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 **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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.

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