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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4721]

Willis Reed: 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 Willis Reed 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. Reed 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. Reed was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 10, 2024 (30 days after receipt of the notice), Mr. Reed has not responded. Mr. Reed'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: Any application by Mr. Reed 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-4721. 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, at 240-402-8743, or 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 October 12, 2023, Mr. Reed 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 of conspiracy to traffick in drugs with counterfeit mark in violation of 18 U.S.C. 371 and 18 U.S.C. 2320(a)(4). The underlying facts supporting the conviction are as follows: As contained in the Second Superseding

Indictment, and as contained in Factual Basis, from approximately April 2015 until January 2019, Mr. Reed conspired with drug traffickers to distribute misbranded and counterfeit cough syrup. Specifically, he worked for Woodfield Pharmaceutical LLC, as its Production Manager, and later, he was promoted to Director of Technical Operations. Woodfield Pharmaceutical LLC was part of a group of pharmaceutical companies that included Woodfield Pharmaceutical LLC, a contract manufacturing company, and Woodfield Distribution LLC, a third-party logistics company (collectively, Woodfield).

On April 25, 2014, Woodfield 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 as he claimed. 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. Cough syrups containing promethazine or codeine were approved by FDA for distribution only under the supervision of a licensed practitioner.

On April 24, 2014, Actavis Holdco U.S. discontinued production of Actavis due to its widespread abuse by recreational drug users. A Pernix product-development scientist worked with Marshall and his associates to recreate the Actavis product without codeine and promethazine to recreate 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 to create the street 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.

In his role with Woodfield, Mr. Reed knew that the Marshall DTO was adding active ingredients to the syrup Woodfield sold to the Marshall DTO. From approximately April 2015 until January 2019, Mr. Reed was principally responsible for the large-scale production of syrup base for the Marshall DTO. Beginning on or about May 26, 2015, Mr. Reed became the Marshall DTO's principal source of supply for promethazine. Mr. Reed brokered the promethazine from a lab chemical supplier based in New York that delivered the promethazine directly to the Marshall DTO. In January 2019 Mr. Reed was fired from his position at Woodfield.

As a result of this conviction, FDA sent Mr. Reed, by certified mail, on January 5, 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. Reed was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal informed Mr. Reed 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. Reed received the proposal and notice of opportunity for a hearing on January 11, 2024. Mr. Reed 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. Willis Reed 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. Reed 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. Reed 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. Reed 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. Reed 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 (21 U.S.C. 335a(c)(1)(B))). 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, 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: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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