4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0269]

Sitesh Bansi Patel: 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 Sitesh Bansi Patel for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Patel was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Patel was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 8, 2021 (30 days after receipt of the notice), Mr. Patel has not responded. Mr. Patel'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: Submit applications for termination of debarment to the Dockets Management Staff (HFA-305), 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.

On February 19, 2020, Mr. Patel was convicted as defined in section 306(l)(1)(A) of the FD&C Act, in the U. S. District Court for the Northern District of Texas-Dallas Division, when the court accepted Mr. Patel's plea of guilty and entered judgment against him for the offense of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 333(a)(2)). FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein.

The factual basis for this conviction is as follows: As contained in the Factual Resume, dated February 22, 2019, Mr. Patel was the Vice President of S.K. Laboratories, LLC, and in that role did business with USP Labs. Beginning in or around October 2008 and continuing until at least in or around August 2014, Mr. Patel and others working at USP Labs and S.K. Laboratories engaged in a plan to import a variety of compounds for use and prospective use in dietary supplements with false labeling. To further this plan, Mr. Patel and his co-conspirators ordered a variety of potential dietary compounds from a Chinese company as prospective and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as other food substances. USP Labs sold dietary supplements called Jack3d and OxyElite Pro, both of which originally contained a substance called 1,3-dimethylamylamine (DMAA), which is also known as methylhexaneamine. The DMAA used in Jack3d and OxyElite Pro was a synthetic stimulant manufactured in China. Mr. Patel and his co-conspirators came to understand that importing and selling purported natural, plant-based substances would be easier than selling synthetic stimulants. USP Labs imported DMAA using false and

fraudulent Certificates of Analysis (COAs) and other false and fraudulent documentation and labeling. Some of the false COAs that USP Labs caused to be created for DMAA shipments stated falsely that the substance in the shipments had been extracted from the geranium plant.

In a September 2008 email, Mr. Patel instructed one of his co-conspirators, "Have your supplier create a COA like this." In an email exchange from May 2009, discussing the DMAA in USP Labs' products, Mr. Patel told two of his co-conspirators, "lol stuff is completely 100% synthethic [sic]." From at least 2008 until at least 2013, USP Labs frequently imported other potential dietary compounds from China, under false labeling, to determine if they could be used in new dietary supplements. One of those synthetic compounds was called "aegeline." The first aegeline-containing version of OxyElite Pro, which was called OxyElite "New Formula," went on sale in November 2012. USP Labs reformulated the DMAA product in the summer of 2013 to contain aegeline and powder derived from a Chinese herb called cynanchum auriculatum. On or about June 15, 2013, one of Mr. Patel's co-conspirators at USP Labs instructed a Chinese company to have 2 metric tons of ground cynanchum auriculatum root powder shipped internationally to S.K. Laboratories in California for inclusion in USP Labs' products, using the false name "cynanchum auriculatum root extract." USP Labs sent false labels listing "cynanchum auriculatum (root) extract" as an ingredient in its OxyElite Pro "Advanced Formula" supplement to retailers and wholesalers. On or about October 4, 2013, Mr. Patel and his co-conspirators shipped and caused the shipment of misbranded OxyElite Pro "Advanced Formula" into interstate commerce. The food was misbranded because its labeling falsely declared cynanchum auriculatum (root) extract as an ingredient even though it was not contained in the product.

As a result of this conviction FDA sent Mr. Patel, by certified mail on May 27, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Patel's felony conviction of conspiracy to

introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 333(a)(2)) constitutes conduct relating to the importation into the United States of an article of food because Mr. Patel was engaged in a conspiracy with others to import a variety of potential dietary compounds from a Chinese company as prospective and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as other food substances. The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Patel should be subject to a 5-year period of debarment. The proposal also offered Mr. Patel an opportunity to request a hearing, providing Mr. Patel 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Patel that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Patel failed to respond 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) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Sitesh Bansi Patel has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Patel is debarred for a period of 5 years from importing articles of food or offering such articles for import 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 an article of food by, with the assistance of, or at the direction of Mr. Sitesh Bansi Patel is a prohibited act.

Any application by Mr. Patel for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0269 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

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: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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