 211. Accordingly, we clarify in proposed § 201.327(*l*) that records documenting proper maintenance of equipment used in final formulation testing must be kept, consistent with existing obligations in 21 CFR 211.68. In our view, this clarification will promote uniformity in adherence to best practices and will help ensure more accurate and reliable labeling of sunscreen products based on final formulation testing. Additional specificity has been proposed here to clarify how the more general recordkeeping provisions of part 211 apply to final formulation testing. To provide assurance that the test results are not compromised by faulty equipment maintenance or equipment failure, FDA proposes that testing entities must keep documentation demonstrating that equipment used for final formulation testing has been maintained in accordance with established written specifications. This requirement will enable FDA to more efficiently monitor compliance. Failure to keep required records of final formulation testing will render a product whose labeling relies on that testing adulterated under section 501(a)(2)(B) of the FD&C Act. Without recordkeeping, there is no assurance that a sunscreen drug product has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

This proposal also elaborates on recordkeeping necessary to document compliance with the requirements of proposed § 201.327 regarding conduct of final formulation testing.

Proposed required records for SPF testing include records that: (1) Identify the facility conducting the testing; (2) identify the equipment used; (3) identify product samples and lots; (4) characterize the SPF standard that is used; (5) document parameters for water resistance testing; and (6) demonstrate compliance with the provisions governing adequate clinical testing procedures and conditions. For example, these would include documentation of IRB review, case histories for each human subject (which must document protocol deviations or injuries), administration of the sunscreen, and reading of test results. These proposed recordkeeping obligations are consistent with those required of parties engaged in human subjects testing governed by other portions of FDA's regulations.

Required records of broad spectrum testing conducted under proposed § 201.327(j) would include those records necessary for identifying the facility conducting the testing, providing information associated with the sample, identifying equipment used, and documenting sunscreen product application. These proposed requirements provide greater specificity than existing requirements in FDA's CGMP regulations, and are expected to increase uniformity in current practice.

We propose to clarify FDA's expectations regarding access to records that responsible persons and other testing entities are required to keep under this paragraph. These provisions are consistent with FDA's inspection authorities in section 704 of the FD&C Act.

i. Minor proposed revisions to test procedures. In addition to the changes discussed in section IX.D, we are proposing several modifications to the technical instructions for sunscreen final formulation testing (§ 201.327(i) and (j)) to clarify how the testing should be conducted.

We are concerned that manufacturers conducting the SPF test procedure may be relying on determinations of the initial minimal erythema dose of unprotected skin (MEDu) generated too far in advance of testing the sunscreen product. The current regulation in § 201.327(i)(5) addresses four different determinations of MED for each test subject: (1) An initial MED for unprotected skin (initial MEDu); (2) a final MED for unprotected skin (final MEDu); (3) an MED for skin to which the SPF standard has been applied (ssMEDp); and (4) an MED for skin to which the sunscreen test product has been applied (tpMEDp). The initial MEDu is used to set the UV exposures administered to determine final MEDu, ssMEDp, and tpMEDp (see § 201.327(i)(5)(iii)).

Although the regulation already requires that each of the MED values be determined 16 to 24 hours after UV exposure, it merely notes that the final MEDu, ssMEDp, and tpMEDp are ''typically determined the day following determination of the initial MEDu'' (see current § 201.327(i)(5)(iv)). Because the skin reactivity of a test subject changes over time, we propose to clarify that the initial MEDu of a person's unprotected skin *must be* determined no more than 1 day before the UV exposures for final MEDu, ssMEDp, and tpMEDp are administered. We are also clarifying that to calculate the SPF value for each test subject, under proposed paragraph § 201.327(i)(6), it is the subject's *final* MEDu that should be used.

In our review of the testing requirements as part of this rulemaking, we also revisited our position on the input slit bandwidth specification in the in vitro broad spectrum test. In the 2011 L&E Final Rule, we modified the in vitro broad spectrum test that was proposed in the 2007 proposed rule to change the input slit spectrometer bandwidth specification from ≤5 nm to ≤1 nm. After the 2011 final rule published, FDA received a comment from a spectrometer manufacturer arguing that the 1 nm input slit bandwidth specification was unreasonable. The manufacturer argued that common spectrometer models that are currently used to test sunscreens cannot comply with the ≤1 nm input slit bandwidth specification, and those that can are more expensive, more difficult to use, and take more time to use. The manufacturer provided data that indicate that spectrometers with ≤1 nm input slit bandwidths do not produce more reliable results than spectrometers with larger input slit bandwidths (see Comment, Docket No. FDA–2010–D–0509–0004). In light of this submission, FDA reassessed the input slit bandwidth parameters and concluded that ≤5 nm will be sufficient for the broad spectrum procedure. Although decreasing bandwidth improves the ability to resolve closely spaced peaks (*i.e.,* the spectral resolution), this is not a significant consideration for in vitro broad spectrum testing of sunscreen products because transmittance/absorbance curves for sunscreen

products are typically smooth with no individual sharp peaks. Accordingly, we propose to revise § 201.327(j)(1)(iv) to require that spectrometer input slits be set to provide a bandwidth that is ≤5 nm.

Establishing standardized testing procedures for sunscreen products and basing the products' labeling on this testing not only helps assure the safety and effectiveness of each product, it also provides consumers with consistent information about the sun protection properties of sunscreen products across brands, which in turn facilitates consumer comparisons when selecting products. Accordingly, we propose to delete the provision in § 352.77 (21 CFR 352.77) addressing test modifications or alternative testing procedures. Section 352.77 indicates that such test modifications or alternative testing procedures require submission of a petition in accordance with § 10.30 (21 CFR 10.30). The proposed removal of § 352.77 does not alter the existing ability of a firm or individual to petition the Agency to amend the monograph (see §§ 330.10(a)(12) and 10.30) to change the conditions that apply to products marketed under its provisions, such as to modify testing procedures for all products having some particular set of characteristics. Rather, the proposed deletion will clarify that the sunscreen monograph does not permit variation for individual products from the standardized testing procedures that are monograph conditions, because such variation could undermine important values supported by standardization.

We are also proposing to correct a minor inaccuracy in the existing regulatory language describing testing procedures. Specifically, § 201.327(i)(1)(ii)(C) currently states that ''emission spectrum must be determined using a handheld radiometer.'' As written, this statement is inaccurate because a handheld radiometer cannot determine the emission spectrum of a solar simulator. We propose to resolve this error by clarifying that the handheld radiometer measures the solar simulator radiation intensity rather than the emission spectrum. Finally, we have proposed edits to certain provisions describing final formulation testing procedures to clarify our long-standing intention that these provisions of the test are requirements, not merely suggestions.

E. Proposed Status of Sunscreen-Insect Repellent Combination Products

1. Background

Sunscreen-insect repellent combination drugs are products used on human skin that contain both a sunscreen drug component and an insect repellent component. A list of insect repellent products on the EPA website identified a number of such products as of November 2017 (including multiple products within a single brand line).[47] Among those products, the majority contained either N,N-Diethyl-meta-toluamide (also called DEET) or IR3535 as the insect repellant, and a few contained oil of citronella as the insect repellent. Combination insect repellent-sunscreen products have been marketed in a variety of dosage forms (see section IX.A for a discussion of dosage forms), with labeled SPF levels ranging from 15 to 30 (Ref. 187). Some products are also labeled as water resistant or very water resistant (Ref. 187). The products are generally labeled for use without regard to age (Ref. 187).

FDA regulates sunscreens as drug products under the FD&C Act, and EPA concurrently regulates insect repellents as pesticides under FIFRA.[48] FIFRA defines a ''pesticide'' in relevant part as ''any substance . . . intended for repelling . . . any pest,'' including insects (7 U.S.C. 136)(u)). Before they can be marketed, most skin-applied insect repellents must be registered by EPA, although a few plant-derived insect repellent active ingredients are exempt from registration because EPA has determined they present minimum risk potential to humans (Ref. 189).

Sunscreen-insect repellent combination products have been marketed in the United States since before the OTC review began, but they have not previously been addressed in the rulemaking for the OTC sunscreen monograph (72 FR 7941 at 7943). Both FDA and EPA have historically declined to object to the marketing of these products pending the issuance of a final sunscreen monograph, provided that the sunscreen active ingredient(s) is listed in the stayed final monograph and the insect repellent component is registered with the EPA (79 FR 7941 at 7943). In 2011, FDA issued a draft enforcement guidance intended for manufacturers who market OTC sunscreen products without an approved application, which recommended that manufacturers of sunscreen-insect repellent combination products should comply as closely as possible with FDA's sunscreen testing and labeling requirements in § 201.327. This guidance was finalized in May 2018 (Ref. 1).

In the **Federal Register** of February 22, 2007 (72 FR 7941), FDA issued a notice seeking public comments on sunscreen-insect repellent combination products, and, in particular, whether FDA should amend the OTC sunscreen monograph to add conditions for marketing insect repellent-sunscreen drug products (FDA Call for Data or call for data). The call for data summarized the regulatory status and history of both sunscreens and insect repellents, and sought public input on a number of issues (see table 6). On that same date (February 22, 2007, 79 FR 7979), EPA published a similar notice announcing that it was also seeking information to determine how insect repellent-sunscreen combination products should be regulated.

TABLE 6—KEY ISSUES AND INFORMATION REQUESTS IN FDA'S 2007 CALL FOR DATA

General issue	Key concerns and information requests
Possible manufacturing conflicts	Requested information about whether there are known conflicts between FDA and EPA manufacturing requirements and, if so, how to resolve them.
	Asked how FDA should address EPA-registered insect repellents in finalizing the OTC sunscreen monograph; which requirements should FDA retain, revise, or eliminate?
	Inquired about manufacturer testing of sunscreen-insect repellent combination products and whether any problems were encountered.
Possible formulation conflicts	Requested comments on the significance of published research suggesting a potential formulation conflict.

[47] EPA Product List (Ref. 187); a similar list of insecticide products on the National Pesticide Information Center (NPIC) website produced similar results (Ref. 188).

[48] Some insect repellents are also regulated by FDA as human drugs (*e.g.,* pediculicides and scabicides intended to control parasites on humans) or animal drugs (*e.g.,* pesticide products for oral administration to animals) (7 U.S.C. 136 *et seq.*); see also ''MOU 225–73–8010 Memorandum of Understanding Between the Environmental Protection Agency and the United States Department of Health, Education and Welfare Food and Drug Administration,'' (available at *https://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm115873.htm* (accessed April 17, 2018).

TABLE 6—KEY ISSUES AND INFORMATION REQUESTS IN FDA'S 2007 CALL FOR DATA—Continued

General issue	Key concerns and information requests
Possible labeling conflicts between OTC sunscreen monograph and EPA registration requirements. Note: Since publication of the call for data, FDA has established additional labeling regulations for certain OTC sunscreen products marketed without approved applications. However, the labeling concerns expressed in the call for data remain relevant.	Labeling differences noted: • FDA uses ''warning''; EPA uses ''caution'' (and only uses the word ''warning'' to indicate toxicity levels). • Many differences in required warning/caution section headings. • Directions for sunscreen use call for liberal application and frequent reapplication; EPA directions may limit where and how to apply product and restrict frequency of application. Asked whether different directions for use can be integrated without leading to improper application, overexposure to insect repellent, and/or underexposure to sunscreen. FDA requires the outside container or wrapper of the retail package or the immediate container label to list all active and inactive ingredients (see section 502(e)(1)(A)(iii) of the FD&C Act; § 201.66(c)). EPA requires listing of the percentage of each active ingredient, and the total percentage of all ''inert'' or ''other'' ingredients, in the pesticide. Inert ingredients are not required to be identified individually on the product except in certain cases (in which case all inert ingredients are listed). Asked whether there is a way to label combination sunscreen-insect repellent drug products in a way that satisfies both the requirements of the FD&C Act and the FIFRA, and whether ''inert'' ingredients under the FIFRA are equivalent to ''inactive'' ingredients under the FD&C Act.
Safety issues	More safety data needed given published animal studies indicating increased absorption of DEET and various sunscreens active ingredients when the components are combined. Asked for more safety data on combined products. Requested data on whether increased absorption of a sunscreen ingredient occurs when combined with an insect repellent. Information needed about incidence of skin irritation from combination products.
Effectiveness issues	Requested information on: • Possible effects of insect repellent on sunscreen SPF; possible decreased sunscreen efficacy or increased exposure to insect repellent without greater efficacy resulting from inconsistent reapplication intervals. • Potential chemical or physical incompatibilities between particular sunscreens and insect repellents. • Potential need to specify minimum SPF for these combinations. • Any potential performance benefits of these combination products other than convenience. • Possible adjustments to formulations to minimize application time disparities.

2. FDA's Evaluation of Sunscreen-Insect Repellent Combination Products

FDA has reviewed the comments submitted in response to FDA's and EPA's calls for data, as well as pertinent scientific literature and publicly available EPA regulatory documents. Based on that review, we have tentatively concluded that sunscreen-insect repellent combination products, as a class, are not GRASE (*i.e.,* are Category II) and are misbranded because conflicting labeling requirements for their sunscreen and insect repellent components cannot be reconciled to create labeling that will sufficiently ensure safe and effective use of the sunscreen component, as well as adequate directions for use as a sunscreen, as required by section 502(f) of the FD&C Act. Also, if we did not have this labeling concern, we would still tentatively determine that available data regarding the safety and effectiveness of these products for their use as sunscreens are insufficient to classify these sunscreen products as GRASE for such use (*i.e.,* Category III). Specifically, evidence suggests that interactions between some sunscreen active ingredients and insect repellents may decrease safety by increasing systemic absorption of one or both components, and potential synergistic effects on the efficacy of sunscreen active ingredients apparently have not been studied. Although the available data are limited and not conclusive, they give rise to questions about the safety and effectiveness of these products. Our reasons for these tentative conclusions are detailed in the discussion that follows.

a. Public comments on the 2007 call for data. FDA received six submissions in response to the 2007 call for data. None of the comments included substantive data, although some cited published scientific and medical literature, which is addressed in the following section of this document. Five of the six comments were from manufacturers or a trade association. Industry comments generally favored retaining joint regulation between EPA and FDA (perhaps with enhanced coordination and information-sharing) and amending the stayed OTC sunscreen monograph to address sunscreen-insect repellent combinations. Several industry comments claimed there was an absence of conflicting requirements relating to manufacturing, formulation, and/or labeling. Others suggested approaches for minimizing labeling conflicts, such as permitting exemptions to FDA's Drug Facts labeling requirements to accommodate EPA-required information, or placing FDA- and EPA-required information in separate areas of the label. The remaining comment was submitted by a medical association that opposed continued marketing of sunscreen-insect repellent products, emphasizing concerns about children's exposure to DEET. Industry comments favoring the continued marketing of combination sunscreen-insect repellent drug products also contended that combining sunscreen and insect repellent ingredients in a single product is more convenient and cost-effective than using separate products. Two comments stated that properly formulated, tested, and labeled, combination products are better than the unpredictable effects that could arise when consumers use two different products. Regarding safety, one comment asserted various flaws in the studies cited in the call for data that questioned the safety of these combination products. (These studies are discussed in section IX.E.2.d.)

In general, the comments that we received in response to the 2007 call for data were not accompanied or corroborated by data. Although the comments did not identify further concerns relating to product manufacturing or formulation, they did not adequately address FDA's concerns about safety, effectiveness, and labeling of these products. FDA renews its request for data to support labeling and safety for sunscreens with insect repellent added.

b. Pesticide-related information. Pesticides that are or have been used in combination products that also contain sunscreens include DEET, IR3535, and oil of citronella. In evaluating combination insect repellent-sunscreen products for the purposes of this rule, FDA defers to EPA's expertise and authority regarding insect repellent ingredients. We have not independently evaluated these pesticides, but instead have focused on potential sunscreen-insect repellent ingredient interactions and the feasibility of effectively labeling these combination products for their use as sunscreens.

As of June 2017, DEET was by far the most commonly used insect repellent. According to the EPA Product list, the amount of DEET in combination sunscreen-insect repellent products ranged from 10 to 20 percent. DEET product labels recommend that users avoid over-application, use just enough repellent to cover exposed skin and/or clothing, and not apply to hands or near the eyes or mouth of young children (Ref. 190). DEET-containing products listed on the EPA website in 2017 had concentrations ranging from 5 percent to 98 percent and provided protection from mosquitos for 2 to 12 hours, with many products having protection times of 4 hours or more (Ref. 187). The American Academy of Pediatrics recommends that repellents should contain no more than 30 percent DEET when used on children, and that insect repellent should not be used on children younger than 2 months (Ref. 191).

EPA classifies the acute toxicity of insect repellents and other pesticides into one of four toxicity categories (ranging from Category I, highly toxic, to Category IV, practically nontoxic) (see 40 FR 156.62). DEET is classified in Category III based on EPA's review of available animal studies, indicating slight acute toxicity for acute oral, dermal, ocular, and inhalation tests in animals, and low acute toxicity for the human health risk assessment (Ref. 192). Although DEET is registered for use in humans of any age, adverse events related to DEET toxicity have been documented and these events primarily relate to the central nervous system. As summarized by Katz et al., DEET has been associated with seizures and other central nervous system symptoms, cardiovascular symptoms, and topical and allergic symptoms (Ref. 193). Most reported cases of adverse or lethal events involved overuse or otherwise incorrect use of the product (Ref. 193), and EPA concluded that available data were insufficient to identify DEET as the cause of the reported adverse events (Ref. 192). EPA is currently in the process of updating its registration of a number of older pesticides, including DEET, and is deferring decision on the regulatory status of combination DEET/sunscreen products as described in the EPA Call for Data.[49] However, EPA has stated that DEET does not pose a significant health risk to the U.S. population.[50]

IR3535 is classified by EPA as a biopesticide because it is biochemically, functionally identical to beta-alanine, a naturally occurring substance that repels insects (Ref. 194). IR3535 is classified in Toxicity Category IV (practically nontoxic) for acute oral, dermal, and inhalation toxicity and Category III (slightly toxic) for eye irritation (Ref. 195). Overall, EPA has assessed IR3535 as not harmful when ingested, inhaled, or used on skin (Ref. 195). Eye irritation could occur if the chemical enters a person's eyes (Ref. 195). IR3535 is used at concentrations of 7.5 percent to 20 percent in a popular line of sunscreen-insect repellent combination products (EPA Product List) (Ref. 187). Products containing IR3535 identified on EPA's website in summer 2017 had concentrations ranging from 7.5 percent to approximately 20 percent and listed protection time against mosquitoes of 2 to 8 hours (EPA Product List) (Ref. 187).

Oil of citronella is a plant-derived biochemical insect repellent (72 FR 7979 at 7981). Depending on its source, it may be categorized as ''Ceylon'' type or ''Java'' type. It is currently listed by EPA as a minimum risk pesticide (registration generally not required if formulated only with EPA-permitted inert ingredients and not labeled as effective against disease-causing pests) (40 FR 152.25(f)). Oil of citronella is also an approved food additive for use as a flavoring agent in foods and beverages (Ref. 196). EPA has designated oil of citronella as Toxicity Category III (slightly toxic) for acute oral toxicity (Java type only), dermal toxicity, dermal irritation, and acute eye irritation (both types), and Category IV (practically nontoxic) for acute oral toxicity (Ceylon type) and acute inhalation (Ref. 197). The National Pesticide Information Center (NPIC) fact sheet on oil of citronella states that oil of citronella products should not be used on children less than 6 months old (Ref. 198).

c. Disparities in required labeling of sunscreens and insect repellents. FDA and EPA regulate the format and content of the labeling of nonprescription sunscreen products and pesticides, respectively. FDA regulations on nonprescription sunscreen labeling include the general drug labeling regulations in subpart A of part 201; the ''Drug Facts'' format and other OTC drug labeling requirements in subpart B of part 201; and the sunscreen-specific labeling requirements that apply to sunscreens marketed without an approved NDA, including those based on the current requirements for SPF and broad spectrum testing in § 201.327. The labeling of registered insect repellents is subject to EPA labeling requirements under FIFRA (40 CFR 156), as well as specific language specified in individual product registration documents. Although the FDA and EPA labeling requirements for nonprescription sunscreens and registered pesticides cover some of the same information (such as ingredient lists, net quantity statements, and warnings/precautions), there is considerable variation in the language, format, and placement of common label elements between the two Agencies, while other elements do not overlap.

Furthermore, both Agencies limit the degree to which a drug manufacturer or pesticide registrant may depart from the prescribed text, format, and/or location of required labeling elements. This is particularly true for the wording and format of ''drug facts'' information for OTC drugs (see § 201.66). Similarly, EPA regulations state that although a registrant may choose to place non-FIFRA-required information on a pesticide label, it may not replace, obscure, conflict with, or supersede the FIFRA-required text (Ref. 199).

The intended uses of sunscreens and insect repellents are quite different, as are the associated labeling requirements; in particular, the instructions for using the two types of products are different. Required labeling for OTC sunscreens marketed without approved NDAs calls for reapplication at least every 2 hours (see § 201.327(e)(3) through (e)(4)). The duration of protection for insect repellents varies according to the active ingredient and strength. Based on information from the EPA product list, many insect repellent-sunscreen products provide protection against mosquitoes and/or ticks for more than 2 hours, and some provide protection for as many as 6 to 10 hours. EPA has stated that it is ''concerned about consumer use of products that contain sunscreens and DEET, since directions to reapply generally and frequently may promote greater use of DEET than needed for pesticidal efficacy and thus pose unnecessary exposure to DEET.[51] The Centers for Disease Control and Prevention (CDC) advises consumers

[49] DEET 2014 reregistration interim review final decision (EPA–HQ–OPP–2012–0162) (available at *https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-080301_1-Apr-98.pdf* (accessed April 17, 2018).

[50] Id. In June 2014, EPA issued an interim review of DEET and did not identify any specific new concerns. The proposed interim registration review decision became final on September 24, 2014. DEET 2014 reregistration interim review final decision (EPA–HQ–OPP–2012–0162) (available at *https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0162-0012 (accessed April 17, 2018).*

[51] DEET 2014 reregistration interim review final decision, *supra* note 49, v.

that ''products that combine sunscreen and repellent are not recommended, because sunscreen may need to be reapplied more often and in larger amounts than needed for the repellent component to provide protection from biting insects.'' (Ref. 200). Similarly, the American Academy of Pediatrics advises consumers not to use products that combine DEET with sunscreen, in part because ''[t]hese products can overexpose your child to DEET because the sunscreen needs to be reapplied often'' (Ref. 201). Additionally, DEET is approved for use on children with no age restriction (Ref. 202), whereas FDA labeling states ''[bullet] children under 6 months of age, ask a doctor'' (see § 201.327(e)(1)(iv)).

The recommended manner of application also differs for sunscreens and insect repellents. For example, the directions on the label for all insect repellent products containing DEET say to apply just enough to cover exposed skin, and avoid over-application (Ref. 190), whereas the labeling of nonprescription sunscreens marketed without approved NDAs calls for liberal or generous application (see § 201.327(e)(1)(ii)). The EPA-mandated directions on the labels of DEET products also state, ''Do not apply near eyes and mouth; apply sparingly around ears; do not use under clothing'' (Ref. 190). Such statements are potentially troublesome from the standpoint of sun protection in light of surveillance data from Australia, which suggest that the incidence of certain skin cancers is more frequent on highly exposed areas of the body such as ears and the backs of hands (Refs. 203 and 204). The CDC advises consumers who need protection from both sun and insects to apply sunscreen product first, followed by an insect repellent (Ref. 200).

Additional disparities in the content and format of labeling elements for sunscreens and registered insect repellents include the following:

- EPA pesticide labeling includes required elements that generally must appear on the front panel of the label, such as the ingredient statement (40 CFR 156.10(g)(2)), specified signal word such as ''CAUTION'' (40 CFR 156.64), and child hazard warning (40 CFR 156.66), which could crowd or detract from drug information required to appear on the principal display panel for drugs (see § 201.60 (''The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part.'')). Other labeling elements that only EPA requires include registration numbers and manufacturing establishment numbers (40 CFR 156.10(a)).
- FDA labeling for sunscreens uses the word ''warning'' (see §§ 201.66(c)(5) and 201.327(d)), while the EPA requirements specify that pesticide products that, like DEET, IR3535, and oil of citronella, meet the criteria of Toxicity Category III or IV as the highest category by any route of exposure bear on the front panel either no signal word or only the signal word ''CAUTION'' (40 CFR 156.64). In EPA labeling the word ''WARNING'' is used as a signal word only for toxicity category II, which is a higher toxicity category than that applicable to any insect repellent ingredients used in sunscreen-insect repellent combination products (40 CFR 156.64(a)(2)).
- FDA labeling uses the term ''directions'' (see §§ 201.66(c)(6) and 201.327(e)), while EPA regulations use the term ''directions for use'' (see 40 CFR 156.10(i)(2)).
- FDA calls for ingredients to be listed as ''active'' and ''inactive'' (see § 201.66(b) through (c)), while EPA labeling uses the term ''inert'' or ''other'' instead of ''inactive'' for all non-pesticide ingredients (40 CFR 156.10(g)).

Given the extent of the disparities discussed above, FDA tentatively concludes that attempting to merge the required labeling for monograph sunscreens and insect repellents in a way that would comply with both Agencies' requirements and permit adequate consumer understanding and proper use would be impracticable. In this regard, we specifically disagree with comments made in response to the 2007 FDA Call for Data suggesting that acceptable ''merged'' labeling could be crafted by varying the OTC sunscreen drug facts to include insect-repellent-related information, and/or by providing EPA-required labeling outside the drug facts box. We are particularly concerned that consumers would be confused by the juxtaposition of two sets of different and, in some cases, contradictory information in the labeling about these products' dual intended uses. We are also concerned that the sheer amount of required information would result in crowded, difficult-to-read labels lacking in the clarity and prominence of important safety and use information that are both required by FDA regulations and vital to consumer comprehension. We solicit comment and data about how to reconcile the labeling of suncreens and insect repellents such that a combined product could meet FD&C Act requirements for OTC sunscreen drugs.

d. FDA's review of published medical literature. The results of FDA's literature review raise potential safety concerns about products that combine sunscreen and insect repellent active ingredients. The available data suggest that the dermal penetration and systemic absorption of at least one combination of a sunscreen active ingredient and an insect repellent is increased when both are present.

There have been some studies assessing the penetration of DEET and the effects of DEET combined with sunscreen (particularly the active ingredient oxybenzone) on dermal penetration. Ross et al. tested for synergistic effects between DEET and oxybenzone using an in vitro mouse skin diffusion model and showed substantial penetration of a 20 percent DEET standard in ethanol, while penetration of sunscreen active ingredients was not found (Ref. 205). Despite a lower DEET content (10 percent), a commercially marketed sunscreen formulation had a 6-fold more rapid detection and a 3- to 4-fold greater penetration of DEET than the 20 percent standard. Other diffusion tests using pigskin or artificial membranes and various combinations of DEET and oxybenzone in different media suggested an enhancing effect on dermal penetration of both DEET and oxybenzone (Refs. 206 and 207). The same investigators obtained similar results in a later in vitro study using human skin (Ref. 207).

Kasichayanula et al. assessed the dermal absorption of DEET and oxybenzone using an in vivo piglet model, in which samples were collected from plasma, urine, and under the skin. Their results indicated that the enhanced dermal penetration evidenced in the in vitro studies translated to increased systemic exposure to both oxybenzone and DEET (Refs. 208 and 209). Finally, a study by Yiin et al. suggests that enhanced systemic absorption would also occur in humans (Ref. 210). Yiin et al. used human urinary metabolites of DEET and oxybenzone to evaluate the mutual enhancing effect on absorption of these ingredients and concluded that their findings confirm that concurrent use of DEET-containing insect repellent and oxybenzone-containing sunscreen results in the enhancement of dermal absorption of DEET when insect repellent (DEET) was applied first and then covered by sunscreen (Ref. 210). The study authors suggested that placing repellent spray on top of sunscreen lotion with no mixing seems to be the best approach to diminish DEET penetration through the skin.

Although insect repellents and sunscreens are designed to exert their

protective effects on the surface of the skin, the studies described above suggest that combining a sunscreen and insect repellent in a single product may result in unintended systemic exposure to the sunscreen ingredient oxybenzone and the insect repellent ingredient DEET. We acknowledge the study limitations cited by comments to the FDA Call for Data, and that in vitro diffusion studies have their limitations in terms of reflecting clinical use. We also note that many of the studies tested formulated commercial products with multiple sunscreen ingredients and excipients for which details were not given, and it is unclear how this may have influenced the results. Although we, therefore, do not view these data as conclusory, we have determined that they raise a valid safety concern that warrants a tentative conclusion that, even if one could overcome the misbranding and associated safety and effectiveness concerns created by the inconsistent application directions for sunscreens and insect repellants, there would not be sufficient evidence to conclude that combination sunscreen and insect repellent products are GRASE for sunscreen use without further investigation.

Regarding future investigations that could assist FDA in determining whether these products have sufficient evidence of safety to be GRASE for use as sunscreen, we are not aware of any data that define the extent of systemic exposure to either DEET or oxybenzone that would occur with maximal exposure to a sunscreen-insect repellent combination product. There also are few data from which to assess whether there would be a similar enhancement of skin penetration for other combinations of sunscreen and insect repellent active ingredients. Moreover, without adequate human absorption studies under maximal use conditions of particular sunscreen-insect repellent combinations (*i.e.,* a MUsT, as discussed in section VII.B.4), it is difficult to evaluate potential risks associated with the use of such combination products. Because of the potential synergistic interaction between the sunscreen active ingredient and the insect repellent active ingredient, human absorption data for the individual components would not provide adequate data to estimate the level of systemic absorption. Likewise, in vitro data would not be able to provide a reliable estimate of the systemic exposure that would occur with such products' use.

In terms of sunscreen active ingredient effectiveness, we have little data from which to determine whether the presence of an insect repellent would affect the determined SPF value of combination sunscreen-insect repellent products. Montemarano et al. reported a reduction in sunscreen efficacy because of concomitant use with insect repellent. However, in that study, the sunscreen and insect repellent ingredients were applied separately and were not part of a combination product (Ref. 211).

With respect to efficacy, we recognize that the testing required by § 201.327 (both the current regulation and the regulation if amended as proposed elsewhere in this proposed rule) to support labeled SPF levels and other efficacy claims that may be made for certain OTC sunscreen products could potentially mitigate concerns about the impact of insect repellent active ingredients on sunscreen effectiveness. However, we are not aware of any data evaluating the reliability of SPF testing for sunscreen formulations that contain insect repellent ingredients. There also is the possibility that increasing the amount of the sunscreen active ingredient to compensate for any loss in efficacy because of the presence of the insect repellent could result in unnecessarily high exposure to the sunscreen active ingredient. For these additional reasons, we tentatively conclude that even if other concerns could be overcome, there is not currently sufficient evidence to conclude that combination sunscreen-insect repellent products are GRASE for use as sunscreens. We solicit comment on the data needs identified above and tentative conclusions, including supporting data and analysis. We also solicit data and information to address these data needs.

3. Conclusion

FDA tentatively concludes that the inherent disparity in labeling requirements that apply to sunscreens marketed under the OTC monograph and insect repellents prevent the creation of labeling that will sufficiently ensure safe and effective use of the sunscreen component of sunscreen-insect repellent combination products, particularly in connection with duration of action. We also conclude that these conflicting requirements prevent these products from having adequate directions for use as a sunscreen, and thus these products would be misbranded under section 502(f) of the FD&C Act. In addition, even if these issues could be overcome, existing safety concerns about potential enhanced systemic absorption resulting from combining individual sunscreen active ingredients and insect repellent ingredients would also need to be addressed by further studies on both combinations of individual sunscreen and insect repellent ingredients and final formulations.

Existing data indicates there is a risk of systemic absorption of insect repellent and/or a sunscreen active ingredient when both are present. Additional data would be needed to identify any interactions between specific sunscreen active ingredients and insect repellents, in particular, to characterize any enhancement of skin penetration and/or systemic absorption if the resulting data presents safety or effectiveness concerns. As stated above, FDA would need adequate human absorption studies, such as a MUsT, as part of the clinical safety assessment (for more discussion on assessment of dermal absorption of sunscreen active ingredients using MUsT, see section VII.B.4). The effectiveness of sunscreen-insect repellent combination products is also a continuing concern. For all of those reasons, we tentatively determine that these products are not GRASE for nonprescription sunscreen use. We solicit comment on this tentative determination.

X. Proposed Actions To Effectuate Lifting of Stay and Harmonize Impacted Regulations

In the 2011 L&E Final Rule, FDA explained that although we were not yet lifting the stay on the 1999 final monograph, the provisions set forth in the L&E Final Rule reflected the Agency's position on the appropriate testing and labeling of sunscreen products that were previously identified as falling within the Stayed 1999 Final Monograph (76 FR 35620 at 35621). We explained that § 201.327 would therefore supersede the prior approach to labeling and effectiveness testing described in the never-effective provisions of part 352, subparts C and D.

We are now proposing to lift the stay on the 1999 final monograph (21 CFR part 352) while making certain changes in its provisions. To fully effectuate this proposal, we are proposing several harmonizing revisions to part 352 and § 201.327. These changes remove certain provisions from part 352 that were superseded by the 2011 L&E Final Rule and, where applicable, replace them with appropriate cross references to the applicable testing and labeling provisions in § 201.327, as we propose to amend these regulations in this document. We also have made minor revisions in parts 347, 352 and § 201.327 to improve readability and to correct certain typographical errors and erroneous internal cross references.

We are also proposing revisions to certain provisions describing requirements for products containing both sunscreen active ingredients and skin protectant active ingredients to avoid duplication between § 201.327 and part 352 and to harmonize the requirements set forth in those provisions. As in the past, the proposed sunscreen monograph would include conditions under which a single product could include certain sunscreen active ingredients as well as certain ingredients determined to be GRASE for use in skin protectants under part 347 (see proposed § 352.20(b), as well as current § 347.20(e) (21 CFR 347.20(e)). Current § 201.327(h) allows for such products to combine certain labeling statements applicable to each ingredient in the product to eliminate duplicative words or phrases. The stayed provisions of part 352 contain similar allowances for products that contain both sunscreen and skin protectant active ingredients, but also outline more detailed requirements for presenting such a product's statement of identity, indications, warnings, and directions. We propose to relocate the labeling requirements for such products from § 352.60 to § 201.327(h), thereby consolidating labeling conditions for these products in one section of the regulations. We also propose to retain compliance with these labeling provisions as a monograph condition for sunscreen/skin protectant products under both parts 352 (the sunscreen monograph) and 347 (the skin protectant monograph) by incorporating cross references to § 201.327(h) in § 352.20(b)(4), and § 352.60, and incorporating cross references to §§ 352.20 and 352.60 in §§ 347.20(e), and 347.60.

Additionally, we propose to consolidate under new § 310.549 (21 CFR 310.549) certain properties that render an OTC drug product offered for use as sunscreen a new drug for which an approved NDA is required prior to marketing. Section 310.545 (21 CFR 310.545) currently contains several such provisions addressing specific ingredients and efficacy claims. We propose to relocate these provisions from § 310.545 to § 310.549. In addition, in the interest of completeness, we are clarifying in § 310.549 that labeling a product with claims that it decreases the risk of skin cancer or early skin aging caused by the sun if that product has an SPF of less than 15 when tested in accordance with § 201.327(i) and/or does not pass the broad spectrum test in § 201.327(j) renders the product a new drug.

Finally, we propose to add to § 310.549 new characteristics that would render a product a new drug. These characteristics include: (1) Containing the ingredients we propose to classify as categories II and III (see sections VIII.B–C); (2) being labeled, represented, or promoted for use as a combined sunscreen-insect repellant (see section IX.E); (3) failing to comply with provisions relating to maximum SPF values and broad spectrum requirements (see section IX.B); and (4) failing to conform to certain other sunscreen formulation and dosage form conditions (see sections IX.A and D).

XI. Comment Period

We are providing a comment period of 90 days (see **DATES**). FDA will also consider requests to defer further rulemaking with respect to a specific sunscreen active ingredient to allow the submission of new safety and/or effectiveness data to the record if such requests are submitted to the docket within the initial 90-day comment period. FDA will review all data and information submitted to the record in conjunction with all timely and complete requests to extend. In assessing whether to extend the comment period to allow for additional time for studies to generate new data and information, FDA will consider the data already in the docket along with any information that is provided in any requests to extend. FDA will determine whether the sum of the data, if timely submitted, is likely to be adequate to provide all the data that are necessary to make a determination of general recognition of safety and effectiveness.

XII. Proposed Effective/Compliance Dates

The proposed effective date of final regulations resulting from the proposals described in this rulemaking is November 26, 2019 (see FD&C Act section 586E). We recognize that industry will need time after publication of any final regulations to comply with their provisions. To allow for orderly implementation of final regulations and help assure continued product availability to consumers, we would not expect full compliance with such final regulations for units of sunscreen product initially introduced or initially delivered for introduction into interstate commerce, until 1 year after the effective date of the final rule. We also would not expect full compliance, even after that date, for units of product that were initially introduced or initially delivered for introduction into interstate commerce before that date, such as those remaining in retail outlets. Our current thinking on implementation is informed in part by our understanding there are no currently marketed sunscreen products that contain the active ingredients we propose here as Category II. We solicit comment on this proposed approach.

XIII. Preliminary Economic Analysis of Impacts

A. Introduction

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

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many sunscreen manufacturers are small entities and the one-time costs of the proposed rule represent a significant fraction of annual revenue to sunscreen manufacturers, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

We have developed a comprehensive preliminary regulatory impact analysis that assesses the impacts of the proposed rule. We present a summary of this analysis below.

B. Summary of Costs and Benefits

If finalized, the proposed rule would update and make effective regulations to ensure the safety and effectiveness of sunscreen products marketed under the OTC drug monograph. The rule would update sunscreen product labeling standards, address the safety of sunscreen active ingredients, revise and clarify our expectations for testing and recordkeeping by entities that conduct sunscreen testing, and address other sunscreen safety or efficacy concerns, like combination sunscreen-insect repellents and alternative dosage forms.

Consumers would benefit from less exposure to sunscreen products containing active ingredients about which safety questions remain, less exposure to sunscreen products labeled with potentially misleading sun protection information, increased consumption of products with better UVA protection, less exposure to flammable spray sunscreens, and less exposure to spray and powder sunscreen products posing inhalation risks. Consumers would also experience transaction cost savings. The costs of the rule to sunscreen manufacturers include administrative costs, costs to fill data gaps for active ingredients and powder dosage forms, product formulation testing costs, and costs to reformulate and relabel sunscreen products. Finally, testing entities would incur recordkeeping costs if they do not already maintain adequate records of testing equipment, methods, and observations in final formulation testing.

Table 7 summarizes the costs and benefits of the proposed rule, if finalized. The annualized benefits of the proposed rule, if finalized, would range from $0.00 million to $3.72 million at a 7 percent discount rate and from $0.00 million to $3.62 million at a 3 percent discount rate. Our primary estimate of annualized benefits would equal $0.91 million at a 7 percent discount rate and $0.88 million at a 3 percent discount rate. The annualized costs of the proposed rule, if finalized, would range from $15.57 million to $75.84 million at a 7 percent discount rate and from $12.40 million to $60.42 million at a 3 percent discount rate. Our primary estimate of annualized costs would be $47.55 million at a 7 percent discount rate and $37.79 million at a 3 percent discount rate.[52]

TABLE 7—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized ($m/year).	$0.91 0.88	$0.00 0.00	$3.72 3.62	2017 2017	7 3	20 20	
Annualized Quantified (mil oz/year) [1].	201.79	98.16	286.26				Increased use of products with improved UVA protection.
Annualized Quantified (mil oz/year) [2].	51.42	19.43	83.41				Less exposure to sunscreens containing active ingredients about which safety questions remain.
Annualized Quantified (mil oz/year) [3].	161.04	159.88	162.20				Less exposure to sunscreens with potentially misleading sun protection information.
Annualized Quantified (mil oz/year) [4].	386.44	384.86	388.02				Less exposure to spray and powder sunscreens posing inhalation risks.
Qualitative	Quicker responses to adverse events, improved inspections, and better protection of human subjects. Potential transaction cost savings related to changes in the effort required to choose a sunscreen.						
Costs:							
Annualized Monetized ($m/year).	47.55	15.57	75.84	2017	7	20	
Annualized Quantified.	37.79	12.40	60.42	2017	3	20	
Qualitative	Recordkeeping costs to testing entities that do not already maintain adequate records.						
Transfers:							
Federal Annualized Monetized ($m/year).							

[52] The primary estimate of the costs is not the average of the lower bound costs and the upper bound costs.

TABLE 7—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Other Annualized Monetized ($m/year).	From:			To:			
	From:			To:			
Effects:	State, Local, or Tribal Government: None. Small Business: Some small businesses could exit the sunscreen market by discontinuing their products or going out of business. Wages: None. Growth: None.						

[1] Values represent the 2016 consumption of sunscreens that would provide improved UVA protection under the proposed rule.
[2] Value represent the 2016 consumption of sunscreens that contain active ingredients about which safety questions remain.
[3] Values represent the 2016 consumption of sunscreens with potentially misleading sun protection information.
[4] Values represent the 2016 consumption of potentially inhalable spray sunscreens and powder sunscreens.

Table 8 shows the Executive Order 13771 summary over an infinite time horizon. In this analysis we assume that the costs and cost savings of the rule would end after 20 years. We estimate that this rule generates $29.85 million in net annualized costs, discounted at 7 percent, over a perpetual time horizon. Based on these costs, this proposed rule would be considered a regulatory action under E.O. 13771.

TABLE 8—E.O. 13771 SUMMARY TABLE

[In $ millions 2016 dollars, over an infinite time horizon) [1]

	Primary estimate (7%)	Lower bound (7%)	Upper bound (7%)	Primary estimate (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$456.33	$149.22	$730.46	$618.16	$201.53	$1,002.22
Present Value of Cost Savings	0.00	0.00	0.00	0.00	0.00	0.00
Present Value of Net Costs	456.33	149.22	730.46	618.16	201.53	1,002.22
Annualized Costs	29.85	9.76	47.79	40.44	13.18	65.57
Annualized Cost Savings	0.00	0.00	0.00	0.00	0.00	0.00
Annualized Net Costs	29.85	9.76	47.79	40.44	13.18	65.57

[1] We assume that the benefits and costs of the proposed rule would diminish after 20 years. Negative values denoted in parentheses.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 63) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

XIV. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

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.

Title: Sunscreen Drug Products for OTC Human Use.

Description: The proposed rule would amend FDA's current sunscreen labeling regulation (§ 201.327) and sunscreen products monograph (part 352) regarding product labeling, testing, and recordkeeping requirements. We note that existing regulations (*e.g.,* current § 201.327) already require SPF testing and labeling. The information collections associated with current testing, labeling, and recordkeeping requirements have previously been approved in accordance with the PRA under OMB control numbers 0910–0139, 0910–0717, and 0910–0755. For more information about current regulations and their history, see the *Background* and *Scope* sections of the

proposed rule (sections III and IV, respectively). The proposed rule would also amend parts 310 and 347.

While the proposed provisions are broadly consistent with current best practices for testing conducted in human subjects and are not expected to require significant changes by reputable and experienced testing establishments, the proposed rule clarifies and confirms the application of existing requirements to sunscreens and adds certain new requirements, particularly for labeling and recordkeeping. The purpose of these changes is to help ensure that sunscreen testing is conducted and documented in a way that verifiably provides for protection of human subjects and increases the reliability of the testing data that underlies sunscreen labeling, and to update the labeling requirements.

Description of Respondents: Affected entities include: (1) ''responsible persons,'' as defined in proposed § 201.327(a); (2) entities to which the responsible person transfers its obligations as permitted under proposed § 201.327(a)(1) (*e.g.,* contract manufacturers, contract testing entities, contract research organizations); and (3) clinical investigators conducting the testing (the investigator(s) required to submit investigator statements and other materials to the responsible person).

FDA estimates that up to 772 entities could meet the proposed definition of *responsible person* (equivalent to ''brands'' in the economic analysis found in section XIII, Preliminary Analysis of Economic Impacts). The estimate of 772 entities also includes nearly all entities to which a responsible person might transfer its obligations (''transferees''), such as contract manufacturers, contract repackagers, contract distributors. For example, a manufacturer may be a responsible person for one brand and a contract manufacturer for another. However, in addition to the 772 entities and potential transferees already described, we estimate that there are approximately 10 U.S.-based contract testing entities used by multiple responsible persons to conduct sunscreen testing (*e.g.,* contract laboratories and contract research organizations). These 10 potential transferees are not included in the 772 figure. Thus, for certain information collections, the estimated respondent number may be 782. We note that this estimate does not include non-U.S.-based contract testing entities.

In addition to the 10 contract testing entities, FDA estimates that approximately 10 of the estimated 772 responsible persons conduct their own SPF or broad spectrum testing. Thus, we estimate that there are approximately 20 entities that conduct covered sunscreen testing; we estimate these entities have approximately 20 lead clinical investigators to whom certain information collection obligations (*e.g.,* reporting) may apply.

A. Labeling for Sunscreen Products and Associated Clinical Testing

The proposed rule includes third-party disclosure obligations for responsible persons. The provisions may also apply to entities to which the responsible persons transfer their responsibilities under section 201.327(a)(1) (''transferees''), depending on the scope of transferred obligations. There are labeling-related information collections (requirements include certain information on product labels) and a related testing burden (requirements for certain clinical testing to determine and support labeling information).

1. Labeling-Related Information Collection and Burden

Proposed § 201.327(b) and § 201.327(h)(1) amend certain labeling requirements applicable to the PDP. Among other things, proposed § 201.327(b) sets forth labeling requirements for the statement of identity and SPF value claims discussed in this section. Proposed § 201.327(h)(1) applies to the statement of identity for sunscreen products that also contain skin protectant active ingredients. Proposed § 352.50 requires that the PDP labeling comply with the requirements of § 201.327(b). The SPF value statements set forth in proposed § 201.327(b) and referenced in proposed § 352.50 are based on the results of the testing required in proposed § 201.327(i) and proposed part 352 (§ 352.70).

a. Statement of identity. Proposed § 201.327(b)(1) requires that sunscreen drug products bear a statement of identity consisting of the name of each sunscreen active ingredient listed in alphabetical order, followed by ''Sunscreen'' and ''[Dosage form]'' (*e.g.,* ''Lotion'', ''Spray''). Proposed § 352.52(a) requires the labeling to contain a statement of identity in accordance with § 201.327(b).

Proposed § 201.327(h)(1) applies to sunscreen drug products that also contain skin protectant active ingredients; it requires that the product bear a statement of identity consisting of the name of all sunscreen and skin protectant active ingredients in alphabetical order, followed by ''Sunscreen/Skin Protectant'' and ''[Dosage form],'' presented in accordance with § 201.327(b)(1)(ii). Proposed § 352.60(a) requires that the product bear a statement of identity as set forth in § 201.327(h)(1). Proposed § 352.20(b)(4) requires that the product must be labeled in accordance with §§ 201.327(h) and 352.60. Proposed § 347.60(a)(3) requires that the labeling of the product bear the statement of identity set forth in proposed § 352.60(a).

We note that current regulations already include a requirement that OTC products bear a statement of identity (see § 201.66). This proposed rule would set forth the specific requirements just described for sunscreen drug products and sunscreen drug products that also contain skin protectant active ingredients. We believe this analysis reflects the additional burden beyond current statement of identity requirements.

b. SPF value. Proposed § 201.327(b)(2) requires, among other things, that the labeling display certain statements regarding the product's SPF value; the statements must be supported by the testing required by proposed § 201.327(i) and referenced in proposed § 352.70. As previously noted, certain SPF testing and labeling is already required under current regulations. This analysis reflects the estimated additional burden of the proposed changes to SPF testing and labeling requirements.

c. Burden for proposed statement of identity and SPF value information collections. The estimated burden for the statement of identity and SPF value information collections just described is provided in table 11 (Estimated Annual Third-Party Disclosure Burden). For currently marketed OTC sunscreen products, FDA believes that responsible persons need only complete the testing (or reanalyze existing testing data) and relabel the product as required by the rule one time, and may then continue to utilize the resultant labeling going forward without additional burden. We estimate that 772 respondents would need to complete this relabeling and related testing (if not already done) or reanalysis of existing test results one time for up to 4,078 total products. In addition, there may be new products introduced each year. We estimate that as many as 1,500 new OTC sunscreen product stock keeping units (SKUs) may be introduced each year by up to 772 respondents. These new products must be tested and labeled with the SPF value and broad spectrum results determined in the tests. We estimate that the 1,500 new sunscreen SKUs represent 975 new formulations.

Table 11, row 1 provides FDA's estimate that 772 respondents will need to create PDP labeling for currently marketed sunscreen formulations in accordance with the statement of identity and SPF value requirements of proposed § 201.327(b)(1), (b)(2), and (h)(1). This would be a one-time burden, and FDA estimates 5.2824 responses per respondent for a total of 4,078 responses. FDA estimates a burden of 0.5 hours per response. We estimate the total burden of this recordkeeping to be 2,039 hours.

Table 11, row 2 provides FDA's estimate that up to 772 respondents will need to create PDP labeling for new formulations each year in accordance with the statement of identity and SPF value requirements of proposed § 201.327(b)(1), (b)(2), and (h)(1). FDA estimates 1.943 responses per respondent for a total of 1,500 responses. FDA estimates a burden of 0.5 hours per response. We estimate the total burden of this recordkeeping to be 750 hours.

Table 11, row 3 provides FDA's estimate that 20 respondents will conduct SPF testing in accordance with § 201.327(i) (to determine the SPF value required by § 201.327(b)(2)) for currently marketed sunscreen formulations, if this has not already been done. This would be a one-time burden. The estimated number of respondents reflects FDA's assumption based on its knowledge of the existing market that, of the 772 responsible persons, approximately 10 will conduct their own final formulation testing under § 201.327(i), while most will delegate the responsibility for conducting final formulation testing to the approximately 10 independent testing entities that FDA believes conduct most final formulation testing. FDA estimates 111 responses per respondent for a total of 2,220 responses. FDA estimates a burden of 24 hours per response. We estimate the total burden to be 53,280 hours.

Table 11, row 4 provides FDA's estimate that 20 respondents will conduct SPF testing in accordance with § 201.327(i) (to determine the SPF value required by § 201.327(b)(2)) for new sunscreen formulations. FDA estimates 48.75 responses per respondent for a total of 975 responses. FDA estimates a burden of 24 hours per response. We estimate the total burden to be 23,400 hours.

Regarding proposed § 352.70, because that section does not add any additional labeling or testing-related information collections not already addressed elsewhere (it incorporates the proposed SPF testing requirements as a condition of the part 352 monograph), there is no additional burden.

2. Clinical Testing-Related Information Collection and Burden

Proposed § 201.327(i) contains requirements for clinical testing of SPF values for inclusion on sunscreen product labeling. As previously noted, current regulations already require SPF testing. While FDA expects that SPF testing and some of the proposed recordkeeping is already being done, the proposed changes are intended to clarify existing requirements applicable to sunscreen drug products and set forth certain new requirements intended to improve the reliability of SPF testing and ensure the protection of human subjects. Proposed § 352.70 references the § 201.327(i) testing requirements and makes the referenced testing requirements part of the monograph conditions of use.

Across disciplines, testing involving human subjects is ordinarily conducted under IRB oversight as a means of ensuring that adequate human subject protections are provided and to ensure the integrity of study design and execution. Thus, in this proposed regulation, FDA is proposing to apply certain human subject protection requirements to sunscreens, with the aim of having a framework similar to that used in the IND context, but tailored to sunscreen testing.

Information collections related to proposed § 201.327(i) are addressed in detail in the sections that follow. Regarding proposed § 352.70, as in the previous section, because the proposed change does not add any additional labeling or testing-related information collections not already addressed elsewhere (it cross-references the proposed § 201.327(i) testing requirements as a condition of the part 352 monograph), there is no additional burden.

a. Investigator statements and notifications. Proposed § 201.327(i), among other things, requires responsible persons to obtain a signed investigator statement and an investigator CV, and to provide certain notifications (*e.g.,* notification of adverse drug experiences). These may result in third-party disclosure or reporting requirements for responsible persons (and entities to which they have transferred relevant obligations) as well as for clinical investigators. As noted above, our experience leads us to believe that most responsible persons will transfer their obligations under § 201.327(i) to the approximately 20 entities that currently conduct clinical SPF testing. This assumption is reflected in the estimates regarding the number of respondents below.

b. Investigator statements, CVs, and related burden. Proposed § 201.327(i)(1)(i) requires responsible persons to, among other things, obtain a signed investigator statement from each investigator. Proposed § 201.327(i)(1)(iv)(B) requires responsible persons to obtain a signed investigator statement and CV. In FDA's experience, investigators for SPF testing are most often employed by the testing entities, and we therefore believe this is a recordkeeping requirement rather than a third-party reporting requirement. We request comment on this assumption. As noted above, we estimate that responsible persons will typically delegate this obligation to the approximately 20 entities conducting final formulation testing. We estimate that each testing entity employs one clinical investigator to run the SPF testing they conduct. One investigator may run multiple SPF tests, and so long as the responsible person (or testing entity) has the investigator statement and CV on file for each investigator, there need not be a separate copy for each investigation.

Table 10, row 1 provides FDA's estimate that approximately 20 respondents will need to obtain and keep a signed investigator statement and CV in accordance with § 201.327(i)(1)(i) and (i)(1)(iv)(B). FDA estimates 2 responses per respondent (1 CV and 1 investigator statement) for a total of 40 annual responses. FDA estimates a burden of 0.6 hours per response. We estimate the total burden of this recordkeeping to be 24 hours.

c. Notifications and related burden. Proposed § 201.327(i)(1)(i) requires responsible persons to, among other things, ensure that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Proposed § 201.327(i)(1)(v) requires responsible persons to keep each participating investigator informed of new observations about the drug, particularly with respect to adverse effects and safe use. As mentioned above, like other obligations associated with testing under proposed § 201.327(i), we anticipate that this obligation will be delegated in most instances to the approximately 20 entities that currently conduct SPF testing on behalf of responsible persons.

Table 9, row 1 provides FDA's estimate that approximately 20 respondents will need to inform FDA and participating investigators of significant new adverse effects or risks in accordance with § 201.327(i)(1)(i) and

of new safety and other observations in accordance with § 201.327(i)(1)(v). FDA estimates up to 40 responses per respondent for a total of up to 800 annual responses. FDA estimates a burden of 0.5 hours per response. We estimate the total burden of this recordkeeping to be 400 hours.

d. Informed consent, IRB review, and related burden. Proposed § 201.327(i)(1)(ii) requires responsible persons to obtain informed consent, as defined in part 50, before clinical final formulation testing and proposed § 201.327(i)(1)(iii) requires that clinical testing under § 201.327(i) be reviewed and approved by an IRB meeting the requirements of part 56. These two proposed provisions make clear that FDA's regulations governing informed consent (part 50) and IRB approval of research (part 56) apply to clinical final formulation testing conducted pursuant to § 201.327(i).

Regarding proposed § 201.327(i)(1)(ii) and (iii), the information collections associated with FDA's regulations governing informed consent (part 50) and IRB approval of research (part 56) have previously been approved in accordance with the PRA under OMB control number 0910–0755. FDA does not expect that proposed § 201.327(i)(1)(ii) or (iii) would affect the number of recordkeepers, records, reports, or associated burdens included in the existing approval (0910–0755), but we invite stakeholders to comment if they have a different view.

Proposed § 201.327(i)(1)(vii) requires investigators to provide safety reports and a final study report to the responsible person. Although investigators are often employees of testing entities, we are basing our estimate on our assumption the respondents in this case are the investigators themselves because of the framing of the duty proposed by the regulation.

Table 9, row 2 provides FDA's estimate that up to 20 respondents will need to provide safety reports in accordance with § 201.327(i)(1)(vii)(A). FDA estimates 24.4 responses per respondent for a total of 488 annual responses. FDA estimates a burden of 0.5 hours per response. We estimate the total burden of this recordkeeping to be 244 hours.

Table 9, row 3 provides FDA's estimate that up to 20 respondents will need to provide a final report in accordance with § 201.327(i)(1)(vii)(B). This will occur one time per study, with each of the 20 investigators conducting multiple studies per year. FDA estimates 48.75 responses per respondent for a total of 975 annual responses. FDA estimates a burden of 3 hours per response. We estimate the total burden of this recordkeeping to be 2,925 hours.

Proposed § 352.40(i)(1) references limitations on particle size for sunscreens in a spray dosage form. Proposed § 352.40(i)(2) and (3) proposes limitations on flammability and drying time for spray sunscreen formulations. These proposed sections (§ 352.40(i)(1) through (3)) make the referenced limitations on flammability and particle size requirements part of the monograph conditions of use. Proposed § 352.40(i)(5) states that applicable requirements for particle size, flammability, and drying time for spray sunscreens must be verified through batch and lot testing as part of CGMP compliance under part 211. Entities conducting testing required by these sections must also comply with associated recordkeeping requirements, including those set forth in parts 210 and 211.

The recordkeeping associated with ensuring compliance with § 352.40(i)(5) (batch and lot testing to ensure compliance with particle size, flammability, and drying time limitations) is considered to be part of the manufacturers' CGMP requirements under parts 210 and 211 (OMB control number 0910–0139). While FDA believes that sunscreen manufacturers are already included among the respondents counted for that collection, and that many of those manufacturers who have spray dosage products may already be conducting flammability and drying time testing (*e.g.,* many are including flammability statements and information about drying time in current product labeling), the proposed inclusion of these requirements in the sunscreen regulations is new. The proposed rule specifies the particle size, flammability, and drying time limitations that would be required for sunscreens in spray dosage forms to be GRASE under the monograph. The proposed rule also specifies that compliance with these limitations must be verified through batch and lot testing. While this greater specificity as to required testing might have a marginal effect on the burden associated with recordkeeping for manufacturing facilities that are not already conducting such testing, FDA believes that the total change would be minimal in light of the total recordkeeping burden under parts 210 and 211, which is estimated across thousands of manufacturers of a wide variety of drugs. We request comment on these assumptions. If FDA determines that the assumptions are incorrect, then, concurrent with publication of the final rule, FDA plans to amend its approved information collection 0910–0139, if necessary, to adjust the respective burden estimate(s) to account for any change. We request comment on the accuracy of our assumptions and the resulting burden estimate.

B. Regulatory Status of Testing Entities

Proposed § 201.327(k) clarifies the regulatory status of final formulation testing, including that final formulation testing conducted pursuant to § 201.327 constitutes ''manufacture'' of a drug. As such, this testing must be conducted in an establishment registered in accordance with part 207 and section 510 of the FD&C Act, and entities conducting final formulation testing required by this section must comply with CGMP and associated recordkeeping requirements, including those set forth in § 201.327(*l*) and in parts 210 and 211. As this provision is intended only to clarify an existing requirement, it does not create a new information collection.

Entities covered by this provision are already included in the burden estimates for the information collections associated with registration and listing requirements. Recordkeeping obligations related to registration and listing under part 207 and section 510 of the FD&C Act are part of FDA's approved information collection for part 207 (OMB control number 0910–0829). CGMP recordkeeping obligations are part of FDA's approved information collection for part 211 (OMB control number 0910–0139).

C. Generating and Maintaining Records of SPF and Broad Spectrum Testing

FDA is proposing specific recordkeeping requirements for SPF and broad spectrum testing to enable FDA to better monitor responsible persons' compliance with the requirements of § 201.327. Recordkeeping is essential for FDA to evaluate whether required testing of final formulations is being conducted properly (both as to human subject protection and as to study design) and to enable the Agency to investigate postmarketing product failures or adverse events. Appropriate recordkeeping also enables FDA to conduct better and more efficient inspections of entities conducting final formulation testing. The proposed recordkeeping requirements are in alignment with the records required for other types of manufacturing under CGMPs as set forth in parts 210 and 211.

Failure to maintain adequate records of testing equipment, methods, and observations can raise broad questions

about the reliability of final formulation testing. In FDA's experience, there has been a lack of uniformity in testing entities' approaches to recordkeeping for final formulation testing, raising concerns about the Agency's ability to assess the reliability of the results of final formulation testing. The proposed regulation would address these concerns, clarify FDA's expectations, and align the regulation with current best practices.

a. Potential transfer of obligations. Proposed § 201.327(a)(1) permits a responsible person (defined in § 201.327(a)) to transfer some or all of its obligations to another entity (a ''transferee''), except for obligations with respect to recordkeeping under § 201.327(*l*). We note that this could create some situations in which both the responsible person and the transferee would be required to comply with applicable recordkeeping requirements. The proposed provision would also require a written record of the transfer of obligations to be maintained by both parties to the transfer.

Regarding the record of an obligation transfer, FDA believes that it is usual and customary business practice for a written record of a transfer of obligations to be maintained by both parties to the transfer. FDA does not believe this requirement would incur any additional recordkeeping burden and believes it would meet the exception at 5 CFR 1320.3(b)(2). Regarding the potential for some recordkeeping obligations to fall on both responsible persons and transferees, although proposed § 201.327(a)(1) does not itself impose a specific requirement to generate records, it does create the potential for some recordkeeping obligations to fall on both responsible persons and transferees. In particular, if a responsible person has delegated all other responsibilities under § 201.327(i) and (j), they would nonetheless need to maintain a copy of the records of final formulation testing required by § 201.327(*l*)(2) and (3). We have included the burden associated with keeping this copy in our assumption that there are 782 respondents for recordkeeping obligations as described below (20 entities that conduct testing, 10 of whom are also responsible persons, plus 762 responsible persons that delegate their responsibility for conducting testing (*e.g.,* to one of the 10 independent testing entities that are not themselves responsible persons)). We invite comment on whether our estimates properly reflect the recordkeeping obligations.

b. Maintenance records and related burden. Proposed § 201.327(*l*)(1) addresses maintenance records. The proposed rule clarifies that, as manufacturing, final formulation testing must comply with CGMPs, and, accordingly, records documenting proper maintenance of equipment used in final formulation testing must be generated and maintained by testing entities, consistent with existing obligations in part 211.

Regarding proposed § 201.327(*l*)(1), the existing maintenance record obligations are part of FDA's approved information collection for part 211 (OMB control number 0910–0139), and FDA believes that most of the respondents for this collection of information (the approximately 20 entities we believe are conducting final formulation testing) are already included among the recordkeepers counted for that collection. The proposed rule provides greater specificity regarding what information should be included in maintenance records maintained by facilities conducting final formulation testing. While this greater specificity might have a marginal effect on the burden associated with recordkeeping for these facilities, and the number of respondents for this requirement may need to be increased by 10 (to reflect contract testing entities that may not be currently registered as manufacturers), FDA believes that the total change would be minimal in light of the total recordkeeping burden under parts 210 and 211, which is estimated across thousands of manufacturers of a wide variety of drugs. We request comment on these assumptions. If FDA determines that the assumptions are incorrect, then, concurrent with publication of the final rule, FDA plans to amend its approved information collection under OMB control number 0910–0139 as necessary to adjust the respective burden estimate(s) in order to account for any change.

c. SPF testing records and related burden. Proposed § 201.327(*l*)(2) addresses SPF testing records and requires that respondents keep records related to the identification of the entity conducting the testing, the formulation being tested, equipment used, investigators, SPF standards, specific subject and test result data, and records demonstrating compliance with § 201.327(i)(1) governing the establishment of adequate clinical testing procedures and conditions. This is important because failure of testing entities to keep adequate records to support final formulation testing may leave FDA unable to verify the reliability of the results of SPF testing. Because one testing entity may conduct final formulation testing on behalf of multiple responsible persons, an error at one testing entity may affect data across multiple clinical SPF testing studies for multiple different final formulations that are ultimately sold under different labels.

In particular, proposed § 201.327(*l*)(2) requires that, in addition to any records required to be kept pursuant to parts 210 and 211, records of SPF testing must include: (1) Identification of the testing entity; (2) the product identifier and expected SPF; (3) characterization of the SPF standard sunscreen required by proposed § 201.327(i)(3) (lot number, manufacturing date, and results of high performance liquid chromatography (HPLC) SPF standard assay); (4) documentation linking any blinded samples with the product lot number and formulation tested; (5) specific testing records for each human subject (identification of the UV source used for testing and various specific test results and the individual(s) who determined the values); (6) the mean and standard deviation from SPFi values, standard error and determined SPF value derived as set forth in proposed § 201.327(i)(7); (7) records for water resistance testing of pool temperature, air temperature, and relative humidity as required by proposed § 201.327(i)(8); and (8) records demonstrating compliance with proposed § 201.327(i)(1) requirements for adequate clinical testing procedures and conditions (*e.g.,* individual case histories and documentation of IRB review).

Table 10, row 2 provides FDA's estimate that approximately 20 respondents will need to generate SPF testing records in accordance with proposed § 201.327(*l*)(2) for existing products that will be reformulated. FDA estimates 85.5 records per recordkeeper for a total of 1,710 records. This is a one-time burden. FDA estimates a burden of 24 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 41,040 hours.

Table 10, row 3 provides FDA's estimate that up to 20 respondents will need to generate SPF testing records in accordance with proposed § 201.327(*l*)(2) for new formulations. FDA estimates 48.75 records per recordkeeper for a total of 975 records. FDA estimates a burden of 24 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 23,400.

Table 10, row 4 provides FDA's estimate that up to 782 respondents will need to keep SPF testing records in accordance with proposed § 201.327(*l*)(2) for existing products that will be reformulated. This is a one-time

burden. FDA estimates 2.1867 records per recordkeeper for a total of 1,710 records. FDA estimates a burden of 0.33 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 564.3 hours.

Table 10, row 5 provides FDA's estimate that up to 782 respondents will need to keep SPF testing records in accordance with proposed § 201.327(*l*)(2) for new formulations. FDA estimates 1.2468 records per recordkeeper for a total of 975 records. FDA estimates a burden of 0.33 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 321.75 hours.

With regard to the testing-related estimates, we note that the requirements for obtaining certain medical history information from test subjects are not considered collections of information because information collected from subjects of clinical testing does not constitute information under 5 CFR 1320.3(h)(5), and that the referenced informed consent and IRB requirements under parts 50 and 56 are covered by existing approvals, as previously discussed.

d. Broad spectrum testing records and related burden. Proposed § 201.327(*l*)(3) addresses broad spectrum testing records. The proposed rule requires records related to the identification of the entity conducting the testing, the formulation being tested, equipment used, investigators, UV standards, sunscreen application, and specific test result data. This is important because failure of testing entities to keep adequate records to support broad spectrum testing may leave FDA unable to verify the reliability of testing results. Failure at one testing entity may affect data across multiple broad spectrum testing studies for multiple different final formulations that are ultimately sold under different labels.

In particular, proposed § 201.327(*l*)(3) requires that records of broad spectrum testing must include: (1) Identification of the testing entity; (2) records of sample information (product identifier and expected SPF, master key for blinded samples, sample number and identifier code, polymethylmethacrylate (PMMA) plate surface topography measurement, and sample holder orientation); (3) identification of each UV source used for sunscreen product pre-irradiation; (4) records of sunscreen product application (sample weights, equipment identification); (5) measurements required by proposed § 201.327(j)(4) to (6)); (6) records of critical wavelength and UVA1/UV ratio values; (7) for each sample: The identity of the individual(s) conducting specific testing steps; and (8) test dates for the broad spectrum test conducted pursuant to § 201.327(j), and sample report forms and supporting data.

Table 10, row 6 provides FDA's estimate that approximately 20 respondents will need to generate broad spectrum testing records in accordance with proposed § 201.327(*l*)(3) for existing products. As with records of SPF testing, this number of respondents reflects FDA's assumption that most responsible persons will delegate responsibility for conducting testing under § 201.327(j) to the approximately 20 testing entities. FDA estimates 203.9 records per recordkeeper for a total of 4,078 records. This is a one-time burden. FDA estimates a burden of 1.5 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 6,117 hours.

Table 10, row 7 provides FDA's estimate that up to 20 respondents will need to generate broad spectrum testing records in accordance with proposed § 201.327(*l*)(3) for new formulations. FDA estimates 48.75 records per recordkeeper for a total of 975 records. FDA estimates a burden of 1.5 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 1,462.5 hours.

Table 10, row 8 provides FDA's estimate that up to 782 respondents will need to keep broad spectrum testing records in accordance with proposed § 201.327(*l*)(3) for existing products. This is a one-time burden. FDA estimates 5.215 records per recordkeeper for a total of 4,078 records. FDA estimates a burden of 0.17 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 693.3 hours.

Table 10, row 9 provides FDA's estimate that up to 782 respondents will need to keep broad spectrum testing records in accordance with proposed § 201.327(*l*)(3) for new formulations. FDA estimates 1.2468 records per recordkeeper for a total of 975 records. FDA estimates a burden of 0.17 hours per recordkeeping. We estimate the total burden of this recordkeeping to be 165.75 hours.

The recordkeeping burden is estimated as described in the tables at the end of the PRA discussion.

With the exceptions noted above, we conclude that the other provisions of this rule are not subject to OMB review under the PRA.

The proposed changes to part 310 do not include any collections of information subject to the PRA.

The remaining sections of part 347 do not include any collections of information not already addressed in this analysis.

Section 201.327 and the remaining sections of part 352 either do not contain an information collection subject to PRA, or contain specific labeling information, including directions and warnings, which are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and, therefore, are not collections of information.

FDA estimates the burden of this information collection as follows:

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Inform FDA and investigators of significant new adverse effects or risks (§ 201.327(i)(1)(i)) and new safety and other observations (§ 201.327(i)(1)(v)).	20	40	800	0.5 (30 minutes)	400
Investigators provide safety reports in accordance with § 201.327(i)(1)(vii)(A).	20	24.4	488	0.5 (30 minutes)	244
Investigators provide a final report in accordance with § 201.327(i)(1)(vii)(B) (one time per study).	20	48.75	975	3	2,925
Total	.....	.....	.....	.....	3,569

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 10—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity and 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Obtain and keep a signed investigator statement and CV in accordance with § 201.327(i)(1)(i) and (iv)(B).	20	2	40	0.6 (36 minutes)	24
Generate SPF testing records for existing products (§ 201.327(*l*)(2)) (one-time).	20	85.5	1,710	24	41,040
Generate SPF testing records for new formulations (§ 201.327(*l*)(2)).	20	48.75	975	24	23,400
Keep SPF testing records for existing products (§ 201.327(*l*)(2)) (one-time).	782	2.1867	1,710	0.33 (20 minutes)	564.3
Keep SPF testing records for new formulations (§ 201.327(*l*)(2)).	782	1.2468	975	0.33 (20 minutes)	321.75
Generate Broad Spectrum testing records for existing products (§ 201.327(*l*)(3)).	20	203.9	4,078	1.5	6,117
Generate Broad Spectrum testing records for new formulations (§ 201.327(*l*)(3).	20	48.75	975	1.5	1,462.5
Keep Broad Spectrum testing records for existing products (§ 201.327(*l*)(3)).	782	5.215	4,078	0.17 (10 minutes)	693.3
Keep Broad Spectrum testing records for new formulations (§ 201.327(*l*)(3)).	782	1.2468	975	0.17 (10 minutes)	165.75
Total					773,788.6

[1] There are no capital costs or operating or maintenance costs associated with this collection of information.

TABLE 11—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity and 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Create PDP labeling in accordance with statement of identity and SPF value requirements (§ 201.327(b)(1), (b)(2) and (h)(1)) for currently marketed sunscreen formulations (one-time burden).	772	5.2824	4,078	0.5 (30 minutes)	2,039
Create PDP labeling in accordance with statement of identity and SPF value requirements (§ 201.327(b)(1), (b)(2), and (h)(1)) for new formulations.	772	1.943	1,500	0.5 (30 minutes)	750
Conduct SPF testing in accordance with § 201.327(i) to determine SPF value for currently marketed sunscreen formulations (if not already done) (one-time burden).	20	111	2,220	24	53,280
Conduct SPF testing in accordance with § 201.327(i) to determine SPF value for new sunscreen formulations.	20	48.75	975	24	23,400
Total					79,469

[1] There are no capital costs or operating or maintenance costs associated with this collection of information.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XVI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' The sole statutory provision giving preemptive effect to this proposed rule is section 751 of the FD&C Act (21 U.S.C. 379r). We have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effect of this proposed rule, if finalized, would be consistent with Executive Order 13132. Through publication of this proposed rule, we are providing notice and an opportunity for State and local officials to comment on this rulemaking.

XVII. Consultation and Coordination With Indian Tribal Governments

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

Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XVIII. References

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

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List of Subjects

21 CFR Part 201

Drugs, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 347

Labeling, Over-the-counter drugs.

21 CFR Part 352

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 201, 310, 347, and 352 be amended as follows:

PART 201—LABELING

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Revise § 201.327 to read as follows:

§ 201.327 Over-the-counter sunscreen drug products; required labeling based on effectiveness testing.

The following provisions apply to an over-the-counter (OTC) sunscreen drug product that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering radiation in the ultraviolet (UV) range at wavelengths from 290 to 400 nanometers (nm), and that contains one or more of the following as an active ingredient: Avobenzone, cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, oxybenzone, padimate O, sulisobenzone, titanium dioxide, or zinc oxide, alone or in combination. The provisions do not apply to OTC sunscreen drug products marketed under approved new drug applications or abbreviated new drug applications. The failure of a product covered by this section to comply with any provision of this section, including the labeling of such a product with any effectiveness claim based on testing that fails to comply with any provision of this section, renders that product misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act.

(a) *General obligations of responsible persons.* As used in this section, a ''responsible person'' is the manufacturer, packer, or distributor whose name appears on the labeling of a product covered by this section. A responsible person must assure that final formulation testing conducted on its product(s) pursuant to paragraphs (i) and (j) of this section complies with all applicable provisions of this section.

(1) *Transfer of obligations.* (i) A responsible person may transfer responsibility for any or all of its obligations set forth in this section to another entity (*e.g.,* a contract research organization and/or testing laboratory), except as set forth in paragraph (l) (recordkeeping) of this section. Any such transfer must be described in writing. If not all obligations are transferred, the writing is required to describe each of the obligations being assumed by the transferee. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description will be deemed not to have been transferred. A written record of the transfer of obligations must be maintained by both parties to the transfer for the time period set forth in paragraph (l) of this section.

(ii) An entity that assumes any obligation(s) of a responsible person must comply with the provisions of this section applicable to the assumed obligation and will be subject to the same regulatory action as a responsible person for failure to comply with any obligation assumed under this section. Thus, all references to ''responsible person'' in this section apply to another entity (*e.g.,* a contract research organization or testing laboratory) to the extent that it assumes one or more obligations of a responsible person.

(2) *Personnel.* A responsible person must select only investigators and other personnel qualified by appropriate training and/or experience to conduct final formulation testing pursuant to this section. Personnel engaged in testing under this section must have the education, training, and experience, or any combination thereof, to enable that person to adequately perform their assigned functions.

(b) *Principal display panel.* The following labeling must be prominently placed on the principal display panel:

(1) *Statement of identity*—(i) *Placement.* The principal display panel of an over-the-counter sunscreen drug product bears a statement of identity as one of its principal features. Except as set forth in paragraph (h) of this section, the statement of identity consists of the name of each sunscreen active ingredient in the product as identified in this section, listed in alphabetical order and followed by ''Sunscreen'' and ''[Dosage form]'' (*e.g.,* ''Lotion'' ''Spray'').

(ii) *Prominence.* The statement of identity must appear on the principal display panel in boldface type at least one-quarter as large as the size of the most prominent printed matter on the principal display panel, in lines generally parallel to the base on which the package rests as it is designed to be displayed and in direct conjunction with the most prominent display of the proprietary name or designation. The entire text of the statement of identity must appear in the same font style, size, and color with the same background color, and as continuous text with no intervening text or graphic, other than additional text provided in accordance with paragraph (h) of this section.

(2) *Effectiveness claim.* For purposes of this section, the term ''determined SPF value'' refers to the SPF value that equals the largest whole number less than $\overline{SPF} - (t*SE)$, determined for a sunscreen product in accordance with paragraph (i) of this section.

(i) *SPF Broad Spectrum Statement.* For a product that has been shown to pass the broad spectrum test in paragraph (j) of this section, the labeling states ''Broad Spectrum SPF [insert the labeled SPF value associated with the range into which the determined SPF value falls, as set forth in the following table.]''

TABLE 1 TO PARAGRAPH (b)(2)(i)—SPF LABELING RANGES

Range of determined SPF values	Associated labeled SPF value
60–80	60+.
50–59	50.
40–49	40.
30–39	30.
25–29	25.
20–24	20.
15–19	15.
2–14	Determined SPF Value.

(ii) *SPF Statement.* For a product that has not been shown to pass the broad spectrum test in paragraph (j) of this section, the labeling states ''SPF [insert labeled SPF value associated with the range into which the determined SPF value falls, as set forth in the table in paragraph (b)(2)(i) of this section]''.

(iii) *For a product with a determined SPF value of at least 2 but less than 15.* The SPF statement is immediately followed by an asterisk (''*''), and the associated statement ''*See Skin Cancer/Skin Aging Alert'' appears in the bottom 30 percent of the principal display panel.

(iv) *Prominence of required statements.* The SPF Broad Spectrum statement, SPF statement, and ''*See Skin Cancer/Skin Aging Alert'' statement, as applicable, must appear in boldface type at least one-quarter as large as the most prominent printed matter on the principal display panel and in lines generally parallel to the base on which the package rests as it is designed to be displayed. The entire text of the Broad Spectrum SPF or SPF statement, as applicable, must appear in the same font style, size, and color with the same background color and must appear as continuous text with no intervening text or graphic. The entire text of the ''See Skin Cancer/Skin Aging Alert'' statement, as applicable, must appear in the same font style, size, and color with the same background color and must appear as continuous text with no intervening text or graphic.

(3) *Water resistance statements*—(i) *For products that provide 40 minutes of water resistance according to the test in paragraph (i)(8)(i) of this section.* The

labeling states ''Water Resistant (40 minutes).''

(ii) *For products that provide 80 minutes of water resistance according to the test in paragraph (i)(8)(ii) of this section.* The labeling states ''Water Resistant (80 minutes).''

(iii) *Prominence of water resistance statement.* For all products bearing a water resistance statement, the statement must appear in boldface type at least one-quarter as large as the most prominent printed matter on the principal display panel and in lines generally parallel to the base on which the package rests as it is designed to be displayed. The entire text of the water resistance statement must appear in the same font style, size, and color with the same background color, and as continuous text with no intervening text or graphic.

(c) *Indications.* The labeling of the product states, under the heading ''Uses,'' the phrases listed in this paragraph, as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act relating to misbranding and the prohibition in section 301(d) of the Federal Food, Drug, and Cosmetic Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act.

(1) For all sunscreen products, the following indication statement must be included under the heading ''Uses'': ''[bullet] helps prevent sunburn''. See § 201.66(b)(4) for definition of bullet.

(2) For sunscreen products that have been shown to pass the broad spectrum test in paragraph (j) of this section and have a determined SPF value of 15 or higher, the labeling may include the following statement in addition to the indication in paragraph (c)(1) of this section: ''[bullet] if used as directed with other sun protection measures (see Directions [in bold italic font]), decreases the risk of skin cancer and early skin aging caused by the sun''.

(3) Any labeling or promotional materials that suggest or imply that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

(d) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings''.

(1) *For all sunscreen products.* (i) The labeling states ''Do not use [bullet] on damaged or broken skin.''

(ii) The labeling states ''When using this product [bullet] keep out of eyes. Rinse with water to remove.''

(iii) The labeling states ''Stop use and ask a doctor if [bullet] rash occurs.''

(2) *For sunscreen products that are broad spectrum with determined SPF values of at least 2 but less than 15 according to the SPF test in paragraph (i) of this section or that have not been shown to pass the broad spectrum test in paragraph (j) of this section.* The first statement under the heading ''Warnings'' states ''Skin Cancer/Skin Aging Alert [in bold font]: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging.''

(3) *For products in a spray dosage form that meet the definition of either the term ''flammable'' or the term ''combustible'' as defined in § 352.3(g) or (h) of this chapter, as applicable, when tested in accordance with 16 CFR 1500.43a*—(i) *Labeling statement.* The labeling states [bullet] ''Flammable'' or ''Combustible'' (as applicable) followed by a colon and the statement ''Keep away from fire or flame.''

(ii) *For products that have a drying time of less than 5 minutes.* The labeling states [bullet] ''Wait 5 minutes after application before approaching a source of heat or flame, or before smoking.''

(iii) *For products that have a drying time of at least 5 minutes but less than 10 minutes.* The labeling states [bullet] ''Wait 10 minutes after application before approaching a source of heat or flame, or before smoking.''

(e) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading ''Directions.'' More detailed directions applicable to a particular product formulation may also be included.

(1) *For all sunscreen products.* (i) As an option, the labeling may state ''For sunscreen use:''.

(ii) The labeling states ''[bullet] apply [select one of the following: 'liberally' or 'generously'] [and, as an option: 'and evenly'] 15 minutes before sun exposure''.

(iii) As an option, the labeling may state ''[bullet] apply to all skin exposed to the sun''.

(iv) The labeling states ''[bullet] children under 6 months of age: Ask a doctor''.

(2) *For sunscreen products that have been shown to pass the broad spectrum test in paragraph (j) of this section and have a determined SPF value of 15 or higher.* The labeling states ''[bullet] Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: [bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses''.

(3) *For products that satisfy the water resistance test in paragraph (i)(8) of this section.* The labeling states ''[bullet] reapply: [bullet] after [select one of the following determined by water resistance test: '40 minutes of' or '80 minutes of'] swimming or sweating [bullet] immediately after towel drying [bullet] at least every 2 hours''.

(4) *For products that do not satisfy the water resistance test in paragraph (i)(8) of this section.* The labeling states ''[bullet] reapply at least every 2 hours [bullet] use a water resistant sunscreen if swimming or sweating''.

(5) *For sunscreen products in a spray dosage form.* The labeling states ''[bullet] Hold container 4 to 6 inches from the skin to apply. [bullet] Do not spray directly into face. Spray on hands then apply to face. [bullet] Do not apply in windy conditions. [bullet] Use in a well-ventilated area and avoid inhalation''.

(f) *Other information.* The labeling of the product contains the following statement under the heading ''Other information:'' ''[bullet] protect the product in this container from excessive heat and direct sun''.

(g) *False or misleading claims.* There are claims that would be false and/or misleading on sunscreen products. These claims include but are not limited to the following: ''Sunblock,'' ''sweatproof,'' and ''waterproof.'' These or similar claims will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act.

(h) *Labeling of products containing a combination of sunscreen and skin protectant active ingredients.* Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Labeling provisions in § 347.50(e) of this chapter do not apply to these products.

(1) *Statement of identity.* The statement of identity of a sunscreen product that also contains one or more skin protectant active ingredients, identified in §§ 347.10(a), (d), (e), (g), h),

(i), (k), (l), (m), and (r) of this chapter, consists of the names of all sunscreen and skin protectant active ingredients in alphabetical order followed by ''Sunscreen/Skin Protectant'' and ''[Dosage form].'' The statement of identity must be prominently placed on the principal display panel and presented in accordance with paragraph (b)(1)(ii) of this section.

(2) *Indications.* The labeling of the product states, under the heading ''Uses,'' any or all of the applicable indication(s) included in § 347.50(b) of this chapter or in paragraph (c) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in § 347.50(b) of this chapter or listed in paragraph (c) of this section, may also be used, as provided by § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act relating to misbranding and the prohibition in section 301(d) of the Federal Food, Drug, and Cosmetic Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act.

(3) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the applicable warnings for sunscreens in paragraph (d) of this section and for skin protectants in § 347.50(c) of this chapter.

(4) *Directions.* The labeling of the product states, under the heading ''Directions,'' any or all of the applicable directions for sunscreens, as set forth in paragraph (e) of this section, and for skin protectants, as set forth in §§ 347.50(d) and 347.60(d) of this chapter, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient. When the directions for administration of the sunscreen and skin protectant differ in any other way, the directions for sunscreens in paragraph (e) of this section should be used.

(i) *Sun Protection Factor (SPF) testing*—(1) *Adequate clinical testing procedures and conditions*—(i) *General obligations of responsible persons for testing under this paragraph.* Responsible persons must provide investigators and other personnel engaged in SPF testing with the information they need to conduct an investigation properly; must obtain a signed investigator statement from each investigator; must ensure proper monitoring of the investigation(s); must ensure that the investigation(s) is conducted in accordance with written general investigational plan(s) and protocol(s); must ensure compliance with paragraphs (i)(1)(ii) and (iii) of this section; and must ensure that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.

(ii) *Informed consent.* Effective informed consent, as defined in part 50 of this chapter, must be obtained from all human subjects before initiating clinical final formulation testing under this paragraph (i).

(iii) *Institutional review board (IRB) approval.* Clinical testing under this paragraph (i), must be reviewed and approved by an IRB meeting the requirements of FDA's regulations in part 56 of this chapter.

(iv) *Control of personnel*—(A) *General obligations.* A responsible person is responsible for ensuring that investigators and other personnel conducting any testing under this paragraph (i), conduct all investigations in accordance with the signed investigator statement, the investigational plan, and applicable regulations. Responsible persons must ensure the implementation of adequate safeguards to protect the rights, safety, and welfare of subjects under he investigator's care. The responsible person must also ensure that investigators or other study personnel will promptly report to the IRB all changes in the clinical final formulation testing and all unanticipated problems involving risk to human subjects or others, and that investigators or other personnel will not make any changes in the clinical final formulation testing without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

(B) *Obtaining information from the investigator.* Before permitting an investigator to begin participating in clinical final formulation testing under this paragraph (i), the responsible person must obtain the following:

(*1*) *Investigator statement.* A signed investigator statement containing the name and address of the investigator and a commitment by the investigator that he or she—

(*i*) Will conduct the testing in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the responsible person and the IRB, except when necessary to protect the safety, the rights, or welfare of subjects;

(*ii*) Will comply with all requirements regarding the obligations of clinical investigators and all other pertinent requirements in this subpart;

(*iii*) Will personally conduct or supervise the described investigation(s);

(*iv*) Will inform any potential subjects that the drugs are being used for investigational purposes and will comply with the requirements relating to obtaining informed consent (part 50 of this chapter) and institutional review board review and approval (part 56 of this chapter);

(*v*) Will report to the responsible person adverse experiences that occur during the investigation(s);

(*vi*) Will ensure that all personnel assisting in the conduct of the testing are informed about their obligations in meeting the above commitments.

(*2*) *Curriculum vitae.* A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator to conduct the final formulation testing pursuant to this paragraph (i).

(v) *Informing investigators.* The responsible person must, as the overall investigation proceeds, keep each participating investigator informed of new observations discovered by or reported to the responsible person on the drug, particularly with respect to adverse effects and safe use.

(vi) *Review of ongoing investigations.* (A) The responsible person must monitor the progress of all clinical testing being conducted on its final formulation pursuant to this paragraph (i).

(B) A responsible person who discovers noncompliance by an investigator or other personnel with the signed agreement, the general investigational plan, or the requirements of this paragraph (i) or other applicable regulations (*e.g.,* parts 50 and 56 of this chapter) must promptly either secure compliance or end the investigator's or other personnel's participation in testing conducted under this paragraph (i).

(C) The responsible person must review and evaluate the evidence relating to the safety and effectiveness of the final formulation as it is obtained from the investigator.

(vii) *Investigator reports*—(A) *Safety reports.* An investigator must immediately report to the responsible person any serious adverse event, whether or not considered related to the final formulation, including those listed in the protocol, and must include an

assessment of whether there is a reasonable possibility that the final formulation being tested caused the adverse event. The investigator must record nonserious adverse events and report them to the responsible person according to the timetable specified in the protocol.

(B) *Final report.* An investigator must provide the responsible person with an adequate report shortly after completion of each investigation conducted by that investigator for the responsible person under this paragraph (i).

(2) *UV source (solar simulator)*—(i) *Emission spectrum.* Filter a single port or multiport solar simulator so that it provides a continuous emission spectrum from 290 to 400 nanometers (nm) with a limit of 1,500 watts per square meter (W/m^2) on total irradiance for all wavelengths between 250 and 1,400 nm.

(A) The solar simulator must have the following percentage of erythema-effective radiation in each specified range of wavelengths:

TABLE 2 TO PARAGRAPH (I)(2)(I)(A)—SOLAR SIMULATOR EMISSION SPECTRUM

Wavelength range (nm)	Percent erythemal contribution [1]
<290	<0.1
290–300	1.0–8.0
290–310	49.0–65.0
290–320	85.0–90.0
290–330	91.5–95.5
290–340	94.0–97.0
290–400	99.9–100.0

[1] Calculation of erythema action spectrum described in paragraph (i)(2)(ii) of this section.

(B) In addition, UVA II (320–340 nm) irradiance must equal or exceed 20 percent of the total UV (290–400 nm) irradiance. UVA I (340–400 nm) irradiance must equal or exceed 60 percent of the total UV irradiance.

(ii) *Erythema action spectrum.* (A) Calculate the erythema action spectrum weighting factor (V_i) at each wavelength λ:

(*1*) $V_i(\lambda) = 1.0$ ($250 < \lambda \leq 298$ nm)

(*2*) $V_i(\lambda) = 10^{0.094 * (298 - \lambda)}$ ($298 < \lambda \leq 328$ nm)

(*3*) $V_i(\lambda) = 10^{0.015 * (140 - \lambda)}$ ($328 < \lambda \leq 400$ nm)

(B) Calculate the erythema-effective UV dose (E) delivered by a solar simulator as follows:

$$E = \sum_{250}^{400} V_i(\lambda) * I(\lambda) * t$$

Where

$V_i(\lambda)$ = erythema action spectrum weighting factor at each wavelength λ

$I(\lambda)$ = irradiance (Watts per square meter) at each wavelength λ

t = exposure time (seconds)

Erythema-effective dose (E) is expressed as effective Joules per square meter (J/m^2-eff).

(C) The solar simulator radiation intensity must be determined using a handheld radiometer with a response weighted to match the spectrum in ISO 17166 CIE S 007/E entitled ''Erythemal reference action spectrum and standard erythema dose,'' dated 1999 (First edition, 1999–12–15; corrected and reprinted 2000–11–15), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the ISO Copyright Office, Case Postale 56, CH–1211, Geneva 20, Switzerland, telephone +41–22–749–01–11 or fax +41–22–74–09–47. *https://www.iso.org.* You may inspect a copy at the Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, call 301–796–2090, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.* The solar simulator output should be measured before and after each phototest or, at a minimum, at the beginning and end of each test day. This radiometer should be calibrated using side-by-side comparison with the spectroradiometer (using the weighting factors determined according to paragraph (i)(2)(ii)(A) of this section) at the time of the annual spectroradiometric measurement of the solar simulator as described in paragraph (i)(2)(iv) of this section.

(iii) *Operation.* A solar simulator must have no significant time-related fluctuations (within 20 percent) in radiation emissions after an appropriate warm-up time and demonstrate good beam uniformity (within 20 percent) in the exposure plane. The delivered dose to the UV exposure site must be within 10 percent of the expected dose.

(iv) *Periodic measurement.* To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, the emission spectrum of the solar simulator must be measured at least annually with an appropriate and accurately calibrated spectroradiometer system (results should be traceable to the National Institute for Standards and Technology). In addition, the solar simulator must be recalibrated if there is any change in the lamp bulb or the optical filtering components (*i.e.,* filters, mirrors, lenses, collimating devices, or focusing devices). Daily solar simulator radiation intensity should be monitored with a broadband radiometer with a response weighted to match the erythema action spectrum in ISO 17166 CIE S 007/E entitled ''Erythemal reference action spectrum and standard erythema dose,'' which is incorporated by reference in paragraph (i)(2)(ii)(C) of this section. If a lamp must be replaced due to failure or aging during a phototest, broadband device readings consistent with those obtained for the original calibrated lamp will suffice until measurements can be performed with the spectroradiometer at the earliest possible opportunity.

(3) *SPF standard*—(i) *Preparation.* The SPF standard must be a formulation containing 7-percent padimate O and 3-percent oxybenzone.

TABLE 3 TO PARAGRAPH (I)(3)(I)—COMPOSITION OF THE PADIMATE O/OXYBENZONE SPF STANDARD

Ingredients	Percent by weight
Part A:	
Lanolin	4.50
Cocoa butter	2.00
Glyceryl monostearate	3.00
Stearic acid	2.00
Padimate O	7.00
Oxybenzone	3.00
Part B:	
Purified water USP	71.60
Sorbitol solution	5.00
Triethanolamine, 99 percent	1.00
Methylparaben	0.30
Propylparaben	0.10
Part C:	
Benzyl alcohol	0.50
Part D:	
Purified water USP	QS [1]

[1] Quantity sufficient to make 100 grams.

(A) *Step 1.* Add the ingredients of Part A into a suitable stainless steel kettle equipped with a propeller agitator. Mix at 77 to 82 °C until uniform.

(B) *Step 2.* Add the water of Part B into a suitable stainless steel kettle equipped with a propeller agitator and begin mixing at 77 to 82 °C. Add the remaining ingredients of Part B and mix until uniform.

(C) *Step 3.* Add the batch of Step 1 to the batch of Step 2 and mix at 77 to 82 °C until smooth and uniform. Slowly cool the batch to 49 to 54 °C.

(D) *Step 4.* Add the benzyl alcohol of Part C to the batch of Step 3 at 49 to 54 °C. Mix until uniform. Continue to cool batch to 35 to 41 °C.

(E) *Step 5.* Add sufficient water of Part D to the batch of Step 4 at 35 to 41 °C to obtain 100 grams of SPF standard. Mix until uniform. Cool batch to 27 to 32 °C.

(ii) *HPLC assay.* Use the following high performance liquid chromatography (HPLC) procedure to verify the concentrations of padimate O and oxybenzone in the SPF standard:

(A) *Instrumentation*—(*1*) Equilibrate a suitable liquid chromatograph to the following or equivalent conditions:

(*i*) Column	C–18, 250 millimeters (mm) length, 4.6 mm inner diameter (5 microns).
(*ii*) Mobile Phase	85:15:0.5 methanol: water: acetic acid.
(*iii*) Flow Rate	1.5 milliliters (mL) per minute.
(*iv*) Temperature	Ambient.
(*v*) Detector	UV spectrophotometer at 308 nanometers.
(*vi*) Attenuation	As needed.

(*2*) Use HPLC grade reagents for mobile phase.

(B) *Preparation of the HPLC reference standard.* (*1*) Weigh 0.5 gram (g) of oxybenzone USP reference standard into a 250-mL volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*2*) Weigh 0.5 g of padimate O USP reference standard into a 250-mL volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*3*) Pipet 3 mL of the oxybenzone solution and 7 mL of the padimate O solution into a 100-mL volumetric flask. Dilute to volume with isopropanol and mix well.

(C) *HPLC system suitability.* (*1*) Make three replicate 10-microliter injections of the HPLC reference standard (described in paragraph (i)(3)(ii)(B) of this section). The relative standard deviation in peak areas should not be more than 2 percent for either oxybenzone or padimate O.

(*2*) Calculate the resolution (R) between the oxybenzone and padimate O peaks from one chromatogram as follows:

$$R = \frac{2 * (t_o - t_p)}{W_o + W_p}$$

Where

t_o = retention time for oxybenzone
t_p = retention time for padimate O
W_o = oxybenzone peak width at baseline
W_p = padimate O peak width at baseline
If the resolution (R) is less than 3, adjust the mobile phase or replace the column.

(D) *SPF standard assay.* (*1*) The SPF standard is diluted to the same concentration as the HPLC reference standard according to the following steps:

(*i*) *Step 1.* Weigh 1 g of the SPF standard (described in paragraph (i)(3)(i) of this section) into a 50-mL volumetric flask.

(*ii*) *Step 2.* Add approximately 30 mL of isopropanol and heat with swirling until contents are evenly dispersed.

(*iii*) *Step 3.* Cool to room temperature (15 to 30 °C) and dilute to volume with isopropanol. Mix well.

(*iv*) *Step 4.* Pipet 5.0 mL of the preparation into a 50-mL volumetric flask and dilute to volume with isopropanol. Mix well.

(*2*)(*i*) Inject 10-microliter of diluted SPF standard from paragraph (i)(3)(ii)(D)(*1*) of this section and calculate the amount of oxybenzone and padimate O as follows:

$$\text{Percent Oxybenzone} = \frac{\text{Peak area of oxybenzone in sunscreen standard}}{\text{Peak area of oxybenzone in HPLC reference standard}} * 100$$

$$\text{Percent Padimate O} = \frac{\text{Peak area of padimate O in sunscreen standard}}{\text{Peak area of padimate O in HPLC reference standard}} * 100$$

(*ii*) The percent of oxybenzone and padimate O in the SPF standard must be between 95 and 105.

(4) *Test subjects*—(i) *Number of subjects.* A test panel should include enough subjects to produce a minimum of 10 valid test results. A maximum of three subjects may be rejected from this panel based on paragraph (i)(6)(v) of this section.

(ii) *Medical history.* (A) Obtain a medical history from each subject with emphasis on the effects of sunlight on the subject's skin. Determine that each subject is in good general health with skin type I, II, or III as follows:

(*1*) Always burns easily; never tans (sensitive).

(*2*) Always burns easily; tans minimally (sensitive).

(*3*) Burns moderately; tans gradually (light brown) (normal).

(*4*) Burns minimally; always tans well (moderate brown) (normal).

(*5*) Rarely burns; tans profusely (dark brown) (insensitive).

(*6*) Never burns; deeply pigmented (insensitive).

(B) Skin type is based on first 30 to 45 minutes of sun exposure after a winter season of no sun exposure. Determine that each subject is not taking topical or systemic medication that is known to alter responses to UV radiation. Determine that each subject has no history of sensitivities to topical products and/or abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(iii) *Physical examination.* Conduct a physical examination to determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. Adequate time must have passed following any previous UV exposure (*e.g.,* participation in a prior SPF clinical study, tanning, etc.) so that the test subject has no preexisting skin pigmentation at the time of enrollment. A suitable source of low power UVA, such as a Woods lamp, is helpful in this process. If any of these conditions are present, the subject is not qualified to participate in the study. The presence of nevi, blemishes, or moles will be acceptable if, in the physician's judgment, they will neither compromise the study nor jeopardize a subject's safety. Subjects with dysplastic nevi should not be enrolled. Excess hair on the back is acceptable if the hair is clipped. Shaving is unacceptable because it may remove a significant portion of the stratum corneum and temporarily alter the skin's response to UV radiation.

(iv) *Informed consent.* Obtain legally effective written informed consent from all test subjects as required by paragraph (i)(1)(ii) of this section.

(5) *Sunscreen application*—(i) *Test site.* Test sites are locations on each subject's back, between the beltline and the shoulder blades (scapulae) and lateral to the midline, where skin responses to UV radiation are determined. Responses on unprotected skin (no test material applied) and protected skin (sunscreen test product(s) or SPF standard applied) are determined at separate unprotected and protected test sites, respectively. Test sites should be randomly located in a blinded manner. Each test site should be a minimum of 30 square centimeters and outlined with indelible ink.

(ii) *Test subsite.* Test subsites are the locations to which UV radiation is administered within a test site. Administer UV doses to at least five test subsites within each test site. Test subsites must be at least 0.5 square centimeters (cm^2) in area and must be separated from each other by at least 0.8 cm. Each test subsite must be outlined with indelible ink.

(iii) *Applying test materials.* Apply the sunscreen test product and the SPF standard at 2 milligrams per square centimeter (mg/cm^2) to their respective test sites. Use a finger cot compatible with the sunscreen to spread the product as evenly as possible.

(iv) *Waiting period.* Wait at least 15 minutes after applying a sunscreen product before exposing the test sites to UV radiation as described in paragraph (i)(6) of this section. For water resistant sunscreen products, proceed with the water resistance testing procedure described in paragraph (i)(8) of this section after waiting at least 15 minutes.

(6) *UV exposure and erythema reading*—(i) *Definition of minimal erythema dose (MED).* The minimal erythema dose (MED) is the smallest UV dose (quantity of erythema-effective energy expressed as Joules per square meter) that produces perceptible redness of the skin (erythema) with clearly defined borders at 16 to 24 hours after UV exposure. The MED for unprotected skin (MED_u) is determined on a test site that does not have sunscreen applied. The MED for protected skin (MED_p) is determined on a test site that has sunscreen applied. An MED_p is determined for the SPF standard ($ssMED_p$). An MED_p is determined for the sunscreen test product ($tpMED_p$).

(ii) *UV exposure for initial MED_u.* For each test subject, no more than 1 day before testing a product, determine the initial MED_u by administering a series of UV radiation doses expressed as J/m^2-eff (as determined according to paragraph (i)(2)(ii)(B) of this section) to the test subsites within an unprotected test site using an accurately calibrated solar simulator. Select doses that are a geometric series represented by 1.25^n (*i.e.,* each dose is 25 percent greater than the previous dose).

(iii) *UV exposure for final MED_u, $_{ss}MED_p$, and $_{tp}MED_p$.* For each subject, determine the final MED_u, $_{ss}MED_p$, and $_{tp}MED_p$ by administering a series of five UV doses to the appropriate test sites. The middle dose (X) in each of these dose series (*i.e.,* the third dose) should equal the initial MED_u times the expected SPF. Note that the expected SPF equals 1 and 16.3 for the final MED_u and $ssMED_p$, respectively. The remaining UV doses in the series depend upon the expected SPF value of the sunscreen test product(s). For products with an expected SPF less than 8, administer UV doses that increase by 25 percent with each successive dose (*i.e.,* 0.64X, 0.80X, 1.00X, 1.25X, and 1.56X). For products with an expected SPF from 8 to 15, administer UV doses that increase by 20 percent with each successive dose (*i.e.,* 0.69X, 0.83X, 1.00X, 1.20X, and 1.44X). For products with an expected SPF higher than 15, administer UV doses that increase by 15 percent with each successive dose (*i.e.,* 0.76X, 0.87X, 1.00X, 1.15X, and 1.32X).

(iv) *Evaluation of test subsites.* In order that the study personnel who evaluates the test subsites is not biased, he/she should not be the same study personnel who applied the sunscreen product to the test site or administered the UV doses. After UV doses are administered, record all immediate responses. These may include an immediate darkening or tanning, typically grayish or purplish in color, which fades in 30 to 60 minutes; an immediate reddening at the subsite, due to heating of the skin, which fades rapidly; and an immediate generalized heat response, spreading beyond the subsite, which fades in 30 to 60 minutes. After the immediate responses are noted, each subject should shield the exposed area from further UV radiation until the MED is determined. Determine the final MED_u, $_{ss}MED_p$, and $_{tp}MED_p$ 16 to 24 hours after UV exposure. Evaluate the erythema responses of each test subsite using either tungsten or warm white fluorescent lighting that provides at least 450 lux of illumination at the test site. For the evaluation, the test subject should be in the same position as when the test site was irradiated.

(v) *Invalid test data.* Reject test data for a test subject if erythema is not present on either the unprotected or protected test sites; or erythema is present at all subsites; or the responses are inconsistent with the series of UV doses administered; or the subject was noncompliant (*e.g.,* the subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined).

(7) *Determination of SPF.* (i) Calculate an SPF value for each test subject (SPF_i) as follows:

$$SPFi = \frac{MEDp}{\text{final } MEDu}$$

(ii) Calculate the mean

$$\overline{SPF}\ (\overline{SPF})$$

and the standard deviation(s) from the SPF_i values. Calculate the standard error (SE), which equals $s/\sqrt{n}$ (where n equals the number of subjects who provided valid test results). Obtain the t value from Student's t distribution table corresponding to the upper 5-percent point with $n - 1$ degrees of freedom. Determine the SPF value that is equal to the largest whole number less than

$$\overline{SPF} - (t * SE).$$

In order for the SPF determination of a test product to be considered valid, the SPF value of the SPF standard must fall within the standard deviation range of the expected SPF (*i.e.,* 16.3 ± 3.43).

(8) *Determination of water resistance.* To support labeling claims of water resistance in accordance with paragraph (b) of this section, the following procedure must be performed in an indoor fresh water pool, whirlpool, and/or hot tub maintained at 23 to 32 °C. Fresh water is clean drinking water that meets the standards in 40 CFR part 141. The pool and air temperature and the relative humidity must be recorded.

(i) *Water resistance (40 minutes).* Determine the SPF value after 40 minutes of water immersion using the following procedure:

(A) *Step 1:* Apply the sunscreen test product as described in paragraph (i)(5) of this section.

(B) *Step 2:* Perform moderate activity in water for 20 minutes.

(C) *Step 3:* Rest out of water for 15 minutes. Do not towel test site(s).

(D) *Step 4:* Perform moderate activity in water for 20 minutes.

(E) *Step 5:* Allow test sites to dry completely without toweling.

(F) *Step 6:* Apply the SPF standard as described in paragraph (i)(5) of this section.

(G) *Step 7:* Expose test sites to UV doses as described in paragraph (i)(6) of this section.

(ii) *Water resistance (80 minutes).* Determine the SPF value after 80 minutes of water immersion using the following procedure:

(A) *Step 1:* Apply the sunscreen test product as described in paragraph (i)(5) of this section.

(B) *Step 2:* Perform moderate activity in water for 20 minutes.

(C) *Step 3:* Rest out of water for 15 minutes. Do not towel test site(s).

(D) *Step 4:* Perform moderate activity in water for 20 minutes.

(E) *Step 5:* Rest out of water for 15 minutes. Do not towel test site(s).

(F) *Step 6:* Perform moderate activity in water for 20 minutes.

(G) *Step 7:* Rest out of water for 15 minutes. Do not towel test site(s).

(H) *Step 8:* Perform moderate activity in water for 20 minutes.

(I) *Step 9:* Allow test sites to dry completely without toweling.

(J) *Step 10:* Apply the SPF standard as described in paragraph (i)(5) of this section.

(K) *Step 11:* Expose test sites to UV doses as described in paragraph (i)(6) of this section.

(j) *Broad spectrum testing*—(1) *UV Spectrometry*—(i) *Plate.* Use optical-grade polymethylmethacrylate (PMMA) plates suitable for UV transmittance measurements. The plate should be roughened on one side to a three-dimensional surface topography measure (Sa) between 2 and 7 micrometers and must have a rectangular application area of at least 16 square centimeters (with no side shorter than 4 cm).

(ii) *Sample holder.* The sample holder should hold the PMMA plate in a horizontal position to avoid flowing of the sunscreen product from one edge of the PMMA plate to the other. Mount the PMMA plate as close as possible to the input optics of the spectrometer to maximize capture of forward scattered radiation. The sample holder should be a thin, flat plate with a suitable aperture through which UV radiation can pass. Place the PMMA plate on the upper surface of the sample holder with the roughened side facing up.

(iii) *Light source.* The light source must produce a continuous spectral distribution of UV radiation from 290 to 400 nanometers.

(iv) *Input optics.* Unless the spectrometer is equipped with an integrating sphere, an ultraviolet radiation diffuser should be placed between the sample and the input optics of the spectrometer. The diffuser will be constructed from any UV radiation transparent material (*e.g.,* Teflon or quartz). The diffuser ensures that the radiation received by the spectrometer is not collimated. Set the spectrometer input slits to provide a bandwidth that is less than or equal to 5 nanometers.

(v) *Dynamic range of the spectrometer.* The dynamic range of the spectrometer should be sufficient to measure transmittance accurately through a highly absorbing sunscreen product at all terrestrial solar UV wavelengths (290 to 400 nm).

(2) *Sunscreen product application to PMMA plate.* The accuracy of the test depends upon the application of a precisely controlled amount of sunscreen product with a uniform distribution over the PMMA plate. The product is applied at 0.75 mg per square centimeter to the roughened side of the PMMA plate. The sunscreen product should be applied in a series of small amounts over the entire PMMA plate and then spread evenly using a gloved finger. Spreading should be done with a very light spreading action for approximately 30 seconds followed by spreading with greater pressure for approximately 30 seconds. The plate should then be allowed to equilibrate for 15 minutes in the dark before the pre-irradiation described in paragraph (j)(3) of this section.

(3) *Sunscreen product pre-irradiation.* To account for lack of photostability, irradiate the PMMA plate with a solar simulator described paragraph (i)(2) of this section. The irradiation dose must be 4 MEDs which is equivalent to an erythemal effective dose of 800 J/m² (*i.e.,* 800 J/m²-eff).

(4) *Calculation of mean transmittance values.* (i) After pre-irradiation, determine the mean transmittance values for each wavelength λ over the full UV spectrum (290 to 400 nanometers). Measure the transmittance values at 1 nanometer intervals. Measurements of spectral irradiance transmitted for each wavelength λ through control PMMA plates coated with 15 microliters of glycerin (no sunscreen product) must be obtained from at least five different locations on the PMMA plate [C1(λ), C2(λ), C3(λ), C4(λ), and C5(λ)]. In addition, a minimum of five measurements of spectral irradiance transmitted for each wavelength λ through the PMMA plate covered with the sunscreen product will be similarly obtained after pre-irradiation of the sunscreen product [P1(λ), P2(λ), P3(λ), P4(λ), and P5(λ)].

(ii) The mean transmittance for each wavelength is the ratio of the mean of the C(λ) values to the mean of the P(λ) values, as follows:

$$\overline{T(\lambda)} = \frac{\sum_{i}^{n} P(\lambda)/n}{\sum_{i}^{n} C(\lambda)/n}$$

Where

n ≥5

(5) *Calculation of mean absorbance values.* (i) Mean transmittance values,

$$\overline{T(\lambda)},$$

are converted into mean absorbance values,

$$\overline{A(\lambda)},$$

at each wavelength by taking the negative logarithm of the mean transmittance value as follows:

$$\overline{A(\lambda)} = -\log \overline{T(\lambda)}$$

(ii) The calculation yields 111 monochromatic absorbance values in 1 nanometer increments from 290 to 400 nanometers.

(6) *Number of plates.* For each sunscreen product, determine mean absorbance values from at least three individual PMMA plates. Because paragraph (j)(4) of this section requires at least 5 measurements per plate, there must be a total of at least 15 measurements.

(7) *Calculation of the critical wavelength.* The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. The following equation defines the critical wavelength:

$$\int_{290}^{\lambda c} A(\lambda)d\lambda = 0.9 \int_{290}^{400} A(\lambda)d\lambda$$

Where

λc = critical wavelength

A(λ) = mean absorbance at each wavelength

dλ = wavelength interval between measurements

(8) *Calculation of the UVA I/UV ratio.* The ratio of UVA I/UV is calculated as the area (per unit wavelength) under the UVA I portions of a plot of wavelength versus A(λ), divided by the area (per unit wavelength) under the total curve, as follows:

$$UVAI/UV = \frac{\int_{340}^{400} A(\lambda)d\lambda\, B(\lambda) / \int_{340}^{400} d\lambda}{\int_{290}^{400} A(\lambda)d\lambda\, B(\lambda) / \int_{290}^{400} d\lambda}$$

Where

A(λ) = effective absorbance given as -log T(λ)mean absorbance at each wavelength,

d(λ) = wavelength interval between measurements

B(λ) = any biological action spectrum factor

Because no appropriate biological action spectrum for UVA radiation damage has been universally accepted, no action spectrum is specified. The value of B(λ) is, therefore, equal to 1.0 for all wavelengths.

(9) *Determination of broad spectrum protection.* A product that has both a mean critical wavelength of 370 nm or

greater, calculated in accordance with paragraph (j)(7) of this section, and a mean UVA I/UV ratio of 0.70 or greater, calculated in accordance with paragraph (j)(8) of this section, is determined to pass the broad spectrum test.

(k) *Regulatory status of final formulation testing and related requirements.* Final formulation testing required under this section is considered a part of the manufacture of a sunscreen product. Therefore, final formulation testing required under this section must be performed in an establishment registered in accordance with part 207 of this chapter and section 510 of the Federal Food, Drug, and Cosmetic Act. Entities conducting final formulation testing required by this section must also comply with current good manufacturing practices (CGMPs) and associated recordkeeping requirements including those set forth in paragraph (*l*) of this section and in parts 210 and 211 of this chapter. Failure to comply with CGMPs or recordkeeping requirements will mean that any product labeled in reliance on that testing will be adulterated.

(l) *Recordkeeping.* Records required to be kept under this section must be maintained for at least 1 year after the expiration date of all products labeled in reliance on that testing or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137 of this chapter, 3 years after distribution of the last lot of drug product bearing labeling that relies on the testing. Recordkeeping requirements under this section may not be transferred. Maintenance records required to be kept under (l)(1) must be kept by the testing entity. Records of final formulation testing as described in paragraphs (l)(2) and (3) of this section must be kept by the responsible person and any entity that is performing final formulation testing required by this section on behalf of a responsible person pursuant to a transfer of obligations.

(1) *Maintenance records.* Entities performing final formulation testing are expected to maintain equipment in accordance with paragraph (k) of this section and, as applicable, parts 210 and 211 of this chapter. Maintenance records must be kept for all equipment used for final formulation testing under this section and must include:

(i) Documentation that equipment has been maintained in accordance with established written specifications as required by paragraph (k) of this section and parts 210 and 211 of this chapter; and

(ii) Documentation of characterization of UV sources including:

(A) Record of emission spectrum, total irradiance, and percent of erythema-effective radiation contribution required by paragraph (i)(2)(i) of this section;

(B) Record of each periodic measurement required by paragraph (i)(2)(iv) of this section for each solar simulator;

(C) Record of each calibration, realignment, or change in components of each solar simulator, or any changes to the broadband radiometer (or UV meter/dose control system), required by paragraph (i)(2)(iv) of this section; and

(D) Record of each solar simulator output measurement required by paragraph (i)(2)(ii)(C) of this section.

(2) *SPF testing records.* In addition to any records required to be kept pursuant to parts 210 and 211 of this chapter, records of SPF testing performed pursuant to paragraph (i) of this section must include:

(i) Identification of the entity that conducted the final formulation testing, including the name and address of the establishment(s) at which testing was carried out;

(ii) The sunscreen test product identifier and characterization of the formulation being tested, including lot number, manufacture date, and expected SPF;

(iii) Characterization of the SPF standard sunscreen required by paragraph (i)(3) of this section, including:

(A) Lot number;

(B) Manufacturing date; and

(C) Results of HPLC SPF standard assay that verify compliance with the concentrations of padimate O and oxybenzone in the SPF standard.

(iv) Documentation linking any blinded samples with the product identifier.

(v) For each human subject, records of:

(A) The identification of the UV source used for testing on that subject, including make, model, and serial number;

(B) Initial and final individual MED for unprotected skin (MED_u), and the identity of the study personnel who determined that value;

(C) Final MED for sunscreen test product protected skin ($_{tp}MED_p$), and the identity of the study personnel who determined that value;

(D) Final MED for SPF standard sunscreen protected skin ($_{ss}MED_p$), and the identity of the study personnel who determined that value; and

(E) Individual SPF_i values, including all valid test data and invalid test data for the test product and for the SPF standard sunscreen, and the identity of the study personnel who determined that value.

(vi) Records of the mean and standard deviation from SPF_i values, standard error, and determined SPF value derived as set forth in paragraph (i)(7) of this section.

(vii) Records for water resistance testing of pool temperature, air temperature, and relative humidity as required by paragraph (i)(8) of this section.

(viii) Records demonstrating compliance with paragraph (i)(1) of this section governing the establishment of adequate clinical testing procedures and conditions, including, but not limited to:

(A) *Case histories.* Responsible persons are required to prepare and maintain adequate and accurate case histories on each individual participant enrolled in SPF testing performed under paragraph (i) of this section. Case histories must record all observations and other data pertinent to the investigation. Case histories include the case report forms and supporting data (for example, signed and dated consent forms, medical records including progress notes of the physician, the individual's hospital chart(s), and the nurses' notes (if applicable)). The case history for each individual participant must document that informed consent was obtained pursuant to part 50 before each individual's participation in the study. Case histories as required by this section must include:

(*1*) Protocol deviations or injuries, if any; and

(*2*) Identification, by subject, of the study personnel who: Examined the potential study site areas, who weighed and applied the sunscreen, and who provided the UV irradiation.

(B) *IRB review.* Documentation that clinical research conducted pursuant to paragraph (i) of this section was reviewed and approved by a registered IRB as required by paragraph (i)(1)(iii) of this section.

(3) *Broad spectrum testing records.* Records of broad spectrum testing conducted pursuant to paragraph (j) of this section must include:

(i) Identification of the entity that conducted the final formulation testing, including the name and address of the establishment(s) at which testing was carried out;

(ii) Records of sample information, including:

(A) A sunscreen test product identifier and expected SPF. If the samples used in testing under paragraph (j) of this section are blinded, then records must include a master key that enables samples to be re-identified. In all other cases, records must include a

master key that links samples used to a sunscreen test product identifier.

(B) Sample number;

(C) Identifier code;

(D) Measurement of PMMA plate surface topography in micrometers; and

(E) Sample holder orientation (vertical or horizontal).

(iii) Identification of each UV source used for sunscreen product pre-irradiation, including make, model, and serial number.

(iv) Records of sunscreen product application, including:

(A) A record of all sample weights, including analytical balance; and

(B) For all equipment used; make, model, and serial number;

(v) For each sample, all measurements required by paragraphs (j)(4) to (6) of this section.

(vi) For each sample, records of critical wavelength and the UVA I/UV ratio values required by paragraphs (j)(7) and (8) of this section.

(vii) For each sample: The identity of the study personnel who weighed and applied the sunscreen to the PMMA plates; the identity of the study personnel who provided the pre-irradiation; and the identity of the study personnel, or, if calculated by software, what software, calculated the mean transmittance, mean absorbance values, critical wavelength, and UVA I/UV.

(viii) For each sample, the test dates for the broad spectrum test conducted pursuant to paragraph (j) of this section, and sample report forms and supporting data including, for example, spectral data, Excel files containing transmittance or absorbance values, or any notes from the lab investigator.

(4) *Food and Drug Administration (FDA) inspection of records*—(i) *Testing entity.* Anentity performing final formulation testing under this section, including a responsible person or an entity that has been transferred any obligations of a responsible person under this section, must, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports of testing pursuant to this section. The testing entity is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

(ii) *Responsible persons.* A responsible person must upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to and copy and verify any records and reports relating to final formulation testing conducted under this section. Upon written request by FDA, the responsible person must submit the records or reports (or copies of them) to FDA. The responsible person must discontinue from further participation in final formulation testing required by this section any investigator who has failed to maintain or make available records or reports of the investigation as required by this paragraph (l).

PART 310—NEW DRUGS

■ 3. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–l; 42 U.S.C. 216, 241, 242(a), 262.

§ 310.545 [Amended]

■ 4. Amend § 310.545 by removing and reserving paragraphs (a)(29) and (d)(31),and (40).

■ 5. Add § 310.549 to subpart E to read as follows:

§ 310.549 Drug products offered over-the-counter (OTC) for use as sunscreen.

(a) Any drug product offered OTC for use as sunscreen and identified in any of paragraphs (b) through (i) of this section is not generally recognized as safe and effective and is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, for which an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application, such product is also misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act. Products offered OTC for use as sunscreen include those represented, labeled, or promoted as sunscreen, or for use to help prevent sunburn, skin cancer, and/or skin aging caused by the sun, or with similar claims or representations. Clinical investigations designed to obtain evidence that any sunscreen drug product covered by this section is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(b) A sunscreen drug product that contains any of the following ingredients:

(1) Diethanolamine methoxycinnamate

(2) Digalloyl trioleate

(3) Ethyl 4-[bis(hydroxypropyl)] aminobenzoate

(4) Glyceryl aminobenzoate

(5) Lawsone with dihydroxyacetone

(6) Red petrolatum

(7) Trolamine salicylate

(8) Aminobenzoic acid

(9) Avobenzone

(10) Cinoxate

(11) Dioxybenzone

(12) Ensulizole

(13) Homosalate

(14) Meradimate

(15) Octinoxate

(16) Octisalate

(17) Octocrylene

(18) Oxybenzone

(19) Padimate O

(20) Sulisobenzone

(c) A sunscreen drug product that has a determined sun protection factor (SPF) value, as defined in § 352.3(d) of this chapter, of at least 15 when tested in accordance with § 201.327(i) of this chapter, but that has not been shown to pass the broad spectrum test in § 201.327(j) of this chapter.

(d) A sunscreen drug product that has a determined sun protection factor (SPF) value, as defined in § 352.3(d) of this chapter, of less than 2 or greater than 80 when tested in accordance with § 201.327(i) of this chapter.

(e) A sunscreen drug product that has a determined sun protection factor (SPF) value, as defined in § 352.3(d) of this chapter, of less than 15 when tested in accordance with § 201.327(i) of this chapter and/or that does not pass the broad spectrum test in § 201.327(j) of this chapter, and labeled with any of the following or similar claims:

(1) Decreases the risk of skin cancer caused by the sun; or

(2) Decreases the risk of early skin aging caused by the sun.

(f) A sunscreen drug product labeled with any of the following or similar claims:

(1) Instant protection or protection immediately upon application; or

(2) Claims for ''all-day'' protection or extended wear claims citing a specific number of hours of protection that is inconsistent with the directions for application in § 201.327 of this chapter.

(g) A sunscreen drug product that is labeled, represented, or promoted for use as a combined sunscreen-insect repellant.

(h) A sunscreen drug product that is in any dosage form other than the following: Oil, lotion, cream, gel, butter, paste, ointment, stick, or spray.

(i) A sunscreen drug product in a spray dosage form that has any of the following properties:

(1) The product meets the definition of the term ''extremely flammable'' as

defined at § 352.3(f) of this chapter when tested in accordance with 16 CFR 1500.43a;

(2) More than 10 percent of the particles dispensed from the consumer container are smaller than 10 micrometers;

(3) Any of the particles dispensed from the consumer container are smaller than 5 micrometers; or

(4) The product meets the definition of either the term ''flammable'' or the term ''combustible'' as defined at §§ 352.3(g) or (h) of this chapter, as applicable, when tested in accordance with 16 CFR 1500.43a and has a measured drying time of 10 minutes or more.

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 6. The authority citation for part 347 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 7. Amend § 347.20 by lifting the stay on paragraph (e) (previously paragraph (d), redesignated at 74 FR 9765, March 6, 2009) and revising paragraph (e) to read as follows:

§ 347.20 Permitted combinations of active ingredients.

* * * * *

(e) *Combinations of skin protectant and sunscreen active ingredients.* Any one (two when required to be in combination) or more of the skin protectant active ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) of this chapter may be combined with any single sunscreen active ingredient identified in § 352.10 of this chapter, or any permitted combination of these ingredients identified in § 352.20 of this chapter, provided the product meets the conditions in § 352.20(b) of this chapter and is labeled according to §§ 347.60 and 352.60 of this chapter.

■ 8. Amend § 347.60 by revising paragraphs (a), (b)(3), (c)(1), and (d)(1) to read as follows:

§ 347.60 Labeling of permitted combinations of active ingredients.

* * * * *

(a) *Statement of identity.* (1) Except as set forth in paragraph (a)(3) of this section, for a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(2) Except as set forth in paragraph (a)(3) of this section, for a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(3) For a product containing a combination of skin protectant and sunscreen active ingredients, the labeling of the product bears the statement of identity set forth in § 352.60(a) of this chapter.

(b) * * *

(3) *Combinations of skin protectant and sunscreen active ingredients in § 347.20(e).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(2)(i) of this chapter, the required indications for sunscreen drug products in § 352.60(b) of this chapter must be used and any or all of the additional indications for sunscreen drug products may be used.

(c) * * *

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(e) and 352.20(b).* The warnings in § 352.60(c) of this chapter are used.

* * * * *

(d) * * *

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(e) and 352.20(b).* The directions in § 352.60(d) of this chapter are used.

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PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 9. The authority citation for part 352 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 10. Lift the stay of 21 CFR part 352.

§ 352.1 [Amended]

■ 11. In paragraph (a), remove the words ''in a form suitable for topical administration''.

■ 12. Revise § 352.3 to read as follows:

§ 352.3 Definitions.

As used in this part:

(a) [Reserved]

(b) [Reserved]

(c) *Sunscreen active ingredient.* An active ingredient listed in § 352.10 that absorbs, reflects, or scatters radiation in the ultraviolet (UV) range at wavelengths from 290 to 400 nanometers.

(d) *Determined sun protection factor (SPF) value.* The SPF value that equals the largest whole number less than $\overline{SPF} - (t * SE)$, determined for a sunscreen product in accordance with § 201.327(i) of this chapter.

(e) *Labeled sun protection factor (SPF) value.* The SPF value associated with the range into which the determined SPF value falls, as set forth in the table in § 201.327(b)(2)(i) of this chapter.

(f) *Extremely flammable.* The term ''extremely flammable'' applies to any product that has a flashpoint at or below 20 °F (−6.7 °C) as determined by the test method described at 16 CFR 1500.43a, except that any product having one component or more with a flashpoint higher than 20 °F (−6.7 °C) that comprises at least 99 percent of the total volume of the product is not considered to be extremely flammable.

(g) *Flammable.* The term ''flammable'' applies to any product that has a flashpoint above 20 °F (−6.7 °C) and below 100 °F (37.8 °C) as determined by the test method described at 16 CFR 1500.43a, except that:

(1) Any product having one component or more with a flashpoint at or above 100 °F (37.8 °C) that comprises at least 99 percent of the total volume of the product is not considered to be flammable; and

(2) Any product containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be flammable if the product does not present a significant flammability hazard when used by consumers.

(h) *Combustible.* The term ''combustible'' applies to any product having a flashpoint at or above 100 °F (37.8 °C) to and including 150 °F (65.6 °C) as determined by the test method described at 16 CFR 1500.43a, except that:

(1) Any product having one component or more with a flashpoint higher than 150 °F (65.6 °C) that comprises at least 99 percent of the total volume of the product is not considered to be combustible; and

(2) Any product containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be combustible if the product does not present a significant flammability hazard when used by consumers.

■ 13. Add § 352.5 to subpart A to read as follows:

§ 352.5 Sun protection factor related conditions.

(a) The product has a determined SPF value of at least 2 but no greater than 80.

(b) If the product has a determined SPF value of at least 15, it also passes

the broad spectrum test in § 201.327(j) of this chapter.

■ 14. Revise § 352.10 to read as follows:

§ 352.10 Sunscreen active ingredients.

The active ingredient of the product consists of any of the following, under the conditions specified, including being within the concentration specified for each ingredient:

(a) through (o) [Reserved]

(p) Titanium dioxide up to 25 percent

(q) [Reserved]

(r) Zinc oxide up to 25 percent.

■ 15. Revise § 352.20 to read as follows:

§ 352.20 Permitted combinations of active ingredients.

The determined SPF of any product containing a sunscreen active ingredient is measured by the testing procedures established in § 201.327(i) of this chapter.

(a) *Combinations of sunscreen active ingredients.* Two or more sunscreen active ingredients identified in § 352.10 may be combined with each other in a single sunscreen product if all of the following conditions are met:

(1) Each sunscreen active ingredient in the product must satisfy the conditions established for its use in § 352.10.

(2) The concentration of each sunscreen active ingredient must be sufficient to contribute a minimum determined SPF of not less than 2 to the finished product.

(3) The finished product must have a minimum determined SPF of not less than the number of sunscreen active ingredients used in the product multiplied by 2.

(b) *Combinations of sunscreen and skin protectant active ingredients.* Any single sunscreen active ingredient identified in § 352.10 or any combination of sunscreen active ingredients permitted under paragraph (a) of this section may be combined with one or more skin protectant active ingredients identified in §§ 347.10(a), (d), (e), (g), (h), (i), (k), (*l*), (m), and (r) of this chapter when all of the following conditions are met:

(1) Each sunscreen active ingredient in the product must satisfy the conditions established for its use in § 352.10.

(2) The concentration of each sunscreen active ingredient must be sufficient to contribute a minimum determined SPF of not less than 2 to the finished product.

(3) The finished product must have a minimum determined SPF of not less than the number of sunscreen active ingredients used in the product multiplied by 2.

(4) The product must be labeled according to § 201.327(h) of this chapter and § 352.60.

(c) [Reserved]

■ 16. Add § 352.30 to subpart B to read as follows:

§ 352.30 Route of administration.

The product is intended for topical administration.

■ 17. Add § 352.40 to subpart B to read as follows:

§ 352.40 Dosage forms.

The product is in one of the following dosage forms and meets any additional conditions specified:

(a) Oil.

(b) Lotion.

(c) Cream.

(d) Gel.

(e) Butter.

(f) Paste.

(g) Ointment.

(h) Stick.

(i) Spray, provided that all of the following conditions are satisfied:

(1) Size of particles as dispensed from the consumer container:

(i) No more than 10 percent of the particles dispensed from the consumer container are smaller than 10 micrometers; and

(ii) None of the particles dispensed from the consumer container are smaller than 5 micrometers.

(2) The product does not meet the definition of the term ''extremely flammable'' as defined in § 352.3(f).

(3) If the product meets the definition of either the term ''flammable'' or the term ''combustible'' as defined at §§ 352.3(g) or (h), as applicable, when tested in accordance with 16 CFR 1500.43a, the product also has a measured drying time of less than 10 minutes.

(4) The product is labeled as required by §§ 201.327(d) and (e)(5) of this chapter.

(5) Testing in accordance with part 211 of this chapter must confirm that the product meets the conditions for particle size, flammability, and drying time as required by this section and reflected in the product labeling.

(i) Testing of each lot of product for size of particles dispensed from the consumer container must be conducted in accordance with adequate written specifications.

(ii) Flammability testing for each batch of product must be conducted in accordance with the specifications set forth in 16 CFR 1500.43a.

(iii) If the product meets the definition of either the term ''flammable'' or ''combustible'' as defined at § 352(g) or (h), as applicable, when tested accordance with 16 CFR 1500.43a, drying time for each lot of product must be conducted in accordance with adequate written specifications.

■ 18. Revise § 352.50 to read as follows:

§ 352.50 Principal display panel of all sunscreen drug products.

The principal display panel labeling must comply with § 201.327(b) of this chapter.

■ 19. Revise § 352.52 to read as follows:

§ 352.52 Labeling of products containing one or more sunscreen active ingredients.

(a) *Statement of identity.* The labeling of the product contains the statement of identity, in accordance with § 201.327(b) of this chapter.

(b) *Indications.* The labeling of the product contains the indication statements identified in § 201.327(c) of this chapter, as appropriate, and subject to the conditions stated therein.

(c) *Warnings.* The labeling of the product contains the warnings in § 201.327(d) of this chapter, as applicable, under the heading ''Warnings:''

(d) *Directions.* The labeling of the product contains the statements in § 201.327(e) of this chapter, as applicable, under the heading ''Directions.''

(e) *Other information.* The labeling of the product contains the statement in § 201.327(f) of this chapter under the heading ''Other information.''

(f) *False or misleading claims.* The labeling of the product must not contain any claims that would be false and/or misleading on sunscreen products, as outlined in § 201.327(g) of this chapter.

■ 20. Revise § 352.60 to read as follows:

§ 352.60 Labeling of products containing a combination of sunscreen and skin protectant active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Labeling provisions in § 347.50(e) of this chapter shall not apply to these products.

(a) *Statement of identity.* The labeling of the product bears the statement of identity, as set forth in § 201.327(h)(1) of this chapter.

(b) *Indications.* The labeling of the product states, under the heading ''Uses,'' the applicable indication statements, as set forth in § 201.327(h)(2) of this chapter.

(c) *Warnings.* The labeling of the product states, under the heading

''Warnings,'' the applicable warning statements, as set forth in § 201.327(h)(3) of this chapter.

(d) *Directions.* The labeling of the product states, under the heading ''Directions,'' the applicable direction statements, as set forth in § 201.327(h)(4) of this chapter.

■ 21. Revise subpart D to read as follows:

Subpart D—Final Formulation Testing

Sec.
352.70 SPF testing.
352.80 Broad spectrum testing.

Subpart D—Final Formulation Testing

§ 352.70 SPF testing.

The product is tested in accordance with § 201.327(i) of this chapter.

§ 352.80 Broad spectrum testing.

If the product's determined SPF value is at least 15, the product is tested and shown to pass the broad spectrum test in § 201.327(j) of this chapter.

Dated: February 14, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Listing the Scarlet Macaw; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R9–ES–2012–0039; 4500030113]

RIN 1018–BC81

Endangered and Threatened Wildlife and Plants; Listing the Scarlet Macaw

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine the northern subspecies of scarlet macaw (*Ara macao cyanoptera*) is an endangered species under the Endangered Species Act of 1973 (Act), as amended; the northern distinct population segment (DPS) of the southern subspecies of scarlet macaw (*A. m. macao*) is a threatened species under the Act, and the southern DPS of the southern subspecies of scarlet macaw (*A. m. macao*) and subspecies crosses (*A. m. cyanoptera* and *A. m. macao*) to be threatened species based on similarity of appearance. We are also establishing a rule pursuant to section 4(d) of the Act for the *A. m. macao* subspecies and subspecies crosses to provide for its further conservation.

DATES: This rule is effective March 28, 2019.

ADDRESSES: Comments and materials we received, as well as supporting documentation used in preparation of this rule, are available for public inspection at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Don Morgan, Chief, Branch of Delisting and Foreign Species, Ecological Services Program, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS:ES, Falls Church, VA 22041; telephone 703–358–2444. If you use a telecommunications device for the deaf (TDD), you 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 protection through listing if it is endangered or threatened throughout all or a significant portion of its range. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

On July 6, 2012, we published in the **Federal Register** (FR) a 12-month finding on a petition to list the scarlet macaw. We determined the scarlet macaw (*A. m. macao*) did not warrant listing under the Act at the species level but found the northern subspecies of scarlet macaw (*Ara macao cyanoptera*) and the northern distinct population segment (DPS) of the southern subspecies (*A. m. macao*) warranted listing and issued a proposed rule to list those entities as endangered under the Act (77 FR 40222). On April 7, 2016, we published a revised proposed rule (81 FR 20302) maintaining the proposed endangered status for *A. m. cyanoptera,* but (1) revising the proposed listing determination for the northern DPS of the southern subspecies (*A. m. macao*) from endangered to threatened; and (2) proposing to treat the southern DPS of *A. m. macao* and subspecies crosses as threatened based on similarity of appearance to *A. m. cyanoptera* and the northern DPS of *A. m. macao.* We also proposed a rule under section 4(d) of the Act (a ''4(d) rule'') that incorporated the prohibitions and provisions of 50 CFR 17.31 and 17.32 that we found necessary and advisable for the species' conservation.

This rule lists the northern subspecies of scarlet macaw (*A. m. cyanoptera*) as an endangered species, the northern DPS of the southern subspecies of scarlet macaw (*A. m. macao*) as a threatened species, and the southern DPS of the southern subspecies of scarlet macaw (*A. m. macao*) and subspecies crosses (*A. m. cyanoptera* and *A. m. macao*) as a threatened species due to similarity of appearance under the Act. This rule also establishes a 4(d) rule for those listed as threatened species to further provide for the species' conservation.

The basis for our action. Under section 4(a)(1) of the Act, we determine that a species is an endangered or threatened species based on any of the following 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. The primary causes attributed to the decline of the scarlet macaw (*A. m. cyanoptera* and *A. m. macao*) include habitat loss and forest degradation (Factor A), poaching for the pet trade (Factor B), lack of enforcement of existing regulations (Factor D), and small population size (Factor E).

Section 4(d) of the Act authorizes the Secretary of the Interior (Secretary) to extend to threatened species the prohibitions provided for endangered species under section 9 of the Act. For threatened species, section 4(d) of the Act gives the Service discretion to specify the prohibitions and any exceptions to those prohibitions that are appropriate for the species, as well as include provisions that are necessary and advisable to provide for the conservation of the species. A rule issued under section 4(d) of the Act allows us to include provisions that are tailored to the specific conservation needs of that threatened species.

Our implementing regulations for threatened wildlife found at 50 CFR 17.31 incorporate the section 9 prohibitions for endangered wildlife, except where a species-specific rule is promulgated under 4(d) of the Act. While we proposed to rescind this provision last summer (83 FR 35174; July 25, 2018), that proposal has not been finalized at this time.

Peer review and public comment. We sought comments from independent specialists to ensure that our designation is based on scientifically sound data, assumptions, and analyses. We invited peer reviewers and the public to comment on our listing proposals. All substantive information from peer review and public comments was fully considered and is incorporated into this final rule, where appropriate.

Previous Federal Actions

Please refer to the proposed listing rule, published in the **Federal Register** on July 6, 2012 (77 FR 40222), for more comprehensive information on previous Federal actions for the scarlet macaw. The publication of the proposed listing rule opened a 60-day public comment period, which closed on September 4, 2012. Based on new information, we published a revised proposed rule (81 FR 20302; April 7, 2016) to make the following changes to our proposed rule: (1) Revise the location of what we consider to be the boundary between the two subspecies of *A. macao;* (2) provide additional information on the species in northeast Costa Rica, southeast Nicaragua, and Panama, and reevaluating the status of *A. m. cyanoptera;* (3) provide additional information on the northern DPS of *A. m. macao,* reevaluating the status of this DPS, and revise our proposed listing of this DPS from endangered status to threatened status; (4) add a proposal to treat the southern DPS of *A. m. macao* and subspecies crosses (*A. m. macao* and *A. m. cyanoptera*) as threatened based on similarity of appearance to *A. m. cyanoptera* and to the northern DPS of *A. m. macao;* and

(5) add a proposed rule pursuant to section 4(d) of the Act (16 U.S.C. 1531 *et seq.*) to define the prohibitions and exceptions that apply to scarlet macaws listed as threatened. That revised proposed rule also opened a 60-day public comment period, which closed on June 6, 2016.

Summary of Changes From the Revised Proposed Rule

In this final rule, and based on public comments, we incorporate additional information regarding the distribution of scarlet macaws in Mesoamerica (Mexico and Central America). Specifically, we include information pertaining to reintroduction programs occurring throughout the range of *Ara macao cyanoptera,* and we include information that indicates the populations in Costa Rica in the northern DPS of the southern subspecies of scarlet macaw (*A. m. macao*) are likely increasing.

We also took into account the relevant information from eBird into our analysis regarding the distribution of the species.

Summary of Comments and Recommendations

We reviewed all comments we received from peer reviewers and the public for substantive issues and new information. All substantive information from peer review and public comments has been fully considered and is incorporated into this final rule, where appropriate.

We received 282 public comments combined on the proposed and revised proposed rules to list the scarlet macaw under the Act during their respective comment periods. Some of the comments we received were similar to comments that we received previously for the proposed rule; therefore, we only address these comments once in this final rule. See the Substantive Changes to the Proposed Rule section in the revised proposed rule (81 FR 20302; April 7, 2016).

The following section summarizes information and issues raised in the public comments and provides our responses.

Comment (1): Several commenters stated that listing the scarlet macaw will hurt U.S. businesses such as aviculture, pet food and supply companies, and veterinarians.

Our Response: Determinations on whether a species should be added to the Federal Lists of Endangered and Threatened Wildlife and Plants are based on whether the species meets the definition of ''endangered species'' or of ''threatened species'' in section 3 of the Act. The Act directs the Service to make these determinations solely on the basis of the best scientific and commercial data available. Therefore, we may not consider economic impacts when determining the status of a species. We understand that listing the scarlet macaw will have an effect on those involved in the pet bird industry, especially bird breeders. The 4(d) rule that we are putting in place streamlines the permitting process by extending certain prohibitions but deferring to existing laws (CITES and the Wild Bird Conservation Act (WBCA) that are protective of scarlet macaws (*A. m. macao* and subspecies crosses) in the course of import and export and by not requiring permits under the Act for certain types of activities. Additionally, we are not prohibiting the interstate commerce of scarlet macaws (*A. m. macao* and subspecies crosses) within the United States (see 4(d) Rule, below).

Comment (2): Several commenters stated that reducing the availability of captive birds by listing the species under the Act may lead to an increase of wild-caught birds for the pet trade.

Our Response: We do not anticipate that listing the scarlet macaw under the Act will further reduce the availability of captive birds or lead to an increase of wild-caught birds for the pet trade. The scarlet macaw is listed in Appendix I of CITES, which is an international agreement among governments to ensure that the international trade of CITES-listed plants and animals does not threaten the survival of the species in the wild. Trade must be authorized through a system of permits and certificates that are issued by the designated CITES Scientific and Management Authorities of each CITES Party. For species included in CITES Appendix I, international trade is permitted only under exceptional circumstances, which generally precludes commercial trade. The United States implements CITES through the Act and our implementing regulations at 50 CFR part 23. It is unlawful for any person subject to the jurisdiction of the United States to engage in any trade in any specimens contrary to the provisions of CITES, or to possess any specimens traded contrary to the provisions of CITES, the Act, or our implementing regulations at 50 CFR part 23. Protections for CITES-listed species are provided independently of whether a species is an endangered species or a threatened species under the Act.

Two other laws in the United States apart from the Act also already provide protection from the illegal import of wild-caught birds into the United States: The WBCA and the Lacey Act (18 U.S.C. 42–43; 16 U.S.C. 3371–3378). The WBCA ensures that exotic bird species are not harmed by international trade and encourages wild bird conservation programs in countries of origin. Under the WBCA and our implementing regulations (50 CFR 15.11), it is unlawful to import into the United States any exotic bird species listed under CITES except under certain circumstances. The Service may issue permits to allow import of listed birds for scientific research, zoological breeding or display, cooperative breeding, or personal pet purposes, when the applicant meets certain criteria (50 CFR 15.22–15.25). Under the Lacey Act, in part, it is unlawful: (1) To import, export, transport, sell, receive, acquire, or purchase any fish, or wildlife taken, possessed, transported, or sold in violation of any law, treaty, or regulation of the United States or in violation of any Indian tribal law; or (2) to import, export, transport, sell, receive, acquire, or purchase in interstate or foreign commerce any fish or wildlife taken, possessed, transported, or sold in violation of any law or regulation of any State or in violation of any foreign law. Similarly, under the Lacey Act it is unlawful to import, export, transport, sell, receive, acquire, or purchase specimens of this species traded contrary to CITES.

Based in large part on the protection from illegal and legal trade afforded to the scarlet macaw by CITES, the WBCA, and the Lacey Act, the best available data indicate that the current threat from trade to the scarlet macaw stems mainly from illegal trade in the domestic markets within Central and South America (Weston and Memon 2009, pp. 77–80; Shanee 2012, pp. 4–9). Additionally, interstate commerce within the United States is not a current threat to the scarlet macaw and will not affect any efforts to recover wild populations. Therefore, we do not anticipate that listing the scarlet macaw under the Act will further reduce the availability of captive-bred birds or lead to an increase of wild-caught birds since those birds are already regulated by existing laws. This 4(d) rule, in large part, adopts the framework of those laws.

Comment (3): Several commenters stated that at least 25 States adopt the Federal Lists of Endangered and Threatened Wildlife and Plants to their State list, which they claim would make it illegal to possess scarlet macaws or its feathers. The commenters stated that these laws do not include ''grandfathering,'' which means that those who have scarlet macaws prior to the listing and live in one of these States would be in violation of the law immediately once the listing is effective.

Our Response: Ownership of a listed species is not prohibited by the Act and therefore, does not require a permit. We further note that, under section 9(b)(1) it is not unlawful to import or export a scarlet macaw that was held in captivity prior to the date of this final rule provided that its holding was not in the course of commercial activity. Further, while we have certainly not conducted an in-depth study on the various provisions of state law, we observe that under Article I of the United States Constitution, retroactive application of a law is permitted only in extraordinary cases. *Ex post facto* laws (or laws that criminalize conduct that was legal when originally performed) are generally prohibited. However, we acknowledge that we have no discretion over regulations that certain States implement regarding federally listed wildlife and plants.

Comment (4): A few commenters stated that breeders and pet owners in the United States have been supplying feathers through sales or trade to Native American artisans, and the Service should find a way to accommodate feather and art sales within the United States because these artisans make ceremonial products to support themselves and their tribes.

Our Response: The 4(d) rule will apply to all commercial and noncommercial international shipments of live and dead scarlet macaws, the southern subspecies of *A. m. macao* and subspecific crosses (*A. m. macao* and *A. m. cyanoptera*), and their parts and products, including the import and export of personal pets and research samples. In most instances, the 4(d) rule adopts existing regulatory requirements of CITES and the WBCA as the appropriate regulatory provisions for the import and export of scarlet macaws. Under the 4(d) rule, a person may deliver, receive, carry, transport, or ship *A. m. macao* and subspecies crosses in interstate commerce in the course of a commercial activity, or sell or offer to sell in interstate commerce without a permit under the Act (see 4(d) rule, below). Therefore, the 4(d) rule would allow individuals to engage in certain commercial activities with *A. m. macao* and subspecies crosses that could provide Tribal artisans materials to make their products.

The 4(d) rule does not include subspecies *A. m. cyanoptera* that is listed as endangered, and therefore, all the prohibitions of 50 CFR 17.31 apply to this subspecies. While the Act does not prohibit intrastate (within a state) sale of a listed species, it does prohibit interstate (between states) commercial sale, unless a buyer obtains a permit. Permits for prohibited activities, such as interstate sale, import and export, can be issued for endangered species if the activities enhance the propagation or survival of the species in the wild. Additionally, a breeder could obtain a Captive-bred Wildlife Registration (CBW), which would authorize interstate commerce. However, it must be shown that the sale enhances the propagation or survival of the affected species and the principal purpose is to facilitate conservation breeding and not for the sale of protected species as pets.

Comment (5): Several commenters stated that the Endangered Species Act is designed to protect domestic species only, and listing scarlet macaws under the Act does not address the main cause of decline for the species, which is habitat destruction in the species' native countries.

Our Response: The broad definitions of ''species,'' ''fish or wildlife,'' and ''plant'' in section 3 of the Act do not differentiate between species native to the United States, species native to both the United States and one or more other countries, and species not native to the United States. Further, sections 4(b)(1)(A) and 4(b)(1)(B)(i) expressly require the Service to consider efforts by a foreign nation prior to making a listing determination. Additionally, the findings and purposes at sections 2(a)(4), 2(a)(5), and 2(b) also speak to the application of the Act to meet the United States international commitments under treaties and conventions, and numerous provisions of the Act and the implementing regulations refer to foreign jurisdictions (*e.g.,* sections 8 and 8A of the Act, 50 CFR 424.11(e)). As such, we have no basis to determine the protections of the Act only apply to domestic species. However, we acknowledge that we do not have authority to directly regulate activities in a foreign country that may cause the species to be endangered or threatened.

Comment (6): Several commenters stated that there is no benefit to listing scarlet macaws under the Act because the species is already sufficiently protected by CITES and the WBCA.

Our Response: The decision to list a species under the Act is based on whether the species meets the definition of an endangered or threatened species as defined under section 3 of the Act and is made solely on the basis of the best scientific and commercial data available. The purpose of the WBCA is to ensure that exotic bird species are not harmed by international trade and encourages wild bird conservation programs in countries of origin. The purpose of CITES is to ensure that international trade in plants and animals does not threaten their survival in the wild. Protection provided by other laws, such as CITES and WBCA, is taken into consideration when determining the status of the species. However, simply being protected by these other laws does not preclude the requirement to list and provide additional protections under the Act where the species meets the definition of a threatened or endangered species. Further, the standards for listing under each legal regime are different, and the protections afforded to species listed under each legal regime are different, though they can overlap in some respects. While CITES regulates the international trade of certain wildlife, it has limited regulatory authority once the species enters the United States for activities that take place within the United States, though there are restrictions on use after import for some specimens, especially Appendix I specimens. Listing under the Act helps ensure that the United States and its citizens do not contribute to the further decline of the species.

Conservation measures or benefits provided to foreign species listed as endangered or threatened under the Act include recognition, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and may encourage and result in conservation actions by foreign governments, Federal and State governments, private agencies and interest groups, and individuals.

Comment (7): Several commenters noted that the International Union for Conservation of Nature (IUCN) classifies the scarlet macaw as ''least concern;'' and therefore, listing under the Act is not warranted.

Our Response: The decision to list a species under the Act is based on whether the species meets the definition of an endangered or threatened species as defined under section 3 of the Act and is made solely on the basis of the best scientific and commercial data available. The IUCN uses different standards and criteria and the designations are not interchangeable. Within certain countries, particularly in the range of *A. m. cyanoptera,* the subspecies is considered in danger of extinction or on a country's list of threatened or endangered species (Government of Mexico 2010a, p. 64; (Biodiversity and Environmental Resource Data System of Belize 2012, unpaginated; Meerman 2005, p. 30; (Government of Guatemala 2001, p. 15; Secretaria de Recursos Naturales y Ambiente. 2008, p. 62). However,

because of the relatively good status of the species in the Amazon, which accounts for the majority of the species range and population, and the scarlet macaw's relative tolerance of degraded and fragmented habitat (BLI 2011c, unpaginated), we found the scarlet macaw did not warrant listing under the Act rangewide at the species level (*A. m. macao*). The IUCN classified this entity—the overall species—as ''Least Concerned.''

Comment (8): A few commenters questioned our decision in the revised proposed rule to change the northern DPS of the southern subspecies of scarlet macaw (*A. m. macao*) from endangered to threatened. The commenters assert that because we revised the boundaries and now attribute the population on Isla Coiba, Panama, to be part of the northern subspecies (*A. m. cyanoptera*), the decline in the number of known populations for the northern DPS of *A. m. macao* does not warrant a reversal of the Service's prior determination. It indicates a reduction in the number of populations; therefore, the DPS is now at a greater risk of extinction.

Our Response: The northern DPS of the southern subspecies, *A. m. macao,* consists of two main populations in Costa Rica, the Central Pacific Costa Rica (Área de Conservación Pacífico Central (ACOPAC)) and South Pacific Costa Rica (Área de Conservación Osa (ACOSA)) populations that are likely stable or increasing Vaughan *et al.* 2005, p. 128; Dear *et al.* 2010, p. 20; Brightsmith 2016, *in litt.,* pp. 10–13) and consist of 1,000 to 2,000 birds; a group of at least 14–25 birds in Palo Verde (Brightsmith 2016, *in litt.,* p. 14; Dear *et al.* 2010, p. 8) in northwest Costa Rica, along with scattered sightings of scarlet macaws from Palo Verde National Park south to Carara National Park and throughout western Guanacaste (Brightsmith 2016, *in litt.,* p. 14); small groups of captive-released birds in some locations within the Costa Rica portion of the DPS; small populations in northwestern Panama in the Chiriquí province (Brightsmith 2016, *in litt.,* p. 17; Sullivan *et al.* 2009, unpaginated), and an unknown number on the southern end of the Azuero Peninsula of Veraguas, near Cerro Hoya National Park (Brightsmith 2016, *in litt.,* p. 17; Sullivan *et al.* 2009, unpaginated; Rodriguez and Hinojosa 2010, in McReynolds 2011, *in litt.,* unpaginated); and an unknown but likely small number of birds in northwest Colombia. Thus, although the two largest populations currently appear to be increasing and appear stable even with ongoing poaching pressure, they both are small and their total range represents only a portion of the range. Northwest Colombia has large tracts of suitable habitat capable of supporting a population (although we have no information about the current population estimate for northwest Colombia). However, because current threats to scarlet macaws are ongoing, enforcement of existing regulations is inadequate, and the population sizes of scarlet macaws in this region are small, we reaffirm our determination that the northern DPS of *A. m. macao* is threatened in accordance with the definition in the Act.

Comment (9): Several commenters stated that by listing the northern subspecies of scarlet macaw (*A. m. cyanoptera*) as endangered, bird owners will not be able to sell birds, and if they cannot sell birds they will not breed birds or will breed hybrids to get around the listing. Thus, the gene pool for *A. m. cyanoptera* will be reduced, if not be eliminated.

Our Response: Commenters responding to the 2012 proposed rule (77 FR 40222; July 6, 2012) noted that aviculturists have bred the species without regard for taxa, resulting in crosses of the two subspecies (*A. m. cyanoptera* and *A. m. macao*). Therefore, the best available information indicates that pet scarlet macaws may be bred with little regard for genetics and include an unknown number of subspecies crosses, regardless of whether the species is listed under the Act (Schmidt 2013, pp. 74–75). The Act does not prohibit intrastate (within a state) sale of a listed species so bird owners could sell birds within state, but because *A. m. cyanoptera* is listed as endangered, interstate (between states) commercial sale is prohibited without a permit. We do not believe that the gene pool will be reduced or eliminated because while some scarlet macaws in captivity in the United States will be a mixture of subspecies, it is possible to determine with genetic techniques where individual scarlet macaws have come from and whether or not they are from one pure single subspecies or a mix of subspecies (Brightsmith 2016, *in litt.,* p. 23).

Comment (10): Several commenters stated that we dismiss the benefit of captive-bred scarlet macaws, which may be used to repopulate the population if a major natural, biological, or manmade disaster occurs in the native habitat of the species, and to educate and raise awareness for the species.

Our Response: We find that there is a difference in conservation value between captive-bred scarlet macaws that are bred for the pet trade and those bred for potential release into the wild and that are not in trade. We are not aware of any evidence indicating that release of pet or pet-trade scarlet macaws benefits wild populations. Pet scarlet macaws are poor candidates for reintroduction programs because those bred for the pet trade are bred with little regard for genetics and include an unknown number of subspecies crosses (Schmidt 2013, pp. 74–75), pets socialized with humans fail to act appropriately with wild individuals when released, and individuals held as pets may pose a disease risk to wild populations (Brightsmith *et al.* 2005, p. 471). However, scarlet macaws bred in captivity for soft-release programs are more appropriate than pet scarlet macaws to contribute to the wild population because of the breeding techniques, decreased level of human interaction, disease testing, and training of these birds to survive on their own in the wild upon release. Refer to ''Reintroduction of Scarlet Macaws,'' below, for examples of captive-bred birds raised and released into the wild to integrate with the wild populations of scarlet macaws. These birds released back into their native range and nearby existing populations may increase the overall population and contribute to the long-term conservation of the species.

Comment (11): A few commenters stated that the information used in the proposed rule was outdated.

Our Response: The Service is required by the Act to make determinations solely on the basis of the best scientific and commercial data available. We use the existing information and are not required to develop new data. We based the proposed rule on all the information we received following the initiation of the status review for the scarlet macaw, as well as all of the information we found during our own research and that received during the comment periods of the 2012 proposed rule and 2016 revised proposed rule. The ''best available'' information depends on research being conducted in the field and the availability of information and may be more, or less, recent depending on the efforts being conducted. After publishing the proposed rule, we found additional information that had become available since the publication of the proposed rule and reviewed information that was submitted by the public, including studies from a species expert and conservation organizations within the scarlet macaw's range countries.

Comment (12): One commenter claimed that the Service violated mandatory statutory deadlines by waiting nearly 4 years to take further action on its original listing proposal

and never formally invoking the legally allowable 6-month extension.

Our Response: We acknowledge that we failed to meet the statutory deadline for this rulemaking. However, we are obligated to make listing determinations under the Act based on the best available scientific and commercial information. In our proposed rule (77 FR 40222; July 6, 2012), we found that the northern subspecies of scarlet macaw, *A. m. cyanoptera,* and the northern DPS of the southern subspecies, *A.m. macao,* were in danger of extinction (an endangered species) based on their populations sizes and the magnitude of threats, such as loss of habitat and poaching, within the subspecies' respective ranges. We also found the southern DPS of the southern subspecies, *A. m. macao,* not to be warranted for listing under the Act. During the public comment period on the proposed rule, we received several requests from the public to extend the comment period. Additionally, subsequent to the proposed rule, we received new information from the public and peer review, and we issued a revised proposed rule (81 FR 20302; April 7, 2016). As a result of this information, we made five substantive changes to our July 6, 2012, proposed rule. Specifically, we: (1) Revised the location of what we consider to be the boundary between the northern subspecies, *A. m. cyanoptera,* and the northern DPS of the southern subspecies, *A. m. macao;* (2) provided additional information on *A. m. cyanoptera* in northeast Costa Rica, southeast Nicaragua, and Panama, and reevaluated the status of the subspecies; (3) provided additional information on the northern DPS of *A. m. macao,* reevaluated the status of this DPS, and revised our proposed listing of this DPS from endangered status to threatened status; (4) added a proposal to treat the southern DPS of *A. m. macao* and subspecies crosses *(A. m. cyanoptera* and *A. m. macao)* as threatened based on similarity of appearance to *A. m. cyanoptera* and to the northern DPS of *A. m. macao;* and (5) added a proposed rule under section 4(d) of the Act to define activities that are necessary and advisable for the conservation of scarlet macaws listed as threatened and crosses of the two scarlet macaw subspecies. We then revised our determination for the southern subspecies of *A. m. macao* in consideration of the new information and comments we received to conclude that the northern DPS of *A. m. macao's* risk of extinction is not as imminent as previously determined and that the southern DPS of *A. m. macao* has similarity of appearance and will therefore be treated at threatened. We opened a new comment period to allow the public the opportunity to submit additional comments in light of the new information and our revised determinations. Thus, we have used this time to consider and incorporate complex data so that we may ensure our rulemaking is based on the best available information.

Comment (13): A few commenters claimed that the Service offers no explanation on how the proposed 4(d) rule allowing all commercial and noncommercial international shipments of live or dead members of the southern subspecies (*A. m. macao*) and subspecies crosses (*A. m. macao* and *A. m. cyanoptera*) can be effectively limited to only those entities given the similarity of appearance. The proposed 4(d) rule depends entirely on the ability to differentiate between birds and products made from their bodies, which the Service has previously stated cannot be done without genetic analysis.

Our Response: Scarlet macaw subspecies, *A. m. macao* and *A. m. cyanoptera,* primarily differ in the coloration of their wing coverts (a type of feather) and wing size. We recognize that differences between *A. m. cyanoptera* and *A. m. macao* are not always apparent, particularly in birds from the middle of the species' range, and evidence in trade is usually in the form of partial remains, detached feathers, and artwork incorporating their feathers. Additionally, aviculturists often breed species without regard to their taxa. Thus, identification of the subspecies or the geographic origin of birds can be difficult or improbable without genetic analysis.

The 4(d) rule allows a person to import or export certain scarlet macaws (*A. m. macao* and subspecies crosses (*A. m. macao* and *A. m. cyanoptera*)) without a permit issued under the Act. However, to import and export scarlet macaws a person must follow procedures and requirements of CITES and the WBCA, as the 4(d) rule adopts existing conservation regulatory requirements of CITES as the appropriate regulatory provisions for the import and export of certain scarlet macaws (see 4(d) Rule, below). Both subspecies of the scarlet macaw are listed in Appendix I of CITES, which ensures that the international trade of CITES-listed species does not threaten the survival of the species in the wild. Trade must be authorized through a system of permits and certificates that are issued by the designated CITES Authorities of each CITES country. For species included in CITES Appendix I, international trade is permitted only under exceptional circumstances, which generally precludes commercial trade.

Any scarlet macaws or parts in international trade to the United States would require documentation that indicates the source and purpose of the specimen or parts, and we identify which countries the southern subspecies (*A. m. macao*) and potential subspecies crosses (*A. m. macao* and *A. m. cyanoptera*) are located in the wild. Birds from the two extremes of the range (Mexico and the Amazon) are morphologically discernable (Schmidt 2011, pers. comm.). However, we recognize that it can be difficult to differentiate between subspecies and determine whether the specimen is part of *A. m. cyanoptera,* and also requires a permit under the Act. Over the last 20 years less than 200 entries in the LEMIS (Law Enforcement Management Information System) database were scarlet macaw parts or unspecified, and 38 percent of the overall entries were seized. Therefore, even if some parts are difficult to determine which subspecies of scarlet macaw without genetic analysis, which would add considerable cost and effort to law enforcement, the quantity of scarlet macaw imports into the United States is not extensive.

Comment (14): One commenter cited Matuzak *et al.* (2008) for evidence that scarlet macaws are willing to feed on introduced species, which makes the species less susceptible to loss of native habitat. The commenter asserts that this is one reason why we should not list *A. m. cyanoptera* as endangered.

Our Response: The fact that scarlet macaws consume nonnative species does not change our determination that *A. m. cyanoptera* is in danger of extinction because of the extent of the decline in the range and numbers of *Ara macao cyanoptera* due to ongoing habitat destruction and degradation, poaching for the pet trade, the lack of enforcement of existing regulatory mechanisms addressing these threats, and the small population sizes that work in combination with the other threats.

Comment (15): A few commenters stated that threats to *A. m. cyanoptera* have been reduced over the past decade due to ongoing conservation efforts. The commenters also assert that our description of ''extreme fragmentation of habitat and population'' is an overstatement and habitat loss and fragmentation do not threaten the survival of *A. m. cyanoptera.* They claim scarlet macaws can fly dozens to hundreds of kilometers in a day and generally overcome fragmentation of populations; scarlet macaws use small

protected areas with sufficient large trees; and large areas of undisturbed habitat exist in Northern Central America. Thus, *A. m. cyanoptera* should not be listed as endangered.

Our Response: Reintroduction programs to introduce captive-bred scarlet macaws into wild populations have proven successful, especially within the range of *A. m. cyanoptera* (see ''Reintroduction of Scarlet Macaws,'' below). Information provided by a peer reviewer of the revised proposed rule (81 FR 20302; April 7, 2016) indicates that the scarlet macaw is likely increasing in numbers in the border region on the Caribbean slope of southeastern Nicaragua and northeastern Costa Rica, as well as showing an ability to inhabit human-disturbed habitats. However, destruction of forest habitat is one of the main causes of the decline of the scarlet macaw in Mesoamerica (Comisión Nacional Para el Conocimiento y Uso de la Biodiversidad (CONABIO) 2011, p. 5; Lezama 2011, pers. comm.; McGinley *et al.* 2009, p. 11; Garcia *et al.* 2008, p. 50; Hansen and Florez 2008, pp. 48–50; Snyder *et al.* 2000, p. 150; Collar 1997, p. 421; Forshaw 1989, p. 406; Ridgely 1981, pp. 251–253). The remaining forest is fragmented and includes few large tracts of forest habitat (Bray 2010, pp. 92–93; Snyder *et al.* 2000, p. 150; Wiedenfeld 1994, p. 101). Although deforestation rates have declined in Mesoamerica since 1990, they are still very high (FAO 2010a, pp. 232–233; Kaimowitz 2008, p. 487). Deforestation is occurring in many areas within the range of *A. m. cyanoptera,* including, but not limited to, in Chiapas, Mexico, western Petén in Guatemala; in the Mosquitia region in eastern Honduras and Nicaragua; and southeastern Nicaragua (Kaimowitz 2008, p. 487; Fagan *et al.* 2013, unpaginated; Chassot and Monge-Arias 2012, p. 63; Chassot and Monge-Arias 2011, p. 1; Chassot *et al.* 2009, p. 9). Therefore, as discussed in our July 6, 2012, and April 7, 2016, proposed rules, and reaffirmed herein, the low numbers of individuals of this subspecies, fragmentation of its habitat and population, and the substantial threats of habitat loss and poaching acting on this subspecies throughout its range place it in danger of extinction at this time.

Comment (16): One commenter disagrees with our determination that disease could be introduced through reintroduction programs that may affect wild populations of scarlet macaws. The commenter stated that disease does not pose a risk to wild populations, especially in northern Central America, and cited Boyd and McNab 2008.

Our Response: We are not aware of any information indicating that disease poses a significant threat to the species, especially in northern Central America. The risk of introducing diseases into wild populations increases when a large number of birds are introduced annually, but this is cost-prohibitive and unlikely (Boyd and McNab 2008, p. vii). Generally speaking, disease risk is small because the probable frequency of occurrence is low (Clum 2008, p. 79). As long as adequate disease testing is performed, and there are existing protocols for minimizing the threat of introducing exogenous diseases (*i.e.,* diseases that originate outside of the organism) into wild populations, the birds for release could come from multiple suitable sources (Boyd and McNab 2008, p. vii, Boyd *et al.* 2008, p. 112).

Comment (17): Some commenters disagreed with proposing a 4(d) rule that would allow the import and export of captive-bred scarlet macaws and interstate commerce without a permit.

Our Response: The Act does not prohibit these activities for threatened species. However, under 4(d), we may extend some or all of the prohibitions of 9(a)(1) to threatened species and are exercising our authority to do so here. We assessed the conservation needs of the scarlet macaw in light of the broad protections provided to the species under CITES and the WBCA. The best available data indicate that the current threat of trade to the scarlet macaw stems mainly from illegal trade in the domestic markets of Central and South America (Weston and Memon 2009, pp. 77–80; Shanee 2012, pp. 4–9). Accordingly, we find that adopting the import and export prohibitions of 9(a)(1), which extend only to the jurisdiction of the United States, would not regulate such activity and is not likely to impact the species status. Additionally, because interstate commerce within the United States has not been found to threaten the scarlet macaw or affect efforts at recovery of wild populations, and international trade of this species is regulated under CITES, we do not find it necessary to regulate such activity for this species. Therefore, we find the 4(d) rule contains all the prohibitions and authorizations necessary and advisable for the conservation of the species.

Comment (18): One commenter asserts that the Service's statement that northwest Colombia has large tracts of forest suitable for supporting a presently unknown scarlet macaw population and could contribute to the resiliency and redundancy of the DPS is both speculative, because it is unknown if scarlet macaws presently exist there, and is undercut by the finding that deforestation is ongoing and expected to continue in this area.

Our Response: The scarlet macaw was reported to occur in relatively small areas outside the Amazon, including west of the Andes in northwest Colombia (Hilty and Brown 1986, p. 200). The best available information indicates that the population in northwest Colombia faces significant ongoing threats and may be potentially extirpated from this region (Donegan 2013, *in litt.;* Ellery 2013, *in litt.;* McMullen 2010, p. 60). However, although no current population estimates are available, this region is reported to have large tracts of forest suitable for supporting scarlet macaws (Ortega and Lagos 2011, p. 82; Salaman *et al.* 2009, p. 21). While the commenter did not provide any additional information to their concern, the information that this region is reported to have large tracts of suitable habitat was not a focus of our status determination regarding the status of the population of *A. m. macao.*

Comment (19): A few commenters provided new information concerning reintroduction efforts in the native range of *A. m. cyanoptera* and the northern DPS of *A. m. macao.* These commenters encouraged us to incorporate information about reintroduction programs into our final rule. The commenters claimed that positive information, such as captive-breeding and release programs that are occurring throughout the species' range, are discounted compared to negative information, such as threats, on population status. They encouraged the Service to equally consider information for and against endangerment, including the potential uses of captive birds in conservation.

Our Response: Captive-bred birds released back into their native ranges and nearby existing populations have the potential to increase the overall population in the wild and contribute to the long-term conservation of the species, although the success of reintroduced scarlet macaws partly depends on the methods used to raise and release captive-bred birds into the wild. We have incorporated this information in our analysis and included a description of the reintroduction efforts for *A. m. cyanoptera* and *A. m. macao* in their respective ranges. See ''Reintroduction of Scarlet Macaws,'' below.

Comment (20): One commenter claims that listing of the southern DPS of *A. m. macao* based on similarity of appearance alone is not warranted in

the absence of any potential threat to wild populations. The movement of the southern DPS of *A. m. macao* would be subjected to extensive permitting and reviews under CITES and the WBCA, so listing it under the Act would provide little extra protection.

Our Response: During the public comment period for the proposed rule (77 FR 40222; July 6, 2012), we received additional information supporting a similarity of appearance listing for the southern DPS of *A. m. macao* and scarlet macaw subspecies crosses between *A. m. cyanoptera* and *A. m. macao,* which we incorporated into the revised proposed rule (81 FR 20302; April 7, 2016) and carry forward in this final rule. Because it can be difficult to visually differentiate between the two subspecies and this difficulty is an additional threat for the northern DPS of *A. m. macao,* we determined that treating the southern DPS of *A. m. macao* under the Act's section 4(e) similarity of appearance provisions will substantially facilitate law enforcement actions to protect and conserve scarlet macaws. Extending the protections of the Act to the similar entities through this listing of those entities due to similarity of appearance under section 4(e) of the Act and providing applicable prohibitions and exceptions in a rule issued under section 4(d) of the Act will provide greater protection to *A. m. cyanoptera* and the northern DPS of *A. m. macao.* For these reasons, we are treating the southern DPS of *A. m. macao* as threatened due to the similarity of appearance to the northern DPS of *A. m. macao,* pursuant to section 4(e) of the Act. Furthermore, simply being protected by CITES and the WBCA does not preclude the need to list and provide additional protections under the Act. Listing under the Act helps ensure that the United States and its citizens do not contribute to the further decline of the species.

Background

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. The Act defines ''endangered species'' as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and ''threatened species'' as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)).

We summarize below the information on which we based our final determination and evaluation of the five factors provided in section 4(a)(1) of the Act. We are also adopting a rule authorized under section 4(d) of the Act for the scarlet macaw to further its conservation. We find this rule contains the prohibitions and authorizations necessary and advisable for the conservation of the scarlet macaw.

Species Information

Species Description

The scarlet macaw (*Ara macao*) is one of several large neotropical parrot species commonly referred to as macaws. They measure 84–89 centimeters (33–35 inches) in length, weigh 900–1490 grams (2.0–3.3 pounds), and are one of the larger macaws (Collar 1997, p. 421). Scarlet macaws are brilliantly colored and predominantly scarlet red; most of the head, body, tail, and underside of the wings are red. Color on the upper side of the wing appears generally as bands of red, yellow, and blue, with varying amounts of green occurring between the yellow and blue band. Lower back, rump, and tail coverts (upper tail feathers) are blue. The species has large white, mostly bare facial patches on either side of its bill. The upper bill is a light, whitish color, whereas the lower bill is black. The sexes are similar, and immature birds are similar to adults, except immature birds have shorter tails (Collar 1997, p. 421; Wiedenfeld 1994, p. 100; Forshaw 1989, pp. 404, 406).

Taxonomy

The scarlet macaw was first described in 1758, by Linnaeus (Collar 1997, p. 421; Wiedenfeld 1994, p. 99). In 1994, the subspecies *Ara macao cyanoptera,* was separated from the originally described taxon (or nominate form), *A. m. macao* (Wiedenfeld 1994, entire). *Ara macao cyanoptera* occurs from southern Mexico south to central Nicaragua. Birds from southern Nicaragua to northern Costa Rica represent a zone of intergradation between the two forms; the nominate form (*A. m. macao*) occurs from this zone southward through the South American range of the species (Wiedenfeld 1994, pp. 100–101). *Ara macao cyanoptera* is different from *A. m. macao* in size and wing color; *A. m. cyanoptera* is larger than *A. m. macao,* with significantly longer wing lengths; and the yellow wing coverts that are tipped in blue have no green band separating the yellow and blue as in *A. m. macao.*

The subspecies classification described by Wiedenfeld (1994, entire) is used in the scientific community and the subspecies are recognized by the Integrated Taxonomic Information System (ITIS) as valid taxa (ITIS 2011, unpaginated). The subspecies classification is supported by genetic analyses (Schmidt 2011, pers. comm.; Schmidt and Amato 2008, pp. 135–137).

Schmidt (2013) represents the only spatial analysis of scarlet macaw genetic variation across the historical range of the species, and we consider this study to be the best available information on the range of the two subspecies. Therefore, the mainland Central America boundary between *A. m. cyanoptera* and *A. m. macao* is the central mountain range of Costa Rica, with *A. m. cyanoptera* found on the Caribbean (eastern) slope of the country and *A. m. macao* on the Pacific (western) slope. Additionally, scarlet macaws on Isla Coiba are likely to be the subspecies *A. m. cyanoptera.* Consequently, we consider scarlet macaws in Mexico, Guatemala, Nicaragua, Honduras, the Caribbean slope of Costa Rica, and Isla Coiba in Panama to be *A. m. cyanoptera.* We consider birds on the Pacific slope of Costa Rica and southward through the remainder of the species' range in South America to be *A. m. macao* (see Figure 1, below).

The data also show genetic differentiation between *A. m. macao* that occur on either side of the Andes in South America, indicating two populations: One consisting of birds west of the Andes in northwest Colombia, mainland Panama, and Pacific slope of Costa Rica; and the other population consisting of birds east and south of the Andes and throughout the species' South American range (Schmidt 2011, pers. comm.).

Range

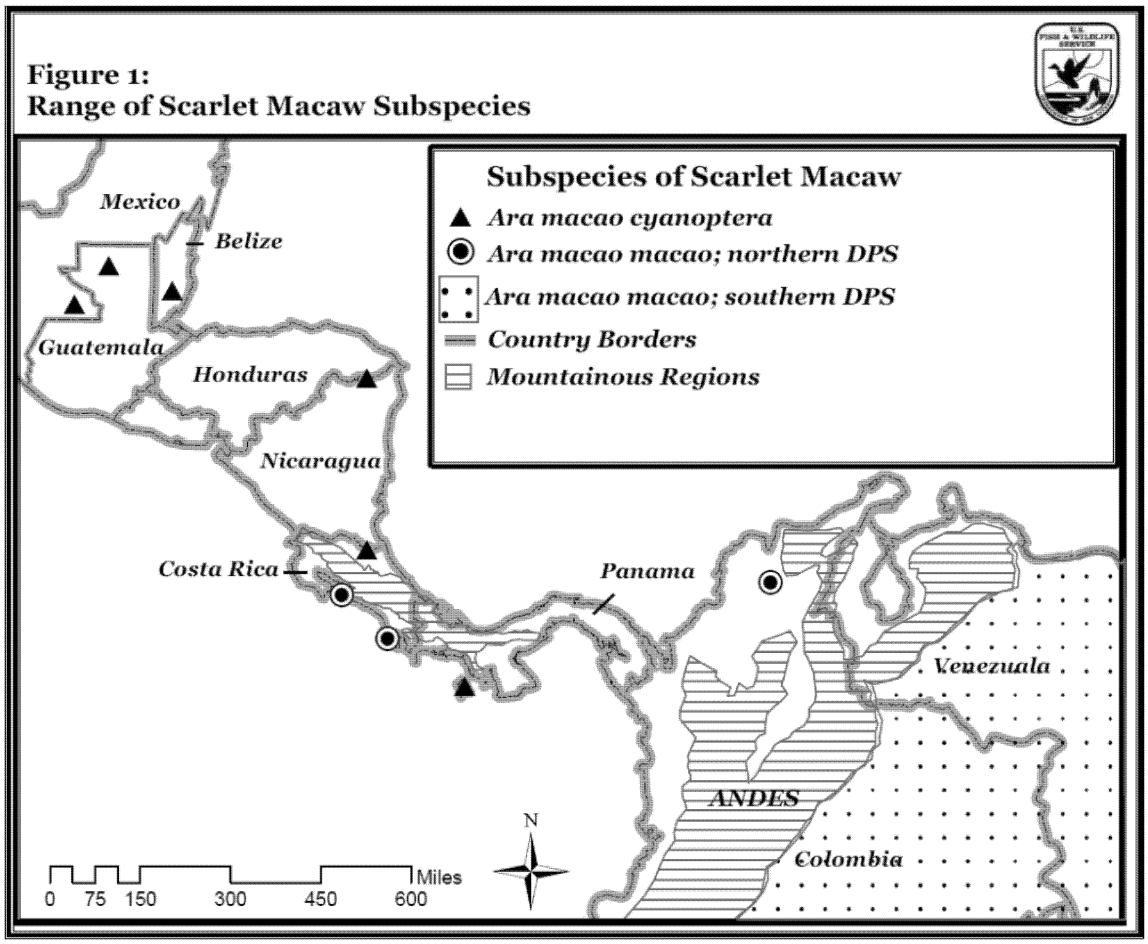
The range of the scarlet macaw is the broadest of all the macaw species (Ridgely 1981, p. 250). Extending from Mexico southward to central Bolivia and Brazil, it covers an estimated 7,030,975–10,200,000 square kilometers (km^2) (2,714,675–3,938,242 square miles (mi^2)) (BirdLife International (BLI) 2018, unpaginated; Vale 2007, p. 112). The majority (83 percent) of the species' range lies within the Amazon Biome of South America (BLI 2011a, unpaginated; BLI 2011b, unpaginated; BLI 2011c, unpaginated).

Historically, the range of the scarlet macaw included the southern portion of the Mexico state of Tamaulipas

southward through the states of Veracruz, Oaxaca, Tabasco, Chiapas, and Campeche; all of Belize; the Pacific and Caribbean slopes of Guatemala, Honduras, Nicaragua, El Salvador, and Costa Rica; the Pacific slope of Panama and Costa Rica; the Magdalena Valley in Colombia; and that part of South America within Colombia, Ecuador, Peru, Venezuela, Suriname, Guyana, French Guiana, and Bolivia and Brazil as far south as Santa Cruz and northern Mato Grosso, respectively (Wiedenfeld 1994, pp. 100–101; Forshaw 1989, p. 406; Ridgely 1981, p. 250; Iñigo-Elias 2010, p. 8). Some authors report the native range of the species to include Trinidad and Tobago (BLI 2011d, unpaginated; Forshaw 1989, p. 406). However, the historical record consists of only two questionable site records of the species in Trinidad and Tobago (Forshaw 1989, p. 407; French 1973, p. 76). The species may occur in that country as a very occasional vagrant or an escapee from captivity (Forshaw 1989, p. 407).

The scarlet macaw's range in Mesoamerica (Mexico and Central America) has been reduced and fragmented over the past several decades primarily as a result of habitat destruction and harvesting the species for the pet trade (Vaughan *et al.* 2003, pp. 2–3; Collar 1997, p. 421; Wiedenfeld 1994, p. 101; Snyder *et al.* 2000, p. 150). It has been extirpated from almost all of its former range in Mexico, all of its former range in El Salvador, and much of its former range throughout Central America.

Currently, in Mesoamerica, the *A. m. cyanoptera* occurs in the Maya Forest region of eastern Chiapas, in Mexico, western Petén, in northern Guatemala, and Chiquibil, in southwest Belize; in the Mosquitia region of eastern Honduras and Nicaragua; in the border region of southeastern Nicaragua and northeastern Costa Rica near the Rio San Juan (San Juan River); the *A. m. macao* occurs in Palo Verde in northwestern Costa Rica; Carara National Park and surrounding area, in west-central Costa Rica; the Osa Peninsula and surrounding area, Costa Rica; and in western border region of Panama and Costa Rica in the Chiriquí province and on the southern end of the Azuero Peninsula and Isla Coiba, Panama. In South America, the *A. m. macao* occurs in small areas outside the Amazon west of the Andes in northwest Colombia and in parts of several northern Venezuelan states. Within the Amazon, the scarlet macaw still occurs over much of its historical range (see Figure 1, below).



Distribution and Abundance

Using 1992 estimates from Honduras, and extrapolating from these estimates, the total number of scarlet macaws in Mesoamerica is approximately 5,000 birds, consisting of 4,000 *A. m. cyanoptera* (occurring from southern Mexico to Nicaragua and Isla Coiba, Panama), and 1,000 *A. m. macao* (northern DPS and occurring in Costa Rica and mainland Panama) (Wiedenfeld 1994, p. 102). More recently, the current population of *A. m. cyanoptera* was estimated to be fewer than 1,000 birds (McNab 2009, p. 1). The known populations of scarlet macaw in their range countries are described below (see Table 1). All the

population estimates are of birds, except Mexico, in which breeding pairs were estimated.

TABLE 1—SCARLET MACAW POPULATIONS THROUGHOUT ITS RANGE

[Estimates are individuals unless otherwise stated]

Population range country	Population name	Population estimates
Ara macao cyanoptera:		
Southeast Mexico	upper Rio Uxpanapa region; Usamacinto Watershed—Eastern Chiapas, Mexico, Lacandón Forest.	~50; < 200 breeding pairs.
Guatemala	Northern Petén	150–250.
Belize	Chiquibul	60–219.
Eastern Honduras, Northeastern Nicaragua	Mosquitia Region	Honduras: 1,000–1,500; Nicaragua: <100–700.
Southeast Nicaragua Border and Northeast Costa Rica.	Rio San Juan (San Juan-La Selva/San Juan-El Castillo).	possibly >200.
Isla Coiba, Panama	Isla Coiba	100–200.
Total *A. m. cyanoptera*		2,000–3,000.
Ara macao macao Northern DPS:		
Cerro Hoya National Park	Mainland Panama	<25.
Costa Rica	Central Pacific Conservation Area (ACOPAC)	~450.
Costa Rica	Osa Conservation Area (ACOSA)	800–1,200; up to 2,000.
Northwest Colombia	Northwest Colombia	unknown.
Total *A. m. macao* Northern DPS		1,000–2,000.
Total Mesoamerica		3,000–5,000.
Ara macao macao Southern DPS:		
Amazon, south and east of the Andes Mountains (Colombia, Ecuador, Peru, Venezuela, Suriname, Guyana, French Guiana, and Bolivia and Brazil).	Amazon	15,000–45,000.
Total *Ara macao*		~20,000–50,000.

Mesoamerica

Mexico, Guatemala, and Belize (Maya Forest) (*A. m. cyanoptera*)

Described as previously abundant in Mexico (CONABIO 20l1, p. 2) and numbering in the many thousands (Patten *et al.* 2010, p. 30), the *A. m. cyanoptera* is now reported to occur in only two small populations in Mexico. One population occurs in the upper Rio Uxpanapa region near San Francisco La Paz in Oaxaca (Inigo-Elias 1996, pp. 16–17). Citing several sources, Inigo-Elias (2010, unpaginated) and McReynolds (2011, *in litt.,* unpaginated) indicate that the upper Uxpanapa River population consists of possibly 50 scarlet macaws. It is possible that the species may occur seasonally in this area (Peterson *et al.* 2003, p. 232). The second population that occurs in Mexico is along the southern Mexico and Guatemala border area of eastern Chiapas, and is discussed below.

Within the tri-national region of southern Mexico, northern Guatemala, and Belize, the species occurs in three small populations or subpopulations: (1) In the Usamacinto watershed in eastern Chiapis, Mexico, located in the Lacandon forest that is within the Maya Forest, which is the largest remaining expanse of tropical rainforest in the Americas (The Nature Conservancy 2018, unpaginated), and includes the Montes Azules Biosphere Reserve (approximately 3,000 km^2 (1,158 mi^2), several smaller protected areas, and the municipality of Maques de Commillas (United Nations Educational, Scientific, and Cultural Organization (UNESCO) 2012a, unpaginated; McReynolds 2011, *in litt.;* Enriquez *et al.* 2009, p. 13; Castillo-Santiago *et al.* 2007, pp. 1215, 1217; Inigo-Elias 1996, pp. 16–17, 23); (2) in the western Department of Petén in northern Guatemala, primarily in the Maya Biosphere Reserve (MBR) (Garcia *et al.* 2008, pp. 49–64; McNab 2009, p. 1); and (3) in southwest Belize, where it is known to breed only in the Chiquibul region, which includes Chiquibul National Park and other protected areas (Salas and Meerman 2008, p. 42).

Based on field studies conducted from 1989 to 1993, it was estimated that probably fewer than 200 breeding pairs exist within Mexico's Usamacinto watershed (Iñigo-Elias 1996, pp. 96–97). In Guatemala, the population is estimated at 150 to 250 birds (McNab 2008, p. 7; Wildlife Conservation Society Guatemala 2005, in McReynolds 2011, *in litt.,* unpaginated; McNab 2009, p. 1). Estimates from Belize vary from 60 to 219 individuals, but based on field observations in 2009, the current Belize population is estimated at 200 individuals (McReynolds 2011, *in litt.,* unpaginated). However, the total population in the tri-national Maya region (Mexico, Guatemala, and Belize), based on habitat modeling and current threats, was estimated to be 399 individuals—137 in Mexico, 159 in Guatemala, and 103 in Belize (Garcia *et al.* 2008, pp. 52–53).

Populations in Mexico, Guatemala, and Belize are described as not being completely isolated from one another. It is likely that the population in western Petén, Guatemala, and the population in southeastern Mexico are connected because there is continuous habitat and the birds from Guatemala, when they disperse in the non-breeding season, are known to go to the west of their breeding grounds (Brightsmith 2016, *in litt.* p. 8). In a radio telemetry study, a fledgling radio-tagged in Guatemala flew 130 km (81 mi) to Mexico in one day (McReynolds 2011, *in litt.,* unpaginated). In addition, studies provide evidence of gene flow between nest sites in Guatemala and Belize, and

high levels of genetic diversity in the tri-national region (Schmidt and Amato 2008, p. 137). However, the Belize population may be more isolated from the Guatemala and Mexico populations because the area between these populations is well covered by eBird observers and no scarlet macaws have been seen even though there is high-quality habitat (Brightsmith *in litt.* 2016, unpaginated).

Honduras (*A. m. cyanoptera*)

The scarlet macaw was widespread in Honduras, occurring in the arid lowlands of the Pacific slope and the interior below 1,100 m (3,609 ft), as well as in the Caribbean lowland rainforest (Monroe 1968, p. 139). The scarlet macaw may have had a distribution over 60 percent of the national territory at the end of the 19th century (Monroe 1968, p. 139; Portillo Reyes et al. 2010, p. 69). Currently, the scarlet macaw is restricted to the Mosquitia region, which is a region of extensive forest straddling the southeastern Honduras-northeastern Nicaragua border (Wiedenfeld 1994, pp. 101–102; Portillo Reyes 2005, p. 71). This region includes several thousand square kilometers in protected areas, such as the Plátano Biosphere Reserve (5,000 km² (1,931 mi²)) Reserva de la Biosfera Tawahka (Tawahka Biosphere Reservation) (2,500 km² (965 mi²)), the Parque Nacional Patuca (Patuca National Park) (3,755 km2 (1,450 mi2)) in Honduras, and the Bosawás Biosphere Reserve (21,815 km² (8,423 mi²)) in neighboring Nicaragua (UNESCO 2012b, unpaginated; UNESCO 2012c, unpaginated; Vallely *et al.* 2010, p. 52).

The total population of Honduras was estimated at 1,000 to 1,500 birds in 1992, reportedly occurring in the Colón area and provinces of Olancho and Gracias a Dios that are in the Mosquitia region of Honduras (Wiedenfeld 1994, pp. 101–102). An estimate of scarlet macaws in the Rus Rus area of the Honduran Mosquitia (Rus Rus is in the province of Gracias a Dios) was 1,000 to 1,500 birds (McReynolds 2011, *in litt.,* unpaginated). However, this estimate was based on the assumption that all the chicks reported as poached by Portillo Reyes *et al.* (2004, in McReynolds 2011, *in litt.,* unpaginated) would fledge and assumed a 20 percent reproductive success rate. There are no population estimates for the Río Patuca and Río Plátano areas, though there have been flocks as large as eight counted on the Río Plátano (Gallardo 2002, in McReynolds 2011, *in litt.,* unpaginated). The most recent information indicates that loss of habitat and demand for the pet trade pose a substantial threat for the species in this region (Portillo Reyes 2005, in Portillo Reyes *et al.* 2010, p. 6; Brightsmith *in litt.* 2016, p. 8).

Nicaragua (*A. m. cyanoptera*)

Scarlet macaws in eastern Nicaragua along the Caribbean slope were estimated to be 1,500 to 2,500 birds in 1995 (Wiedenfeld 1995, in Snyder *et al.* 2000, p. 150). However, the species was not detected during either of two national surveys of parrots conducted in 1999 and 2004 (Lezama *et al.* 2004, p. 102; McReynolds 2011, *in litt.,* unpaginated). Some estimates predict up to 700 birds in this region of Nicaragua; groups of 30 to 40 scarlet macaws are frequently reported in the Río Coco area (Lezama 2011, pers. comm., in McReynolds 2011, *in litt.,* unpaginated), which forms the border with Honduras. Others consider the number in eastern Nicaragua to be fewer than 100 birds (Feria and de los Monteros 2007, in McReynolds 2011, *in litt.,* unpaginated)). The only scarlet macaws on the Pacific slope of Nicaragua are confined to Cosigüina Volcán Nature Preserve, with approximately 20 to 50 birds (Bjork 2008, p. 15; Lezama 2011, pers. comm., in McReynolds 2011, *in litt.,* unpaginated).

Costa Rica (*A. m. cyanoptera* and *A. m. macao*)

Scarlet macaws (*A. m. cyanoptera*) occur in southeastern Nicaragua and northeastern Costa Rica on both sides of the border. This region consists of the El Castillo-San Juan-La Selva Biological Corridor that is located on both sides of the Río San Juan (San Juan River) (Monge *et al.* 2012, p. 6), which separates Nicaragua and Costa Rica. In 2004, several groups of scarlet macaws were reported in the Río San Carlos area close to the border with Nicaragua, in what is now designated as Maquenque National Wildlife Refuge (Refugio Nacional de Vida Silvestre mixto Maquenque), which also abuts the Indio Maíz Biological Reserve in Nicaragua (Chassot and Monge-Arias 2004, pp. 12–13; Chassot 2011, pers. comm.). Multiple scarlet macaws were observed flying from Nicaragua over the Río San Juan into Costa Rica (Chassot and Monge-Arias 2004, pp. 12–13).

Evidence of scarlet macaws in northeast Costa Rica obtained during several years of research on great green macaws (*Ara ambiguus*) indicates that scarlet macaws in this region are increasing (Chassot and Monge-Arias 2004, pp. 12–13; Brightsmith 2012, *in litt.,* unpaginated). During the 2009 scarlet macaw breeding season, an intensive search for scarlet macaw nests was conducted on both sides of the Río San Juan as part of a larger study to quantify and characterize nests of both scarlet and great green macaws (Monge *et al.* 2012, entire). They found six scarlet macaw nests (five in Costa Rica, one in Nicaragua). The scarlet macaw has recently expanded its range southward to La Selva Biological Station, which is approximately 35–40 km (15–18 miles) south of the Río San Juan, and sightings of scarlet macaws have increased in the region (Brightsmith 2016, *in litt.,* p. 5; Sullivan *et al.* 2009, unpaginated). Scarlet macaws were absent from this station since it was established in the 1960s, but they have been observed breeding on adjacent land since the mid-2000s (Brightsmith 2012, *in litt.,* unpaginated). Approximately 50 scarlet macaws occur in Maquenque National Wildlife Refuge in northeast Costa Rica (Penard *et al.* 2008, in McReynolds 2011 *in litt.,* unpaginated). There are no density estimates of scarlet macaws from this area, but based on the density reported for great green macaws (0.07 birds per km²) in an area of 3,000 km² (1,158 mi²), there could be more than 200 scarlet macaws in northeastern Costa Rica (Brightsmith *in litt.* 2016, p. 6; Brightsmith 2012, *in litt.,* unpaginated).

Scarlet macaws were described as having previously occurred in tropical wet and dry forests throughout most of Costa Rica (Vaughan *et al.* 1991, abstract), while Ridgely (1981, p. 252) describes the species as having always occurred primarily on the Pacific slope of the country. Aside from the birds in northeastern Costa Rica, the scarlet macaw (*A. m. macao*) occurs in two viable populations on the Pacific slope: In the ACOPAC in the region of Carara National Park, which contains approximately 450 birds (Arias *et al.* 2008, in McReynolds 2011, *in litt.*); and in Costa Rica's Osa Conservation Area (ACOSA) in the region of Corcovado National Park and the Osa Peninsula, which contains between 800 and 1,200, but possibly up to 2,000 birds (Dear *et al.* 2005 and Guzman 2008, in McReynolds 2011, *in litt.*). However, based on plausible regional estimates, the population for the entire country is approximately 1,800 birds (McReynolds 2011, *in litt.,* unpaginated).

By all indications, the scarlet macaw (*A. m. macao*) has been expanding from the traditional stronghold in and around Carara National Park (Brightsmith 2016, *in litt.,* p. 11). Since 2013, scarlet macaws in groups of up to 30, along with pairs during the height of the breeding season, were observed hundreds of times down the coast and approximately 70 km (43 mi) south of

the point where the census is usually conducted. In addition, scarlet macaws from the areas immediately to the northwest of Carara have been reported. Scarlet macaws may frequently pass through these areas but may not be present continuously or at high densities (Brightsmith 2016, *in litt.,* p. 12). The nearest areas with repeated sightings of the species are Ensenada Lodge at 60 km (37 mi) north of the census location for Carara; 40 km (25 mi) from the small population of 14–25 birds in Palo Verde (Brightsmith 2016, *in litt.,* p. 12; Dear *et al.* 2010, p. 8); and 60 km (37 mi) from the core of the ACOPAC population. This site has 16 sightings, with 13 since 2012, and group sizes have been small (1 to 4). But it is unclear what the source of these birds may be; they could be escaped or released birds, or could be natural dispersers from either the Palo Verde or ACOPAC populations (Brightsmith 2016, *in litt.,* p. 14). Because there have been scattered sightings of scarlet macaws from Palo Verde National Park south to Carara National Park and throughout western Guanacaste, the birds near Palo Verde are no longer considered completely isolated (Brightsmith 2016, *in litt.,* p. 14). However, evidence to support successful expansion and establishment to the north is weak (Brightsmith 2016, *in litt.,* p. 13).

The ACOSA population is simultaneously expanding up the coast from the south, so sightings of scarlet macaws between the ACOPAC and ACOSA may represent individuals from either of the populations. In fact, birds were reported to occur in a 50-km (31-mi) area, which is the midpoint between the two populations (Brightsmith 2016, *in litt.,* p. 11). Moreover, 85 percent of residents interviewed in 2005 believed scarlet macaws were more abundant than 5 years prior, suggesting this population may be increasing (Dear *et al.* 2010, p. 10). However, it is difficult to distinguish between expansion of the ACOPAC population to the south and the expansion of the ACOSA population to the north (Brightsmith 2016, *in litt.,* p. 11).

Panama (*A. m. macao*)

The scarlet macaw was once described as almost extinct on the mainland of Panama, but abundant and occurring in substantial numbers on Isla Coiba, which once was a penal colony where settlement and most hunting was prohibited (Ridgely 1981, p. 253). More recent information on distribution and abundance in the country indicates that mainland Panama has very few scarlet macaws (McReynolds 2011, *in litt.,* unpaginated). In 1998, there were sporadic sightings of scarlet macaws in the western border region of Panama and Costa Rica, in the area of the upper Río Corotu (or Río Bartolo Arriba) near Puerto Armuelles in the Chiriquí province (Burica Press 2007, unpaginated; McReynolds 2011, *in litt.,* unpaginated). A few (fewer than 10) scarlet macaws were observed in 2015, in northwestern Panama, near Querevalo and also in the Chiriquí province (Brightsmith *in litt.* 2016, p. 17; Sullivan *et al.* 2009, unpaginated), but it is uncertain if these birds were wild or escaped captively-raised birds dispersing south from a reintroduction program at Tiskita, Costa Rica (Brightsmith 2016, *in litt.,* p. 17) (see ''Reintroduction of Scarlet Macaws,'' below). Additionally, there is a small, but unknown, number on the southern end of the Azuero Peninsula of Veraguas, near Cerro Hoya National Park, Tonosi Forest Reserve, and farther to the east (Brightsmith 2016, *in litt.,* p. 17; Sullivan *et al.* 2009, unpaginated; Rodriguez and Hinojosa 2010, in McReynolds 2011, *in litt.,* unpaginated). The current population of scarlet macaws in Panama is likely less than 200, with the vast majority of the population occurring on Isla Coiba (Keller and Schmitt 2008, in Brightsmith 2012, in litt. and McReynolds 2011, in litt., unpaginated).

South America (A. m. macao)

Within South America, the scarlet macaw occurs primarily in the Amazon Biome, which overlaps eastern Colombia, Venezuela, Guyana, Suriname, French Guyana, northeast Ecuador, eastern Peru, northern Bolivia, and most of Brazil (collectively referred to as the Amazon in this document) (BLI 2011a, unpaginated; Iñigo-Elias 2010, unpaginated; Juniper and Parr 1998, p. 425; Collar 1997, p. 421; Forshaw 1989, pp. 406–407). The Amazon comprises approximately 83 percent of the species' entire range (BLI 2011c, unpaginated). The scarlet macaw is also reported to occur in relatively small areas outside the Amazon, including west of the Andes in northwest Colombia (Hilty and Brown 1986, p. 200) and in parts of several northern Venezuelan states (Hilty 2003, p. 327).

We are aware of little recent information on local (country, region) populations within South America. The only local population estimate we are aware of includes the Tambopata Province of Peru (Lloyd 2004, p. 270). Using density estimates calculated from field counts in different forest types, and area of forest cover presented in Kratter (1995, in Lloyd 2004, p. 269), the Tambopata population was calculated to number from 4,734–24,332 individuals. The population of scarlet macaws in Peru is adjacent to large populations in adjacent Ecuador, Brazil, Bolivia, and Colombia (Brightsmith 2009, *in litt.,* unpaginated). Therefore, the total individuals could represent scarlet macaws from more than just Peru.

The remaining information on the species' populations in South America is qualitative. In Colombia, the species is believed to occur west of the Andes in the Magdalena Valley and in gallery forest and partially cleared rainforest where large trees have been left (Hilty and Brown 1986, p. 200; Forshaw 1989, p. 407); their presence may be the result of seasonal movements for food resources (Juniper and Parr 1998, p. 425). The species is also common east of the Andes and in the Orinoco and Amazon Basins in Colombia, but there are no current population estimates (Hilty and Brown 1986, p. 200; Iñigo-Elias 2010, unpaginated). In Venezuela, the species is becoming rare with patchy distribution in the states of Bolívar, Monagas, Apure, and Amazonas (Iñigo-Elias 2010, unpaginated; Meyer de Schauensee and Phelps, Jr. 1978, p. 99; Juniper and Parr 1998, p. 425); there are no current population estimates. The species has been described as occurring widely throughout the Amazon basin of Brazil, eastern Ecuador, and eastern Peru (Juniper and Parr 1998, p. 425). However, more recently it was described as uncommon, locally extirpated in areas, and declining in eastern Peru (Inigo-Elias 2010, unpaginated). Citing several published works from the 1970s and 1980s, scarlet macaws were described as locally extirpated from areas with a history of ornithological study in northeastern Ecuador and northeastern Bolivia (Forshaw 1989, p. 407), although it has also been described as occurring in northern and eastern Bolivia in Santa Cruz (Juniper and Parr 1998, p. 425). Other authors reported that in recent decades scarlet macaws have rapidly declined in the lowland Ecuadorian Amazon in Ecuador (Ridgely and Greenfield 2001, in Karubian *et al.* 2005, p. 618). The scarlet macaw occurs widely in the Guianas, which includes Guyana, Suriname, and French Guiana (Juniper and Parr 1998, p. 425), although the species may be uncommon in the vicinity of settlements (Forshaw 1989, p. 407). In Suriname, scarlet macaws are common in the interior rainforest but seldom seen in the coastal area and are rare in the eastern part of the country (Spaans *et al.* 2018, unpaginated). Other sources indicate

that the species is found along tropical riparian evergreen forests in western and central Suriname (Haverschmidt and Mees 1994, in Iñigo-Elias 2010, unpaginated). In Brazil, the species is widely distributed throughout the Amazon, but there are no current population estimates (Iñigo-Elias 2010, unpaginated; Juniper and Parr 1998, p. 425).

Overall, the scarlet macaw is generally considered common and widespread over much of its range in the Amazon (Hilty 2003, p. 327; Angehr *et al.* 2001, p. 161; Juniper and Parr 1998, p. 425; Collar 1997, p. 421; Forshaw 1989, p. 406; Hilty and Brown 1986, p. 200; Ridgely 1981, p. 251). Using the estimate of 20,000–50,000 birds for the total population, and the estimate of 5,000 birds in Mesoamerica, the South American population of the scarlet macaw can be very roughly estimated to be 15,000–45,000 birds.

Essential Needs of the Species

Habitat

The scarlet macaw inhabits various habitat types throughout its range, including tropical humid evergreen forest, deciduous and humid forest, intact and partially cleared lowland rain forest, mixed pine and broad-leaved woodlands, open areas and edges with scattered stands of tall trees, gallery forest, mangroves, and savannas, with many of the areas that scarlet macaw inhabit near rivers (Juniper and Parr 1998, p. 425; Wiedenfeld 1994, p. 101; Forshaw 1989, p. 407; Meyer de Schauensee and Phelps, Jr. 1978, p. 99). The species generally occurs from sea level to about 500 meters (m) (1,640 feet (ft)) elevation, but has been reported ranging up to 1,500 m (4,921 ft) in Central America (Juniper and Parr 1998, p. 425; Vaughan 1983, in Vaughan *et al.* 2006, p. 919).

The scarlet macaw is considered somewhat tolerant of degraded or fragmented habitat (BLI 2011c, unpaginated; Forshaw 1989, p. 406; Brightsmith *in litt.* 2016, pp. 4–7). If not hunted or captured for the pet trade, they can survive in human-modified landscapes provided sufficient large trees remain for nesting and feeding requirements (BLI 2011c, unpaginated; Forshaw 1989, p. 406; Ridgely 1981, p. 251). Landscapes may include a combination of agricultural land, pastureland, timber harvesting areas, and remnant forest patches (Vaughn *et al.* 2006, p. 920; Vaughan *et al.* 2005, p. 120; Vaughan *et al.* 2003, p. 7); partially cleared forest where large trees have been left standing (Forshaw 89, p. 407); pastureland with scattered woodlots or remnant patches of rainforest (Vaughn *et al.* 2009, p. 396; Forshaw 89, p. 407); and areas of human settlement (towns) (Guittar *et al.* 2009, p. 390). However, the species occurs at lower densities in disturbed or secondary (recovering) forest habitat than in primary (undisturbed) forest (Cowen 2009, pp. 11–15; Karubian *et al.* 2005, pp. 622–623; Lloyd 2004, pp. 269, 272).

Diet and Foraging

Scarlet macaws, like most parrots, feed primarily in the canopy (Vaughan *et al.* 2006, p. 920; Renton 2006, p. 282; Lee 2010, p. 20) and display a wide dietary breadth. They have been reported to consume up to 52 plant species in the Amazon of Peru (Gilardi 1996, in Matuzak *et al.* 2008, p. 361) and up to 43 different plant species in Costa Rica (Vaughan *et al.* 2006, p. 920; Matuzak *et al.* 2008, p. 355). Fruits and seeds comprise the majority of a scarlet macaw's diet, but they also consume, to a lesser degree, fruit pulp, flowers, leaves, bark, lichen, and bromeliads (Lee 2010, pp. 153–160; Matuzak *et al.* 2008, p. 355; Renton 2006, p. 281; Vaughan *et al.* 2006, pp. 920, 924; Marineros and Vaughan 1995, pp. 451–452; Nycander *et al.* 1995, p. 424).

Plant species consumed by scarlet macaws are both seasonal and available year round (Abramson *et al.* 1995, p. 24). Changes in local abundance patterns of parrots can be triggered by seasonal availability of food resources within habitat mosaics (Renton 2002, p. 17; Haugaasen and Peres 2007, p. 4179). Fluctuations in food abundance are likely to result in seasonal movements of scarlet macaws to areas with greater food availability (Karubian *et al.* 2005, p. 624; Haugaasen and Peres 2007, pp. 4179–4180; Renton 2002, pp. 17–18; Juniper and Parr 1998, p. 425). Additionally, in some areas of the scarlet macaw's range, they regularly visit claylicks (naturally forming wall of clay on a riverbank) where they consume soil or minerals; it is unclear whether this provides a nutritional or other benefit to the species such as counteracting toxins in food sources (Brightsmith *et al.* 2010, entire; Brightsmith 2004, pp. 136–137; Lee 2010, p. 141).

Nesting and Reproduction

Reproductive biology of large parrots, including the scarlet macaw, is generally characterized by low rates of reproduction, small clutch sizes, low survival of nestlings and fledglings, late age to first reproduction, a large proportion of nonbreeding adults in any given year, and restrictive nesting requirements (Wright *et al.* 2001, p. 711; Collar 1997, pp. 296, 298; Munn 1992, pp. 53–56).

Scarlet macaws are secondary cavity-nesting birds, meaning they do not create their own cavities but rely upon natural or abandoned cavities for nesting; their breeding success is dependent upon the availability and quality of nesting sites. They nest in both live and dead trees and in a variety of tree species, including, but not limited to, *Ceiba pentandra* (kapok tree), *Schizolobium parahybum* (Brazilian firetree), *Vatairea lundellii* (bitter angelim), *Caryocar costaricense* (no common name), *Acacia glomerosa* (white tamarind), *Dipteryx micrantha* (Brazilian teak), *Iriartea deltoidea* (stilt palm), and *Erythrina* spp. (coral tree) (Guittar *et al.* 2009, pp. 389–399; Renton and Brightsmith 2009, pp. 3–4; Brightsmith 2005, p. 297; Vaughan *et al.* 2003, p. 8; Iñigo-Elias 1996, p. 57; Marineros and Vaughan 1995, p. 456; Nycander *et al.* 1995, p. 431). Due to their large size, scarlet macaws require large cavities, which are usually found in older trees. The average height of scarlet macaw nests ranges from about 16 to 24 m (52.5 to 79 ft) above the ground (Guittar *et al.* 2009, pp. 389–391; Anleu *et al.* 2005, p. 44; Inigo-Elias 1996, p. 59; Marineros and Vaughn 1995, p. 455). In addition to cavity size and height parameters, scarlet macaws appear to select nest sites with a clear understory or isolated from surrounding vegetation, possibly to reduce predation rates (Inigo-Elias 1996, p. 93; Brightsmith 2005, p. 302). The species will also nest in previously used cavities (Renton and Brightsmith 2009, pp. 4–5; Nycander *et al.* 1995, p. 428), and will readily investigate and nest in artificial (human-made) cavities when supplied (Brightsmith 2005, p. 297; Vaughan *et al.* 2003, p. 10; Nycander *et al.* 1995, pp. 435–436).

Scarlet macaws are frequently observed competing for nest cavities with other macaws, including other species and other scarlet macaw pairs (Renton and Brightsmith 2009, p. 5; Vaughan *et al.* 2003, p. 10; Inigo-Elias 1996, pp.79, 96; Nycander 1995, p. 428). Thus, intense competition for nest cavities suggests suitable nesting sites may be limited in some areas (Vaughan *et al.* 2003, pp. 10–12; Inigo-Elias 1996, p. 92; Nycander *et al.* 1995, p. 428; Munn 1992, pp. 55–56).

Conservation Status

The scarlet macaw has been included in Appendix I of CITES since 1985 (United Nations Environment Programme–World Conservation Monitoring Center (UNEP–WCMC) 2012, unpaginated). The species is

currently classified as ''Least Concern'' by the IUCN. In 2011, BLI proposed reclassifying the scarlet macaw in the IUCN Red List of Threatened Species from ''Least Concern'' to ''Threatened,'' based on the area of Amazon habitat projected to be lost to deforestation by 2050 (BLI 2011b, unpaginated; BLI 2011e, unpaginated). However, based on review and recommendations from regional experts, a current revision of the proposal recommends the species remain classified as ''Least Concern'' due to its level of tolerance of degraded and fragmented habitat (BLI 2011c, unpaginated) and the relatively good status of the species in the Amazon, which accounts for the majority of the species range and population.

In Mesoamerica, the northern subspecies of scarlet macaw (*A. m. cyanoptera*) is considered in danger of extinction in Mexico (Government of Mexico 2010a, p. 32), Belize (Biodiversity and Environmental Resource Data System of Belize 2012, unpaginated; Meerman 2005, p. 30), Costa Rica (Costa Rica Sistema Nacional de Areas de Conservacion 2012, unpaginated), and Panama (Fundación de Parques Nacionales y Medio Ambiente 2007, p. 125). This subspecies is also on Guatemala's *Listado de Especies de Fauna Silvestre Amenazadas de Extinción (Lista Roja de Fauna)* (list of species threatened with extinction (red list of fauna)) (Government of Guatemala 2001, p. 15), Honduras's *Listado Oficial de Especies de Animales Silvestres de Preocupación Especial en Honduras* (Official List of Species of Wild Animals of Special Concern in Honduras) (Secretaria de Recursos Naturales y Ambiente. 2008, p. 62), and Nicaragua's list of species for which the season of use (*e.g.,* for harvest or capture) is indefinitely closed (Nicaragua Ministerio del Ambiente y Los Recursos Naturales 2010, entire).

In South America, the subspecies *A. m. macao* is listed as vulnerable in Peru (Government of Peru 2004, p. 276855), but a more recent evaluation of the species categorizes it at the lower threat level of ''near threatened'' (Brightsmith 2009, *in litt.,* unpaginated). The species is also categorized as ''near threatened'' in Ecuador (Ridgely and Greenfield 2001, in Karubian *et al.* 2005, p. 618) and as ''near threatened'' on Venezuela's red list (Rodriguez and Rojas-Suarez 2008, p. 50). We are unaware of the scarlet macaw having official conservation status in any other of the species' range countries (*e.g.,* Colombia, the Guianas, Brazil, and Bolivia).

Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations in title 50 of the Code of Federal Regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on (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.

In considering what factors may constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to the factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine if it may drive or contribute to the risk of extinction of the species such that the species warrants listing as an endangered or threatened species as those terms are defined by the Act. In 2016, we revised our proposal to list the northern subspecies of the scarlet macaw (*Ara macao cyanoptera)* as an endangered species under the Act, the northern DPS of the southern subspecies *Ara macao macao* as a threatened species under the Act, and the southern DPS of the southern subspecies *Ara macao macao* as threatened due to similarity of appearance under the Act (81 FR 20302, April 7, 2016). Please see our analysis of those entities and the factors affecting their status below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

One of the two main threats to neotropical parrot species is loss of forest habitat (Snyder *et al.* 2000, p. 98). Deforestation, which includes clear-cutting forests to convert them to other land uses such as agriculture and cattle ranching, as well as forest degradation, which is the reduction in forest biomass such as through selective logging or fire, occurs throughout much of the scarlet macaw's range. The primary cause of forest loss is conversion to agriculture (crop and pasture), although other land uses such as infrastructure, logging, fires, oil and gas extraction, and mining also contribute significantly and to varying degrees in different areas of the species' range (Blaser *et al.* 2011, pp. 263, 290, 299, 310, 319, 334, 343–344, 354, 363–364, 375, 393–394; Boucher *et al.* 2011, entire; Clark and Aide 2011, entire; FAO 2011a, pp. 17–18; May *et al.* 2011, pp. 7–13; Pacheco 2011, entire; Government of Costa Rica 2010, pp. 38–39; Belize Ministry of Natural Resources and Environment 2010, pp. 40–45; Armenteras and Morales 2009, pp. 133–145, 176–191; Kaimowitz 2008, p. 487; Mosandl *et al.* 2008, pp. 38–40; Nepstad *et al.* 2008, entire; Foley *et al.* 2007, pp. 26–27; Fearnside 2005, pp. 681–683).

The construction of roads are an important driver of deforestation because they provide access to previously remote areas and allow further expansion of activities that result in additional areas of deforestation and degradation (Davidson *et al.* 2012, p. 323; Lambin and Meyfroidt 2011, pp. 3468–3469; May *et al.* 2011, pp. 6, 9–11; Foley 2007, pp. 26–27; Soares-Filho *et al.* 2006, p. 520; Fearnside 2005, pp. 681–683; Laurance *et al.* 2004, entire). Historically, large areas of forest have been removed throughout Mesoamerica, and the large tracts of forest that remain, such as the Maya and Lacandon Forests, the transnational forest in the Mosquitia region, and the major transnational forest on the Atlantic border of Costa Rica and Panama, have almost been cut off from each other by deforestation (Bray 2010, p. 93).

Activities that lead to deforestation and forest degradation pose a threat to the scarlet macaw because they directly eliminate the species' tropical forest habitat by removing the trees that support the species' essential needs for nesting, roosting, and food (see *Essential Needs of the Species,* above). Removing large sections of forest habitat may fragment the landscape and reduce and isolate populations. As the size of the habitat is reduced, it is less likely to provide the essential resources for species that require large ranges—such as scarlet macaws—and small patches of habitat retain far fewer species and populations than large patches (Ibarra-Macias 2009, p. 6; Lees and Peres 2006, pp. 203–205). Scarlet macaws use partially cleared and cultivated landscapes if the landscape provides dietary requirements and maintains enough large trees. This species is dependent on larger, older trees that have large nesting cavities. However, scarlet macaws have a better chance of surviving in large tracts of forest where suitable cavities are more common than in open and small forest remnants (Inigo-Elias 1996, p. 91). Selective

logging can lead to forest degradation because this practice generally targets older and larger trees, thus decreasing suitable nesting sites, increasing competition, and causing the loss of current generations through an increase in infanticide and egg destruction (Lee 2010, pp. 2, 12). Indirectly, clearing or degrading forests often provides people with easier access to previously inaccessible areas inhabited by scarlet macaws, which in turn increases the vulnerability of species to overexploitation by humans (Peres 2001, entire; Putz *et al.* 2000, pp. 16, 23) (see *Factor B* discussion, below). Additionally, gaining access is also often followed by full deforestation and lands cleared for agricultural use (Kaimowitz and Angelsen 1998, in Putz *et al.* 2000, p. 16).

Below, we provide a summary of information on deforestation and forest degradation within the range countries of the *A. m. cyanoptera* and northern DPS of *A. m. macao.*

Mesoamerica

Destruction of forest habitat is one of the main causes of the decline of the scarlet macaw in Mesoamerica (CONABIO 2011, p. 5; Lezama 2011, pers. comm.; McGinley *et al.* 2009, p. 11; Garcia *et al.* 2008, p. 50; Hansen and Florez 2008, pp. 48–50; Snyder *et al.* 2000, p. 150; Collar 1997, p. 421; Forshaw 1989, p. 406; Ridgely 1981, pp. 251–253). Habitat destruction is occurring rapidly in many areas within the range of the scarlet macaw in this region, including in Chiapas, Mexico; western Petén in Guatemala; eastern Olancho in Honduras; and eastern Nicaragua (Kaimowitz 2008, p. 487; Hansen *et al.* 2013, entire). This region has deforestation rates that are among the highest rates in the world (Bray 2010, pp. 92–95; Kaimowitz 2008, p. 487; Carr *et al.* 2006, pp. 10–11; FAO 2015, pp. 9–14); the remaining forest is fragmented and includes few large tracts of forest habitat (Bray 2010, pp. 92–93; Snyder *et al.* 2000, p. 150; Wiedenfeld 1994, p. 101). Although deforestation rates have declined in Mesoamerica since 1990, they are still very high (FAO 2010a, pp. 232–233; Kaimowitz 2008, p. 487; FAO 2015, pp. 9–14) and include the loss of significant amounts of primary forest (FAO 2010a, pp. 55, 259).

Mexico (*A. m. cyanoptera*)

The main drivers of deforestation and forest degradation in Mexico are conversion of forest to pasture and agriculture, and uncontrolled logging (Government of Mexico 2010b, pp. 22–24; Jimenez-Ferrer *et al.* 2008, pp. 195–196; Castillo-Santiago *et al.* 2007, p. 1217; Oglethorpe *et al.* 2007, p. 85). From 1990 to 2015, Mexico lost approximately 3.7 million hectares (ha) (9.2 million acres (ac)) of total forest (FAO 2015, p. 12) (see Tables 2a and 2b, below), and had one of the largest decreases in primary forests worldwide (FAO 2010a, pp. 56, 233), although the rate slowed toward the latter part of that period (FAO 2015, p. 12).

In southeastern Mexico, the area of land devoted to cattle ranching has increased dramatically due to the increase of regional meat prices and a decrease in the economy of staple crop cultivation (Jimenez-Ferrer *et al.* 2008, pp. 195–196; Soberanes 2018, unpaginated). Most of Mexico's remaining scarlet macaws occur in the Lacandon Forest of the southeastern state of Chiapas. This state encourages cattle ranching through subsidies, and clearing of forest for pasture in the state is ongoing (Enriquez *et al.* 2009, pp. 48–49, 58). In fact, Chiapas had the second highest rate of deforestation of Mexico's 31 states, with forest losses averaging approximately 600 km² (232 m²) per year (Masek *et al.* 2011, p. 10). Within the Lacandon Forest, cattle ranching is the most profitable activity, and it is extensive in the region (Jimenez-Ferrer *et al.* 2008, pp. 195–196). Outside of protected areas in the Lacandon Forest, the deforestation risk is primarily categorized as high to very high; inside protected areas the risk of deforestation is categorized as low to very low (Secretaría de Medio Ambiente y Recursos Naturales de México—SEMARNAT 2011, unpaginated). Monte Azules Biosphere Reserve is the largest protected area in the Lacandon Forest, and it has been relatively successful at conserving the resources within its boundaries (Castillo-Santiago *et al.* 2007, pp. 1223–1224; Figueroa and Sanchez-Cordero 2008, p. 3231). However, according to Mexico's Federal Environmental Protection Agency (*Procuraduría Federal de Protección al Ambiente* (Profepa)) more than 60 percent of illegal logging in the country occurs in 32 priority forest regions, including the reserve (Enriquez *et al.* 2009, pp. 28, 57). While illegal logging has received more attention from Mexico's policy makers, efforts to address the problem have had limited success due to insufficient human and financial resources to enforce laws, and poorly designed control efforts (Blaser *et al.* 2010, p. 346; Enriquez *et al.* 2009, p. 57; Kaimowitz 2008, p. 491) (see *Factor D* discussion, below). From 2001 to 2007, Profepa secured about 0.13 percent of the calculated total of timber illegally extracted in the country (CCMSS 2007, in Enriquez *et al.* 2009, p. 57).

We are unaware of information on projected future rates of deforestation specifically in the Lacandon Forest region, but a loss of approximately 20,000 km² (7,722 mi²) between 2000 and 2015 in the southeastern States (which include Chiapas) was projected, assuming the same rate of loss that occurred during the period 1987–2000 (Diaz-Gallegos *et al.* 2010, p. 194). By 2030, forest area in Mexico as a whole is projected to decrease, with anywhere from about 10 to 60 percent of mature forests lost, and up to 54 percent of regrowth forests lost (Commission for Environmental Cooperation 2010, pp. 45, 75).

Mexico implements several forest conservation measures and has made significant progress in conserving forest within its boundaries (Blaser *et al.* 2011, pp. 344–346; Center for International Forestry Research (CIFOR) 2010, pp. 34–36; Masek *et al.* 2011, p. 17; FAO 2010a, p. 233; Enriquez *et al.* 2009, pp. 4, 36–41). However, deforestation and forest degradation continue to be a threat to the subspecies in Mexico because the clearing of forest for agriculture, cattle ranching, and illegal logging is ongoing in Chiapas and projected to continue, and illegal logging is ongoing in the largest reserve in the Lacandon Forest in conjunction with the high risk of deforestation in protected areas outside of the forest.

Guatemala, Belize, Honduras, and Nicaragua (*A. m. cyanoptera*)

The countries of Guatemala, Honduras, and Nicaragua have the highest deforestation rate in Latin America (FAO 2010a, p. 232; FAO 2015, pp. 9–14). Guatemala lost 483 km² (186.5 mi² or 1.2 percent), Honduras lost 1,418 km² (547.5 mi² or 2.3 percent), and Nicaragua lost, 560 km² (216 mi² or 1.5 percent) of total forest, per year between 1990 and 2015 (FAO 2015, pp. 9–14) (see Tables 2a and 2b, below). Belize has a lower deforestation rate of 100 km² (39 mi² or 0.7 percent) per year (FAO 2015, pp. 9), but deforestation is increasing in the Chiquibul region, which is the only region scarlet macaws are known to nest in the country (Belize Ministry of Natural Resources and Environment 2010, pp. 44–45; Salas and Meerman 2008, pp. 22, 42).

The main causes of deforestation and forest degradation within the range of the scarlet macaw in these countries include clearing for agriculture and cattle ranching, illegal human settlements in protected areas, illegal logging, purposefully set fires, and in

some areas, activities related to drug trafficking. Some or all of these activities are ongoing in areas occupied by the species, including in the MBR in Guatemala; Río Plátano Biosphere in Honduras; Bosawas Biosphere Reserve in Nicaragua; and the Chiquibul region in Belize.

Guatemala (*A. m. cyanoptera*)

Guatemala has lost approximately 1.2 million ha (3 million ac) of forest area over the past 25 years (FAO 2015, p. 11). Approximately 38 percent of Guatemala's remaining forest area is primary forest (FAO 2015, p. 36). Deforestation is the dominant trend nationally, but rates of loss appear to be much higher in tropical over temperate areas. The most significant threat to the conservation of biodiversity and tropical forests is habitat loss, degradation, and fragmentation from wildfires, agriculture and cattle ranching, mineral and petroleum development, and drug trafficking (Tolisano and Lopez-Selva 2010, p. 3). Deforestation in the conifer forests of the highlands has existed for centuries, but today it mostly takes place in the Petén (Blaser *et al.* 2011, p. 310) where a population of *A. m. cyanoptera* occurs. Approximately 65 percent of the deforestation in Guatemala occurs in the Petén region, with most (approximately 60 percent) occurring outside protected areas (IARNA 2006, in Tolisana and Lopez-Selva 2010, p. 22). Additionally, the Petén of Guatemala is one of the few areas in the entire region that is still undergoing intensive tropical colonization resulting in forest loss from agriculture and represents the most intense deforestation threats to the Maya Forest (Bray 2010, pp. 100–102). Colonization pressure in the MBR is strong in the western and central regions; the human population increased 20-fold since 1960 and was predicted to double from 2008 to 2018 in the Petén (Bray *et al.* 2008, unpaginated).

Habitat destruction is particularly severe in two protected areas, Laguna del Tigre National Park and Sierra del Lacandón National Park; both of these areas were former strongholds of scarlet macaws (Garcia *et al.* 2008, p. 50). Furthermore, some parks that compose the MBR lost approximately 10 percent of forest cover between 1986 and 2004, with forest loss thought to be accelerating (Bray 2010, p. 100). Between 1974 and 1997, the MBR lost 65 percent of its buffer zone, and areas near roads showed increasing deforestation pressures in 1995–1997 (Hayes *et al.* 2002, p. 305; Bray *et al.* 2008, unpaginated).

Considerable efforts have been made since the start of the 21st century to reorganize the control and management of forest resources in Guatemala (Blaser *et al.* 2011, p. 317). In the rainforests of the Petén, large community-run timber concessions allow local people to improve their livelihoods on the basis of forest resources. However, forest management is hindered by high rates of deforestation and forest degradation driven by agricultural expansion, mining, illegal logging, drug-trafficking, and other threats (Blaser *et al.* 2011, p. 317; Reynolds 2008, pp. 6–7).

Belize (*A. m. cyanoptera*)

Belize has a lower deforestation rate (100 km^2 (39 mi^2, or 0.7 percent)) per year than the other countries in Mesoamerica (FAO 2015, p. 9), but deforestation is increasing in the Chiquibul region, which is the only region scarlet macaws are known to nest in the country (Belize Ministry of Natural Resources and Environment 2010, pp. 44–45; Salas and Meerman 2008, pp. 22, 42). Belize lost 250,000 ha (618,000 ac) of total forest area over the past 25 years (FAO 2015, pp. 9, 40).

The Chiquibul National Park (CNP) is Belize's largest protected area, measuring approximately 161,874 ha (400,000 ac). It is located in the Cayo District and within a larger forest region known as the Chiquibul Forest, which abuts the Belize-Guatemala border and is contiguous to the Chiquibul-Montañas Mayas Biosphere Reserve that is located in the Department of Petén, Guatemala (Salas and Meerman 2008, p. 10). This region also includes the Chiquibul Forest Reserve and the Caracol Archaeological Reserve. The most significant pressure on the CNP, the Chiquibul Forest, and biodiversity within this region includes deforestation from urban encroachment, agriculture expansion, wildfires, legal and illegal logging, illegal hunting, mining and oil exploration, and dam construction (Salas and Meerman 2008, pp. 45–46; Belize Ministry of Natural Resources and Environment 2010, p. 42).

The border areas of Belize, including the Chiquibul Maya Mountain that contains the CNP, Chiquibul Forest Reserve, and Caracoal Archaeological Reserve, are vulnerable because insufficient enforcement resources are available, particularly for Guatemalans who are impacting forested areas on the Belize side of the border. Satellite imagery showed 113 ha (280 ac) in the CNP had been cleared as of 1987 by Guatemalans for agricultural use, this increased six-fold to 692 ha (1,710 ac) by 1994, and to approximately 3,126 ha (7,725 ac) by 2007 (FCD 2007, in Belize Ministry of Natural Resources and Environment 2010, p. 45). Additionally, more than 405 ha (1,000 ac) of freshly cultivated area was reported in the CNP and incursions into Belize by Guatemalan armed forces have also been observed (FCD 2007, in Belize Ministry of Natural Resources and Environment 2010, p. 45). Unlike legal extraction, which can be regulated, illegal extraction and particularly illegal extraction by non-Belizean nationals continues to escalate, which poses a greater threat to forests than legal extraction (Belize Ministry of Natural Resources and Environment 2010, pp. 42–45). Transboundary incursions, while temporary, can have a severe impact on the forest because of the increase in demand for land for housing and farms, as well as the introduction or reinforcement of unsustainable agricultural practices (Belize Ministry of Natural Resources and Environment 2010, p. 42).

Honduras (*A. m. cyanoptera*)

Honduras lost approximately 3.5 million ha (8.7 million ac) of forest area over the past 25 years (FAO 2015, p. 11) and had the highest rate of deforestation in the Americas (see Tables 2a and 2b, below). The Honduran forest landscape is characterized by relative stability in temperate areas with localized areas of variability in forest cover but with continuing deforestation in tropical areas (Bray 2010, p. 104), especially in the eastern tropical broadleaved forest (Blaser *et al.* 2011, p. 334; Humphries *et al.* 1998, p. 99; Hansen and Florez 2008, p. 12). The most dramatic losses have been in the forests of the Atlantic Coast, which declined by approximately 73 percent between 1962 and 1990, compared to only 30 percent loss for other broadleaf forests in the same period (Humphries 1998, p. 99).

The high level of deforestation is due to illegal logging, infrastructure (*e.g.,* roads), institutionalized forest sector corruption, production of biofuels, and expanding agricultural frontiers (although some of the latter may be regarded as socially desirable) (Richards *et al.* 2003, p. 282). In the past, deforestation was due to agro-industrial development, mainly for banana plantations. However, more recently demand for land by small-scale farmers is thought to be the major cause (ITTO 2006, in Blaser *et al.* 2011, p. 334); often, such small-scale farmers ultimately sell the deforested land to larger farmers and agro-industrial owners (Blaser *et al.* 2011, p. 334). In addition, the country has a high dependence on wood as an energy

source for poor households; thirty-eight percent of the population uses firewood for domestic purposes, which is considered a very high consumption rate (Government of Honduras 2009, unpaginated).

The Mosquitia region has been characterized by relatively low population density and inaccessibility, and its indigenous inhabitants have maintained the forest cover for centuries. However, the Honduran Mosquitia appears to be under significant deforestation pressure and continues to suffer from colonization, agricultural expansion, and illegal logging, which has led to deforestation and degradation in this region and parts of the Río Plátano Biosphere Reserve (Bray 2010, p. 102; Anderson and Devenish 2009, pp. 256–257; Hayes 2007, pp. 733–734). Recent information indicates that loss of habitat and demand for the pet trade (see *Factor B* discussion, below) are significant threats in this region (Portillo Reyes 2005, in Portillo Reyes *et al.* 2010, p. 6; Brightsmith *in litt.* 2016, p. 8).

Nicaragua (*A. m. cyanoptera*)

In terms of total forest loss, Nicaragua has lost more forest than all other Central American countries except Honduras. Nicaragua has lost approximately 1.4 million ha (3.5 million ac) of forest area over the past 25 years (FAO 2015, pp. 11, 41) (see Tables 2a and 2b, below).

Much of the historic deforestation in Nicaragua was due to the expansion of cattle ranching and cotton farming until both industries declined in the 1980s, resulting in abandonment of much pasture land that left almost 1 million ha (2.5 million ac) in forest fallow (Bray 2010, p. 106). More recently, forest loss and degradation in Nicaragua was due to the expansion of agricultural and grazing land, slash-and-burn agricultural practices that create a mosaic of forest and cultivated patches across an increasing expanse of the landscape (Global Witness 2007, in McGinley 2009, p. 13). Illegal logging and institutionalized forest sector corruption have also led to forest loss and degradation (Richards *et al.* 2003, p. 282). Deforestation and forest degradation has also been attributed to forest fires, pests (*e.g.,* pine bark beetle (*Dendroctonus* sp.)) and hurricanes, though to a much lesser degree than to anthropogenic factors (Rodríguez Quiros 2005, in McGinley 2009, p. 13). Farmers often use fire to clear forest and scrubland in preparation for crops, and though these practices are typically intended to be limited to a specific area, they can spread to adjacent vegetation and lead to uncontrollable wildfires that result in forest and other biodiversity degradation and loss (McGinley 2009, p. 35).

The Nicaraguan Mosquitia (on the Caribbean slope), which is one area where the scarlet macaw is known to occur in the country, is considered an important area of extensive lowland tropical forest that it is threatened by rapid deforestation due to colonization and the advancement of the agricultural frontier (Kaimowitz 2008, p. 487; McGinley 2009, p. 31; Bray 2010, p. 105). The bulk of Nicaragua's forests on the Caribbean slope are in indigenous territories that hold rights to own their own forests, but most lack formal titles and tenure conflicts are widespread (Kaimowitz 2008, p. 487; McGinley 2009, p. 13). For example, Mosquitia residents contend that public management of protected areas fails to control agricultural expansion and violates indigenous ancestral rights to the land and its resources (Hayes 2007, p. 734). Illegal logging is a threat to forests in the Caribbean region and the Mosquitia (Bray 2010, p. 105). Illegal logging in broadleaf forests was estimated to be 30,000 to 50,000 m^3/year (1.1 to 1.8 million ft^3/year), or approximately 50 percent of the total production (Richards *et al.* 2003, p. 284). However, with respect to the binational Mosquitia region, the pressures appear to be greater on the Honduran side, although areas outside the core of the Bosawas Biosphere Reserve area are also under pressure (Bray 2010, p. 106). The indigenous occupied core zones of Bosawas are showing virtually no deforestation, with one such area having 97 percent forest cover in 2003 (Hayes 2007, p. 741). In contrast, the Río Plátano Biosphere Reserve on the Honduran side of the Mosquitia is under great deforestation pressures because of failed efforts to centralize management in the government, while protection is much more effective in the Bosawas core area due to the decentralization of management in the hands of the indigenous inhabitants (Bray 2010, p. 106).

Deforestation is ongoing in southeast Nicaragua and resulted in forest cover loss from 2000–2017 (Hansen *et al.* 2013, entire). Southeast Nicaragua includes the Indio Maíz Biological Reserve (IMBR) and its buffer zone. The reserve is situated at the southeastern border of the country (Chassot and Monge-Arias 2012, p. 63) and is one of Nicaragua's best preserved forested areas (Ravnborg *et al.* 2006, p. 2). However, the reserve is threatened by the growing human population in or around the reserve, a result of the continuous arrival of families from other parts of the country into the region in search of cheap land (Ravnborg 2010, pp. 12–13; Ravnborg *et al.* 2006, pp. 4–5). Between 1998 and 2005, the population increased more than 100 percent in the municipality of El Castillo, which is composed entirely of IMBR buffer zone and core area (Ravnborg 2010, p. 10). The expansion of African palm plantations, pasture lands, human settlements, and logging have contributed to an estimated 60 percent deforestation of the buffer zones surrounding IMBR and these activities are expanding in the reserve (Fundacion del Rio and IUCN 2011, pp. 7–8; Ravnborg 2010, pp. 12–13; Nygren 2004, pp. 193–194; Ravnborg *et al.* 2006, p. 2). Forest conservation efforts in the Nicaragua-Costa Rica border region have resulted in lower deforestation rates within the San Juan-La Selva Biological Corridor, which includes the IMBR along with other protected areas (Chassot *et al.* 2010a, in Chassot and Monge-Arias 2012, p. 67), although both primary and regrowth forest within the corridor and within the larger border region continue to decrease due to timber extraction and agricultural expansion (Fagan *et al.* 2013, unpaginated; Chassot and Monge-Arias 2012, p. 63; Chassot and Monge-Arias 2011, p. 1; Chassot *et al.* 2009, p. 9). Thus, despite the existence of protected areas, deforestation continues to occur and is a serious threat to biodiversity in this region (Fundacion del Rio 2012a, pp. 2–3; Fundacion del Rio 2012b, pp. 2–3; Fundacion del Rio and IUCN 2011, pp. 34, 37, 73–74; Chassot *et al.* 2006, p. 84). According to eBird (Sullivan et al. 2009, unpaginated), many sightings of scarlet macaws exist in southeastern Nicaragua and northeastern Costa Rica since the issuance of our proposed rules (77 FR 40222, July 6, 2012; 81 FR 20302, April 7, 2016), indicating that the species has continued to expand its range in this region. However, expansion of scarlet macaws in this region will likely be limited due to high rates of deforestation (Brightsmith 2016, *in litt.,* pp. 4–8).

Costa Rica (*A. m. cyanoptera* and *A. m. macao* Northern DPS)

Costa Rica experienced some of the highest rates of deforestation in the world historically (Bray 2010, p. 107; Government of Costa Rica 2010, p. 68), and as a result, the country's forest cover declined from 67 percent in 1940, to 17–20 percent in 1983 (Bray 2010, p. 107). Much of this deforestation was driven by agriculture and cattle ranching; however, agriculture

expansion was not as prevalent as livestock expansion (Government of Costa Rica 2010, p. 38). Cattle ranching underwent a serious contraction after 1989 (Arroyo-Mora *et al.* 2005, p. 28). In 1993, only 20 percent of original scarlet macaw habitat remained, all within protected areas (Marineros and Vaughan 1995, pp. 445–446). However, during the 1990s, Costa Rica implemented several forest conservation strategies, including new laws protecting forests and mechanisms of payment for ecosystem services (Bray 2010, pp. 107–109; Kaimowitz 2008, pp. 488–491; Pagiola 2008, entire; Sanchez-Azofeifa *et al.* 2003, entire).

Costa Rica is the only country in Mesoamerica to experience a positive change in forest cover from 1990 to 2015 (FAO 2015, p. 10) (see Tables 2a and 2b, below). Total forest cover in 2005 was estimated to be 53 percent (Government of Costa Rica 2010, p. 68), more than double the country's forest cover in the 1980s. Between 1990 and 2015, Costa Rica gained 192,000 ha (474,442 ac) of total forest area, with an annual rate of approximately 7,700 ha (19,000 ac or 0.3 percent) (FAO 2015, p. 10).

Even though Costa Rica has an increase in total forest over the past 25 years (1990–2015), some level of deforestation still occurs in parts of the country due to expansion of agriculture and livestock activities, and to illegal logging in private forests, national parks, and reserves (Government of Costa Rica 2011, p. 2; Government of Costa Rica 2010, pp. 10–11, 38, 52–54; Parks in Peril 2008, unpaginated). Fifty percent of forests in Costa Rica are found in individual rural private properties (Government of Costa Rica 2011, p. 1). The major driver of deforestation on private lands is the conversion of forest to livestock and agricultural uses. In many cases, land users generate a higher annual income with agriculture or livestock-raising than with forests. In protected areas, underfunding and lack of human resources allows the penetration of squatters and illegal loggers. Additionally, land tenure issues contribute to forest loss because indigenous communities have difficulties keeping nonindigenous farmers from encroaching onto their lands (Government of Costa Rica 2011, p. 1)

National Parks on the Caribbean slope are experiencing higher deforestation on surrounding lands than those on the Pacific slopes, which is attributed to the intensification and expansion of agricultural cash crops such as banana and pineapple (Sanchez-Azofeifa *et al.* 2003, p. 129). However, Corcovado National Park, the largest protected area in ACOSA, is one of the protected areas in Costa Rica most affected by deforestation close to its boundaries (Sanchez-Azofeifa *et al.* 2003, pp. 128–129). A comprehensive study of deforestation in Costa Rica's park system found that deforestation inside protected areas was negligible from 1987 to 1997, and that 1-km (0.62-mi) buffer zones around the protected areas had a net forest gain for the same period. However, a 1 percent annual deforestation rate was found in 10-km (6.2-mi) buffer zones, suggesting increased isolation of protected areas (Sanchez-Azofeifa *et al.* 2003, pp. 128–134). Additionally, in the ACOPAC population region, more deforestation is ongoing northwest of Carara than to the south (Brightsmith 2016, *in litt.,* p. 12).

The scarlet macaw occurs in northeastern Costa Rica, near Palo Verde and surrounding areas in northwest Costa Rica, and in the two main populations of the ACOPAC and ACOSA. Overall, Costa Rica is both losing and gaining forest cover throughout the country (Hansen *et al.* 2013, entire; Brightsmith 2016, *in litt.* p. 1). However, the best available information indicates that the scarlet macaw population in Costa Rica appears to be increasing, and Costa Rica is the only country in Central America to experience a positive change in forest cover over the past 25 years (1990–2015). We conclude that deforestation or forest degradation in the current range of the scarlet macaw in Costa Rica is not occurring at a level that is causing a further decline in the species; however, this area is not enough to sustain the northern DPS of *A. m. macao* in the future in given the threats occurring in the remainder of the range.

Panama (*A. m. macao* Northern DPS)

Deforestation in Panama is relatively low for the Mesoamerica region; the annual decrease from 1990–2015 was 169 km^2 (65 mi^2 or 0.4 percent) (FAO 2015, p. 12) (see Tables 2a and 2b, below). Drivers of deforestation include urbanization, cattle ranching, agro-industrial development, unregulated shifting cultivation, open mining, poor logging practices, charcoal-making, and fire (ITTO 2005, in Blaser *et al.* 2011, p. 354). Deforestation in the country currently occurs primarily in the Darien, Colon, Ngabe Bugle, and Bocas del Toro provinces (Blaser *et al.* 2011, p. 354), which are outside the range in which scarlet macaw currently occurs in Panama. Illegal logging is widespread in the humid forests, even in protected areas (Blaser *et al.* 2011, p. 361).

Most of Panama's scarlet macaw population occurs on Isla Coiba, which was used by the government of Panama as a penal colony until 2004, thus limiting human access and development on the island (Government of Panama 2005, p. 23; Steinitz *et al.* 2005, p. 26). Consequently, forests on the island remain largely intact. The Panamanian Tourism Authority has developed a master plan for sustainable tourism for Isla Coiba (2007–2020), which includes strategic guidelines for tourism management. Further details on these guidelines are not provided, but the plan does not include infrastructure or high-impact development (UNESCO 2011c, p. 60). Available information indicates that deforestation is not occurring on Isla Coiba (Brightsmith 2016, *in litt.,* p. 1; Hansen *et al.* 2013, entire), although some level of degradation on the island may occur by a herd of approximately 2,500 to 3,500 feral cattle (UNESCO 2011c, pp. 23, 43; Suman *et al.* 2010, p. 25). However, the extent of the cattle's impact is unknown. The complete eradication of the cattle from Coiba National Park was classified as a priority issue (Suman *et al.* 2010, p. 25), but we are not aware of information indicating that the removal of cattle has occurred. While cattle on Isla Coiba may be inhibiting the regrowth of former pasture to secondary forest, they are probably not having a significant impact on the larger forest trees on which scarlet macaws depend (Angehr 2012, *in litt.,* unpaginated).

On the mainland of Panama, in the area of the upper Río Corotú near Puerto Armuelles and Querévalo in the Chiriquí province where there have been sporadic sightings of scarlet macaws, we are unaware of information indicating that deforestation and forest degradation are impacting scarlet macaws. We are also unaware of information indicating that deforestation is occurring near the small (but unknown) number of scarlet macaws on the southern end of the Azuero Peninsula of Veraguas, near Cerro Hoya National Park and in the forest reserves just to the east. Less than 15 percent of the peninsula is covered by mature forest, but most of the remaining forest can be found in Cerro Hoya National Park and the Tronosa Forest Reserve to the east (Miller *et al.* 2015, p. 1).

We are aware of little information on the magnitude and extent of deforestation and forest degradation on Panama's mainland and Isla Coiba, although the most recent information indicates that deforestation is not occurring on Isla Coiba or any areas where the scarlet macaw remains in

very small populations on the mainland. The World Heritage Centre and IUCN concluded that the main conservation concerns (*i.e.,* cattle) on Isla Coiba remain poorly addressed (UNESCO 2011c, p. 61).

Summary Tables

TABLE 2a—TOTAL FOREST AREA IN MESOAMERICA 1990–2015

	Forest area (1,000 ha)				
	1990	2000	2005	2010	2015
Belize	1,616	1,459	1,417	1,391	1,366
Costa Rica	2,564	2,376	2,491	2,605	2,756
Guatemala	4,748	4,208	3,938	3,722	3,540
Honduras	8,136	6,392	5,792	5,192	4,592
Mexico	69,760	67,856	67,083	66,498	66,040
Nicaragua	4,514	3,814	3,464	3,114	3,114
Panama	5,040	4,867	4,782	4,699	4,617

TABLE 2b—PERCENT CHANGE OF TOTAL FOREST AREA IN MESOAMERICA 1990–2015

	Annual change rate							
	1990–2000		2000–2010		2010–2015		1990–2015	
	1,000 ha/yr	% change	1,000 ha/yr	% change	1,000 ha/yr	% change	1,000 ha/yr	% change
Belize	−15.7	−1.0	−6.8	−0.5	−5.0	−0.4	−10.0	−0.7
Costa Rica	−18.8	−0.8	22.9	0.9	30.2	1.1	7.7	0.3
Guatemala	−54.0	−1.2	−48.6	−1.2	−36.4	−1.0	−48.3	−1.2
Honduras	−174.4	−2.4	−120.0	−2.1	−120.0	−2.4	−141.8	−2.3
Mexico	−190.4	−0.3	−135.8	−0.2	−91.6	−0.1	−148.8	−0.2
Nicaragua	−70.0	−1.7	−70.0	−2.0	0.0	0.0	−56.0	−1.5
Panama	−17.3	−0.3	−16.8	−0.4	−16.4	−0.4	−16.9	−0.4

South America

Northwest Colombia (*A. m. macao* Northern DPS)

Colombia has lost approximately 5.9 million ha (14.6 million ac) of forest over the past 25 years, with a steady rate of change over that time frame (FAO 2015, p. 10). In northwest Colombia, forest loss is due primarily to conversion of land to pasture and agriculture, but also mining, illicit crops, and logging (Ortega and Lagos 2011, pp. 85–86). Scarlet macaws in northwest Colombia are believed to be affected primarily by habitat loss, and to a lesser extent trade (Donegan 2013, *in litt.,* unpaginated).

The Magdalena and Caribbean regions of northwest Colombia have approximately 7 percent and 23 percent (respectively) of their land area in original vegetation, with the remainder converted primarily to grazing land (Etter *et al.* 2006, p. 376). The Magdalena region lost 40 percent of its forest cover between 1970 and 1990, and an additional 15 percent between 1990 and 1996 (Restrepo and Syvitski 2006, pp. 69, 72). Within the Caribbean region, Parque Nacional Natural (PNN) Paramillo (460,000 ha (1,136,680 ac)), Santuario de Fauna y Flora Los Colorados (Los Colorados Fauna and Flora Sanctuary) (1,000 ha (2,500 ac)), and Reserva Forestal de Montes de Maria (Montes Maria Forest Reserve) (7,460 ha (18,500 ac)) have lost 42, 71, and 70 percent of their forest, respectively, since they were created in the late 1970s and early 1980s (Millet *et al.* 2004, p. 454). The Caribbean region of northwest Colombia showed the highest projected rate of change of forest cover by the year 2030 of all regions evaluated (Gonzáles *et al.* 2011, p. 45).

Deforestation is ongoing in northwest Colombia (Colombia Gold Letter 2012, pp. 1–2; Ortega and Lagos 2011, pp. 81–82). Few large tracts of forest remain within the range of the scarlet macaw in this region, for instance, in the areas of Serrania de San Lucas and PNN Paramillo, but these areas in northwest Colombia are also deforestation hotspots (Ortega and Lagos 2011, p. 82; Salaman *et al.* 2009, p. 21).

Summary of Factor A

The destruction and modification of the scarlet macaw's habitat because of deforestation and forest degradation is a threat to the scarlet macaw throughout parts of its current range, although the magnitude of this impact varies across its range. Deforestation has fragmented habitat and continues to reduce and isolate areas that support populations of scarlet macaws. It directly eliminates the species' tropical forest habitat by removing the trees that support the species' nesting, roosting, and food requirements. Further, clearing or degradation of forests, including selective logging and the development of roads, provides additional opportunities for humans to expand into previously inaccessible areas, which in turn creates easier access and opportunity to exploit previously undisturbed areas. Subsequent encroachment is often followed by additional deforestation as lands are cleared for cattle ranching and agriculture. Although scarlet macaws are known to use partially cleared and cultivated landscapes, they are only able to do so if the landscape maintains enough large, older trees that provide the essential needs of the species.

Deforestation rates in Mesoamerica, excluding Costa Rica, are the highest in Latin America due to expanding agriculture, cattle ranching, and selective and often illegal logging. Destruction of forest habitat is one of the main causes of the decline of scarlet macaw subspecies *Ara macao cyanoptera.* Throughout the range of the northern subspecies (*A. m. cyanoptera*) where most of the species' historical habitat has been eliminated, evidence indicates that deforestation is ongoing. We consider deforestation and forest degradation to be an immediate threat to

the subspecies because clearing of forest for agriculture, cattle ranching, and illegal logging that leads to the loss of scarlet macaw habitat are ongoing in Mexico in the Lacandon Forest and Chiapas, in the western Petén of Guatemala, and in the Chiquibul region of Belize. The Honduran Mosquitia appears to be under significant deforestation pressure and continues to suffer from rapid colonization, agricultural expansion, and illegal logging. Nicaragua lost more forest than all other Central American countries except Honduras. With respect to the binational Mosquitia region, pressure appears to be greater on the Honduran side, but Nicaragua suffers rapid deforestation due to colonization and illegal logging. The border region (Río San Juan (San Juan River) of southeastern Nicaragua and northeastern Costa Rica has sections of contiguous forests; however, deforestation continues to occur and is a serious threat to biodiversity in this area.

Throughout the range of the northern DPS of the southern subspecies (*Ara macao macao*) evidence indicates that Costa Rica is both losing and gaining forest cover throughout the country. Costa Rica experienced some of the highest rates of deforestation in the world historically. More recently, Costa Rica has an increase in total forest over the 25-year period from 1990–2015 and is the only country in Central America to experience a positive change in forest cover. But some level of deforestation still occurs in parts of the country due to expansion of agriculture and livestock activities, and illegal logging in private forests and in national parks and reserves. The available information indicates that the scarlet macaw population in Costa Rica appears to be increasing, and we are unaware of any information indicating that deforestation or forest degradation in the current range of the scarlet macaw in Costa Rica is occurring at a level that is causing or likely to cause a further decline in the species.

In Panama, we are aware of little information on the magnitude and extent of deforestation and forest degradation on the mainland, although the scarlet macaw was described as almost extinct from mainland Panama. Currently, deforestation is concentrated in provinces outside the range of where scarlet macaws occur in Panama. On Isla Coiba, where most of the population in Panama occurs, evidence indicates large-scale deforestation is not a threat to the species.

Much of northwest Colombia has been deforested and it is expected to continue in the region. The Caribbean region of northwest Colombia showed the highest projected rate of change of forest cover of all regions evaluated. Forest loss in the region is due primarily to conversion of land to pasture and agriculture, mining, illicit crops, and logging. The number of scarlet macaws in northwest Colombia is unknown, but habitat loss has caused the decline of the species there, such that the species has been all but extirpated from large areas in the region. However, the region is reported to have large tracts of suitable forest habitat.

The scarlet macaw subspecies (*Ara macao cyanoptera* and *A. m. macao*) in Mesoamerica are significantly impacted by deforestation in many countries in this region, which comprises less than 17 percent of the species' range. Because deforestation is ongoing and the populations of the scarlet macaw subspecies *A. m. cyanoptera* are small, we consider habitat destruction and modification to be a substantial threat to the northern subspecies *A. m. cyanoptera* throughout its range in Mexico, Guatemala, Belize, Honduras, Nicaragua, and Costa Rica (Atlantic slope). But even though deforestation continues in parts of Costa Rica, we do not find that it is occurring at a level that is an immediate threat to *A. m. macao* on the Pacific Coast of Costa Rica, especially because the data indicate that the species is likely increasing within the two main populations on the Pacific Coast. Similarly, the data indicate that deforestation is not impacting the scarlet macaw in Panama where it currently occurs. Therefore, we do not consider deforestation to be as significant of a stressor to *A. m. macao* in Costa Rica and Panama. However, in Colombia, habitat loss has caused the decline of the species from large areas in the region, and many of the areas in northwest Colombia are deforestation hotspots, even though the region is reported to have large tracts of suitable forest habitat.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Parrots and macaws have been captured and traded for centuries in the Neotropics (Cantu-Guzman *et al.* 2007, p. 9; Guedes 2004, p. 279; Snyder *et al.* 2000, pp. 98–99). Because they are colorful, adapt to captivity, and can imitate language, they are captured for their feathers and used as pets (Guedes 2004, p. 279). The scarlet macaw is a popular pet species within its range countries, and the majority of birds sold as pets remain within country (Snyder *et al.* 2000, p. 150; Wiedenfeld 1994, p. 102). Poaching of parrots from the wild is driven by demand from the pet industry and rural poverty where wild parrot populations exist. Capture for sale in local markets can provide a significant source of supplemental income in rural areas (Huson 2010, p. 58; González 2003, p. 438). Overall, capture for the pet trade, along with habitat loss as described above, are the main factors impacting the existence of scarlet macaws in the wild (Iñigo-Elias *in litt.* 1997, in Snyder *et al.* 2000, p. 150; Guedes 2004, p. 280).

Because the scarlet macaw is a long-lived species with a low reproductive rate, low survival of chicks and fledglings, late age to first reproduction, and large proportions of nonbreeding adults, this species is particularly vulnerable to overexploitation from harvesting (Munn 1992, p. 57; Wright *et al.* 2001, p. 712). Capture of parrots decreases the population, inhibits future breeding by removing reproductive age adults, causes mortality of eggs or chicks, causes the loss of or damage to nesting sites, and can stop population growth and cause local extirpations if individuals are removed year after year (Cantu-Guzman *et al.* 2007, p. 14). When chicks are targeted, the effects on the population may be difficult to detect because scarlet macaws are long-lived and it would take time to show a decline (Wright 2001, p. 717). When adults are targeted, the population is depleted more rapidly because reproductive individuals are removed from the population and the impact is immediate (Collar *et al.* 1992, p. 6).

Legal International Trade

The United States and Europe were historically the main markets for wild birds in international trade (FAO 2011b, p. 3). Trade in parrots was particularly high in the 1980s, due to a huge demand from developed countries (Rosales *et al.* 2007, pp. 85, 94; Best *et al.* 1995, p. 234). However, in the years following the enactment of the WBCA in 1992 (16 U.S.C. 4901 *et seq.*), poaching levels were lower than in prior years, suggesting that import bans in developed countries reduced poaching levels in exporting countries (Wright *et al.* 2001, pp. 715, 718). A massive reduction occurred in the number of wild-caught parrots imported to the United States, both from Central and South America and the rest of the world, following the enactment of the WBCA (Pain *et al.* 2006, p. 327). The European Union, which was the largest market for wild birds following enactment of the WBCA, banned the import of wild birds in 2006 due to

disease concerns (FAO 2011b, p. 21), thus eliminating another market for wild birds and further reducing international trade.

The scarlet macaw was initially listed in Appendix II of CITES (June 6, 1981), but effective January 8, 1985, was included in Appendix I. Species included in Appendix I are considered threatened with extinction, and international trade is permitted only under exceptional circumstances, which generally precludes commercial trade. Of the total live specimens reported in trade between 1985 and 2016, approximately 95 percent of the total live, wild-sourced scarlet macaws that were in trade during 1985 to 2016 were exported from Suriname, which is one of only two countries in South America that still legally export significant quantities of wildlife (Duplaix 2001, p. ii) and the only scarlet macaw range country that entered a reservation to the Appendix I listing of the species. A reservation means that these countries are treated as a country not party to CITES with respect to the species concerned. However, if a country with a reservation to a listing in the CITES Appendices wishes to trade that species with a country that has not taken the same reservation, then that trade must follow the CITES permit requirements (CITES 2018, unpaginated). Wildlife exports generate significant income and jobs in Suriname, and the country has set an annual voluntary export quota of 100 live specimens per year since 1998. The quota includes a notation that Parties may not authorize import for primarily commercial purposes (CITES 2018, unpaginated). Suriname's wildlife export quotas are reported to be ''realistic'' in that they are based on the belief that larger parrots cannot sustain large harvests (Duplaix 2001, pp. 10, 65, 68). Actual exports of CITES listed species are often lower than Suriname's allowed quotas (FAO 2010b, p. 42; Duplaix 2001, p. 10). However, in a number of recent years, Suriname has also reported exports in excess of its quota of 100 live specimens.

Poaching Within Mesoamerica

The scarlet macaw is protected by domestic laws within all countries in Mesoamerica (see *Factor D* discussion, below). However, enforcement of wildlife laws in these countries is generally lacking because they often do not have the resources, personnel, or both to adequately enforce their laws (TRAFFIC NA 2009, p. 20; Valdez *et al.* 2006, p. 276; Mauri 2002, entire). Additionally, low salaries and high unemployment in the region drives people to search for extra sources of income, and as a result, scarlet macaws are still captured throughout the region and traded illegally (TRAFFIC NA 2009, pp. 23–24). Due to the high mortality rate associated with capture and transport, the number of birds actually sold or exported for the pet trade represents only a portion of those removed from the wild. Cumulative mortality rates before parrots reach customers have been estimated to be as high as 77 percent; for nestlings, approximately 80 percent died before reaching a pet store (Inigo and Ramos 1991 and Enkerlin 2000, in Cantu-Guzman *et al.* 2007, p. 60).

Mexico, Guatemala, and Belize (*A. m. cyanoptera*)

Poaching has occurred at significant levels in the Maya Forest region of Mexico, Guatemala, and Belize, and is one of the most important factors influencing population growth of the scarlet macaw in this region, indicating that even relatively low levels of poaching could result in population declines (Clum 2008, pp. 76–80).

Poaching is a persistent problem and the second largest threat to scarlet macaws in Mexico after deforestation, although information on the extent of poaching in Mexico is largely unavailable (Inigo-Elias 1996, p. 62; Boyd and McNab 2008, p. xiii). In many instances, poachers damage trees to reach the birds. During the 1993 breeding season, four nest trees from a total of 41 were cut down and another was burned (Inigo-Elias 1996, p. 62). Detained traffickers reported that parrot populations in Chiapas (the primary state in which the species occurs in Mexico) have decreased so much that trapping is now conducted in protected areas in Chiapas (Cantu-Guzman *et al.* 2007, p. 14). Fewer than 50 scarlet macaws are captured annually in Mexico (Cantu-Guzman *et al.* 2007, p. 35).

Much of the scarlet macaw population in Guatemala is currently protected through conservation efforts. Prior to the Wildlife Conservation Society (WCS) monitoring nests in 2002, poaching was a serious concern. Between 1992 and 2002, citing Proyecto Guacamaya of ProPeten data, 115 chicks were poached from the Laguna del Tigre area (Moya and Castillo Villeda 2002, in McReynolds 2016, *in litt.,* unpaginated). However, since 2003, the severity of poaching has greatly decreased because of WCS's conservation efforts (Garcia *et al.* 2008, p. 51). Although in areas where the WCS is not working and protection is lacking, which is up to 25 percent of the population in Guatemala, it is likely that these nests are poached (Boyd and McNab 2008, p. vi; Garcia *et al.* 2008, p. 51).

In the Chiquibul Forest in Belize, poaching is a threat to scarlet macaws, but the situation has improved in recent years. In 2011, the poaching rate was 89 percent (Breaking Belize News 2017, unpaginated). Nests were being poached by guaceros and xateros, which are Guatemalans who illegally cross the border into Belize for economic reasons. Thus, with this high percentage of poached chicks, scarlet macaws essentially had no productivity (Harbison 2017, unpaginated). Of the nests monitored in 2013, approximately 30 percent of the failed nests were attributed to poaching; these nests contained 33 percent of the total hatchlings (The Guardian Belize 2014, unpaginated). Incidences of poaching were reduced to an average of 35 percent between 2012 and 2015 (Breaking Belize News 2017, unpaginated). Over the past 5 years, the Scarlet Six team (see *Conservation Measures,* below) has reduced overall nest poaching from higher than 90 percent to less than 30 percent, and 2017 is the second year in a row that no known nests were poached (Harbison 2017, unpaginated).

Honduras and Nicaragua (*A. m. cyanoptera*)

Poaching of the scarlet macaw occurs in both Honduras and Nicaragua, although little quantitative information is available (TRAFFIC NA 2009, p. 5).

In Honduras, the scarlet macaw population has decreased and is experiencing severe reproductive limits due to poaching (Lafeber Conservation and Wildlife 2011, unpaginated). Nest monitoring indicated 5 of 6 nests active in February 2003 were poached by August (McReynolds 2016, *in litt.,* unpaginated). In 2003, an estimated 200 to 300 chicks were poached just in the Rus Rus area of the Honduran Mosquitia (Portillo Reyes *et al.* 2004, in McReynolds 2011, *in litt.,* unpaginated). In a 2010–2011 survey of 20 nests previously used by parrots, 16 of which were scarlet macaws, 17 showed evidence of poaching including all the scarlet macaw nests (Lafeber Conservation and Wildlife 2011, unpaginated).

In Nicaragua, capture of parrots for the pet trade is described as common (Herrera 2004, p. 1). Scarlet macaws are one of the three most preferred species in Nicaragua's parrot trade and are among the main CITES-species harvested for illegal trade in the country (McGinley *et al.* 2009, p. 16; Lezama 2008, abstract; Nicaragua Ministerio del Ambiente y Los Recursos Naturales

(MARENA) 2008, p. 25). Based on interviews with locals, Nicaraguan poachers bring chicks into Honduras from Nicaragua, where they more easily enter into trade (Portillo-Reyes *et al.* 2004, in McReynolds 2016, *in litt.,* unpaginated). Confiscations and prosecutions by government authorities occurred in 2009 in the Caribbean region of the county and in 2010 in Managua where a dozen scarlet macaws were for sale (McReynolds 2016, *in litt.,* unpaginated). Parrot populations in Nicaragua have declined by as much as 60 percent since the mid-1990s, although the loss of habitat has also contributed to the decline (MARENA 2008, p. 51). Additionally, the small population in the Cosigüina Nature Reserve on the Pacific Coast suffers from poaching of both chicks and adults (Boyd and McNab 2008, p. x).

Costa Rica (*A. m. cyanoptera* and *A. m. macao*)

Historically, scarlet macaws in Costa Rica experienced heavy poaching pressure. Of 56 known nest cavities in the ACOPAC studied from 1992 to 2000, 64 percent were considered at high risk and 23 percent were at medium risk (Vaughan *et al.* 2003, p. 8; McReynolds 2016, *in litt.,* unpaginated). In studies conducted in the 1990s in Carara National Park, which is the traditional stronghold of the ACOPAC population of scarlet macaws, 56 to 64 percent of evaluated nest sites showed signs of being poached with some nests poached yearly (Vaughan *et al.* 2003, pp. 6, 8; Snyder *et al.* 2000, p. 150; Marineros and Vaughan 1995, p. 460). However, anti-poaching efforts in ACOPAC during 1995–1996 may have increased recruitment into the population (Vaughan *et al.* 2005, p. 127). From 2004 to 2009, most of the poached animals were paca (*Cuniculus paca*), but scarlet macaws were also poached and were among the top four species identified by park officials as most at risk of poaching, local extinction, or both (Huson 2010, pp. 19–20). Hunting is important in the communities for both subsistence and monetary gain; with low-income communities surrounding the park, the incentives to poach are great (Huson 2010, p. 66). A significant effort to control poaching in the Carara area is ongoing because poaching continues to be a serious problem (Vaughan 2005, pers. comm., in McReynolds 2016, *in litt.,* unpaginated). However, the ACOPAC population of scarlet macaws was believed to be self-sustaining, even with heavy poaching pressure (Vaughan *et al.* 2005, p. 128).

In 2005, in the ACOSA, approximately half (48 percent) of residents interviewed believed that scarlet macaws were still being poached in the ACOSA, although 85 percent of the interviewees believed numbers of scarlet macaws were increasing (Dear *et al.* 2010, pp. 10–13). Forty-three percent of the interviewees mentioned that less poaching occurs now than before, and none said the activity had increased (Dear *et al.* 2010, p. 13). Therefore, it is believed that poaching is ongoing but has decreased and the ACOSA population is increasing (Dear *et al.* 2010, p. 19). Based on interviews, it was estimated that 25 to 50 chicks are poached each year (Dear *et al.* 2005, p. 19). In 2006, 11 of 57 (19 percent) potential nest cavities found in ACOSA were reported by local residents as recently poached, but the actual number of poached nests is likely greater (Guittar *et al.* 2009, pp. 390, 392).

Panama (*A. m. macao*)

Little information is available on capture of scarlet macaws in Panama, although it was a factor leading to the virtual extirpation of this species from the country (McReynolds 2016, *in litt.* unpaginated). Trade in rare and endangered species is a constant threat in the country due to the high prices paid for these animals and their parts (Parker *et al.* 2004, p. II–6; Keller and Schmitt 2008, abstract). Additionally, poaching is a common occurrence in rural areas because wild game is a traditional source of protein for residents (Parker *et al.* 2004, p. II–6). Cerro Hoya National Park is located within Panama's most impoverished province, and thus the capture of scarlet macaws is a potential threat because campesinos (a Latin American Indian farmer or farm laborer) invade unoccupied lands and poaching for sustenance and monetary gain is common (Government of Panama 2005, p. 36). Moreover, despite a program to use captive scarlet macaw feathers to cut down on hunting of wild birds for their feathers, hunting still occurs and poaching of chicks for pets remains a problem at Cerro Hoya National Park (Rodriquez and Hinojosa 2010, in McReynolds 2016, *in litt.,* unpaginated).

While scarlet macaws may occasionally be illegally captured on Isla Coiba, we are not aware of any information that poaching is currently a threat to the species on the island. The scarlet macaw primarily occurs on the south end where poaching is a possibility. However, based on interviews with the owner of Bird Coiba (the bird guide service for the island), two rangers with many years of experience on the island, and a discussion with the superintendent of Isla Coiba National Park, poaching is not a known problem on the island (McReynolds 2016, *in litt.* unpaginated). The island has no permanent habitations except a police base and the ranger base; the island has no roads and very few maintained trails, which are all short; and access is by boats that are boarded and checked regularly (McReynolds 2016, *in litt.* p. 8).

Summary of Factor B

Parrots and macaws have been captured and traded for centuries in the Neotropics. Despite regulation of international scarlet macaw trade through CITES, the WBCA, and similar stricter measures by the European Union, some level of international trade occurs with wild scarlet macaws. However, most scarlet macaws reported in trade are from non-wild sources; were captive-bred; or were parts, feathers, or scientific specimens rather than live birds. Of the wild-sourced, live birds, the vast majority were exported from Suriname, which is reported to set realistic quotas. Therefore, international trade of scarlet macaws is not a current threat to the species.

The scarlet macaw is a popular pet species within its range countries and overutilization as a result of poaching for the pet trade is a significant threat to the scarlet macaw in some areas of its current range. The scarlet macaw is susceptible to overharvest because it is a long-lived species with a low reproductive rate and it is slow to recover from harvesting pressures; thus, removal of individuals year after year can stop population growth and cause local extirpation. Most harvested birds likely remain within the species' range countries.

The subspecies *Ara macao cyanoptera* occurs mainly in small populations; thus, poaching wild birds for the pet trade is detrimental to sustaining these populations. Evidence suggests poaching occurs at significant levels in the Maya Forest region, where even moderate levels of poaching could cause a decline in these already small populations. Many of the scarlet macaws nesting sites in Guatemala are currently protected through conservation efforts compared to nesting sites in Mexico; therefore, success rates in Mexico are almost certainly lower than in Guatemala, even though about 25 percent of Guatemala's population is unprotected. In Belize, nest poaching has been dramatically reduced over the past 5 years but continues. Although quantitative data from Honduras and Nicaragua are lacking, poaching is recognized as a significant threat to the scarlet macaws in these countries.

The subspecies *Ara macao macao* in Costa Rica and Panama has experienced heavy poaching pressure historically. Efforts to control poaching are ongoing in Costa Rica, but it continues to be a substantial problem. Little information is available regarding poaching of scarlet macaws in Panama. It is one factor that led to the near extirpation of this species from mainland Panama and remains a concern at Cerro Hoya National Park. Poaching is not a threat on Isla Coiba.

The scarlet macaw in Mesoamerica consists mostly of small populations, and it is reasonable to conclude that any level of poaching poses a significant threat to the species in this portion of its range, especially considering the susceptibility of scarlet macaws because of its reproductive traits. The available information indicates that poaching of *Ara macao cyanoptera* chicks and adults is a significant stressor throughout its range. Populations of *A. m. macao* in Costa Rica on the Pacific slope are likely increasing even with poaching pressure, indicating that poaching may not be a major threat in Costa Rica. However, poaching continues and remains a concern. Little information exists regarding poaching of scarlet macaws in Panama, but because poaching was one of the reasons for the species' almost extirpation on the mainland and the remaining populations are very small and susceptible to poaching, we consider poaching to be a stressor to scarlet macaws on mainland Panama. We are not aware of information regarding the level of poaching in northwest Colombia.

Factor C. Disease or Predation

In our proposed rule (77 FR 40237–40238; July 6, 2012), we concluded that disease and predation are not threats to the northern subspecies of scarlet macaw or the northern DPS of the southern subspecies. We received no additional information indicating otherwise.

Factor D: Inadequacy of Existing Regulatory Mechanisms

Forest Conservation Regulations

With the exception of Belize, all countries in the range of *A. m. cyanoptera* and the northern DPS of *A. m. macao* have a national or subnational policy framework on forests and their management, although Belize has a variety of regulations that protect their natural resources. Of those countries with a policy framework, all but Colombia have specific national forest laws in support of these policies, but laws supporting national forest policy in Colombia are incorporated within other laws (FAO 2010a, pp. 302–303). All range countries except Belize also have National Forest programs that provide the framework to develop and implement their forest policies, although the status of Panama's program is unknown (for information on regulatory mechanisms pertaining to forest management in scarlet macaw range countries see: Peña-Claros et al. 2011, entire; Espinosa et al. 2011, pp. 21–26; FAO 2011c, p. 78; Government of Colombia 2011, pp. 89–91, 203–211; Guignier 2011, pp. 12–22; Larson and Petkova 2011, entire; May et al. 2011, pp. 16–55; Stern and Kernan 2011, pp. 52–54, 88– 90; United Nations Collaborative Programme on Reducing Emissions from Deforestation and Forest Degradation in Developing Countries (UN–REDD) 2011, unpaginated; Belize Ministry of Natural Resources and Development 2010, pp. 54, 57–58; Blaser et al. 2010, pp. 263– 267, 277–281, 291–293, 300–302, 311– 312, 320–323, 334–337, 345–346, 365– 367, 376–377, 394–396; CIFOR 2010, p. 45; FAO 2010a, pp. 150–158, 302–303; Government of Belize 2010, pp. 27–34; Sparovek 2010, pp. 6046–6047; Tolisano and Lopez-Selva 2010, pp. 24–28; Bauch et al. 2009, entire; McGinley et al. 2009, pp. 18–30; Patriota 2009, pp. 612–615; Trevin and Nasi 2009, entire; Byers and Israel 2008, pp. 29–34; Torres-Lezama et al. 2008, entire; Hopkins 2007, pp. 398–405; Playfair 2007, entire; Portilla and Eguren 2007, pp. 19–32; World Bank 2007, pp. 10–28, 71–76; Clark 2006, pp. 19–29; Grenand et al. 2006, pp. 49, 54–56; Baal 2005, unpaginated; Parker et al. 2004, pp. III–1–III–8, Annex H, Annex I; Government of Belize 2003, entire; Bevilacqua et al. 2002, pp. 6–9; Mauri 2002, entire; Vreugdenhil et al. 2002, pp. 6–10).

Habitat destruction or modification from deforestation and forest degradation occurs in most portions of the range of the *A. m. cyanoptera*. Many, if not all, of these countries have regulations aimed at conserving forested area, but for the most part they are not able to adequately enforce their regulations due to lack of financial, personnel, and technical resources; conflicts over land ownership, which can lead to illegal logging and expansion of agriculture and pasture; and lack of oversight or coordination with a governing body.

In the northern DPS of the southern subspecies *A. m. macao,* Costa Rica is both losing and gaining forested land, but we are unaware of any information indicating that deforestation or forest degradation in the current range of the scarlet macaw in Costa Rica is occurring at a level that is causing a decline in the species. Forest area has increased over 25 years and the range of scarlet macaws on the Pacific slope of Costa Rica has increased. In Panama, although large-scale deforestation is not occurring where the small populations of scarlet macaws are currently known to exist, small-scale logging continues with little oversight and significantly contributes to ongoing forest degradation. In northwest Colombia, even though the region is reported to have large tracts of suitable forest, many of the areas in northwest Colombia are deforestation hotspots. Habitat loss has caused the decline of the species from large areas in the region, and existing regulations have not been sufficient to reverse the transformation of natural ecosystems. Major forest reserves have been degraded from their original condition. Therefore, the existing regulatory mechanisms addressing this threat in Panama and Colombia are not adequate to protect forested land that the species depends on.

Illegal Capture and Trade

The scarlet macaw is protected under CITES, an international agreement among governments to ensure that the international trade of CITES-listed plant and animal species does not threaten species' survival in the wild. Under this treaty, CITES Parties (member countries or signatories) regulate the import, export, and re-export of specimens, parts, and products of CITES-listed plant and animal species. Trade under CITES is authorized through a system of permits and certificates that are issued by the designated CITES Management Authority of each CITES Party (CITES 2018, unpaginated). All the countries within the range of the scarlet macaw are Parties to CITES. However, when the species was included in Appendix I in 1985, Suriname (along with three European countries: Austria, Switzerland, and Liechtenstein) entered a reservation to the listing (Austria withdrew its reservation in 1989) (UNEP–WCMC 2012, unpaginated). A reservation means that a country is treated as not a party to CITES with respect to the species concerned. However, if a country with a reservation to a listing in the CITES Appendices wishes to trade that species with a country that has not taken the same reservation, then that trade is subject to the CITES permit requirements since the non-reserving Party is bound by the CITES requirements (CITES 2018, unpaginated).

The import of scarlet macaws into the United States is also regulated by the

WBCA, which was enacted on October 23, 1992. The purpose of the WBCA is to promote the conservation of exotic birds by ensuring that all imports of exotic birds to the United States are biologically sustainable and not detrimental to the species in the wild. The WBCA restricts the import of most CITES-listed live or dead exotic birds. Import of dead specimens is allowed for scientific purposes and museum specimens. Permits may be issued to allow import of listed birds for various purposes, such as scientific research, zoological breeding or display, or personal pets, when certain criteria are met. The Service may also approve cooperative breeding programs and subsequently issue import permits to allow the import of birds for use in such programs. The United States may also approve foreign sustainable use management plants under the WBCA. At this time, the scarlet macaw is not part of a Service-approved cooperative breeding program, and very few wild-caught birds have been recorded for importation.

The Lacey Act (18 U.S.C. 42; 16 U.S.C. 3371–3378) was originally passed in 1900, and was the first Federal law protecting wildlife. Today, it provides civil and criminal penalties for the illegal trade of animals and plants. Under the Lacey Act, in part, it is unlawful to import, export, transport, sell, receive, acquire, or purchase any fish or wildlife taken, possessed, transported, or sold: (1) In violation of any law, treaty, or regulation of the United States or in violation of any Indian tribal law; or (2) in interstate or foreign commerce, any fish or wildlife taken, possessed, transported, or sold in violation of any law or regulation of any State or in violation of any foreign law. The Lacey Act covers all fish and wildlife and their parts or products, plants protected by CITES.

Although illegal trapping for the pet trade occurred at high levels during the 1980s, international trade has decreased significantly as a result of tighter enforcement of CITES regulations, adoption of the WBCA, and similar stricter measures under European Union legislation, along with adoption of national legislation in range countries (Snyder *et al.* 2000, p. 99). Based on the best available data, we found no information indicating international trade is currently a threat to the scarlet macaw populations.

The laws and regulations that govern capture and trade of scarlet macaw in the range countries are briefly discussed below.

Mexico (*A. m. cyanoptera*)

The General Law of Wildlife for Mexico establishes that no bird specimen corresponding to the family Psittacidae or psittacid (including *Ara macao cyanoptera*), whose natural distribution is within the national territory, may be subject to extractive exploitation for subsistence or commercial purposes, especially species that are endemic, threatened, endangered, or protected by international treaties (Official Mexican Standard NOM–059–SEMARNAT–1994; Animal Legal and Historical Center 2018, unpaginated; Cantu-Guzman 2007, p. 45). Mexico considers the scarlet macaw to be in danger of extinction within the country (Government of Mexico 2010a, p. 32). The Secretariat may only grant authorizations for extractive use for conservation or scientific research purposes. Responsibility for implementation lies with Profepa, the agency of the Environment Ministry in charge of policing environmental laws (Cantu-Guzman *et al.* 2007, p. 45). The most serious difficulty Profepa faces in the combat against illegal bird trade is the limited number of inspectors it has for the whole country (Profepa 2002, in Cantu-Guzman *et al.* 2007, p. 45). Seizures by Profepa was estimated at approximately 2 percent of the annual illegal trade, which represents a very small portion of the number of parrots captured each year (Cantu-Guzman *et al.* 2007, p. 49). Of the 65,000 parrots that were captured annually, data indicate as few as up to 50 scarlet macaws (or less than 0.1 percent of the total parrots) were captured annually in Mexico, even though some of these may be from Central American countries (Cantu-Guzman *et al.* 2007, p. 35). From 1995 to 2005, 144 scarlet macaws were seized by Profepa (Cantu-Guzman *et al.* 2007, p. 52).

Guatemala (*A. m. cyanoptera*)

National hunting legislation was first passed in Guatemala in 1970, with the mandates of this national policy reinforced in the legislation passed on protected areas in 1989. Hunting is widely used by most rural residents in Guatemala to supplement food and income needs, and is largely unregulated and inconsistently monitored (Tolisano and Lopez-Selva 2010, p. 44).

Most of the data on hunting has not been published or systematically organized to indicate the magnitude or intensity of local and national hunting pressures (CECON–PROBIOMA 2005, in Tolisano and Lopez-Selva 2010, p. 44). National and municipal agencies generally have insufficient human resources, have insufficient training, and lack the necessary equipment to effectively monitor or mitigate hunting impacts, and much of the monitoring that does occur is done on a relatively haphazard basis by different research institutions and nongovernmental organizations (Tolisano and Lopez-Selva 2010, p. 44).

A similar situation to unregulated hunting exists for the capture and sale of live animals to supply the pet trade, research institutions, and zoological collections. Scarlet macaws are overexploited; nestlings are taken from their tree cavity nests prior to fledging and sold on the local market in the Petén (Tolisano and Lopez-Selva 2010, p. 44). Guatemalan authorities do a relatively good job of trying to control this traffic, but rumors that scarlet macaw chicks can fetch $300–$600 USD on the black market continue to fuel illegal trade within the country (Muccio 2009, p. 14).

Belize (*A. m. cyanoptera*)

Belize's Wildlife Protection Act provides for the regulation of hunting and the commercial dealing in wildlife. It prohibits hunting of specific species, in closed areas, and of immature wildlife or females accompanied by their young. It is administered by the Forest Department of the Ministry of Natural Resources and the Environment (Government of Belize 2010, p. 29). This law prohibits hunting of the scarlet macaw and prohibits hunting wildlife in a forest reserve without a license (Wildlife Protection Act 2000, entire). Scarlet macaws have been poached by Guatemalans (guaceros and xateros) that illicitly cross the border into Belize for economic reasons. Most poaching is opportunistic. Past incidences of conflict between law enforcement and Guatemalan nationals have occurred (Harbison 2017, unpaginated). The Belize Defense Force cooperates with the Scarlet Six team to deter poaching scarlet macaw chicks (see *Conservation Measures,* below).

Honduras (*A. m. cyanoptera*)

Three institutions are charged with biodiversity conservation in Honduras: The Secretariat of Natural Resources and Environment (SERNA); the Secretariat of Agriculture and Cattle Ranching (SAG); and the ICF who develops programs, regulations, or projects for biodiversity conservation with an emphasis on species in danger of extinction (Hansen and Florez 2008, p. 17). Internal legislation concerning biodiversity centered on a 1990

government decree prohibiting the capture and sale of wildlife within Honduras. However, it has been criticized for contributing to illegal trafficking of wildlife through neighboring countries, particularly through the sparsely populated border with Nicaragua (Anderson and Devenish 2009, p. 257). A National Biodiversity Strategy was published in 2000 (Anderson and Devenish 2009, p. 257). However, no specific legislation to manage biodiversity exists (World Bank 2007, p. 12).Wildlife is sold openly in the streets, and families maintain scarlet macaws as pets (Hansen and Florez 2008, p. 22). Also, despite the Río Plátano Biosphere Reserve's status, poaching occurs within its boundaries.

Nicaragua (*A. m. cyanoptera*)

Historically, wildlife in Nicaragua has been used as food for poor rural and indigenous populations, for sport hunting, for medicinal and cultural use, and as pets (MARENA 2008, p. 22). Illegal capture and trade of wildlife species is also a source of income (McGinley *et al.* 2009, p. 16). Despite the scarcity of records, laws to regulate wildlife trade in Nicaragua have existed since the late 19th century.

MARENA is a key agency responsible for conservation of endangered species in Nicaragua. In 2008, 123 species were permanently banned from harvest or use, and another 61 species were partially banned; many of these banned species are also listed by the IUCN or by CITES. Hunting of the scarlet macaw is prohibited (Nicaraguan laws 559 and 641; FAOLEX 2018, unpaginated). Nonetheless, these national species protection bans are rarely applied and enforced (McGinley *et al.* 2009, p. 22). The scarlet macaw is a principal species involved in illegal trade (McGinley *et al.* 2009 p. 16; MARENA 2008, p. 25). On the Caribbean coast, commercial harvesting occurs of species such as scarlet macaws, which is not currently subject to a harvesting quota and are sold on the local market (MARENA 2008, p. 25).

Nicaragua's adoption of CITES has led to improvement in the management and regulation of domestic and international wildlife trade. Nonetheless, the existing legal framework is inadequate for the protection and sustainability of domestic wildlife trade (McGinley *et al.* 2009, p. 22). Furthermore, nonregulatory instruments, such as monitoring, research, education, and information, are poorly, if at all, used in the oversight of commercial wildlife trade in Nicaragua (McGinley *et al.* 2009, p. 22).

Costa Rica (*A. m. cyanoptera* and *A. m. macao*)

Costa Rica's Wildlife Conservation Law and its amendments prohibit the hunting, collection, and extraction of species, except in certain cases for subsistence by indigenous groups, scientific purposes, or species control (Costa Rican Embassy 2013, unpaginated; NOVA 2013, unpaginated; Tico Times 2017, unpaginated).

The Biodiversity Law has the objective of conserving biodiversity and the sustainable use of the resources, as well as to distribute in an equitable manner the benefits and derived costs. The law includes the obligation of the state to avoid and prevent damage or destruction, present or future, to human, animal, or plant health, or to the integrity of the ecosystems, and to avoid any risk or danger which threatens the permanence of ecosystems (Hopkins 2007, p. 404).

Costa Rica has protected its resources through an ambitious national parks and biological reserves system, but they are inadequately funded and insufficiently controlled (Government of Costa Rica 2010, p. 34). Poaching by local communities is a problem of great concern; hunting within national park boundaries is illegal, but such activities are difficult to monitor and enforce with limited funds and supervision (Huson 2010, p. 18; Government of Costa Rica 2010, p. 52). This limitation is reported in Carara National Park, in which park officials believe that they do not have enough enforcement staff to effectively control poaching (Huson 2010, p. 8).

Panama (*A. m. macao*)

To protect and regulate the use of wildlife, flora and fauna, the Panamanian government has created numerous laws. The initial legislation protecting Panama's biological diversity was Law 23 (1967) on the protection and conservation of wildlife (Parker *et al.* 2004, p. III–2). Another important piece of legislation is Resolution DIR–002–80 (1980) that identifies 82 species in danger of extinction and bans hunting, capturing, buying, selling, or exporting of all species included in this list (Parker *et al.* 2004, p. III–2). Scarlet macaw is one of these species. Other important regulatory mechanisms include Resolution DIR–003–80 (1980) that regulates wildlife in captivity and its importation and exportation, and the Wildlife Law 24 (1995), which establishes that wildlife is part of the natural heritage of Panama and provides for the protection, restoration, research, management and development of the country's genetic resources, including rare species (Parker *et al.* 2004, p. III–2; Blaser *et al.* 2011, p. 355).

The Panamanian national police force is responsible for preventing all infractions of the law, such as hunting violations (Parker *et al.* 2004, p. III–8). ANAM counts on police support, which is often more concerned about major crime, and routinely treats environmental infractions as minor nuisances. Local corregidores (*i.e.,* local administrative officials) often have little knowledge of environmental laws and little impact on their enforcement, but these local officials are important links in the enforcement of environmental laws, and have influence on resident's behavior (Parker *et al.* 2004, p. V–10). Training officials adjacent to or within protected areas results in less illegal hunting and harvesting in protected areas (Parker *et al.* 2004, pp. III–2, V–10). Nonetheless, sport and commercial hunting without regulation and subsistence hunting in the country continue.

Colombia (*A. m. macao* Northern DPS)

Under Colombian wildlife legislation, all wildlife belongs to the State; although local communities (*e.g.,* mayors, regional autonomous corporations, indigenous reserves) have the right to participate in decisions regarding resources under their jurisdictions and to enjoy a healthy environment (International Institute for Environment and Development 2018, unpaginated; Blaser *et al.* 2011, p. 297). Wildlife legislation stipulates a general ban on hunting, but subsistence hunting and fishing are allowed provided no ban is in place for a particular species. In 1994, illegal hunting was established as a crime in the penal code, which includes penalties for poaching and illicit use of renewable natural resources (Gomez *et al.* 2015, unpaginated). Trade of scarlet macaws taken from the wild is forbidden in Colombia, although regulations are not always followed and scarlet macaws are involved in illegal trade in the country (CITES 2001, p. 8). The Colombian National Army and National Police are cooperating with the Ministry of the Environment to protect the country's wildlife and combat illegal wildlife trafficking, much of that illegally acquired wildlife is intercepted near the northern Colombian coasts (Pedraza 2015, unpaginated).

Summary of Illegal Capture and Trade

Legal international trade is not a current threat because of international laws such as CITES, the WBCA, and similar stricter measures under European Union legislation that restrict the trade of wild scarlet macaws. All

range countries have laws and policies that aim to prevent illegal capture and trade of scarlet macaws, although some hunting and capture continues. However, illegal capture for the domestic pet trade within most range countries occurs at a level that is likely to negatively impact the species throughout all of the range of subspecies *A. m. cyanoptera,* and in the range of the subspecies *A. m. macao* in Costa Rica and Panama. Because capture for the pet trade is ongoing and poses a threat to scarlet macaws in these regions, we conclude that the regulatory mechanisms addressing this threat in these regions are inadequate.

Summary of Factor D

We found threats discussed under Factors A and B to be threats to the species throughout all of the range of subspecies *A. m. cyanoptera,* except on Isla Coiba, Panama; and in the range of the subspecies *A. m. macao* in Costa Rica (Factor B only), Panama, and Colombia west of the Andes (Factor A only). The existing regulatory mechanisms do not appear to be adequate to address threats, primarily because these countries lack resources to effectively enforce all their laws. Therefore, we conclude that the existing regulatory mechanisms are not adequate to protect subspecies *A. m. cyanoptera* throughout all of its range, and the northern DPS of *A. m. macao* from the threats of deforestation and overutilization.

Factor E: Other Natural or Manmade Factors Affecting the Species' Continued Existence

Small Population Size and Synergistic Effects of Threats

Small, isolated populations place species at greater risk of local extirpation or extinction due to a variety of factors, including loss of genetic variability, demographic and environmental stochasticity, and natural catastrophes (Lande 1995, entire; Lehmkuhl and Ruggiero 1991, p. 37; Gilpin and Soulé 1986, pp. 25–33; Soulé and Simberloff 1986, pp. 28–32; Shaffer 1981, p. 131; Franklin 1980, entire). Stochastic events that put small populations at risk include, but are not limited to, variation in birth and death rates, fluctuations in gender ratio, inbreeding depression, and random environmental disturbances such as fire and climatic shifts (Blomqvist *et al.* 2010, entire; Gilpin and Soulé 1986, p. 27; Shaffer 1981, p. 131).

Overall levels of genetic variation in the scarlet macaw remain high, but a decrease in diversity was noted among birds from the Chiquibul Forest Reserve in Belize (Schmidt 2013, abstract). Gene flow occurs between nest sites in Guatemala and Belize, and levels of genetic diversity are high in the tri-national region (Schmidt and Amato 2008, p. 137), but the Belize population may be more isolated from the Guatemala and Mexico populations (Brightsmith 2016, *in litt.,* p. 8). The isolation of populations and subsequent loss of genetic exchange would impact the population at different timescales. In the short term, populations may suffer the deleterious consequences of inbreeding; over the long term, the loss of genetic variability diminishes a species' capacity to adapt to changes in the environment (Blomqvist *et al.* 2010, entire; Reed and Frankham 2003, pp. 233–234; Nunney and Campbell 1993, pp. 236–237; Soulé and Simberloff 1986, pp. 28–29; Franklin 1980, pp. 140–144).

Negative impacts associated with small population size and vulnerability to random demographic fluctuations or natural catastrophes may be further magnified by synergistic interactions with other threats, such as those discussed in Factors A and B.

Small populations that are declining can be especially vulnerable to habitat loss (O'Grady *et al.* 2004, pp. 513–514). As bird assemblages in forest habitat are reduced because the size of the habitat is reduced, smaller areas are less likely to provide the essential resources for species such as scarlet macaw that have large ranges. Thus, deforestation in combination with other negative impacts can have profound effects and potentially reduce a species' effective population (the proportion of the actual population that contributes to future generations) by orders of magnitude (Gilpin and Soulé 1986, p. 31). For example, an increase in habitat fragmentation can separate populations to the point where individuals can no longer disperse and breed among habitat patches, causing a shift in the demographic characteristics of a population and a reduction in genetic fitness (Gilpin and Soulé 1986, p. 31). This risk is especially applicable for scarlet macaws in Mesoamerica, where the species was once wide-ranging but has lost a significant amount of its historical range due to habitat loss and degradation. Large forests areas have been removed throughout Mesoamerica and the large tracts of forest that remain, such as the Maya and Lacandon Forests, the transnational forest in the Mosquitia region, and the transnational forest on the border of Costa Rica and Panama, have almost been cut off from each other by deforestation (Bray 2010, p. 93). Scarlet macaws may use partially cleared and cultivated landscapes if the landscape provides dietary requirements and maintains enough large trees because this species is dependent on larger, older trees that have large nesting cavities. However, scarlet macaws have a better chance of surviving in large tracts of forest where suitable cavities are more common than in open and small forest remnants (Inigo-Elias 1996, p. 91).

Commercial exploitation of scarlet macaw chicks may further contribute to inbreeding depression and loss of genetic diversity. However, other large, long-lived avian species have demonstrated significant retention of molecular diversity after marked declines, thus indicating that longevity of the species may act as an intrinsic buffer against the rapid loss of genetic variation (Schmidt 2013, pp. 132–133). But the presence of high genetic variation in long-lived species may mask demographic instability introduced by habitat alteration and overexploitation, resulting in a sudden and marked loss of diversity (Schmidt 2013, p. 133). Systematic removal of scarlet macaw nestlings over extended periods of time has likely produced an unstable age distribution in the tri-national region (Mexico, Guatemala, and Belize), heavily skewed toward older individuals with low recruitment (Clum 2008, p. 79).

Historically, the scarlet macaw in Mesoamerica existed in much higher numbers in more continuous habitat. Currently, the scarlet macaw occurs in relatively small and fragmented populations within Mesoamerica; most populations in this region are believed to contain approximately 100 to 700 individuals, with only two populations potentially containing more than 1,000 individuals. The total population size for scarlet macaws in Mesoamerica is likely no greater than 5,000 individuals. Overall, suitable habitat is becoming increasingly limited and is not likely to expand in the future. Therefore, the species' reproductive and life-history traits, combined with its limited and fragmented habitat, increases the species' vulnerability to deforestation and overutilization in the *A. m. cyanoptera* and northern DPS of *A. m. macao* subspecies due to the small size of the species' populations.

Competition for Nest Cavities

Competition for suitable nest cavities limits reproductive success by limiting the available nesting sites and thus limiting the number of pairs that can breed, or by causing nest mortality as a result of agonistic interactions.

Intraspecific competition between different pairs of scarlet macaws, and competition with pairs of other macaw species, is reported to be intense in some areas (Renton and Brightsmith 2009, p. 5; Inigo-Elias 1996, p. 96; Nycander 1995, p. 428).

Competition for nesting sites occurs throughout the scarlet macaw's range. In Mexico, species including other psittacines (*Amazona farinosa, Amazona autumnalis*), toucans (*Ramphastos sulfuratus*), and falconiforms (*Herpetotheres cachinnans*) breed synchronously with scarlet macaws and compete to use the same nest cavities (Inígo-Elias 1996, p. 61). In Costa Rica, quality nest sites appear to be in demand because at least four pairs of scarlet macaws were seen competing for the same nest cavity, which may be a limiting factor in the successful fledgling in the population (Vaughan *et al.* 2003, p. 10). Additional avian nest competitors include chestnut-mandibled toucan (*Ramphastos swainsonii*), barred forest falcon (*Micrastur semitorquatus*), and yellow-napped parrot (*Amazona auropalliata*) (Vaughan *et al.* 2003, p. 10). At a remote site in southeastern Peru, approximately 70 percent of the nesting attempts involved competition over nests (Brightsmith 2010, unpaginated). Competition for nest sites with other macaws was found to be the primary cause of failure of nests with chicks. Scarlet macaws and red-and-green macaws (*Ara chloropterus*) frequently compete for nest cavities, which have been recorded annually. The smaller and less competitive scarlet macaws are at a disadvantage, perhaps contributing to their use of a wider range of cavity resources (Renton and Brightsmith 2009, p. 5).

Africanized honey bees (*Apis mellifera scutellata)* are also reported to be a serious competitor with scarlet macaws for nest cavities (Garcia *et al.* 2008, p. 52; Vaughan *et al.* 2003, p. 13; Inigo-Elias 1996, p. 61). Africanized honey bees are an exotic species originally introduced in Brazil in 1956 (Whitfield *et al.* 2006, p. 644). They subsequently spread throughout South and Central America, displacing naturalized European honey bees (*Apis mellifera*), and arriving in Mexico, Guatemala, and Belize around 1986 (Whitfield *et al.* 2006, pp. 643–644; Clarke *et al.* 2002 and Rogel *et al.* 1991, in Berry *et al.* 2010, p. 486; Fierro *et al.* 1987, unpaginated). Africanized honey bees occur at higher densities and are more aggressive than naturalized European honey bees (Rogel 1991 and Clarke *et al.* 2002, in Berry *et al.* 2010, p. 486). Studies in Mexico, Guatemala, and Costa Rica reported bees attacking nests with eggs and chicks and that the bees usurped nesting cavities, resulting in the failure of the scarlet macaw nest (Inígo-Elias 1996, p. 61; Garcia *et al.* 2008, p. 52). Additionally, breeding pairs of scarlet macaws were attacked when they approached the nest cavity (Inígo-Elias 1996, p. 61; Garcia *et al.* 2008, p. 52). Because these bees occur throughout the scarlet macaw's range in Central and South America and have demonstrated a negative effect on scarlet macaw nesting, we assume these bees are competitors for nest cavities throughout the scarlet macaw's range, but we are unaware of any other data or information regarding the magnitude of these impacts on scarlet macaw nesting success.

Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate and the effects of any such change. Described in general terms, climate refers to the mean and variability of different types of weather conditions over a long period of time, which may be reported as decades, centuries, or thousands of years. The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (*e.g.,* temperature, precipitation) that persists for an extended period, typically decades or longer, and whether the change is due to natural variability, human activity, or both (Intergovernmental Panel on Climate Change (IPCC) 2007, p. 78). Various types of changes in climate can have direct or indirect effects on species, and these may be positive or negative depending on the species and other relevant considerations, such as the effects of interactions with non-climate conditions (*e.g.,* habitat fragmentation). We use our expert judgment to weigh information, including uncertainty, in our consideration of various aspects of the effects of climate change that are relevant to the scarlet macaw.

Several studies project various changes in climate in Mesoamerica and the Amazon by the mid- to late century or sooner (Karmalkar *et al.* 2011, entire; Kitoh *et al.* 2011, entire; Giorgi and Bi 2009, entire; Anderson *et al.* 2008, entire; Cook and Vizy 2008, entire; Li *et al.* 2008, entire; Christensen *et al.* 2007, pp. 892–896). Although there are uncertainties in these models and variation in projections, the general trajectory under most scenarios is one of increased warming in Mesoamerica and the Amazon, and decreased precipitation in Mesoamerica and some areas of the Amazon. Several studies project changes in habitat in areas of the species' range, either from the effects of climate change or from the effects of climate change in combination with deforestation (Imbach *et al.* 2011, abstract; Marengo *et al.* 2011, entire; Asner *et al.* 2010, entire; Vergara and Scholz 2010, entire; Malhi *et al.* 2009, entire; Malhi *et al.* 2008, entire; Nepstad *et al.* 2008, entire). However, high levels of uncertainty remain in projecting habitat changes within the species' range (see review by Davidson *et al.* 2012, entire), and there is no consensus on the type or extent of habitat changes that will occur. Therefore, because the scarlet macaw is tolerant of a relatively broad range of ecological conditions; occurs in a variety of habitat types including wet forest, dry forest, and savanna provided they contain suitable nest cavities and roosting sites; has a broad diet including nonnative species; and is known to inhabit patchworks of forest and human-modified landscapes, we assume the scarlet macaw is likely to adapt to some level of change in its environment provided its essential needs are met. Overall, we are unaware of any information indicating that the effects of climate change are now causing, or will in the future cause, declines in the scarlet macaw population.

Summary of Factor E

Small population size and competition for next cavities may be threats to the scarlet macaw in some parts of its range in Mesoamerica and northwest Colombia. Populations have a high level of genetic diversity, but they remain vulnerable to stochastic demographic and environmental events because of their small populations. Competition for nest cavities may be a limiting factor and likely reduces reproductive success. The general consensus is that the scarlet macaw's range is going to become hotter and drier; however, the scarlet macaw is tolerant of a relatively broad range of ecological conditions. Because the species persists in small and mostly isolated populations, threats often operate synergistically, particularly when populations of a species are decreasing. Thus, the initial effects of one threat factor can exacerbate the effects of other threats (Gilpin and Soulé 1986, pp. 25–26).

Within the preceding review of the five factors, we have identified threat factors A and B that may have interrelated impacts on this species, particularly in Mesoamerica. The species' productivity in Mesoamerica may be reduced because of any of these threats, either singularly or in

combination. For example, deforestation reduces the amount of nesting cavities, which increases competition among pairs of scarlet macaws and other species for nesting sites. Deforestation and the infrastructure that may accompany it creates access to previously inaccessible areas, thereby opening up new areas of the species' range to the threat of poaching and further habitat loss. Therefore, because the populations of scarlet macaw are small and mostly isolated in Mesoamerica, and these small populations are subject to a combination of threats, we believe that small population size is a contributing stressor to scarlet macaws throughout Mesoamerica, including the entire range of subspecies *A. m. cyanoptera* and the range of *A. m. macao* in Costa Rica, Panama, and northwest Colombia.

Conservation Measures

Reintroduction of Scarlet Macaws

Reintroduction efforts for the scarlet macaw have occurred throughout the range of *A. m. cyanoptera* and the northern DPS of the southern subspecies *A. m. macao.* We briefly discussed some of the reintroduction efforts in our July 6, 2012, and April 7, 2016, proposed rules to list the scarlet macaw (77 FR 40222 and 81 FR 20302, respectively). However, based on public and peer reviewer comments we received, we are incorporating additional information regarding these conservation efforts and programs that reintroduce captive-bred and confiscated scarlet macaws back into the wild within their respective historical ranges. We received information on some of the release sites and reintroduction programs and describe many of them, although we may not have information on every reintroduction program occurring for scarlet macaws. Most, if not all, of the reintroduction sites are within, adjacent to, or at least within flight distance of currently existing populations.

Because of the increasing number of reintroduction projects involving various species worldwide, the IUCN Species Survival Commission published guidelines for reintroductions to help ensure that reintroduction efforts achieve intended conservation benefits and do not cause adverse side effects of greater impact (IUCN/SSC 2013, entire; IUCN/SSC 1998, entire). Additionally, recommendations were made specific to parrot reintroductions based on a review of previous releases and reintroductions of psittacines worldwide (White *et al.* 2012, entire). We considered these guidelines and recommendations when evaluating the effectiveness of the reintroduction programs to conserve scarlet macaw throughout its range in Mesoamerica.

Reintroduction of *Ara macao cyanoptera*

Mexico

In 1993, Xcaret began a program of scarlet macaw reproduction in captivity, developing and using the best protocols for hand rearing, and establishing new procedures to facilitate parental rearing of the chicks without human intervention (Raigoza Figueras 2014, p. 51). The aim is to rear captive-bred macaws that will adapt to the wild successfully and not require post-release supplemental feeding (Raigoza Figueras 2014, p. 48). The release program began in 2013. Xcaret supplies captive scarlet macaws for reintroduction at two sites in Mexico: (1) Palenque, Chiapas; and (2) Los Tuxtlas, Veracruz (Xcaret 2014, unpaginated).

The Palenque, Chiapas, release site is located in forested habitat of Aluxes Ecopark of Palenque, a wildlife rescue and rehabilitation center that encompasses 44 ha (108 ac). This site is approximately 0.5 km (0.3 mi) from Palenque National Park (Amaya *et al.* 2015, p. 457) and more than 100 km (62 mi) away from the nearest current wild population (Brightsmith *in litt.* 2016, p. 21). All scarlet macaws used for reintroduction were captive bred at Xcaret Ecopark.

In the April 7, 2016, proposed rule (81 FR 20302), we identified the program in Palenque, Chiapas, Mexico, in which 96 scarlet macaws were released between April 2013 and June 2014, with a 91 percent survival rate as of May 2015, including nine nesting events and successful use of wild foods by released birds (Estrada 2014, p. 345). Results of the reintroduction program in Palenque, Chiapas, show that the dietary diversity and breadth of the reintroduced scarlet macaws closely approaches that of wild macaws; the reintroduced birds have the capacity to find and track wild food sources; they have very low mortality in the released population (9 percent); they have had nine successful nesting events, including seven in natural cavities (Estrada, unpublished, in Amaya *et al.* 2015, p. 471); and they have expanded their foraging and activity range outside of the release site (Amaya *et al.* 2015, pp. 466–471). This reintroduction appears successful at integrating captive-reared scarlet macaws into the wild and could be a model for reintroduction efforts throughout the range.

During the years of 2008–2010, the status of parrot species in Los Tuxtlas, Veracruz, Mexico, was assessed by obtaining data on abundance, habitat use, and date of pet trade. Only three species out of the nine species previously reported remain in this area (De Labra *et al.* 2010, p. 599). Scarlet macaw was not recorded, and there is a consensus of local and historical extinction of the *Ara macao* in this region (Schaldach and Escalante 1997 and Winker 1997, in De Labra *et al.* 2010, p. 607).

Since that time, La Otra Opción is a 336-ac (136-ha) private ecological reserve and breeding center for endangered species in the Los Tuxtlas Biosphere Reserve buffer zone has worked to reintroduce scarlet macaws in the Los Tuxtlas region. In 2014, scarlet macaws were reintroduced to this area after disappearing for 40 years, and to date, more than 100 scarlet macaws have been released (Raigosa *et al* 2016, in Defenders of Wildlife 2016, *in litt.,* p. 4; Mexico Daily News 2017, unpaginated; Escalante 2016, unpaginated). Many captive-bred scarlet macaws remain in the wild with pairing observed and potential nesting (Mexico Daily News 2017, unpaginated; Escalante 2016, unpaginated). Thus, this reintroduction effort appears moderately successful integrating scarlet macaws into the wild population in Mexico.

The reintroduction programs in Palenque and Los Tuxtlas were aligned with the IUCN guidelines and the recommendations made by White *et al.* 2012. After the first year of implementation in Palenque, the number of reintroduced and surviving macaws raises the number of extant macaws in the wild in Mexico by about 34 percent (Estrada 2014, p. 360). Considering Palenque and Los Tuxtlas together, the population of scarlet macaws in Mexico has increased up to 82 percent in 3 years (Rodriguez 2016, unpaginated; Lopez 2018, unpaginated).

Guatemala

The Wildlife Conservation Society (WCS) started working in Guatemala in 1992, with the mission of conserving the MBR as one of Mesoamerica's most important wildlife conservation areas. The MBR is the last stronghold for scarlet macaws in Guatemala and contains the most important nesting area for the species in the country. The WCS has worked to reduce poaching, protect nesting sites from deforestation, monitor nesting success and distribution, construct artificial nests, provide environmental education in local communities, and create a captive-release program (WCS 2016, pp. 6–16). In addition, they started a veterinarian evaluation program, supplementary

feeding, and management of wild chicks during nesting season (WCS 2018, unpaginated). In June 2016, WCS placed six rehabilitated chicks in safe scarlet macaw nests (Boyd 2016, *in litt.,* p. 9). With these interventions, they have increased the number of fledglings per nest (WCS 2018, unpaginated; WCS 2016, p. 11). WCS Guatemala is also working in collaboration to eradicate wildlife trafficking between Belize and Guatemala.

The Wildlife Rescue and Conservation Association (Asociación Rescate y Conservación de Vida Silvestre (ARCAS)) is a rehabilitation and breeding-for-release center for Guatemalan wildlife that has been confiscated from the black market by the Guatemalan government. Since its establishment, the ARCAS Rescue Center has grown into one of the largest and most complex wildlife rehabilitation centers in the world and a leader in training programs for other wildlife rescue groups and veterinary students (Oakland Zoo 2018, unpaginated). In October 2015, in Petén, ARCAS released nine captive-bred scarlet macaws into the wild in Guatemala, which was the first time captive-bred scarlet macaws were released into the wild in Guatemala. At least 60 percent of the released birds survived more than 10 months on their own, showing that they successfully adapted to the environment and were able to feed and fly on their own. This program for rehabilitation and release has generated quantifiable results that can be used to prove the viability of such a strategy in the reinforcement of the depleted scarlet macaw population of the Sierra del Lacandón National Park, which is where the scarlet macaws were released and is one of the largest and best protected natural areas in the MBR (ARCAS 2016, pp. 5–6). In 2016, they planned to release 10 more scarlet macaws (Boyd 2016, *in litt.,* p. 10), but we do not have any information regarding the results of this release.

Belize

In Belize, the protection of the scarlet macaw in the Chiquibul region is provided by numerous organizations, some of which have joined efforts to improve protection with the goal of increasing the chance of survival for this species (Hagen Avicultural Research Institute 2015, unpaginated). For example, the Scarlet Six Biomonitoring Team (Scarlet Six), Friends for Conservation and Development (FCD), and the Belize Self-Defense Forces work together to reduce illegal gold mining; timber extraction; and poaching of animals, particularly scarlet macaw chicks.

The FCD rangers patrol the Chiquibul Forest, collaborate with the Scarlet Six, and receive support from the Belize Defense Force. Their goal is to conserve the natural and cultural resources of the western Chiquibul-Maya Mountains (FCD 2016, p. 4). In addition to protecting scarlet macaws in the wild, the FCD also started a captive-rearing program modeled after successful programs in Mexico and Guatemala (Harbison 2017, unpaginated). If a nest cannot be effectively protected by the rangers while the chicks are growing, or if a nest produces a third chick that will not survive, FCD removes the chicks from the nest and brings them to the lab. All eight macaws in 2015's cohort successfully fledged, but it took until January 2016 before they left the area for good (Harbison 2017, unpaginated). The FCD also signed an agreement with WCS in Guatemala and Natura y Ecosistemas Mexicanos A.C. in July to coordinate research, management, and conservation efforts of scarlet macaws in the Maya Forest (FCD 2016, p. 13). In January 2016, FCD signed an extended agreement of cooperation with Asociación Balam for the protection of the Chiquibul ecosystem for the period 2016–2020. This agreement primarily seeks to jointly promote the protection of the Chiquibul Maya Mountains ecosystem and reduce conflict among communities located on the Belize and Guatemala adjacency zone (FCD 2016, p. 9).

Honduras

In Honduras, scarlet macaws have been released into multiple sites. Releasing scarlet macaws at the Isla Zacate Grande biological station in Honduras began around 1996–1997 (Raigoza Figueras 2014, p. 50; Boyd and McNab 2008, p. x). A private reserve released scarlet macaws on the island. This reintroduction effort started with four chicks; a few years later, they received and released another five scarlet macaws (adults and chicks) of unknown origin (Boyd and McNab 2008, p. x). About 20 scarlet macaws have been released at the site (Bjork 2008, pp. x, 17–18; Raigoza Figueras 2014, p. 50). Some of the reintroduced birds have ranged outside the release point to nearby communities and the adjacent island of Amapala, Honduras. Released birds have been observed around the Gulf of Fonseca, where Paso Pacifico is conducting a scarlet macaw conservation program on the Cosigüina Peninsula, Nicaragua (see ''Nicaragua,'' below), which hosts a small wild population of 20 to 50 birds (Paso Pacifico 2017, unpaginated; Boyd and McNab 2008, p. x). Isla Zacate Grande is approximately 35 km (22 mi) (overwater) from the Cosigüina Peninsula, an overland flight distance within documented range for scarlet macaws (Boyd and McNab 2008, p. x). Although no formal records are kept, nesting activity has been observed in artificial nests placed in natural hollows (Raigoza Figueras 2014, p. 50). However, as a model, there are concerns about the reintroduction at this site because disease testing was not performed; there was no documentation of the project; the birds have no fear of humans and continue to depend on regular supplemental food; and the birds appear to have been conditioned to nest in inappropriate situations (*i.e.,* low to the ground), which makes them highly vulnerable to human and non-human predators alike. High security and long-term daily maintenance is required (Boyd and McNab 2008, p. x; Bjork 2008, pp. 17–18).

A reintroduction of scarlet macaw at the Copán archaeological site (Parque Arqueológico Copán Ruinas) in Honduras began in 2011. The World Parrot Trust, the Macaw Mountain Bird Park and Nature Reserve, the Institute of Anthropology and History of Honduras and the Association Copán have organized a long-running program to return the scarlet macaw to the Parque Arqueológico Copán Ruinas, a national park (Raigoza Figueras 2014, pp. 50–51). The Macaw Mountain scarlet macaw breeding program is releasing birds into the forests surrounding the Copán Ruins (Boyd 2016, *in litt.,* p. 6). Most of the birds come from private donations of pet birds; others were confiscated by the Environment Office of the Public Ministry (Macaw Mountain 2017, unpaginated). In 2018, scarlet macaws released produced seven chicks (World Parrot Trust 2019, unpaginated). We are not aware of the release methods or if this program takes into account the IUCN guidelines and White *et al.* (2012) recommendations. However, this program has been judged a resounding success (Macaw Mountain 2019, unpaginated; Asociación Copan 2017, unpaginated).

A macaw conservation and local development program was started in the Mosquitia region of Honduras by the Lafeber Company, Dr. Kim Joyner, indigenous peoples of several villages, the Forestry Service of Honduras, Universidad Nacional Autónoma Honduras, and the Universidad Nacional de Agricultura (Boyd 2016, *in litt.,* p. 7; Lafeber 2018, unpaginated). This program started in 2010, and in 2011 through 2012, confiscated scarlet

macaws were released at the village Mabita. Once these birds grew large enough to fly, they were released from their cages, slowly learning to fly around the village. Government officials have released more birds, for a total of 22, and approximately 16 regularly visit the village, coming in every morning to feed. The earliest birds released in Mabita (in 2011) have an active nest; they have produced two chicks, which demonstrates that the program can successfully raise birds to reproduce in the wild (Lafeber 2018, unpaginated). However, it is not ideal that the birds are so dependent on humans for food. We are not aware of the release methods or if this program takes into account the IUCN guidelines and White *et al.* (2012) recommendations.

Nicaragua

Paso Pacifico works throughout Nicaragua, focusing on the natural ecosystems of Central America's Pacific slope (Boyd 2016, *in litt.,* p. 5). In 2015, they launched a scarlet macaw conservation program in the Cosigüina Volcano area of northern Nicaragua (Paso Pacifico 2017, unpaginated). With financial support from the Loro Parque Fundación, among others, community rangers protect and monitor the remaining scarlet macaws. Their objectives are to establish accurate baseline information about the population, focusing on demographics, nesting success, and habitat use in the reserve; to strengthen the ability of the Nicaraguan army to deter poachers; to involve and empower the local community to protect nesting scarlet macaws; and to increase awareness among Ministry of Environment officials and the Nicaraguan environmental community (Loro Parque Fundación 2015, unpaginated). They have also been working closely with families from La Salvia, the village nearest to the scarlet macaw nesting area, through an educational program involving birdwatching and other field-based activities that highlight the significance of the scarlet macaw and the dry tropical forests at Cosigüina (pasopacifico 2017, unpaginated). Two scarlet macaw chicks have safely fledged, which was the first successful macaw nest documented in this area in over 20 years (pasopacifico 2017, unpaginated).

Reintroduction of *Ara macao macao*

Costa Rica

On the Nicoya Peninsula in northwestern Costa Rica, scarlet macaws are currently released at Punta Islita, Playa Tamboor, and Curú National Wildlife Refuge, which are all within 50 km (31 mi) of each other. It is difficult to determine how these populations will fare over time because these populations are fairly isolated, but these three release sites could help repopulate the Nicoya Peninsula (Brightsmith 2016, *in litt.,* p. 15). The Punta Islita release site is situated in the tropical moist forest of Costa Rica's North Pacific coast; wild scarlet macaws had been locally extinct in this area for decades. Between 2011 and 2018, 37 scarlet macaws were released at this site (Ara Project 2017, unpaginated). We have no data concerning the current status of the released birds. At Curú, scarlet macaws were released starting in January 1999. Ten of the 13 birds released were still alive after 4 years, and pairs have attempted to nest in natural tree cavities in two different years, but no chicks have been produced (Brightsmith *et al.* 2005, p. 468). At Playa Tambor, we do not have information on the number of scarlet macaws released into the wild or the success of the releases at this site.

Within the scarlet macaw's range in southwestern Costa Rica, a few reintroduction programs exist around the Gulf (Golfo Dulce) and the Osa Peninsula. These include Santuario Silvestre de Osa (SSO), which releases birds close to Piedras Blancas National Park; Zoo Ave, which releases birds in the Golfito area; Amigos de las Aves, which releases offspring of confiscated birds in Alajuela, Punta Banco (Dear *et al.* 2010, pp. 15–17; Forbes 2005, p. 97); and Tiskita Lodge and the Ara project, which releases birds in Tiskita Jungle Lodge's private reserve also in Punta Blanco (Ara Project 2018, unpaginated). These organizations receive and release birds confiscated from poachers from all parts of the country (Dear *et al.* 2010, p. 15). Seventy-seven scarlet macaws were released in 1997; as of 2002, almost 90 percent of the released birds were still alive (Dear *et al.* 2010, p. 16). Additionally, the range of birds released at Punta Banco has grown to reach 84 km^2 (32 mi^2) (Forbes 2005, in Dear *et al.* 2010, p. 17). The breeding center in Alajuela has since closed and moved to Tiskita (Tiskita Jungle Lodge 2018, unpaginated). Between 2002 and 2014, nine groups of birds were released in Tiskita, most of which are thriving and reproducing in the wild (Ara Project 2018, unpaginated; Tiskita Jungle Lodge 2018, unpaginated). To date, the survival rate is close to 90 percent, and at least five pairs have successfully fledged chicks in natural cavities since 2008. Over 75 scarlet macaws have been released into the wild at this site (Tiskita Jungle Lodge 2018, unpaginated). This reintroduction program has ceased because a viable population has been established that is large enough to potentially connect with populations in the ACOSA that are farther north along the coast (Tiskita Jungle Lodge 2018, unpaginated). Thus, releases could potentially aid in recolonization of the macaw population's original range, to the extent that the habitat within that range remains suitable.

In total, the past and ongoing reintroduction efforts have added hundreds of scarlet macaws to the wild in Costa Rica. Additionally, most reintroduction projects conduct environmental education at a local level and attract additional media attention at the local and national level. As a result, each reintroduction project educates the public about the importance of scarlet macaws and of conservation and the environment in general (Brightsmith 2016, *in litt.,* p. 22).

Impacts of Reintroducing Captive-Bred Scarlet Macaws Into the Wild

Releases of captive scarlet macaws could increase the wild populations because many of the reintroduced captive-raised and confiscated birds are released adjacent to existing populations or at least within the range that scarlet macaws are known to disperse, and some of the release birds have adapted to surviving in the wild by finding mates and food and nesting resources similar to what wild scarlet macaws use. In addition, releases of scarlet macaws could potentially aid in recolonization of the population's original range in Mesoamerica, to the extent that the habitat within that range remains suitable and programs are available to protect scarlet macaws in the wild from poachers. Conversely, releases of captive scarlet macaws could potentially pose a threat to wild populations by exposing wild birds to diseases for which wild populations have no resistance, invoking behavioral changes in wild macaws that negatively affect their survival, or compromising the genetic integrity of wild populations (Dear *et al.* 2010, p. 20; Schmidt 2013, pp. 74–75; also see IUCN 2013, pp. 15–17). However, generally speaking, disease risks are small because the probable frequency of occurrence is low (see *Factor C* discussion in 77 FR 40237–40238; July 6, 2012).

Other Conservation Programs

Conservation programs operate in some areas of the scarlet macaw's range but not throughout its entire range. Many partner organizations work together to implement these

conservation programs that study and aim to increase the viability of scarlet macaw populations in the wild. To the extent that we have information indicating the effects of these programs on the scarlet macaw's status, we included information in the **Factors Affecting the Species,** above. In addition, general conservation measures such as education, use of artificial nest boxes, and nest monitoring are discussed below. Because too many organizations exist to list them all here, we summarize the general actions taken. Organizations in certain regions where scarlet macaws persist conduct the following conservation efforts:

(1) Implement education programs that promote the scarlet macaw, as well as sustainable forest management, because much of the territory in the scarlet macaw's range is held by local communities or indigenous people (Ara Project 2017, unpaginated; Vaughan *et al.* 1999, entire; WCS 2010, entire; FAO 2010a, pp. 238–239, Blaser *et al.* 2011, pp. 312, 346; Marineros and Vaughan 1995, pp. 462–463);

(2) Protect and monitor nests to reduce poaching, which has reduced overall nest poaching in Belize from higher than 90 percent to less than 30 percent, with 2017 the second year in a row that no known nests were poached, and has greatly decreased the severity of poaching in Guatemala (Harbison 2017, unpaginated; Garcia *et al.* 2008, p. xii);

(3) Construct artificial nest boxes, which increases nesting sites and ultimately recruitment (Vaughan *et al.* 2003, p. 10; Brightsmith 2000a, entire; Brightsmith 2000b, entire; Brightsmith 2005, p. 297; Nycander *et al.* 1995, pp. 435–436); and

(4) Use local conservation organizations to coordinate conservation activities with stakeholders (Vaughan *et al.* 2005, p. 123; WCS 2008, entire).

Finding

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Section 3 of the Act defines an ''endangered species'' as ''any species which is in danger of extinction throughout all or a significant portion of its range,'' and a ''threatened species'' as ''any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' As required by the Act, we conducted a review of the status of the species and considered the five factors in assessing whether the scarlet macaw meets the definition of an endangered species or threatened species. We examined the best scientific and commercial information available regarding factors affecting the status of the scarlet macaw. We reviewed the petition, information available in our files, information provided by peer review and public comments, and other available published and unpublished information.

Final Determination for the Northern Subspecies (Ara macao cyanoptera)

The northern subspecies of scarlet macaw, *Ara macao cyanoptera,* exists in Mexico, Guatemala, Belize, Honduras, Nicaragua, eastern Costa Rica, and Isla Coiba in Panama. Little quantitative data on historical populations are available, but evidence indicates that the range of this subspecies has been greatly reduced and the total current population of *A. m. cyanoptera,* based on available data (see Table 1), is estimated to be approximately 2,000 to 3,000 individuals.

The primary threats we identified to *A. m. cyanoptera* are habitat loss due to activities that cause deforestation and forest degradation (Factor A), poaching for the pet trade and sustenance (Factor B), and small population size that works in combination with the other threats (Factor E). The existing regulatory mechanisms are not adequate to protect the species from these threats to the level that the species is not in danger of extinction (Factor D).

Destruction of forest habitat is one of the main causes of the decline of *A. m. cyanoptera.* Deforestation rates in Mesoamerica, excluding Costa Rica, are the highest in Latin America due to expanding agriculture, cattle ranching, and selective and often illegal logging. Throughout the range of the subspecies where most of the species' historical habitat has been eliminated, deforestation is rapidly occurring, including in all the forested areas where scarlet macaws currently exist (except Isla Coiba, Panama). Activities that lead to deforestation and forest degradation directly eliminate the scarlet macaw's tropical forest habitat by removing the trees that support the species' essential needs for nesting, roosting, and food. Scarlet macaws are known to use partially cleared and cultivated landscapes, but they are only able to do so if the landscape maintains enough large, older trees that provide the essential needs of the species.

Poaching, mainly for the pet trade but also for sustenance, is the other main cause of decline of *A. m. cyanoptera.* The scarlet macaw is a popular pet species within its range countries, and overutilization as a result of poaching is a significant threat to *A. m. cyanoptera* (except on Isla Coiba, Panama). The scarlet macaw is susceptible to overharvest because it is a long-lived species with a low reproductive rate and slow to recover from harvesting pressures. Thus, removal of individuals year after year can inhibit population growth and cause local extirpation. Evidence suggests poaching occurs at significant levels in the Maya Forest region, even with conservation measures such as monitoring and protecting nesting sites in Guatemala and Belize, and is a significant threat in Honduras and Nicaragua. Poaching is exacerbated by habitat removal because it increases access to previously inaccessible areas, thereby opening up new areas to poaching.

Most if not all of the countries within the range of *A. m. cyanoptera* have regulations aimed at conserving forested lands, biodiversity, and prohibit poaching of scarlet macaws. However, these countries are not able to adequately enforce their regulations due to lack of resources, conflicts over land ownership that lead to illegal logging and expansion of agriculture and pasture, and lack of oversight or a governing body to enforce the regulations.

Some range countries employ conservation measures such as protecting nesting sites from poachers and reintroducing captive-bred scarlet macaws into the wild. While these programs have had success protecting nests from poachers and slightly increasing the number of scarlet macaws in the wild in some populations (see *Conservation Measures,* above), many of the reintroduction programs do not have data to show long-term viability of reintroduced birds. Therefore, while conservation measures have had a positive impact on the populations of *A. m. cyanoptera,* these conservation actions occur in small sections of the range of the subspecies and the threats identified above are ongoing.

Scarlet macaws in Mesoamerica maintain a high level of genetic diversity, but because of the few populations and the small numbers in each of the populations, and their virtual isolation from other populations due to deforestation, they remain vulnerable to extirpation and extinction. Fewer than 5,000 scarlet macaws remain in this relatively large geographic area.

Because of the extent of the decline in the range and numbers of *Ara macao cyanoptera* due to ongoing habitat destruction and degradation, poaching,

the lack of enforcement of existing regulatory mechanisms addressing these threats, and the small population sizes that work in combination with the other threats, we find that these threats place *A. m. cyanoptera* in danger of extinction. Therefore, on the basis of the best scientific and commercial information available, we find that *A. m. cyanoptera* meets the definition of an ''endangered species'' in accordance with the definition in the Act.

Final Determination for the Northern DPS of Southern Subspecies (Ara macao macao)

The range of *Ara macao macao* north and west of the Andes has been greatly reduced and fragmented. The scarlet macaw has been almost extirpated from mainland Panama and much of its former range in Costa Rica. Its remaining distribution is on the Pacific slope of Costa Rica, in the Chiriquí province and at the southern end of the Azuero Peninsula of Veraguas, near Cerro Hoya National Park in Panama, and in northwest Colombia.

Because information indicates that the ACOPAC and ACOSA populations in Costa Rica, which make up the bulk of the northern DPS of *A. m. macao,* may be stable and likely increasing and expanding their range on the Pacific slope of Costa Rica, it is reasonable to conclude that the northern DPS of *A. m. macao* is not currently in danger of extinction and does not meet the definition of an ''endangered species'' under the Act. A threatened species'' is ''any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act does not define the phrase ''foreseeable future,'' but we interpret it to describe the extent to which we can reasonably rely on the predictions about the future in making determinations about the future conservation status of the species. We conclude that it is reasonable to rely on the information contained in the studies discussed above under ''Factors Affecting the Species'' involving land-use trends and population sizes, as well as the information regarding enforcement of existing regulations and other factors that negatively influence the species, to make a determination about the future conservation status of the northern DPS of *A. m. macao.*

Poaching continues and remains a concern for the future viability of the species for the foreseeable future. In Panama, poaching of scarlet macaws was one factor that led to the virtual extirpation of this species from the mainland, and poaching remains a concern at Cerro Hoya National Park, which is one of the only locations where a very small population of scarlet macaws exists on mainland Panama. Additionally, the best available information indicates that the population in northwest Colombia faces significant ongoing threats from deforestation within the foreseeable future. No current population estimates are available for northwest Colombia, and this region is reported to have large tracts of suitable forest habitat, but many areas in northwest Colombia are considered deforestation hotspots. Thus, although the two largest populations currently appear to be increasing, they both are small and their total range represents only a portion of the range of the northern DPS. Therefore, we find that the best available information indicates that current threats to scarlet macaws in northwest Colombia (deforestation); ongoing poaching of scarlet macaws in Costa Rica and mainland Panama; ongoing, small-scale, subsistence logging in Panama; inadequate enforcement of existing regulations; and the small population sizes of scarlet macaws in this region put this DPS in danger of extinction in the foreseeable future. On the basis of the best scientific and commercial information available, we find that the northern DPS of *A. m. macao* meets the definition of a ''threatened species'' in accordance with the definition in the Act.

Similarity of Appearance

Final Determination for Southern DPS of Southern Subspecies (Ara macao macao)

In our proposed rule we found that the southern DPS of the southern subspecies *A. m. macao* did not warrant listing as an endangered species or a threatened species based on its status. However, we determined that it is advisable to treat the southern DPS as a threatened species based on its similarity of appearance to the northern DPS of *A. m. macao* and subspecies crosses of *A. m. cyanoptera* and *A. m. macao.* Section 4(e) of the Act authorizes the treatment of a species, subspecies, or distinct population segment as endangered or threatened if: ''(A) [S]uch species so closely resembles in appearance, at the point in question, a species which has been listed pursuant to [section 4 of the Act] that enforcement personnel would have substantial difficulty in attempting to differentiate between the listed and unlisted species; (B) the effect of this substantial difficulty is an additional threat to an endangered or threatened species; and (C) such treatment of an unlisted species will substantially facilitate the enforcement and further the policy of this [Act].'' All applicable prohibitions and exceptions for species treated as threatened under section 4(e) of the Act due to similarity of appearance to a threatened or endangered species will be set forth in a rule issued under section 4(d) of the Act.

Several factors make differentiating between scarlet macaw listable entities difficult. First, the scarlet macaw subspecies, *Ara macao macao* and *Ara macao cyanoptera,* primarily differ in the coloration of their wing coverts (a type of feather) and wing size. But these differences are not always apparent, especially in birds from the middle of the species' range (which may include crosses between *A. m. cyanoptera* and *A. m. macao*), sometimes making it difficult to visually differentiate between subspecies (Schmidt 2011, pers. comm.; Weidenfeld 1994, pp. 99–100). According to information received from the Service's Forensics Laboratory, many scarlet macaw remains submitted for examination by Office of Law Enforcement special agents and wildlife inspectors do not consist of intact carcasses; rather, evidence is usually in the form of partial remains, detached feathers, and artwork incorporating their feathers. Therefore, identification of the subspecies or the geographic origin of these birds is difficult or improbable without genetic analysis, which would add considerable difficulties and cost for law enforcement.

Second, we are not aware of any information indicating that distinguishing morphological differences between the northern and southern DPSs of *A. m. macao* would allow for visual identification of the origin of a bird of this subspecies. Lastly, aviculturists have bred the species without regard for taxa, resulting in crosses of the two subspecies (*A. m. cyanoptera* and *A. m. macao*) that maintain a combination of characteristics of either parent being present in trade (Wiedenfeld 1994, p. 103). As a result, the similarity of appearance between an unlisted southern DPS of *A. m. macao* and subspecies crosses to the listed northern DPS of *A. m. macao* and *A. m. cyanoptera* may result in the ability to pass off a protected specimen as an unlisted DPS or unlisted subspecies cross and poses an additional threat to the northern DPS of *A. m. macao* and subspecies *A. m. cyanoptera.* Therefore, we consider this difficulty in discerning an unlisted southern DPS and unlisted subspecies crosses from the listed northern DPS of *A. m. macao* and

subspecies *A.m. cyanoptera* as an additional threat to the listed entities.

The close resemblance between the listed and the unlisted entities would make differentiating the listed scarlet macaws (the subspecies *Ara macao cyanoptera* and the northern DPS of the subspecies *Ara macao macao*) from those that are not listed (individuals of the southern DPS of *A. m. macao* and subspecies crossings (*A. m. cyanoptera* and *A. m. macao*)) difficult for law enforcement to enforce. Therefore, we determine that treating the southern DPS of *A. m. macao* and subspecies crosses (*A. m. cyanoptera* and *A. m. macao*) under the 4(e) similarity of appearance provisions of the Act will substantially facilitate law enforcement actions to protect and conserve scarlet macaws. If the southern DPS of *A. m. macao* or subspecies crosses (*A. m. cyanoptera* and *A. m. macao*) were not listed, importers and exporters could inadvertently or purposefully misrepresent a specimen of *A. m. cyanoptera* or the northern DPS of *A. m. macao* as a specimen of the unlisted entity, creating a loophole in enforcing the Act's protections for listed species of scarlet macaw. Thus, the listing will facilitate Federal and State law-enforcement efforts to curtail unauthorized import and trade in *A. m. cyanoptera* or the northern DPS of *A. m. macao.*

Extending the prohibitions of the Act to the similar entities through this listing of those entities due to similarity of appearance under section 4(e) of the Act and providing applicable prohibitions and exceptions in a rule issued under section 4(d) of the Act will provide greater protection to *A. m. cyanoptera* and the northern DPS of *A. m. macao.* Although the 4(e) provisions of the Act do not contain criteria as to whether a species listed under the similarity of appearance provisions should be treated as endangered or threatened, we find that treating the southern DPS of *A. m. macao* and subspecies crosses (*A. m. cyanoptera* and *A. m. macao*) as threatened is appropriate because the 4(d) rule, for the reasons mentioned in our finding below, provides adequate protection for these entities. For these reasons, we are proposing to treat the southern DPS of *A. m. macao* and subspecies crosses (*A. m. cyanoptera* and *A. m. macao*) as threatened due to the similarity of appearance pursuant to section 4(e) of the Act.

4(d) Rule

When a species is listed as endangered, certain actions are prohibited under section 9 of the Act and our regulations at 50 CFR 17.21. These include, among others, prohibitions on take within the United States, within the territorial seas of the United States, or upon the high seas; import; export; and shipment in interstate or foreign commerce in the course of a commercial activity. Exceptions to the prohibitions for endangered species may be granted in accordance with section 10 of the Act and our regulations at 50 CFR 17.22.

The Act does not specify particular prohibitions and exceptions to those prohibitions for threatened species. Instead, under section 4(d) of the Act, the Secretary, as well as the Secretary of Commerce depending on the species, was given the discretion to issue such regulations as deemed necessary and advisable to provide for the conservation of such species. The Secretary also has the discretion to prohibit by regulation with respect to any threatened species any act prohibited under section 9(a)(1) of the Act. For the scarlet macaw, the Service is exercising our discretion to issue a 4(d) rule. By adopting the existing parrot 4(d) rule for the scarlet macaw, we are incorporating all prohibitions and provisions of 50 CFR 17.31 and 17.32. However, import and export of certain scarlet macaws into and from the United States and certain acts in interstate commerce are allowed without a permit under the Act, as explained below.

The 4(d) rule will apply to the southern subspecies of scarlet macaw (*Ara macao macao*) and to crosses of the two scarlet macaw subspecies, *A. m. macao* and *A. m. cyanoptera.* We are including subspecies crosses in this rule because aviculturists have bred the species without regard to their taxa, resulting in crosses of the two subspecies being present in trade. All prohibitions of 50 CFR 17.31 will apply to *A. m. macao* and subspecies crosses of *A. m. macao* and *A. m. cyanoptera,* except that import and export of certain *A. m. macao* and subspecies crosses into and from the United States and certain acts in interstate commerce will be allowed without a permit under the Act, as explained below. For activities otherwise prohibited under the 4(d) rule involving specimens of the southern DPS of the scarlet macaw and subspecies crosses, such activities will require authorization pursuant to the similarity-of-appearance permit regulations at 50 CFR 17.52. If an applicant is unable to meet the issuance criteria for a similarity-of-appearance permit and demonstrate that the scarlet macaw in question is a subspecific cross or originated from the southern DPS, authorization for an otherwise prohibited activity would need to be obtained under the general permit provisions for threatened species found at 50 CFR 17.32. For activities otherwise prohibited under the 4(d) rule involving specimen of the northern DPS of the scarlet macaw (*A. m. macao*), such activities would require authorization pursuant to the general permit provisions for threatened species found at 50 CFR 17.32.

Import and Export

The 4(d) rule will apply to all commercial and noncommercial international shipments of live and dead southern subspecies of scarlet macaws and subspecific crosses of *A. m. macao* and *A. m. cyanoptera* and their parts and products, including the import and export of personal pets and research samples. In most instances, the rule will adopt the existing conservation regulatory requirements of CITES and the WBCA as the appropriate regulatory provisions for the import and export of certain scarlet macaws. The import into the United States and export from the United States of birds taken from the wild after the date this species is listed under the Act; conducting an activity that could take or incidentally take scarlet macaws; and foreign commerce must meet the requirements of 50 CFR 17.31 and 17.32, including obtaining a permit under the Act. However, the 4(d) rule allows a person to import or export without a permit issued under that Act if the specimen either: (1) Was held in captivity prior to the date this species is listed under the Act; or (2) is a captive-bred specimen, provided the export is authorized under CITES and the import is authorized under CITES and the WBCA. If a specimen was taken from the wild and held in captivity prior to the date this species is listed under the Act, the importer or exporter must provide documentation to support that status, such as a copy of the original CITES permit indicating when the bird was removed from the wild or museum specimen reports. For captive-bred birds, the importer must provide either a valid CITES export/re-export document issued by a foreign Management Authority that indicates that the specimen was captive-bred by using a source code on the face of the permit of either ''C,'' ''D,'' or ''F.'' Exporters of captive-bred birds must provide a signed and dated statement from the breeder of the bird confirming its captive status, and documentation on the source of their breeding stock. The source codes of C, D, and F for CITES permits and certificates are as follows:

(C) Animals bred in captivity in accordance with Resolution Conf. 10.16 (Rev.), as well as parts and derivatives thereof, exported under the provisions of Article VII, paragraph 5 of the Convention.

(D) Appendix-I animals bred in captivity for commercial purposes in operations included in the Secretariat's Register, in accordance with Resolution Conf. 12.10 (Rev. CoP15), and Appendix-I plants artificially propagated for commercial purposes, as well as parts and derivatives thereof, exported under the provisions of Article VII, paragraph 4, of the Convention.

(F) Animals born in captivity (F1 or subsequent generations) that do not fulfill the definition of ''bred in captivity'' in Resolution Conf. 10.16 (Rev.), as well as parts and derivatives thereof.

The 4(d) rule's provisions regarding captive-bred birds apply to birds bred in the United States and abroad. The terms ''captive-bred'' and ''captivity''' used in the 4(d) rule are defined in the regulations at 50 CFR 17.3 and refer to wildlife produced in a controlled environment that is intensively manipulated by man from parents that mated or otherwise transferred gametes in captivity. Although the 4(d) rule requires a permit under the Act to ''take'' (including harm and harass) a scarlet macaw, our regulations at 50 CFR 17.3 establish that ''take'' when applied to captive wildlife does not include generally accepted animal-husbandry practices; breeding procedures; or provisions of veterinary care for confining, tranquilizing, or anesthetizing, when such practices, procedures, or provisions are not likely to result in injury to the wildlife.

We assessed the conservation needs of the scarlet macaw in light of the broad protections provided to the species under CITES and the WBCA. The scarlet macaw is included in Appendix I of CITES, a treaty that contributes to the conservation of the species by regulating international trade and ensuring that trade in Appendix-I species is not detrimental to the survival of the species. The purpose of the WBCA is to promote the conservation of exotic birds and to ensure that imports of exotic birds into the United States do not harm them. The best available data indicate that the current threat of trade of the scarlet macaw stems mainly from illegal trade that stays within the domestic markets of Central and South America. Thus, the general prohibitions on import and export contained in 50 CFR 17.31, which extend only within the jurisdiction of the United States, would not regulate such activities. Accordingly, we find that the import and export requirements of the 4(d) rule provide the necessary and advisable conservation measures for this species. This 4(d) rule streamlines the permitting process by deferring to existing laws that are protective of scarlet macaws in the course of import and export and not requiring permits under the Act for certain types of activities.

Interstate Commerce

Under the 4(d) rule, a person may deliver, receive, carry, transport, or ship *Ara macao macao* and subspecies crosses (*A. m. macao* and *A. m. cyanoptera*) in interstate commerce in the course of a commercial activity, or sell or offer to sell in interstate commerce *A. m. macao* and subspecies crosses without a permit under the Act. At the same time, the prohibitions on take under 50 CFR 17.21, as presently extended to threatened species under 50 CFR 17.31, will apply under this 4(d) rule, and any interstate commerce activities that could incidentally take *A. m. macao* and subspecies crosses or otherwise prohibited acts in foreign commerce will require a permit under 50 CFR 17.32.

We have no information that suggests current interstate commerce activities are associated with threats to the scarlet macaw or would negatively affect any efforts aimed at the recovery of wild populations of the species. Therefore, we are not placing into effect any prohibitions on interstate commerce of scarlet macaw within the United States. Because the species will be otherwise protected in the course of interstate commercial activities under the take provisions and foreign commerce provisions contained in 50 CFR 17.31 as applied to this species, and international trade of this species is regulated under CITES, we find this 4(d) rule contains all the prohibitions and authorizations necessary and advisable for the conservation of the scarlet macaw.

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that we do not need to prepare an environmental assessment, as defined under the authority of the National Environmental Policy Act of 1969, in connection with regulations adopted under section 4(a) of the Endangered Species Act. 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 references cited in this rulemaking is available on the internet at *http://www.regulations.gov* and upon request from the U.S. Fish and Wildlife Service, Ecological Services, Branch of Delisting and Foreign Species (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are staff members of the Branch of Delisting and Foreign Species, Ecological Services Program, U.S. Fish and Wildlife Service.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we 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; 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding entries for ''Macaw, scarlet'', ''Macaw, scarlet [Northern DPS]'', ''Macaw, scarlet [Southern DPS]'', and ''Macaw, scarlet [Subspecies crosses]'' in alphabetical order under BIRDS to 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				
* *	*	*	*	* *
Macaw, scarlet	*Ara macao cyanoptera*	Wherever found	E	84 FR [insert **Federal Register** page where the document begins], 2/26/2019.
Macaw, scarlet [Northern DPS]	*Ara macao macao*	Colombia (northwest of the Andes), Costa Rica (Pacific slope), Panama (mainland).	T	84 FR [insert **Federal Register** page where the document begins], 2/26/2019; 50 CFR 17.41(c).[4d]
Macaw, scarlet [Southern DPS]	*Ara macao macao*	Bolivia, Brazil, Colombia (southeast of the Andes), Ecuador, French Guiana, Guyana, Peru, Suriname, Venezuela.	T(S/A)	84 FR [insert **Federal Register** page where the document begins], 2/26/2019; 50 CFR 17.41(c).[4d]
Macaw, scarlet [Subspecies crosses].	*Ara macao macao* X *Ara macao cyanoptera.*	Costa Rica, Nicaragua (Atlantic slope border region).	T(S/A)	84 FR [insert **Federal Register** page where the document begins], 2/26/2019; 50 CFR 17.41(c).[4d]
* *	*	*	*	* *

■ 3. Amend § 17.41 by revising paragraphs (c) introductory text and (c)(2)(ii) introductory text and by adding paragraph (c)(2)(ii)(E) to read as follows:

§ 17.41 Special rules—birds.

* * * * *

(c) The following species in the parrot family: Salmon-crested cockatoo *(Cacatua moluccensis),* yellow-billed parrot *(Amazona collaria),* white cockatoo (*Cacatua alba),* hyacinth macaw (*Anodorhynchus hyacinthinus*), and scarlet macaw (*Ara macao macao* and scarlet macaw subspecies crosses (*Ara macao macao* and *Ara macao cyanoptera*)).

* * * * *

(2) * * *

(ii) *Specimens held in captivity prior to certain dates:* You must provide documentation to demonstrate that the specimen was held in captivity prior to the dates specified in paragraph (c)(2)(ii)(A), (B), (C), (D), or (E) of this section. Such documentation may include copies of receipts, accession or veterinary records, CITES documents, or wildlife declaration forms, which must be dated prior to the specified dates.

* * * * *

(E) For *scarlet macaws:* March 28, 2019 (the date this species was listed under the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*)).

* * * * *

Dated: February 4, 2019.

Margaret E. Everson,

Principal Deputy Director Exercising the Authority of the Director for the U.S. Fish and Wildlife Service.

[FR Doc. 2019–03165 Filed 2–25–19; 8:45 am]

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