or via regular mail if email is not an option. Invoices must be paid within 30 days.

C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at—*https://userfees.fda.gov/pay.* (Note: only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. If paying with a paper check: Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Include invoice number on check. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013).

3. When paying by wire transfer, the invoice number must be included. Without the invoice number the payment may not be applied. Regarding reinspection fees, if the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that the outsourcing facility add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16057 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–2021–N–0652]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of 15 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 15 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 27, 2021.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040265	Methotrexate Sodium Injection, Equivalent to (EQ) 25 milligrams (mg) base/milliliters (mL).	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 070963	Clonidine Hydrochloride (HCl) Tablets, 0.3 mg	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 074292	Dobutamine HCl Injection, EQ 12.5 mg base/mL	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 075069	Etodolac Tablets, 400 mg	Watson Laboratories, Inc.
ANDA 075856	Midazolam HCl Injection, EQ 1 mg base/mL and EQ 5 mg base/mL.	Hospira, Inc.
ANDA 084504	Hydralazine HCl Tablets, 25 mg	Watson Laboratories, Inc.
ANDA 090379	Budesonide Delayed Release Capsules, 3 mg	Barr Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Morris Corporate Center III, Parsippany, NJ 07054.
ANDA 091590	Losartan Potassium Tablets, 25 mg, 50 mg, and 100 mg.	Mylan Pharmaceuticals Inc., a Viatris Company, 81 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 091652	Hydrochlorothiazide and Losartan Potassium Tablets, 12.5 mg/50 mg, 12.5 mg/100 mg, and 25 mg/100 mg.	Do.
ANDA 204361	Eptifibatide Injection, 2 mg/mL and 75 mg/100 mL	USV Private Limited, U.S. Agent, Omega Pharmaceutical Consulting, Inc., 752 West Shuhthagi Lane, New Harmony, UT 84757.
ANDA 204362	Eptifibatide Injection, 2 mg/mL	Do.

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