to debar him for two consecutive 5-year periods (10 years) from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Park's felony convictions for introducing misbranded drugs into interstate commerce and importing merchandise contrary to law were for conduct relating to the importation into the United States of any drug or controlled substance because he knew that the 14,000 pills containing Tadalafil were illegally imported, yet Mr. Park decided to repackage them and sell them to U.S. consumers. In addition, he did in fact illegally import Dapoxetine and Rhodiola rosea and intended to sell them to consumers in the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Park's offenses, and concluded that each of these felony offenses independently warranted a 5-year period of debarment, and proposed that these debarment periods be served consecutively under section 306(c)(2)(A)(iii).

The proposal informed Mr. Park of the proposed debarment and offered Mr. Park an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Park received the proposal and notice of opportunity for a hearing on December 20, 2019. Mr. Park failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Park has been convicted of two felony counts under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that each offense should be accorded a debarment period of 5 years. Under section 306(c)(2)(A)(iii) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 5-year period of debarment for each of the two offenses of conviction will be served consecutively, resulting in a total debarment period of 10 years.

As a result of the foregoing finding, Mr. Park is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to 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 any drug or controlled substance by, with the assistance of, or at the direction of Mr. Park is a prohibited act.

Any application by Mr. Park for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–4829 and sent to the Dockets Management Staff (see **ADDRESSSES**). 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 will be placed in the docket and will be viewable at *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16085 Filed 7–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

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: Submit written comments (including recommendations) on the collection of information by August 24, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0037. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers 21 CFR 108.25 and 108.35, and 21 CFR parts 113 and 114

OMB Control Number 0910–0037—Extension

Section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance that may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures, and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing

procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(1) (21 CFR 108.25(c)(1) and 108.35(c)(1)). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Forms FDA 2541d, FDA 2541e, and FDA 2541f for all methods except aseptic processing, or Form FDA 2541g for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (21 CFR 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms also must document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§ 113.60(c)) (thermally processed foods) and § 114.80(b) (acidified foods).

The records of processing information are periodically reviewed during factory inspections by FDA to verify fulfillment of the requirements in parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

As described in our regulations, processors may obtain the paper version of Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g by contacting us at a particular address by visiting *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm*. Processors mail completed paper forms to us. However, processors who are subject to § 108.25 and/or § 108.35 have an option to submit Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g electronically.

Although we encourage commercial processors to use the electronic submission system for plant registration and process filing, we will continue to make paper-based forms available. To standardize the burden associated with process filing, regardless of whether the process filing is submitted electronically or using a paper form, we are offering the public the opportunity to use four forms, each of which pertains to a specific type of commercial processing and is available both on the electronic submission system and as a paper-based form. The electronic submission system and paper-based form ''mirror'' each other to the extent practicable. The four process filing forms are as follows:

- Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method);
- Form FDA 2541e (Food Process Filing for Acidified Method);
- Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method); and
- Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems).

At this time, the paper-based versions of the four forms and their instructions are all available for review at *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm*.

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

In the **Federal Register** of April 3, 2020 (85 FR 18995), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
108.25(c)(1) and 108.35(c)(1); Food canning establishment registration	2541	645	1	645	0.17 (10 minutes)	110
108.25(c)(2); Food process filing for acidified method	2541e	726	11	7,986	0.33 (20 minutes)	2,659
108.35(c)(2); Food process filing for low-acid retorted method	2541d	336	12	4,032	0.33 (20 minutes)	1,343
108.35(c)(2); Food process filing for water activity/formulation control method	2541f	37	6	222	0.33 (20 minutes)	74
108.35(c)(2); Food process filing for low-acid aseptic systems	2541g	42	22	924	0.75 (45 minutes)	693
108.25(d); 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce	N/A	1	1	1	4	4

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Total						4,883

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The calculation for 20 minutes uses 0.333 hour.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We base our estimate of the number of respondents in table 1 on registrations, process filings, and reports received. The hours per response reporting estimates are based on our experience with similar programs and information received from industry. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. We estimate that we will receive one report annually under §§ 108.25(d) and 108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
108, 113, and 114	10,392	1	10,392	250	2,598,000

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

We base our estimate of 10,392 recordkeepers in table 2 on the number of registered firms, excluding firms that were inactive or out of business, yet still registered. We estimate that 10,392 firms will each expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. No burden has been estimated for the third-party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: July 20, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16037 Filed 7–23–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5969]

John Seil Lee: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring John Seil Lee for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lee was convicted of one felony count under Federal law for conspiracy to import merchandise contrary to law and to defraud the United States and of one felony count under Federal law for importing merchandise contrary to law. The factual basis supporting both of Mr. Lee's convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lee was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 15, 2020 (30 days after receipt of the notice), Mr. Lee had not responded. Mr. Lee's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable July 24, 2020.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) 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 drug or controlled substance.

On August 20, 2019, Mr. Lee was convicted, as defined in section 306(*l*)(1)(A) of the FD&C Act, in the U.S. District Court for the Central District of California, when the court accepted his plea of guilty and entered judgment against him for the felony offenses of conspiracy to commit offense or to defraud the United States in violation of 18 U.S.C. 371 and smuggling goods into