4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2080]

Jeremy Walenty: 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 (the FD&C Act) debarring Jeremy Walenty 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. Walenty was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. Walenty's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Walenty was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of October 15, 2023 (30 days after receipt of the notice), Mr. Walenty had not responded. Mr. Walenty's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application by Mr. Walenty for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on https://www.regulations.gov.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2023-N-2080. Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will

review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240-402-8743, or 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 February 24, 2023, Jeremy Walenty was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for Western District of Michigan when the court

accepted his plea of guilty and entered judgment against him for the offense of conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545. The underlying facts supporting the conviction are as follows:

As contained in the indictment and plea agreement from Mr. Walenty's case, filed on March 1, 2022, and July 15, 2022, respectively, Brendon Gagne owned and operated www.ExpressPCT.com, which sold misbranded prescription drugs, obtained from overseas suppliers, and sold to customers in the United States without requiring a prescription. Mr. Walenty was recruited by Brendon Gagne to receive, repackage, and reship the misbranded prescription drugs he received from coconspirators outside of the United States that were purchased by customers on the website www.ExpressPCT.com. In Mr. Walenty's plea agreement he acknowledged that he knew that receiving and reshipping prescription drugs in this manner was illegal. Later on, Mr. Walenty also began receiving bulk shipments of prescription drugs from coconspirators in the U.S. which had originally been sent to these coconspirators from overseas suppliers. Mr. Walenty then would use these shipments to fulfill orders that customers had placed on www.ExpressPCT.com, without ever seeing a prescription from these customers. In exchange for Mr. Walenty's participation in the scheme, Mr. Walenty received monetary compensation.

As a result of this conviction, FDA sent Mr. Walenty, by certified mail, on September 6, 2023, a notice proposing to debar him for a 5-year period 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. Walenty's felony conviction under Federal law for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545, was for conduct relating to the importation into the United States of any drug or controlled substance because he was involved in a scheme to illegally import and introduce prescription drugs into 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. Walenty's offense and concluded that the offense warranted the imposition of a 5 year period of debarment.

The proposal informed Mr. Walenty of the proposed debarment and offered him 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. Walenty received the proposal and notice of opportunity for a hearing on September 15, 2023. Mr. Walenty 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 Jeremy Walenty 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 provided by section 306(c)(2)(A)(iii) of the FD&C Act.

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

Dated: December 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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