4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5257]

Robert Lance Shuffert: 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) debarring Robert Lance Shuffert 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. Shuffert was convicted of one felony count under Federal law for, with the intent to defraud and mislead, causing a drug to be misbranded while it was held for sale after shipment in interstate commerce. The factual basis supporting Mr. Shuffert's conviction, as described below, is conduct relating to the importation into the United States of any drug or controlled substance. Mr. Shuffert was given notice of the proposed debarment and an opportunity to request a hearing to show why he should not be debarred. As of March 4, 2024 (30 days after receipt of the notice), Mr. Shuffert had not responded. Mr. Shuffert'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. Shuffert for termination of debarment under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) 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-5257. 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(b)(1)(D) of the FD&C Act permits FDA to debar a person 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 October 26, 2023, Robert Lance Shuffert was convicted as defined in section 306(l)(1) of the FD&C Act , in the U.S. District Court for the Southern District of Texas when

the court accepted his plea of guilty and entered judgment against him for the offense of importing, causing misbranding, and distribution for sale a misbranded drug in violation of 21 U.S.C. 331(k) and 333(a)(2) (sections 301(k) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows:

As contained in the Information from his case, Mr. Shuffert worked for Science Production Products LLC (SPP); although, in SPP's corporate filings with the Texas Secretary of State, he was listed as SPP's owner and operator, and someone else owned SPP and directed Mr. Shuffert's activities. SPP imported, created, marketed, and distributed for sale purported bodybuilding and dietary supplements, including, but not limited to, Selective Androgen Receptor Modulators (SARMs). SARMs are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. At the direction of SPP's owner, Mr. Shuffert operated SPP and SPP manufactured, marketed, and sold a SARM product called Ostarine MK-2866. This product was misbranded because it was labeled as a "Research Product" but was in fact intended to be used by humans as a drug to increase lean muscle mass and lose unwanted fat. Mr. Shuffert worked with others to import SARMs from China. Mr. Shuffert then would use the imported SARMs as components of a drug (Ostarine MK-2866) that he and others caused to become misbranded and then distributed for sale such misbranded drugs in the United States. Mr. Shuffert knowingly took steps to mislead and defraud the Government and consumers in the sale of SARMs, including Ostarine MK-2866.

FDA sent Mr. Shuffert, by certified mail, on January 30, 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 FDA's finding under section 306(b)(3)(C) of the FD&C Act that Mr. Shuffert's felony conviction under Federal law for importing, causing misbranding, and distribution for sale a misbranded drug in violation of 21 U.S.C. 331(k) and 333(a)(2), was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Shuffert illegally imported SARMs from China, which he would use as components

of a drug (Ostarine MK-2866) that he caused to become misbranded and then distributed for sale in the United States. Mr. Shuffert knowingly took steps to mislead and defraud the Government and consumers in the sale of SARMs, including Ostarine MK-2866. 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. Shuffert's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Shuffert 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. Shuffert received the proposal and notice of opportunity for a hearing on February 3, 2024. Mr. Shuffert 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 Mr. Shuffert 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. Shuffert 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, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Shuffert is a prohibited act.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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