4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0304]

Brian Michael Parks: 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 Brian Michael Parks for a period of 5 years from importing or offering for import any article of food (including dietary supplements) or drug into the United States. FDA bases this order on a finding that Mr. Parks was convicted of one felony count under Federal law for distribution of an unapproved new drug with the intent to defraud and mislead. The factual basis supporting Mr. Parks' conviction, as described below, is conduct relating to the importation into the United States of any food and of any drug or controlled substance. Mr. Parks 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 17, 2021 (30 days after receipt of the notice), Mr. Parks had not responded. Mr. Parks' 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: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) 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 food. Section 306(b)(1)(D) of the FD&C Act permits debarment of an individual from importing or offering for import any drug into the United States if the 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 February 16, 2021, Mr. Parks was convicted, as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Western District of Virginia, after his plea of guilty, when the court entered judgment against him for the offense of distribution of an unapproved new drug with the intent to defraud and mislead, in violation of sections 301(d) and 303(a)(2) of the FD&C Act 21 U.S.C. 331(d) and 333(a)(2). The FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows:

As contained in the information in Mr. Parks' case, filed on November 23, 2020, he was the owner and operator of MedFitRX Inc., later known as MedFit Sarmacuticals Inc. (collectively referred to as MedFitRX herein), a purported sport supplement company based in North Carolina. MedFitRX imported Selective Androgen Receptor Modulators (SARMs) in order to use them in MedFitRx products. SARMs are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. From approximately March 2016 to

September 2019, Mr. Parks imported SARMs and other drug active ingredients from China on multiple occasions. The drug active ingredients he imported included MK-677, S-4, MK-2866, GW-501516, LGD-4033, and RAD140, among others. In addition, on or about May 17, 2018, Mr. Parks sold two MedFitRX products to undercover FDA Office of Criminal Investigation agents posing as consumers. The first product Mr. Parks sold to these undercover agents, Lucky SARMS Magical AF, contained the drugs S-23 and SR9009, which he had caused to be imported into the United States. The second product, Estrovert, contained the anabolic steroid Methyldienolone, a controlled substance prohibited under the Designer Steroid Act, 21 U.S.C. 802(41), which Mr. Parks also caused to be imported into the United States. Mr. Parks worked with others to conceal the importation of these and other unapproved drugs as they were disguised and misdeclared as articles of food, specifically "biscuit mix powder," "corn powder," "grain mix powder," "bread mix powder," and "milk tea powder." Mr. Parks then included these drug active ingredients in MedFitRX products, which were unapproved drugs that he introduced and delivered for introduction into interstate commerce. Mr. Parks knowingly marketed these MedFitRX products as "dietary supplements" and "sports supplements" to create the impression they were safe and legal to use, and otherwise intentionally failed to include certain drug active ingredients on the product labels.

As a result of this conviction, FDA sent Mr. Parks, by certified mail, on October 12, 2021, a notice proposing to debar him for a 5-year period from importing or offering for import any article of food or drug into the United States. The proposal was based on a finding under section 306(b)(1)(C) and (b)(3)(C) of the FD&C Act that Mr. Parks' felony conviction of distribution of an unapproved new drug with the intent to defraud and mislead constitutes conduct relating to the importation into the United States of an article of food and any drug or controlled substance because Mr. Parks illegally imported unapproved drugs into the United States, working with others to disguise and misdeclare them as articles of food, and then distributed those unapproved drugs to consumers in the United States, marketing them as

"dietary supplements" and "sports supplements." 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. Parks' offense, and concluded that the felony offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Parks 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. Parks received the proposal and notice of opportunity for a hearing on October 18, 2021. Mr. Parks 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)(1)(C) and (b)(3)(C) of the FD&C Act , under authority delegated to the Assistant Commissioner, finds that Mr. Brian Michael Parks has been convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food and of a drug or controlled substance, and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Parks is debarred for a period of 5 years from importing or offering for import articles of food or any drug or controlled substances into the United States, applicable (see DATES). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of an article of food or of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Parks is a prohibited act.

Any application by Mr. Parks for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0304 and sent to the Dockets

Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-03098 Filed: 2/11/2022 8:45 am; Publication Date: 2/14/2022]