E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 25,380 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual INDs and biologics license applications (BLAs) submitted to FDA's Center for Biologics Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 4, we estimate 423 sponsors of clinical trials of biological products will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in a clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 660 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 1,980 reporting hours annually. As described previously, these estimates are based on past experiences with INDs and BLAs submitted to FDA.

Although our estimated burden for the information collection reflects an overall decrease of 433 hours, we have increased the estimate by 861 records. We are making this adjustment based on an increase in the number of submissions we received over the last few years. We have also finalized the guidance since last OMB review, consistent with our good guidance practices regulation, which provide for public comment at any time, announcing its availability in the **Federal Register** of March 1, 2018 (83 FR 8882).

Dated: July 20, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16036 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–2019–N–4829]

Jin Su Park: 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 Jin Su Park 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. Park was convicted of one felony count under Federal law for Importing Merchandise Contrary to Law, Causing an Act to be Done and of one felony count of introducing Misbranded Drugs into Interstate Commerce, causing an Act to be Done. The factual basis supporting both of Mr. Park's convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Park 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 January 19, 2019 (30 days after receipt of the notice), Mr. Park had not responded. Mr. Park'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, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, 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 the 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 March 25, 2019, Mr. Park was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, in the United States 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 Importing Merchandise Contrary to Law, Causing an Act to be Done in violation of 18 U.S.C. 545, 2(b) and of Introducing Misbranded Drugs into Interstate Commerce, causing an Act to be Done in violation of 21 U.S.C. 331(a), 352, and 333(a)(2) (sections 301(a), 502, and 303(a)(2) of the FD&C Act).

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: As contained in the Plea Agreement, filed on February 7, 2019, Mr. Park did, no later than 2015, begin providing minor assistance to his long-time friend ''J.L.'' who owned and operated several companies that manufactured and distributed misbranded male sexual enhancement pills across the United States. In February 2017, J.L.'s operation was shut down after the FDA and Department of Homeland Security executed a search warrant at J.L.'s pill business as part of an investigation into J.L.'s smuggling of Tadalafil into the United States from China. Mr. Park knew that J.L. had been unlawfully selling misbranded pills containing Tadalafil and other active pharmaceutical ingredients smuggled from China. Mr. Park took approximately 14,000 male sexual enhancement pills, all containing undisclosed Tadalafil, from J.L.'s business, and stored them at Mr. Park's home. Mr. Park then set up a new company, RNG Global Management and Trading Group, Inc. (RNG). Mr. Park repackaged the 14,000 pills with new labeling that failed to disclose the presence of Tadalafil and he commenced selling the misbranded pills to various customers throughout the United States.

Furthermore, in April 2018, Mr. Park ordered, and subsequently paid for, five kilograms of Dapoxetine and five kilograms of Rhodiola rosea from suppliers in China. Mr. Park had the Chinese supplier ship five kilograms of Dapoxetine to him, through a Korean intermediary, in a parcel mislabeled as containing, ''Glass Colour Sample (Zinc Sulfide)'' to a commercial mailbox Mr. Park controlled in Michigan. Mr. Park subsequently had the same Chinese supplier ship to his Michigan mailbox the five kilograms of Rhodiola rosea, through the same Korean intermediary, in a parcel mislabeled as containing, ''Glass Colour (Zinc Sulfide) Sample.'' Mr. Park intended to use both the Dapoxetine and Rhodiola rosea in the male sexual enhancement pills he would sell.

As a result of this conviction, FDA sent Mr. Park by certified mail on December 16, 2019, a notice proposing

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