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FDA–2019–P–4523), under 21 CFR 10.30, requesting that the Agency determine whether the products listed in table 1 were withdrawn from sale for reasons of safety or effectiveness.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this time, FDA has determined under § 314.161 that the potassium chloride drug products listed in this notice were not withdrawn for reasons of safety or effectiveness.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identified no data or other information suggesting that the potassium chloride drug products listed in this notice were withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that the potassium chloride drug products listed in this notice were withdrawn from sale for reasons of safety or effectiveness.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

knowingly and intentionally attempting to import into the United States a mixture and substance containing a detectable amount of gamma-Hydroxybutyric Acid, a Schedule I controlled substance in violation of 21 U.S.C. 952(a), 960(a)(1), 960(b)(3), and 963 on or about April 16, 2018, as described in the Superseding Indictment in his case dated October 10, 2018.

As a result of this conviction, FDA sent Mr. Jodoin by certified mail on September 25, 2019, a notice proposing to debar him for 5 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. Jodoin's felony conviction was for conduct relating to the importation into the United States of any drug or controlled substance because he smuggled into the United States a Schedule I controlled substance. 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. Jodoin's offense and concluded Mr. Jodoin's felony offense warranted a 5-year period of debarment.

The proposal informed Mr. Jodoin of the proposed debarment and offered Mr. Jodoin 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. Jodoin received the proposal and notice of opportunity for a hearing on October 8, 2019. Mr. Jodoin 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. Jodoin has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that this offense should be accorded a debarment period of 5 years.

As a result of the foregoing finding, Mr. Jodoin is debarred for a period of 5 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. Jodoin is a prohibited act.

Any application by Mr. Jodoin for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–2734 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.

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.

Dated: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05444 Filed 3–16–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on February 1, 2020, through February 29, 2020. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated