assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

H. Regulations Affecting Intrastate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the FAA, when modifying its regulations in a manner affecting intrastate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish appropriate regulatory distinctions. As discussed in the Helicopter Air Ambulance, Commercial Helicopter, and Part 91 Helicopter Operations final rule which instituted the requirements being delayed by this action, the FAA finds that there is no need to make any regulatory distinctions in the provisions of this rule. *See* 79 FR 9932, 9971–72.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this immediately adopted final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule with request for comments under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a ''significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VI. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document my be obtained by using the Internet—

1. Search the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visit the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/* or

3. Access the Government Printing Office's Web page at: *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680.

B. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Parts 91, 120, and 135

Air taxis, Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 1. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 41706, 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–45105, Pub. L. 112–95, 126 Stat. 58 (49 U.S.C. 44730).

■ 2. Amend § 135.293 by removing the phrase ''After the next scheduled competency check after April 22, 2014'' from the beginning of paragraph (a)(9) and adding paragraph (h) to read as follows:

§ 135.293 Initial and recurrent pilot testing requirements.

* * * * *

(h) Rotorcraft pilots must be tested on the subjects in paragraph (a)(9) of this section when taking a written or oral knowledge test after April 22, 2015. Rotorcraft pilots must be checked on the maneuvers and procedures in paragraph (c) of this section when taking a competency check after April 22, 2015.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on April 15, 2014.

Michael G. Whitaker,

Deputy Administrator, Federal Aviation Administration.

[FR Doc. 2014–09034 Filed 4–17–14; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2013–N–0069]

Medical Devices; Ophthalmic Devices; Classification of the Eyelid Weight

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the eyelid weight into class II (special controls). The Agency is exempting the external eyelid weight from premarket notification, but continuing to require premarket notification for implantable eyelid weights in order to provide a reasonable assurance of safety and effectiveness of the device. Both external and implantable eyelid weight devices are subject to special controls. The eyelid weight may be adhered to the outer skin of the upper eyelid (external eyelid weight) or implanted into the upper eyelid (implantable eyelid weight), and is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

DATES: *Effective Date:* July 21, 2014.

Compliance Dates: Premarket notification submissions (510(k)s) for

eyelid weights filed on or after the effective date of this rule are expected to comply with the requirement of special controls at the time that the 510(k) is submitted.

Premarket notification submissions (510(k)s) for eyelid weights filed before the effective date of this rule, but not yet cleared for marketing, are expected to comply with the requirement of special controls prior to receiving marketing clearance.

External eyelid weights exempt from premarket notification under this rule and not currently marketed are expected to comply with the requirement of special controls prior to introducing devices into interstate commerce.

Eyelid weights (both implantable and external) legally marketed before the effective date of this rule are expected to comply with the requirement of special controls by April 21, 2015. See section V of this document, ''Compliance Dates,'' for further information.

FOR FURTHER INFORMATION CONTACT: Tina Kiang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2414, Silver Spring, MD 20993–0002, 301–796–6860, *Tina.Kiang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the Agency takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.'' These devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 510(m) of the FD&C Act (21 U.S.C. 360(m)) provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Device

In the **Federal Register** of February 8, 2013 (78 FR 9349), FDA proposed to classify eyelid weight devices intended for the gravity-assisted treatment of lagophthalmos (incomplete eyelid closure) into class II (special controls) and proposed special controls for these devices. FDA also proposed to exempt the devices from premarket notification requirements if the device is an external eyelid weight. FDA invited interested persons to comment on the proposed regulation by May 9, 2013. FDA received three comments on the proposed rule.

III. Summary of the Final Rule

In accordance with 21 CFR 860.84(g)(2), FDA is classifying eyelid weights into class II (special controls). FDA is codifying the classification of eyelid weights by adding § 886.5700.

A. External Eyelid Weights

Under section 510(m) of the FD&C Act, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of external eyelid weights, and the Agency is exempting these devices from premarket notification requirements. The Agency has also identified special controls for these devices. On or before the effective date of this final rule, firms who wish to market external eyelid weight devices that are not already legally marketed are required to either (1) comply with the particular mitigation measures set forth in the special controls in § 886.5700(b)(1) or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. As discussed in sections IV and V, in response to comments regarding compliance with the special controls for existing legally marketed devices, FDA has extended the compliance date for special controls to 1 year from the effective date of this rule to allow manufacturers of existing legally marketed devices adequate time to review the design history files and complete any needed testing and implement any required labeling changes for their devices.

FDA also made changes to the final rule as related to external eyelid weights in response to the comments and for clarification. Proposed § 886.5700(b)(1)(iii) has been edited to remove the words ''required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter'' to minimize any confusion since this section describes special controls and the labeling requirements in 21 CFR part 801 are a general control. FDA also removed the special controls for external eyelid weights related to magnetic resonance (MR) compatibility testing (see additional discussion in section IV).

B. Implantable Eyelid Weights

FDA has determined that premarket notification is necessary to provide

reasonable assurance of safety and effectiveness of implantable eyelid weights, and, therefore, this device type is not exempt from premarket notification requirements. The Agency has also identified special controls for these devices. On or before the effective date of this final rule, firms who wish to market external eyelid weight devices that are not already legally marketed are required to either (1) comply with the particular mitigation measures set forth in the special controls in § 886.5700(b)(2) or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. As discussed in section IV, in response to comments regarding compliance with the special controls for existing legally marketed devices, FDA has extended the compliance date for special controls to 1 year from the effective date of this rule to allow manufacturers of existing legally marketed devices adequate time to review the design history files and complete any needed testing and implement any required labeling changes for their devices.

IV. Analysis of Comments and FDA's Response

FDA received three comments on the proposed rule. One of the comments was supportive of FDA's proposed rule, including the classification and the special controls for both the external and implantable eyelid weights and the exemption of external eyelid weights from premarket notification requirements (510(k)). A second comment agreed with the proposed classification into class II, but indicated that the risks associated with long-term use of external eyelid weights were similar to those for implantable eyelid weights, and that as such external eyelid weights should not be exempted from the premarket notification requirements. FDA disagrees with the comment. FDA believes that the identified special controls adequately mitigate the risks to health for the device regardless of the duration of use. The increased risks associated with implanted eyelid weights are related to the need for the device to be provided sterile and the increased biocompatibility requirements. These risks are significantly reduced with external eyelid weight devices. FDA believes that compliance with the special controls in § 886.5700(b)(1) provides a reasonable assurance of safety and effectiveness for external eyelid weight devices without the need for premarket notification.

The third comment requested clarification on whether existing eyelid weight manufacturers (for both implantable and external eyelid weight devices) need to address the identified special controls. The special controls established in this rule apply to existing legally marketed devices, as well as to new eyelid weight devices not currently marketed for which marketing authority is sought and to any modification of a currently legally marketed eyelid weight. In response to this comment, FDA has extended the compliance date for special controls for manufacturers of existing legally marketed devices to 1 year from the effective date of this rule, as outlined in section V, ''Compliance Dates.''

Submission of a new 510(k) solely to demonstrate conformance to the special controls is not needed unless complying with the special controls leads to changes to the device that would independently trigger the need for a new 510(k) under § 807.81(a)(3). However, manufacturers should maintain documentation in their design history file (see § 820.30 (21 CFR 820.30)) to demonstrate that they meet the special controls. To ensure that manufacturers of existing legally marketed devices have adequate time to review their design history files and complete any needed testing and implement any required labeling changes for their devices, FDA has extended the compliance date for existing legally marketed devices to comply with the special controls to 1 year after the effective date of this final rule. Manufacturers with questions regarding their existing devices are encouraged to interact with FDA via the pre-submission process.

The third comment further suggested that the biocompatibility testing requirements as described in the proposed special controls are more extensive and burdensome than the requirements under which existing legally marketed eyelid weights devices were originally reviewed. The comment stated that, for external eyelid weights, limited biocompatibility testing with supportive literature review and reference to material in predicate devices should be acceptable in lieu of a full battery of biocompatibility testing. FDA agrees that based on the material and manufacturing processes being used, a full battery of biocompatibility testing may not be required. Discussion of the specific biocompatibility testing requirements for existing legally marketed eyelid weight devices is beyond the scope of this rule; however, FDA encourages manufacturers to review existing Agency guidance on this topic and contact FDA via the pre-submission process to discuss specific biocompatibility requirements for their devices.

The third comment further requested clarification on whether a labeling change to address MR compatibility would trigger additional compliance expectations regarding MR testing and suggested that because external eyelid weights are removable devices, MR compatibility should not be a requirement for these devices. FDA agrees with the commenter that removal of the device when the patient is in the MR environment would mitigate this risk and has thus removed MR testing compatibility testing as a special control. However, to ensure that the patient is aware that the device should be removed in these circumstances, the special control regarding labeling has been revised to include a requirement for a warning stating that the patient should be instructed to remove the device prior to entering an MR environment.

Finally, the third comment also requested clarification on the special control for implanted eyelid weights: ''testing demonstrating the sterility and shelf life of the device'' and suggested that the shelf life of the implanted device is limited by the ability of the associated packaging to maintain a protective barrier and not by the device itself, and therefore, validated packaging and sterilization procedures would satisfy this requirement. Although FDA agrees that validation of the packaging and sterilization processes is important to comply with this special control, each manufacturer must assess the materials and processes used to manufacture their device when determining the testing necessary to provide assurance that the sterility and functionality of the device are maintained over its shelf life.

V. Compliance Dates

This final rule will become effective July 21, 2014.

The special controls established in this rule for external eyelid weights and the special controls established in this rule for implantable eyelid weights apply to any external or implantable eyelid weight respectively, whether the device is an existing legally marketed device, a new eyelid weight device not currently marketed for which marketing authority is sought, or a modification of a currently legally marketed eyelid weight. Devices of this type that were legally marketed before the effective date of this rule may continue to be legally marketed; however 1 year after the effective date of this rule, such

devices must comply with applicable special controls in order to continue to be legally marketed. Submission of a new 510(k) solely to demonstrate conformance to the special controls is not needed unless complying with the special controls leads to changes to the device that would independently trigger the need for a new 510(k) under § 807.81(a)(3). However, manufacturers should maintain documentation in their design history file (see § 820.30(j)) to demonstrate that they meet the special controls. One year after the effective date of this rule, any external eyelid weight that does not comply with the special controls established in § 886.5700(b)(1) or implantable eyelid weight that does not comply with the special controls established in § 886.5700(b)(2) this rule will be considered adulterated and misbranded (sections 501(f)(1)(B) and 502(o) of the FD&C Act (21 U.S.C. 351(f)(1)(B) and 352(o)) until such time as the device: (1) Complies with the special controls and any premarket notification requirements; (2) is approved in a PMA application; or (3) is classified into class I or II under section 513(f)(2) or (3) of the FD&C Act.

A 510(k) submission for an eyelid weight either filed before the effective date of this rule, but not yet cleared for marketing or filed after the effective date of this rule may be cleared for marketing only if the device complies with the special controls established for this device type. The submitter may demonstrate that the special controls have been met by incorporating previously submitted information by reference, or by providing newly generated information. A submitter's first 510(k) submission for an implantable eyelid weight filed following the publication of this final rule should be a traditional 510(k) submission. Filing of a special 510(k) submission for a modified implantable eyelid weight is only appropriate after FDA has cleared an initial 510(k) submission that establishes that the device complies with the special controls established for the device type.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, 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 Agencies 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). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final regulation classifies a previously unclassified pre-amendment device type, there are only five registered establishments listed in the Establishment Registration and Device Listing database, and the regulation designating the classification of eyelid weights as class II is consistent with the historical regulatory oversight given to this device type, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VIII. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other 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 collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 886.5700 to subpart E to read as follows:

§ 886.5700 Eyelid weight.

(a) *Identification.* An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

(1) The external eyelid weight is adhered to the outer skin of the upper eyelid.

(2) The implantable eyelid weight is implanted into the upper eyelid.

(b) *Classification.* (1) Class II (special controls) for the external eyelid weight. The external eyelid weight is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9. The special controls for the external eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device; and

(ii) Labeling must include the following information:

(A) Specific instructions regarding the proper placement, sizing, and removal of the device; and

(B) A warning stating that the patient should be instructed to remove the device prior to entering a magnetic resonance environment.

(2) Class II (special controls) for the implantable eyelid weight. The special controls for the implantable eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device;

(ii) Testing demonstrating the sterility and shelf life of the device;

(iii) Nonclinical testing evaluating the compatibility of the device in a magnetic resonance environment.

(iv) Patient labeling to convey information regarding the safety and compatibility of the device in a magnetic resonance environment, the conditions under which a patient with

the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about magnetic resonance safety and compatibility if needed.

Dated: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08940 Filed 4–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF STATE

22 CFR Part 173

[Public Notice 8703]

RIN 1400–AD50

Availability of Public Diplomacy Program Material Within the United States

AGENCY: Department of State.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of State (''Department'') is amending its regulations to implement Section 1078 of the National Defense Authorization Act of 2013. This statutory provision, which entered into effect on July 2, 2013, amends previous law to allow the Department and the Broadcasting Board of Governors (''BBG'') to make public diplomacy program material available within the United States, upon request, following the dissemination of such material abroad, and requires the Department to issue regulations implementing this change.

DATES: This interim final rule will become April 21, 2014. The Department will accept comments on the interim final rule from the public until June 20, 2014.

ADDRESSES: You may submit comments by any of the following methods:

- *Online:* Persons with access to the Internet may view this rule and provide comments by going to the regulations.gov Web site at: *http://www.regulations.gov.*
- *Mail (paper, disk, or CD–ROM submission):* Director, Office of Policy and Outreach, Bureau of International Information Programs, U.S. Department of State, State Annex 5 (SA–5), Floor 5, 2200 C Street NW., Washington, DC 20522–0505.
- *Email: IIP_Inquiries@state.gov.* You must include the RIN (1400–AD50) in the subject line of your message.

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business or financial information that is included in a comment. The Department of State will post all comments received before the close of the comment period at *http://www.regulations.gov.* You may search on the RIN for this rule, 1400–AD50.

FOR FURTHER INFORMATION CONTACT: Kim DeBlauw, Director, Office of Policy and Outreach, Bureau of International Information Programs, U.S. Department of State, SA–5, Floor 5, 2200 C Street NW., Washington, DC 20522–0505; phone: (202) 632–9938; fax (202) 632–9901.

SUPPLEMENTARY INFORMATION:

Executive Summary

Section 1078 of the National Defense Authorization Act for Fiscal Year 2013, Public Law 112–239 (''NDAA''), which entered into effect on July 2, 2013, amends and clarifies, respectively, section 501 of the United States Information and Educational Exchange Act of 1948, as amended (22 U.S.C. 1461; ''the Smith-Mundt Act'') (''Section 501''), governing the domestic distribution of certain information about the United States, its people, and policies (''Program Material'') prepared for dissemination abroad; and section 208 of the Foreign Relations Authorization Act, Fiscal Years 1986 and 1987 (22 U.S.C. 1461–1a) (''Section 208''), governing the creation of such material for the purpose of influencing domestic public opinion.

The revised Section 501 authorizes the use of public diplomacy funds for the preparation, dissemination and use of Program Material ''intended for foreign audiences abroad.'' With respect to Program Material disseminated abroad on or after July 2, the Department and/or the BBG may, upon request, make such material available within the United States, and both the Department and BBG must issue necessary regulations to establish procedures to maintain such material, for reimbursement of reasonable costs incurred in fulfilling requests for such material, and to ensure that persons seeking the release of such material have secured and paid for necessary U.S. rights and licenses. (The BBG published its interim final rule on July 2, 2013, with a final rule published on November 8, 2013 (78 FR 67025).)

The mission of U.S. public diplomacy is to support the achievement of U.S. foreign policy goals and objectives, advance national interests, and enhance national security by informing and influencing foreign publics, and by expanding and strengthening the relationship between the people and Government of the United States and citizens of the rest of the world. Public diplomacy outreach includes communications with foreign audiences abroad through Program Material prepared with, and efforts supported by, funds appropriated or otherwise made available for this purpose. Prior to the 2013 NDAA, such material could not be disseminated within the United States but could be available at the Department following its release abroad, upon request, for examination only to limited categories of requesters (*i.e.,* representatives of U.S. press associations, newspapers, magazines; research students and scholars; Members of Congress).

Regulatory Analysis

Administrative Procedure Act

The Department is of the opinion that this rulemaking is exempt from the notice-and-comment provisions of 5 U.S.C. 553 under the good cause exception of 5 U.S.C. 553(b). There is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to have this rule effective at the time of publication. Because one of the purposes of this rule and the law underlying this rule is to allow information dissemination outside of the Freedom of Information Act for Program Material, and because of the already-past effective date of the law, the intent of the law would be frustrated if the Department could not begin implementing this rule and responding to domestic requests for Program Material as soon as possible. Accordingly, the Department finds that normal public rulemaking procedures are impracticable and unnecessary, and that there is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to exempt this rule from public rulemaking procedures and to implement this rule upon publication. Without prejudice to the Department's determination that there is good cause to exempt this rule from public rulemaking procedures, in the interests of transparency and public participation, the Department is publishing this rule as an interim final rule with a 60-day provision for public comment.

Furthermore, because this is a substantive rule that relieves restrictions imposed by previous versions of 22 U.S.C. 1461 and 1461–1a, the Department may implement this rule at the time of publication under 5 U.S.C. 553(d)(1). This rule does not require or prompt the public to take any action; rather, it functions to relieve the prohibition that prevented the Department from responding to requests