U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: June 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4466]

Jonathan R. Shaver: 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 Jonathan R. Shaver 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. Shaver 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. Shaver was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 16, 2024 (30 days after receipt of the notice), Mr. Shaver has not responded. Mr. Shaver's failure to respond and request a hearing constitutes a waiver of Mr. Shaver's right to a hearing concerning this matter.

DATES: This order is applicable June 13, 2024.

ADDRESSES: Any application by Mr. Shaver 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–4466. 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 September 19, 2023, Mr. Shaver 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 accepted his plea of guilty and entered judgment against him for the offense 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 and Stipulation memorandum, between April 2015 and January 2019, Mr. Shaver conspired to distribute misbranded and counterfeit cough syrup. Mr. Shaver worked for Woodfield Pharmaceutical LLC, within its manufacturing and operations division and then later as Production Manager. Woodfield Pharmaceutical LLC was a part of a group of pharmaceutical companies which 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). In January 2014, Pernix 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. Cough syrups containing promethazine and codeine were approved by FDA for distribution only under the supervision of a licensed practitioner. On April 24, 2014, Actavis Holdco US 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 in order 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 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.

In his position within Woodfield, Mr. Shaver assisted in the production of the syrup. In his role with Woodfield, Mr. Shaver 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. Shaver along with Woodfield's Director of Technical Operations were principally responsible for the large-scale production of syrup base for the Marshall DTO. When Marshall and his DTO had difficulty dissolving promethazine into the syrup base, Mr. Shaver, along with others, worked to resolve that issue. Later, Mr. Shaver agreed with other Woodfield employees to create additional syrup base supply not authorized by Woodfield in order to sell that additional supply to the Marshall DTO at a reduced price in order to split the fee from the sale with other Woodfield employees, a practice Mr. Shaver and other employees called ''double batching.'' No records of the ''double batching'' were created by Mr. Shaver or any of the other participants. Later in the conspiracy, upon request from Marshall and his DTO, Woodfield employees reformulated other cough syrup for use by Marshall and his DTO in their drug trafficking scheme to include Hi-Tech Promethazine Hydrocholoride and Codeine Phosphate Oral Solution and Wockhardt Promethazine Syrup Plain. 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.

As a result of this conviction, FDA sent Mr. Shaver, 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) of the FD&C Act, that Mr. Shaver 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. Shaver 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. Shaver received the proposal and notice of opportunity for a hearing on January 17, 2024. Mr. Shaver 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. Jonathan R. Shaver 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. Shaver 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. Shaver 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. Shaver 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. Shaver during his period of debarment, other than in connection with an audit under 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, 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: June 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3081]

Richard B. Smith III: 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 Richard B. Smith III 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. Smith was convicted of two felony counts under Federal law, only one of which serves as the basis of this debarment: receiving misbranded drugs in interstate commerce and delivering for pay. The factual basis supporting Mr. Smith's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Smith 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 November 29, 2023 (30 days after receipt of the notice), Mr. Smith had not responded. Mr. Smith's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.