of the FD&C Act that Mr. Dailey'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 illegally imported kratom, a misbranded drug, for repackaging, sale, and distribution to U.S. consumers. 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. Dailey'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) of the FD&C Act.

The proposal informed Mr. Dailey of the proposed debarment and offered Mr. Dailey 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. Dailey received the proposal and notice of opportunity for a hearing on October 7, 2019. Mr. Dailey 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. Dailey 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 2 offenses of conviction needs to be served consecutively, resulting in a total debarment period of 10 years.

As a result of the foregoing finding, Mr. Dailey 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, 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. Dailey is a prohibited act.

Any application by Mr. Dailey for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–3310 and sent to the Dockets Management Staff (see **ADDRESSES**). 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: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05450 Filed 3–16–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–4523]

Determination That Potassium Chloride in 5% Dextrose and 0.225% Sodium Chloride Injection, 5 Milliequivalents, 10 Milliequivalents, 15 Milliequivalents, 20 Milliequivalents, 30 Milliequivalents, and 40 Milliequivalents, in Plastic Containers, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the potassium chloride drug products listed in this notice were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to these drug products, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 301–796–3977, *Linda.Jong@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

The drug products listed in table 1 of this notice are no longer being marketed. All the products listed in table 1 are the subject of NDA 018365, held by ICU Medical, Inc., and initially approved on May 29, 1980. The products are indicated in patients requiring parenteral administration of potassium chloride with minimal carbohydrate calories and sodium chloride.

TABLE 1

Drug	Dosage form/route	Strength
Potassium Chloride (5 milliequivalents (mEq)) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Injectable/Injection	5 grams (g)/100 milliliters (mL); 74.5 milligrams (mg)/100 mL; 225 mg/100 mL.
Potassium Chloride (5 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 149 mg/100 mL; 225 mg/100 mL.
Potassium Chloride (10 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 74.5 mg/100 mL; 225 mg/100 mL.
Potassium Chloride (10 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 149 mg/100 mL; 225 mg/100 mL.
Potassium Chloride (15 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 224 mg/100 mL; 225 mg/100 mL.
Potassium Chloride (20 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 298 mg/100 mL; 225 mg/100 mL.
Potassium Chloride (30 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 224 mg/100 mL; 225 mg/100 mL.
Potassium Chloride (40 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container.	Do	5 g/100 mL; 298 mg/100 mL; 225 mg/100 mL.

The products listed in table 1 are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Fresenius Kabi USA, LLC, submitted a citizen petition dated September 26, 2019 (Docket No. FDA–2019–P–4523), under 21 CFR 10.30, requesting that the Agency determine whether the products listed in table 1 were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that the potassium chloride drug products listed in this notice were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that the potassium chloride drug products listed in this notice were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of the potassium chloride drug products listed in this notice from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that the potassium chloride drug products listed in this notice were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list the potassium chloride drug products listed in this notice, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05442 Filed 3–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2734]

Robert Richard Jodoin: 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 Robert Richard Jodoin for a period of 5 years from importing any drug into the United States. FDA bases this order on a finding that Mr. Jodoin was convicted, as defined in the FD&C Act, of one felony count under Federal law for unlawfully importing and attempting to import a controlled substance into the United States. The factual basis supporting the conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Jodoin was given notice of the proposed debarment and, in accordance with the FD&C Act, was given an opportunity to request a hearing to show why he should not be debarred. As of November 9, 2019 (30 days after receipt of the notice), Mr. Jodoin had not responded. Mr. Jodoin'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 March 17, 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 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 February 25, 2019, Mr. Jodoin was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Middle District of Florida, Jackson Division, when the court accepted his plea of guilty and entered judgment against him for multiple offenses, one of which is relevant to this debarment. Specifically, FDA's finding that debarment is appropriate is based on Mr. Jodoin's felony conviction for