(PMA) for VIVISTIM SYSTEM (PMA P210007) was initially submitted March 2, 2021.

3. *The date the application was approved:* August 27, 2021. FDA has verified the applicant's claim that PMA P210007 was approved on August 27, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,359 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03025 Filed 2–13–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4094]

Kalpen D. 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) permanently debarring Kalpen D. Patel from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Patel was convicted of a felony under Federal law for conduct that relates to the regulation of any drug product under the FD&C Act. Mr. Patel was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Patel responded to the notice by submitting correspondence to FDA, but he did not request a hearing. Mr. Patel's failure to request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable February 14, 2024.

ADDRESSES: Any application by Mr. Patel for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted 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–4094. 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(a)(2)(B) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On September 7, 2023, Mr. Patel was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Texas-Beaumont Division, when the court accepted his plea of guilty and entered a judgment against him for the felony offense of conspiracy to traffick in drugs with counterfeit mark in violation of 18 U.S.C. 371 and 18 U.S.C. 2320(a)(4).

The factual basis for this conviction is as follows: as contained in the Second Superseding Indictment and in the Factual Basis, between approximately April 2014 and February 2021, Mr. Patel conspired with drug traffickers to distribute misbranded and counterfeit cough syrup. Specifically, Mr. Patel worked for Pernix Manufacturing LLC (Pernix) as a product-development scientist. Pernix had, in January 2014, entered into an agreement with Byron A. Marshall and his drug trafficking organization (DTO) to copy and manufacture cough syrup according to the directions of Marshall and his associates. Marshall was not licensed or authorized to distribute cough syrup, and any background check of the personal information provided by Marshall to Pernix would have revealed that he was not a licensed physician as he claimed. Marshall sought to copy Actavis Prometh VC with Codeine (Actavis). Actavis is a purple, peach-mint flavor prescription cough syrup that was in demand as a street drug. Marshall and his associates wanted to mass produce and traffic a counterfeit version of Actavis that contained promethazine, but not codeine.

On April 24, 2014, Actavis Holdco US discontinued production of Actavis due to its widespread abuse by recreational drug users. In his role at Pernix as a product-development scientist, Mr. Patel worked with Marshall and his associates to recreate Actavis without codeine and promethazine in order to recreate the syrup base, which is a necessary component of cough syrup. Mr. Patel referred to the new product as a ''placebo.'' Marshall and his associates would then add promethazine to this counterfeit ''placebo'' substance prior to bottling and distribution in order to create the street drug.

On April 25, 2014, as Pernix was scaling-up production of the ''placebo'' syrup base, Pernix was acquired by Woodfield Pharmaceutical LLC, a contract manufacturing company, and Woodfield Distribution LLC, a third-party logistics company (collectively, Woodfield). Mr. Patel was subsequently promoted to Woodfield's Research and Development Manager. In that role he supervised Woodfield's chemical formulation development, optimization, and scale-up for clients, and he worked with Marshall and his associates to develop and distribute the misbranded and counterfeit cough syrup. When Marshall and his DTO had difficulty dissolving promethazine into the ''placebo'' syrup base, Mr. Patel, along with others, worked to resolve that issue.

In or about July 2017, Marshall and his DTO asked Mr. Patel to reformulate another cough syrup to use in their drug trafficking scheme: Hi-Tech Promethazine Hydrocholoride and Codeine Phosphate Oral Solution (Hi-Tech). Mr. Patel reformulated Hi-Tech without the promethazine and codeine, and Woodfield began producing it for Marshall and his DTO. Later, Mr. Patel was promoted to Woodfield's Director of Technical Operations, and in that role, he agreed with other Woodfield employees to create additional ''placebo'' syrup base supply not authorized by Woodfield's ownership in order to sell that additional supply to Marshall and DTO at a reduced price and split the fee with other Woodfield employees.

On or about December 10, 2019, Marshall and his DTO asked Mr. Patel to reformulate another cough syrup to use in their drug trafficking scheme: Wockhardt Promethazine Syrup Plain (Wockhardt). Mr. Patel reformulated Wockhardt, and Woodfield eventually produced the ''placebo'' syrup base for Marshall and his DTO.

Initially, there were no batch records to document the production of the ''placebo'' cough syrups as required; Woodfield provided the syrup to Marshall and his DTO without any corresponding documentation that identified the ingredients of the syrup. This practice continued until February 2019, when Mr. Patel started creating paper records for some of the cough syrup batches Woodfield made for the DTO. Based on the records that do exist and Mr. Patel's own statements, from 2014 through February 2021, the conspiracy with the Marshall DTO produced and distributed, or attempted to produce and distribute, approximately 65,920 gallons of counterfeit cough syrup.

Based on this conviction, FDA sent Mr. Patel by certified mail on October 30, 2023, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Patel was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Patel 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 file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Patel received the proposal on November 8, 2023. On December 12, 2023, Mr. Patel submitted correspondence to FDA explaining the reasons why he believed he was not guilty of the offenses he pled guilty to in court. However, in his request he did not request a hearing and has, therefore, waived his opportunity for a hearing and 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(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Patel has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Patel is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Patel during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Patel provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new

drug application from Mr. Patel during his period of debarment, other than in connection with an audit under section 306(c)(1)(B) of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: February 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03036 Filed 2–13–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2180]

Ross Lucien: 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 Ross Lucien 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. Lucien was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. Lucien's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lucien 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 December 20, 2023 (30 days after receipt of the notice), Mr. Lucien had not responded. Mr. Lucien'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 February 14, 2024.

ADDRESSES: Any application by Mr. Lucien for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted 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–2180. 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, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday. 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, at 240–402–8743, or *debarments@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

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 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 23, 2023, Mr. Lucien was convicted, as defined in section 306(l)(1) of FD&C Act, in the United States District Court for Western District of Michigan, when the court entered judgment against him for the offense of conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545. 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 indictment and plea agreement in Mr. Lucien's case, both filed on May 6, 2022, Mr. Lucien agreed to participate in a scheme to receive, repackage, and reship misbranded prescription drugs purchased by customers on the website *www.ExpressPCT.com,* without a prescription, and shipped to the United States from foreign countries. Mr. Lucien received approximately 11 packages containing bulk quantities of misbranded prescription drugs, all shipped mostly from India but also from