4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1873]

William Goldsmith: 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 William Goldsmith 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. Goldsmith was convicted of one felony count under Federal law for introducing misbranded drugs into interstate commerce. The factual basis supporting Mr. Goldsmith's conviction, as described below, is conduct relating to the importation of a drug into the United States. Mr. Goldsmith 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 August 19, 2025 (more than 30 days after receipt of the notice), Mr. Goldsmith had not responded. Mr. Goldsmith'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. Goldsmith for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) 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-2024-N-1873. 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 Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 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 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 March 18, 2024, Mr. Goldsmith was convicted in the United States District Court for the Southern District of Illinois when the court accepted his plea of guilty and entered judgment

against him for the offense of introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows: As contained in the Stipulation of Fact, Mr. Goldsmith was the registered agent of Malosi Fitness Corporation (Malosi) in Illinois. Through Malosi's website Mr. Goldsmith sold and dispensed products labeled as "Ma'Kava," "Ma'Kava Private Stock," and "Night Cap X," all of which were marketed as "all natural" male sexual performance enhancement supplements to hundreds of purchasers located throughout the United States. The labels of the products Mr. Goldsmith sold claimed the products included only "natural" herbal ingredients. In reality, the products Mr. Goldsmith sold contained sildenafil citrate, which was not listed as an ingredient on the labels of any of the products he sold. Sildenafil citrate is the active pharmaceutical ingredient in Viagra, a prescription drug approved by FDA for the treatment of erectile dysfunction. The Ma'Kava products Mr. Goldsmith sold were drugs within the meaning of section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)) because they were intended to be used to treat erectile dysfunction.

Mr. Goldsmith ordered and received raw sildenafil from companies in China and India in one-kilogram packages. Mr. Goldsmith mixed the raw sildenafil he received with other ingredients and placed the mixture into empty capsules. Mr. Goldsmith packaged these capsules into small bottles, printed with labels he made but which did not list sildenafil citrate as an ingredient on the labels. Mr. Goldsmith shipped his products containing the imported sildenafil citrate to customers across the United States. The selling of sildenafil generated Mr. Goldsmith more than $250,000 in gross proceeds.

FDA sent Mr. Goldsmith, by certified mail, on May 29, 2024, 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. Goldsmith was convicted, within the meaning of section 306(l)(1) of the FD&C Act, of a felony under federal law. This conviction for introducing misbranded drugs into interstate commerce in

violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act) was for conduct relating to the importation of any drug or controlled substance into the United States, as discussed above. 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. Goldsmith's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Goldsmith 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. Goldsmith received the proposal and notice of opportunity for a hearing on June 7, 2024. Mr. Goldsmith 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 Division of Field Enforcement, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. William Goldsmith 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. Goldsmith 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. Goldsmith is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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