to participate in the CDAD clinical trial, received and taken the study medication, provided stool samples, completed the required documents and journals, and participated in assessments conducted by the clinical investigator. In addition, Ms. Portela Martinez knew that 10 or more individuals' means of identification were used unlawfully or without authority in furtherance of the conspiracy. Specifically, Ms. Portela Martinez, along with some of her co-conspirators, used the means of identification of real persons, to create subject identification numbers for those persons, and then used those subject identification numbers to falsely portray the persons as legitimate subjects in the CDAD clinical trial, when in fact they were not. In addition, Ms. Portela Martinez along with her co-conspirators submitted her own stool and blood samples to make it appear as if they came from study participants.

Furthermore, Ms. Portela Martinez was one of only two individuals who inputted CDAD clinical trial data in the Almac Clinical Technology Integrated Response Technology database (Almac database). The information in the Almac database was the foundation for all subsequent subject CDAD clinical trial data. Ms. Portela Martinez repeatedly entered false and fabricated subject screening and randomization information in the Almac database.

Ms. Portela Martinez received $19,620 in proceeds for the CDAD clinical trial. AMB received over $277,000 for the CDAD clinical trial.

FDA sent Ms. Portela Martinez, by certified mail, on August 12, 2024, a notice proposing to permanently debar her 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)(A) of the FD&C Act, that Ms. Portela Martinez was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. The proposal informed Ms. Portela Martinez of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Portela Martinez received the proposal and notice of opportunity for a hearing on August 15, 2024. Ms. Portela Martinez failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Division of Field Enforcement Director, finds that Ms. Ivette Maria Portela Martinez has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product.

As a result of the foregoing finding, Ms. Portela Martinez 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)(A) 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 Ms. Portela Martinez during her 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 Ms. Portela Martinez provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she 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 Ms. Portela Martinez during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (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, 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: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26912 Filed 11–18–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1178]

Kevin Sheng Hsiang Fang: 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 Kevin Sheng Hsiang Fang 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. Fang 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. Fang was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 1, 2024 (30 days after receipt of the notice), Mr. Fang has not responded. Mr. Fang's failure to respond and request a hearing constitutes a waiver of Mr. Fang's right to a hearing concerning this matter.

DATES: This order is applicable November 19, 2024.

ADDRESSES: Any application by Mr. Fang for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–2024–N–1178. 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 Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act 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 26, 2024, Mr. Fang was convicted as defined in section 306(l)(1)(A) of the FD&C Act, in the U. S. District Court for the Central District of California, when the court entered judgment against him, after his plea of guilty, to the offense of importing merchandise contrary to law in violation of 18 U.S.C. 545 and 18 U.S.C. 2(b). The underlying facts supporting the conviction are as follows: As contained in the information from his case, Mr. Fang worked as a manager at a company called Heng Xing Foods, Inc., which was a business entity that imported shipments of Chinese roasted eel as a food wholesaler. Mr. Fang also imported shipments of Chinese roasted eel as a food wholesaler and did business as Young Chang Trading Co., Ltd. in or about October 16, 2017, in Los Angeles County. Mr. Fang knowingly and fraudulently imported and brought, and willfully caused to be imported and brought, Chinese roasted eel adulterated with Gentian Violet and Leucogentian Violent, both being new unsafe animal drugs, into the United States and contrary to law.

As a result of this conviction, FDA sent Mr. Fang, by certified mail, on May 29, 2024, a notice proposing to debar him for a 5-year period 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. Fang's felony conviction under Federal law for importing merchandise contrary to law in violation of 18 U.S.C. 545 and 18 U.S.C. 2(b), was for conduct relating to the importation into the United States of an article of food because the offense involved Mr. Fang and his company importing roasted eel adulterated with Gentian Violet and Leucogentian Violent, both being new unsafe animal drugs. 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. Fang's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Fang 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. Fang received the proposal and notice of opportunity for a hearing on June 1, 2024. Mr. Fang 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Division of Field Enforcement Director, finds that Mr. Kevin Sheng Hsiang Fang 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 that he is subject to a 5-year period of debarment. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Fang 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. Fang is a prohibited act.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26917 Filed 11–18–24; 8:45 am]

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