



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3131]

Jagen D. Lewicki: 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) debaring Jagen Lewicki for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lewicki was convicted, as defined in the FD&C Act, of one felony count under Federal law for conspiracy to distribute Human Growth Hormone (HGH) imported from China for a purpose other than the treatment of a disease or other recognized medical condition, the use of which had been authorized by the Secretary of Health and Human Services, and not pursuant to an order of a physician, in violation of the FD&C Act. The factual basis supporting this felony conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lewicki was given notice of the proposed debarment and, in accordance with the FD&C Act and FDA's regulations, was given an opportunity to request a hearing to show why he should not be debarred. As of October 28, 2019 (30 days after receipt of the notice), Mr. Lewicki had not responded. Mr. Lewicki'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, 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 the 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 December 20, 2018, Mr. Lewicki was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty for the offense of conspiracy to distribute HGH imported from China for unapproved purposes in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e) (section 303(e) of FD&C Act).

The FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into the Plea Agreement, filed on December 20, 2018, from on

or about January 2017 to February 2018, Mr. Lewicki conspired with certain other known and unknown individuals to unlawfully distribute HGH imported from China. Specifically, Mr. Lewicki submitted periodic orders, and gave money, for HGH to co-conspirators, for the purchase of HGH from manufacturers based in China. In addition, Mr. Lewicki set up various post office boxes at private carriers in the Eastern District of Virginia. The Chinese based manufacturers delivered vials of HGH from China to Mr. Lewicki at post office boxes he set up. Mr. Lewicki received approximately 90 packages from Chinese manufacturers, each containing 200 vials of HGH. Mr. Lewicki would then sell these vials to individual customers throughout the United States for bodybuilding and other unapproved purposes. Mr. Lewicki's actions were in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e) (section 303(e) of the FD&C Act).

As a result of this conviction FDA sent Mr. Lewicki, 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. Lewicki's felony conviction for conspiracy in violation of 18 U.S.C. 371 and section 303(e) of the FD&C Act was for conduct relating to the importation into the United States of any drug or controlled substance because on multiple occasions, he imported HGH from China and conspired to distribute it within the United States. 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. Lewicki's offense and, for the reasons detailed in the notice, concluded that his offense warranted a 5-year period of debarment under section 306(c)(2)(A)(iii).

The proposal informed Mr. Lewicki of the proposed debarment and offered Mr. Lewicki 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. Lewicki received the proposal and notice of opportunity for a hearing on September 28, 2019. Mr. Lewicki 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. Lewicki 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 the offense should be accorded a debarment period of 5 years.

As a result of the foregoing finding, pursuant to section 306(b)(1)(D) of the FD&C Act, Mr. Lewicki 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 by, with the assistance of, or at the direction of, Mr. Lewicki is a prohibited act.

Any application by Mr. Lewicki for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2019-N-3131 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 <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. 2020-05449 Filed: 3/16/2020 8:45 am; Publication Date: 3/17/2020]