not intended to address any performance appraisal processes that any State, local, Territorial, or Tribal agency may use to evaluate its employees' performance. Funding opportunities are available to respondents who choose to implement the ERPS; however, these opportunities are limited and contingent upon the availability of funds, and are available to those respondents who currently have an egg inspection contract with FDA and thus are subject to auditing. A copy of the ERPS has been posted to FDA–2021–N–0341 and is available at *https://www.regulations.gov.*

In the **Federal Register** of May 14, 2021 (86 FR 26528), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondents; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	10	10	100	50	5,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our experience with similar information collection, we estimate an initial 10 respondents will participate in the ERPS, and assume an average of 50 burden hours per response is necessary for the attendant recordkeeping and submission of data elements to FDA. We expect participation in the ERPS to increase. Finally, upon submission of the Information Collection Request, we are correcting an inadvertent calculation error in the total burden hours as displayed on page 26530, in Table 1, in our 60-day notice in the **Federal Register** of May 14, 2021 (86 FR 26528).

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21367 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–0843]

Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments'' that appeared in the **Federal Register** of August 9, 2021. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the notice published on August 9, 2021 (86 FR 43553). Submit either electronic or written comments by November 30, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 30, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0843 for ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 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