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This draft guidance also refers to previously approved collections of information found in FDA regulations.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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.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