submitting the information to FDA each year.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 10 have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381. The collections of information in section 403(w) of the FD&C Act have been approved under OMB control number 0910–0792. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information for Form FDA 3800 have been approved under OMB control number 0910–0645. The collections of information for Form FDA 3500 have been approved under OMB control number 0910–0291. The collections of information in 21 CFR 70.25, 71.1, 170.36, 171.1, 172, 173, 179, and 180 have been approved under OMB control number 0910–0016.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08303 Filed 4–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0030]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on February 28, 2022. The document announced the withdrawal of approval of five abbreviated new drug applications (ANDAs) from multiple applicants as of March 30, 2022. The document indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, Venus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540: ANDA 091008, Gabapentin Capsules, 100 milligrams (mg), 300 mg, and 400 mg. Before FDA withdrew the approval of this ANDA, Jiangsu Hengrui Pharmaceuticals Co., Ltd., informed FDA that it did not want the approval of the ANDA withdrawn. Because Jiangsu Hengrui Pharmaceuticals Co., Ltd., timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 091008 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 28, 2022 (87 FR 11079), appearing on page 11079 in FR Doc. 2022–04153, the following correction is made:

On page 11079, in the table, the entry for ANDA 091008 is removed.

Dated: April 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08299 Filed 4–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0317]

Yvelice Villaman-Bencosme: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Yvelice Villaman-Bencosme 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 Yvelice Villaman-Bencosme was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of a drug product under the FD&C Act. Ms. Villaman-Bencosme was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 13, 2021 (30 days after receipt of the notice), Ms. Villaman-Bencosme had not responded. Ms. Villaman-Bencosme's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable April 19, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, 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, *debarments@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) 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 under the FD&C Act. On March 19, 2021, Ms. Villaman-Bencosme was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Southern District of Florida-Miami Division, after her plea of guilty, to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: Ms. Villaman-Bencosme was a licensed medical doctor who served as a clinical investigator at Unlimited Medical Research, LLC from about September 2013 through June 2016. Ms. Villaman-Bencosme conspired with others to unlawfully enrich herself by making materially false representations about clinical trials; fabricating data and the participation of subjects in those clinical trials; concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been

fabricated; and inducing sponsors and contract research organizations to pay money for Ms. Villaman-Bencosme and her co-conspirators' own benefit. On or about October 25, 2013, Ms. Villaman-Bencosme entered into a contract with a Contract Research Organization retained by a drug manufacturer (Sponsor) to serve as a clinical investigator for a clinical trial initiated by the Sponsor. The study was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years. As the clinical investigator Ms. Villaman-Bencosme was responsible for all aspects of the study to include ensuring that subjects provided informed consent and understood the risks of participating in the study, reporting adverse events to the Sponsor, and maintaining honest and accurate records known as ''case histories.'' Instead, Ms. Villaman-Bencosme used personal identification information from pediatric patient medical records maintained at her private medical practice to falsify case histories. This included a number of false details. Ms. Villaman-Bencosme made it appear that: The study subjects satisfied the eligibility criteria to participate in the study; the subjects received a physical examination from her; the patients received the study drug at the study site; the patients returned the study drug to the study site; and the patients received payment for visits to the study site.

As a result of this conviction, FDA sent Ms. Villaman-Bencosme by certified mail on November 3, 2021, 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. Villaman-Bencosme 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 under the FD&C Act. The proposal also offered Ms. Villaman-Bencosme 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Villaman-Bencosme received the proposal on November 13, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her 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)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Villaman-Bencosme 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 under the FD&C Act.

As a result of the foregoing finding, Ms. Villaman-Bencosme, 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 the services of Ms. Villaman-Bencosme, in any capacity 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. Villaman-Bencosme 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. Villaman-Bencosme 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 this 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)).

Any application by Ms. Villaman-Bencosme for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2021–N–0317 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

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: April 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08302 Filed 4–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting

AGENCY: Department of Health and Human Services, Office of the Secretary, Office for Civil Rights, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders will hold a meeting on May 12, 2022. The meeting is the second in a series of federal advisory committee meetings regarding the development of recommendations to promote equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) communities. The meeting is open to the public and will be live streamed. Registration is required through the following link: *https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpis-registration-311578077417.* The Commission, co-chaired by HHS Secretary Xavier Becerra and the U.S. Trade Representative Ambassador Katherine Tai, will advise the President on: (i) The development, monitoring, and coordination of executive branch efforts to advance equity, justice, and opportunity for AA and NHPI communities in the United States, including efforts to close gaps in health, socioeconomic, employment, and educational outcomes; (ii) policies to address and end anti-Asian bias, xenophobia, racism, and nativism, and opportunities for the executive branch to advance inclusion, belonging, and public awareness of the diversity and accomplishments of AA and NHPI people, cultures, and histories; (iii) policies, programs, and initiatives to prevent, report, respond to, and track anti-Asian hate crimes and hate incidents; (iv) ways in which the Federal Government can build on the capacity and contributions of AA and