Histamine (CPG 7108.24).'' This draft CPG would update and replace existing guidance for FDA staff on adulteration associated with decomposition and histamine identified during surveillance sampling and testing of fish and fishery products susceptible to histamine formation. We gave interested parties until February 25, 2022, to submit comments before we began work on the final guidance.

FDA has received a request for a 30-day extension for this comment period to allow additional time for interested parties to develop and submit data, other information, and comments for this draft Compliance Policy Guide before we begin work on the final version of the guidance. We have considered this request and are reopening the comment period for 30 days. FDA believes that this additional 30 days will allow adequate time for any interested parties to submit data, other information, and comments before we begin work on the final guidance.

Dated: March 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05476 Filed 3–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0968]

Nayade Varona: 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 Nayade Varona 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. Varona was convicted of a felony under Federal law for conduct related to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Ms. Varona 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 22, 2021 (30 days after receipt of the notice), Ms. Varona had not responded. Ms. Varona's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable March 15, 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 *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, or at *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 August 11, 2021, Ms. Varona 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 accepted her plea of guilty and entered judgment against her for one count of Conspiracy to Defraud the United States in violation of 18 U.S.C. 371.

The factual basis for this conviction is as follows: As contained in the Information, entered into the docket on March 16, 2021, and the Factual Proffer in Support of Ms. Varona's guilty plea, entered into the docket on June 8, 2021, both from her case, Ms. Varona was employed as an assistant study coordinator at Tellus Clinical Research (Tellus). Tellus was a medical clinic that conducted clinical trials on behalf of pharmaceutical company sponsors. A drug manufacturer (Sponsor) initiated a clinical trial concerning a new investigational drug intended to treat patients suffering from irritable bowel syndrome (Study or IBS Trial). The Sponsor retained a Contract Research Organization (CRO) to manage various aspects of the IBS Trial. CRO entered into a contract with Tellus and Martin Valdes, a medical doctor serving as a clinical investigator for clinical trials conducted at Tellus and as the clinical investigator for the IBS Trial. The study protocol for the IBS Trial required subjects to make periodic scheduled visits to the clinical trial site for which they were paid $100 per visit. During some of these visits, subjects were required to provide blood samples for pharmacokinetic analysis, receive physical exams by clinical trial staff, and undergo electrocardiograms. Subjects were also required to use an ''e-diary'' system to report their daily experience with the Study drugs. They would do this by making daily phone calls to a number maintained by a third party and answering automated questions nonverbally by touch-tone buttons.

In her role as an assistant study coordinator, Ms. Varona was responsible for administering procedures to subjects in the Study and creating written records reflecting the participation in the Study. However, Ms. Varona and her co-conspirators engaged in an effort to impair, impede, and obstruct FDA's legitimate function of regulating clinical trials of drugs in order to obtain money. Ms. Varona and her co-conspirators did this by fabricating medical records to portray persons as legitimate Study subjects when they were not. She and her co-conspirators falsified these records to make it appear that the Study subjects had consented to participating in the Study, satisfied the Study's eligibility criteria, appeared for scheduled visits at the Study's site, taken Study drugs as required, and received checks as payment for site visits, among other things. For example, Ms. Varona represented that she had seen a purported Study subject, spoken to her about her dietary habits, lifestyle, and exercise regimen, collected a urine sample, taken vital signs, and dispensed the Study drug to her when Ms. Varona well knew that the individual was not a Study subject and that these representations were false. Ms. Varona also knew that one or more of her co-conspirators placed telephone calls to the e-diary system for the purposes of reporting fabricated data on behalf of purportedly legitimate Study subjects.

As a result of this conviction, FDA sent Ms. Varona by certified mail on November 8, 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. Varona 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 development or approval, including the process of development or

approval, of any drug product under the FD&C Act. The proposal also offered Ms. Varona 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. Varona received the proposal on November 22, 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. Varona 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. Varona 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, (21 U.S.C. 355a(2)(A) and 335a(c)(2)(A)(ii))). 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. Varona 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. Varona 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. Varona 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))).

Any application by Ms. Varona for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2021–N–0968 and sent to the Division of Dockets Management (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: March 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05401 Filed 3–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0375]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

DATES: Submit either electronic or written comments on the collection of information by May 16, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 16, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 16, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0375 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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