4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3827]

Adam Paul Runsdorf: 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) permanently debarring Adam Paul Runsdorf from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Runsdorf was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Runsdorf was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 25, 2024 (30 days after receipt of the notice), Mr. Runsdorf has not responded. Mr. Runsdorf's failure to respond and request a hearing constitutes a waiver of Mr. Runsdorf's right to a hearing concerning this matter.

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

ADDRESSES: Any application by Mr. Runsdorf for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time 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-3827. 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, 240-402-7500. 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, 240-402-8743, debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 27, 2023, Adam Paul Runsdorf was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Texas-Beaumont Division, when the court entered judgment against him, after his plea of guilty, to Conspiracy to Traffick in Drugs with Counterfeit Mark in violation of 18 U.S.C. 371, 18 U.S.C. 2320(a)(4) and Trafficking in Drugs

with Counterfeit Mark in violation of 18 U.S.C. 2320(a)(4), 18 U.S.C. 2320(b)(3)(A). The underlying facts supporting the conviction are as follows:

As contained in the Third Superseding Indictment, and as contained in Factual Basis and Stipulation memorandum, between approximately April 2014 and February 2021, Mr. Runsdorf conspired to distribute counterfeit cough syrup. Specifically, Mr. Runsdorf owned a group of pharmaceutical companies including Woodfield Pharmaceutical LLC, a contract manufacturing company, and Woodfield Distribution LLC, a third-party logistics company (collectively, "Woodfield"). On April 25, 2014, Mr. Runsdorf acquired Pernix Manufacturing LLC (Pernix). Pernix had, in January 2014, entered into an agreement with Byron A. Marshall and his Drug Trafficking Organization (DTO) to copy and manufacture cough syrup according to the directions of Marshall and his associates.

Marshall was not licensed or authorized to distribute cough syrup and any background check of the personal information provided by Marshall to Pernix or later Woodfield would have revealed that he was not a licensed physician. Initially, Marshall sought to copy Actavis Prometh VC with Codeine (Actavis). Actavis is a purple, peach-mint flavor prescription cough syrup that was in demand as a street drug. Marshall and his associates wanted to mass produce and traffic a counterfeit version of Actavis that contained Promethazine, but not Codeine. On April 24, 2014, Actavis Holdco US discontinued production of the Actavis product due to its widespread abuse by recreational drug users. A Pernix product-development scientist worked with Marshall and his associates to re-create the Actavis product without Codeine and Promethazine in order to re-create the syrup base, which is a necessary component of cough syrup. Marshall and his associates would add Promethazine to the counterfeit substance prior to bottling and distribution in order to create the drug. Marshall and his DTO also obtained counterfeited commercial-grade pharmaceutical labels designed to look exactly like the genuine labels for the prescription cough syrup from another supplier. Later in the conspiracy, Marshall and his DTO asked Woodfield employees to reformulate other cough syrup to use in their drug trafficking scheme to include

Hi-Tech Promethazine Hydrocholoride and Codeine Phosphate Oral Solution and Wockhardt Promethazine Syrup Plain.

As Pernix was scaling-up production of the syrup base for Marshall and his DTO in April 2014, Mr. Runsdorf acquired Pernix. Mr. Runsdorf retained Pernix employees but made changes to management staff who oversaw and were responsible for producing the syrup base for the Marshall DTO, to which they knew the Marshall DTO was adding active ingredients. During the conspiracy, Marshall communicated directly with Mr. Runsdorf regarding production of the counterfeit cough syrup. At Mr. Runsdorf's request, Marshall paid Woodfield in cash only, and Woodfield employees mailed the cash directly to him.

Mr. Runsdorf knew his company was producing thousands of gallons of the counterfeit cough syrup to be distributed to drug traffickers in Texas and other States. Woodfield's production of syrup base for Marshall and his DTO bypassed the protocols for safety and quality testing. Initially, there were no batch records to document the production of the syrup as required. Woodfield provided the syrup to Marshall and his DTO without any corresponding documentation that identified the ingredients of the syrup; practices that continued until February 2019 when Woodfield started creating paper records for some of the cough syrup batches Woodfield made for the DTO. From 2014 through February 2021, the conspiracy between the Marshall DTO produced and distributed, or attempted to produce and distribute, approximately 65,920 gallons of counterfeit cough syrup. The total amount of cash paid by Marshall and his DTO to Mr. Runsdorf was approximately at least $3 million.

As a result of this conviction, FDA sent Mr. Runsdorf, by certified mail, on January 23, 2024, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B), that Mr. Runsdorf was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal informed Mr. Runsdorf 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. Runsdorf received the proposal and notice of opportunity for a hearing on January 26, 2024. Mr. Runsdorf 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(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Runsdorf has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Runsdorf is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Runsdorf during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Runsdorf provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Runsdorf during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a "drug product" is defined as a "drug subject to regulation under section 505, 512, or 802 of this FD&C Act [(21 U.S.C. 355, 360b, or 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]" (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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