suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, is the subject of NDA 012052, held by Merck & Co., Inc., and initially approved on June 8, 1960. HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, is synthetic glucocorticoid for use as an anti-inflammatory or immunosuppressant agent.

The indications for glucocorticoid drugs, including HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL (Merck Sharpe & Dohme (now Merck & Co., Inc.); NDA 012052) were reviewed for efficacy under the Drug Efficacy Study Implementation program. Under this program, which was implemented in response to the 1962 amendments to the FD&C Act requiring demonstration of effectiveness (Kefauver-Harris Amendments of 1962 (Pub. L. 87–781)), the National Academy of Sciences-National Research Council (NAS–NRC) studied about 4,000 drug formulations to assess the efficacy of the drug products. Upon consideration of the findings and recommendations of the NAS–NRC, FDA set forth in the **Federal Register** its conclusions and assessment of whether and under what circumstances the reviewed drug products are considered ''effective'' for use as required by the FD&C Act. In the **Federal Register** of February 19, 1972 (37 FR 3775), FDA announced that preparations containing hydrocortisone sodium phosphate are effective or probably effective for parenteral use by the appropriate route of administration.

FDA published a subsequent notice in the **Federal Register** of March 1, 1977 (42 FR 11893), in which the Agency set forth the indications that it found to be effective for certain drug products, including for HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL (NDA 012052). The March 1, 1977, notice announced FDA was prepared to approve NDAs and supplements to previously approved NDAs under the conditions described in the notice, including the condition that the revised labeling include only the indications for which the drug was classified as effective set forth in that notice (42 FR 11893 at 11894–5).

HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated April 4, 2003, Merck & Co., Inc., notified FDA that HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was discontinued effective September 20, 2002. In the same letter, Merck & Co., Inc., also requested withdrawal of NDA 012052 for HYDROCORTONE (hydrocortisone sodium phosphate), and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of NDA 012052, effective June 4, 2004.

Hyman, Phelps & McNamara, P.C., submitted an initial citizen petition dated September 21, 2020 (Docket No. FDA–2020–P–1991) as well as a second citizen petition dated August 25, 2021 (Docket No. FDA–2021–P–0940), under 21 CFR 10.30, requesting that the Agency determine whether HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, may be approved by the Agency if they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26916 Filed 11–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3111]

Ivette Maria Portela Martinez: 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 Ivette Maria Portela Martinez 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 Ms. Portela Martinez was convicted of two felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Ms. Portela Martinez was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of September 14, 2024 (30 days after receipt of the notice), Ms. Portela Martinez has not responded. Ms. Portela Martinez's failure to respond and request a hearing constitutes a waiver of Ms. Portela Martinez's right to a hearing concerning this matter.

DATES: This order is applicable November 19, 2024.

ADDRESSES: Any application by Ms. Portela Martinez 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 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–3111. 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(a)(2)(A) 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 development or approval, including the process of development or approval, of any drug product. On November 30, 2023, Ms. Portela Martinez was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Southern District of Florida-Miami Division when the court entered judgment against her, after a jury trial, for one count of conspiracy to commit wire fraud in violation of 18 U.S.C. 1349 and one count of wire fraud in violation of 18 U.S.C. 1343.

The underlying facts supporting the conviction are as follows: as contained in the witness testimony reflected in the transcripts from her trial, Ms. Portela Martinez worked for AMB Research Center, Inc. (AMB), a medical clinic located in Miami, Florida. AMB conducted clinical trials of new drugs for pharmaceutical companies and other sponsors. At AMB, Ms. Portela Martinez served as recruiter, site manager, data entry specialist, and pharmacist. In March 2016, AMB entered into a Clinical Trial Agreement with a Contract Research Organization (CRO) that managed and oversaw a clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea (CDAD clinical trial) on behalf of a sponsor (a pharmaceutical company). Ms. Portela Martinez, along with her co-conspirators, entered into a conspiracy to cause the sponsor and/or the CRO to make payments on the contracts for the CDAD clinical trial, by making false and fraudulent representations regarding, among other things, subject eligibility for and participation in the CDAD clinical trial, and falsifying and fabricating documents, data, and other items relating to the CDAD clinical trial including subject informed consent forms, case histories, and data. Ms. Portela Martinez participated with two other co-conspirators with falsifying and fabricating study documents. Ms. Portela Martinez and her co-conspirators falsified the study data of subjects who did not participate in the CDAD clinical trial in full compliance with the protocol. Ms. Portela Martinez participated in falsifying the consent forms and falsifying subjects' signatures to make it appear as though the patients had consented to participate in the clinical trial when they had not.

For purposes of obtaining money from the sponsor and/or CRO, Ms. Portela Martinez, along with her co-conspirators, created false and fraudulent study records, and submitted fraudulent stool and blood samples. For example, electronic case record files (eCRFs) falsely represented that the subjects completed the informed consent form (ICF) process with the Principal Investigator which required her to review the ICF with each subject and personally obtain the subject's written informed consent. In fact, the Principal Investigator never completed the ICF process with subjects, and some subjects had never been to AMB or did not participate in the trial. Ms. Portela Martinez knew that false information and data was submitted in the case report forms and eCRFs including false information and data representing that subjects had satisfied eligibility criteria

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