DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

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 20, 2015.

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 0910–0704. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties—(OMB Control No. 0910–0704)—(Extension)

Since 1992, when FDA issued its ''Statement of Policy: Foods Derived from New Plant Varieties'' (the 1992 policy) (57 FR 22984, May 29, 1992), FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, FDA explained that, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), developers of new foods (in this document food refers to both human food and animal feed) have a responsibility to ensure that the foods they offer to consumers are safe and are in compliance with all requirements of the FD&C Act (57 FR 22984 at 22985).

FDA recommends that producers who use biotechnology in the manufacture or development of foods and food ingredients work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements, and has instituted a voluntary consultation process with industry. To facilitate this process the Agency has issued a guidance entitled, ''Guidance on Consultation Procedures: Foods From New Plant Varieties,'' which is available on FDA's Web site at *http://www.fda.gov/FoodGuidances.* The guidance describes FDA's consultation process for the evaluation of information on new plant varieties provided by developers. The Agency believes this consultation process will help ensure that human food and animal feed safety issues or other regulatory issues (*e.g.* labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the FD&C Act.

Description of Respondents: Respondents to this collection of information include developers of new plant varieties intended for food use.

In the **Federal Register** of December 11, 2014 (79 FR 73590), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was not responsive to the information collection topics solicited in the notice and is not, therefore, addressed in this document.

FDA estimates the burden of this collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial consultation	None	20	2	40	4	160
Final consultation	FDA 3665	12	1	12	150	1,800
Total						1,960

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in the guidance, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, firms developing a new bioengineered plant variety intended for food use have generally initiated consultation with FDA early in the process of developing such a variety, even though there is no legal obligation for such consultation. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the Agency in exercising their mutual responsibilities under the FD&C Act.

FDA estimates that its Center for Veterinary Medicine and its Center for Food Safety and Applied Nutrition jointly received an average of 40 initial consultations per year in the last 3 years via telephone, email, or written letter. Based on this information, we expect to receive no more than 40 annually in the next 3 years.

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]

BILLING CODE 4164–01–P

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