the claimed confidential information, in its consideration of comments. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Alexandra Lucas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0230, *Drug_Device_Transition_Inquiry@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 9, 2021 (86 FR 43553), FDA published a notice announcing that implementation of a decision from the U.S. Court of Appeals for the District of Columbia Circuit in *Genus Med. Techs., LLC* v. *FDA,* 2021 U.S. app. Lexis 10928 (April 16, 2021) is expected to require some approved products to transition from drug status to device status. That notice provides a 60-day comment period and solicits public comment to inform the Agency's deliberations about products potentially impacted by the *Genus* decision and the way in which impacted products should be transitioned from drug to device status.

FDA is extending the comment period until November 30, 2021, based on requests FDA received from relevant stakeholders. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments to inform the Agency's implementation of the *Genus* decision.

Dated: September 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21403 Filed 9–30–21; 8:45 am]

BILLING CODE 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 October 1, 2021.

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.

[FR Doc. 2021–21375 Filed 9–30–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–2231; FDA–2011–N–0362; FDA–2018–N–0073; FDA–2018–N–0074; FDA–2010–N–0155; FDA–2011–N–0781; FDA–2021–N–0525; FDA–2014–N–0987; FDA–2020–N–1657; FDA–2017–N–6931; FDA–2020–N–2217; FDA–2012–N–0369; FDA–2017–N–6730; FDA–2020–N–1207; FDA–2012–N–0115; FDA–2021–N–0363; FDA–2009–N–0025; FDA–2012–N–0547; FDA–2014–N–2347; FDA–2018–N–1129; FDA–2021–N–0387; FDA–2020–N–1261; and FDA–2020–N–1644]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.