a period of 12 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Ms. Lin's felony convictions for entry of goods by means of false statements in violation of 18 U.S.C. 542 constitute conduct relating to the importation into the United States of an article of food because she committed an offense related to the importation of Chinese honey into the United States.

The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act, that Ms. Lin should be subject to a 12-year period of debarment. The proposal also offered Ms. Lin an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Lin failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Hung Yi Lin has been convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food and that she is subject to a 12-year period of debarment.

As a result of the foregoing finding, Hung Yi Lin is debarred for a period of 12 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Under section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Hung Yi Lin is a prohibited act.

Any application by Ms. Lin for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2013–N–1484 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03210 Filed 2–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2245]

Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs).'' This guidance describes FDA's policy with respect to certain LIPs that comply with International Electrotechnical Commission (IEC) standards during laser product classification under the Electronic Product Radiation Control provisions of the Federal Food, Drug and Cosmetic Act (the FD&C Act) that apply to electronic products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment, submit either electronic or written comments on the guidance by April 20, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patrick Hintz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4248, Silver Spring, MD 20993–0002, 301–796–6927.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors.'' This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The Agency made this determination because the guidance presents a less burdensome policy consistent with the public health. Although this guidance is immediately in effect, it remains subject to comment in accordance with the Agency's GGPs regulation. This guidance describes FDA's policy with respect to certain LIPs that comply with IEC standards during laser product classification under the Electronic Product Radiation Control provisions of the FD&C Act that apply to electronic products. The regulations for classifying laser products are set forth in part 1040 (21 CFR part 1040).

For purposes of this guidance, the term ''laser illuminated projector'' refers to a type of demonstration laser product regulated under § 1040.10(b)(13) that is designed to project full-frame digital images. The term ''demonstration laser product'' is defined under § 1040.10(b)(13) to mean, ''Any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition.'' LIPs may be used in locations such as indoor or outdoor cinema theaters, laser shows, presentations at conventions, as image/data projectors in an office setting, or in a home.

Lasers are being used in LIPs as an alternative to conventional lamps in

projectors. Although these LIPs emit laser light from extended sources and their uncollimated beams do not present the same hazards as other lasers, they are laser products that present risks and must undergo classification in accordance with § 1040.10(c).

Under § 1040.10(c), FDA recognizes four major hazard classes (I to IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). Under this classification procedure, higher laser classes correspond to more powerful lasers and the potential to pose serious danger if used improperly.

As demonstration laser products, LIPs cannot exceed class IIIa (which is comparable to IEC class 3R) emissions limits as specified in § 1040.11(c) unless granted a variance by FDA under § 1010.4. Many LIPs and applications for LIPs will exceed the class IIIa limits and therefore require a variance to exceed those emission limits.

This guidance document describes FDA's intent with regard to the application of certain aspects of the performance standard requirements in § 1040.11(c) for LIPs. The IEC standards used to evaluate lamps are applicable to characterizing ocular hazards in LIPs, because a laser retinal hazard is related to the radiance of the laser source and the radiant emission levels produced by LIPs are comparable to conventional lamps. Because the radiant emission levels produced by LIPs can scientifically be characterized by an alternative IEC standard, FDA does not intend to consider whether LIP manufacturers that conform to these standards under the situations described in this guidance also comply with §§ 1040.10(c) and 1040.11(c).

II. Significance of Guidance

The guidance represents the Agency's current thinking on the classifications and requirements for LIPs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400056 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 (the PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 1002, 1010, and 1040 are approved under OMB control number 0910–0025.

The labeling referenced in section (IV)(c)(ii) of the guidance does not constitute a ''collection of information'' under the PRA because the labeling is a ''public disclosure of information supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03209 Filed 2–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Negotiation Cooperative Agreement

Announcement Type: New—Limited Competition.

Funding Announcement Number: HHS–2015–IHS–TSGN–0001.

Catalog of Federal Domestic Assistance Number: 93.444.

Key Dates

Application Deadline Date: June 3, 2015.

Review Date: June 10, 2015.

Earliest Anticipated Start Date: July 1, 2015.

Signed Tribal Resolutions Due Date: June 10, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting limited competition Negotiation Cooperative Agreement applications for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 458aaa–2(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA), available at *https://www.cfda.gov/,* under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the government-to- government relationship between the United States and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP is one of three ways that Tribes can choose to obtain health care from the Federal Government for their members. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual PSFAs that the IHS would otherwise provide (referred to as Title I Self-Determination Contracting), or (3) compact with the IHS to assume control over healthcare PSFAs that the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances. Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs to the needs of their communities.

The TSGP is a Tribally-driven initiative and strong Tribal/Federal partnerships are essential for program success. The IHS established the OTSG to implement Tribal Self-Governance authorities. The OTSG: (1) Serves as the primary liaison and advocate for Tribes participating in the TSGP, (2) develops,