Application No.	Drug	Applicant
ANDA 204464	Sodium Fluoride F–18 Injection, 10–200 millicurie/mL	Decatur Memorial Hospital, 2300 North Edward St., Suite 100, Decatur, IL 62526.
ANDA 206177	Docetaxel Injection, 20 mg/mL (20 mg/mL), 80 mg/4 mL (20 mg/mL), and 200 mg/10 mL (20 mg/mL).	DFB Oncology, LLC, 3909 Hulen St., Fort Worth, TX 76107.
ANDA 206631	Olmesartan Medoxomil Tablets, 5 mg, 20 mg, and 40 mg.	Lupin Limited, U.S. Agent, Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202.
ANDA 209399	Olanzapine Tablets, 2.5 mg, 5 mg, and 10 mg	Jiangsu Hansoh Pharmaceutical Group Co., Ltd., U.S. Agent, eVenus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 27, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on August 27, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16047 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2169]

Jacobo Geissler: Final Debarment Order

AGENCY: Food and Drug Administration, Health and Human Services (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 Jacobo Geissler for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Geissler was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Geissler was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of April 7, 2021 (30 days after receipt of the notice), Mr. Geissler has not responded. Mr. Geissler's failure to respond and request a hearing constitutes a waiver of Mr. Geissler's right to a hearing concerning this matter.

DATES: This order is applicable July 28, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), 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)(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 October 13, 2020, Mr. Geissler was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act (21 U.S.C. 335a(*l*)(1)(A)), in the U.S. District Court for the Northern District of Texas-Dallas Division, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Factual Resume, dated February 24, 2019, in Mr. Geissler's case, he was the Chief Executive Officer (CEO) and coowner of USPlabs, LLC (USP Labs). USP Labs sold dietary supplements. Beginning in or around October 2008 and continuing until at least around August 2014, Mr. Geissler engaged in a conspiracy with others to import a variety of chemicals with false labeling in order to either use those chemicals in dietary supplements which would themselves also contain false labeling, or to determine whether those chemicals could be used in new dietary supplements. To further this conspiracy, Mr. Geissler's coconspirators ordered chemicals from a Chinese company to be used as ingredients in dietary supplements and had them labeled falsely as other food substances. USP Labs sold dietary supplements called Jack3d and OxyElite Pro, which originally contained a substance called 1,3-dimethylamine (DMAA), which is also known as methylhexaneamine. USP Labs imported the DMAA it used in its products, Jack3d and OxyElite Pro, from a Chinese chemical factory by using false and fraudulent Certificate of Analysis (COA) and other false and fraudulent documentation and labeling. At least some of the false COAs that USP Labs caused to be created for their DMAA shipments stated falsely that the substance in the shipments had been extracted from the geranium plant.

Further, as contained in the factual resume and superseding indictment, filed January 5, 2016, in December 2011, Mr. Geissler instructed a Chinese company via email to misbrand a shipment of nine different chemicals sent from China to USP Labs in Texas. One of those synthetic chemicals was called ''aegeline.'' The first aegeline containing version of OxyElite Pro, which was called OxyElite ''New Formula'', went on sale in December 2012, but did not sell as well as the DMAA-containing version. Therefore, in the summer 2013, USP Labs began using

pulverized roots of cynanchum auriculatum, in addition to aegeline, in its OxyElite Pro ''Advanced Formula'' supplement. The cynanchum auriculatum-containing product was called OxyElite Pro ''Advanced Formula.'' On or about June 15, 2013, Mr. Geissler's coconspirator instructed a Chinese chemical seller to have two metric tons of ground cynanchum auriculatum root powder, rather than an extract, shipped internationally to laboratories in California for inclusion in USP Labs' products, using the false name ''cynanchum auriculatum root extract.'' USP Labs then used the substance in its OxyElite Pro ''Advanced Formula'' supplement which it shipped to retailers and wholesalers using false labels. When there was a liver-injury outbreak, USP Labs put out a misleading press release stating that the ingredients in OxyElite Pro had been studied and showed ''no negative liver issues,'' but USP Labs knew that a study had shown ''liver issues'' related to cynanchum auriculatum. Mr. Geissler did, with intent to defraud and mislead, cause the shipment of misbranded OxyElite Pro ''Advanced Formula'' to be shipped in interstate commerce. The conspirators collected millions in revenue.

As a result of this conviction FDA sent Mr. Geissler, by certified mail on March 4, 2021, a notice proposing to debar him for a period of 5 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 Mr. Geissler's felony conviction of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)), constitutes conduct relating to the importation of an article of food into the United States because the offense involved a conspiracy with others to import a variety of chemicals with false labeling in order to either use those chemicals in dietary supplements which would themselves also contain false labeling or to determine whether those chemicals could be used in new dietary supplements.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Geissler should be subject to a 5-year period of debarment. The proposal also offered Mr. Geissler 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 Mr. Geissler that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Geissler failed to respond 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)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Jacobo Geissler has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Geissler is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective July 28, 2021. 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 an article of food by, with the assistance of, or at the direction of Jacobo Geissler is a prohibited act.

Any application by Mr. Geissler for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–2169 and sent to the Dockets Management Staff (**ADDRESSSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16045 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting

AGENCY: Food and Drug Administration, Health and Human Services (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 27, 2021.

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 0910–0437. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Medical Device Reporting—21 CFR Part 803

OMB Control Number 0910–0437—Extension

This information collection supports FDA regulations and FDA's Medical Device Reporting program. Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, importers, and distributors of medical devices to report adverse events involving medical