Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the FD&C Act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed. FDA has developed a form that prompts a developer to include certain elements in the final consultation in a standard format: Form FDA 3665, entitled, ''Final Consultation for Food Derived From a New Plant Variety (Biotechnology Final Consultation).'' The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format.

Upon implementation of the collection, FDA contacted five firms that had made one or more biotechnology consultation submissions. We asked each of these firms for an estimate of the hourly burden to prepare a submission under the voluntary biotechnology consultation process. Based on information provided by the three firms who responded, we estimate the average time to prepare a submission for final consultation to be 150 hours.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03207 Filed 2–17–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1484]

Hung Yi Lin; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Hung Yi Lin for a period of 12 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Ms. Lin was convicted, as defined in the FD&C Act, of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Lin was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of August 29, 2014 (30 days after receipt of the notice), Ms. Lin had not responded. Ms. Lin's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective February 18, 2015.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division Of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM4144), Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On September 30, 2013, Ms. Lin was convicted, as defined in section 306(*l*)(1)(B) of the FD&C Act, when the U.S. District Court for the Northern District of Illinois accepted her plea of guilty and entered judgment against her for the following offense: Three counts of entry of goods into the United States by means of false statements, in violation of 18 U.S.C. 542.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Ms. Lin owned and operated KBB Express Inc., a freight forwarding company located in South El Monte, CA that provided nationwide transportation, delivery, and other logistical services for imported and entered merchandise, including Chinese-origin honey. Ms. Lin also served as the U.S. agent for at least 12 importers for which she handled the process of importing, and coordinating with brokers to enter and bring in, Chinese-origin honey into the United States.

On or about December 13, 2009, Ms. Lin entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including Bureau of Customs and Border Protection (CBP) forms that falsely declared that approximately four container loads of Chinese-origin honey with a declared value upon entry of approximately $92,822 was Chinese honey syrup. By so doing, Ms. Lin caused losses to the United States of approximately $205,141 in uncollected anti-dumping duties and honey assessment fees, when in fact she knew the product was Chinese honey. This was in violation of 18 U.S.C. 542.

On or about December 13, 2009, Ms. Lin entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including CBP forms that falsely declared that approximately three container loads of Chinese-origin honey with a declared value upon entry of approximately $69,617 was Chinese honey syrup. By so doing, Ms. Lin caused losses to the United States of approximately $153,855 in uncollected anti-dumping duties and honey assessment fees, when in fact she knew the product was Chinese honey. This was in violation of 18 U.S.C. 542.

On or about December 13, 2009, Ms. Lin entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including CPB forms that falsely declared that approximately three container loads of Chinese-origin honey with a declared value upon entry of approximately $69,617 was Chinese honey syrup. By so doing, Ms. Lin caused losses to the United States of approximately $153,855 in uncollected anti-dumping duties and honey assessment fees, when in fact she knew the product was Chinese honey. This was in violation of 18 U.S.C. 542.

Ms. Lin admitted that between 2009 and 2012, she caused up to 764 shipping containers of Chinese-origin honey valued at approximately $11,489,306 to be fraudulently imported and entered into the United States, thereby causing losses to the United States of as much as $39,203,144 through her fraudulent practices.

As a result of her conviction, on July 25, 2014, FDA sent Ms. Lin a notice by certified mail proposing to debar her for

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]

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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