a. Name, address, and FEI number of the sterilization facility.

b. Master File number in which the referenced sterilization procedures are described, with signed right of reference from the Master File holder.

c. List of device(s) sterilized (identified by manufacturer, trade name, model number, and PMA number).

Upon receipt of a postapproval report containing the above information, FDA will notify the PMA holder of whether the postapproval report is permitted as an alternate submission under § 814.39(a) and (e). Additionally, FDA will notify the PMA holder of whether the PMA identified device(s) and referenced Master File are eligible for the sterilization provider's participation in the pilot. If the PMA is not eligible for the sterilization provider's participation in the pilot program, FDA will notify the PMA holder of the reasons for rejection.

This Pilot Program does not otherwise remove or replace any requirements, such as, but not limited to, recordkeeping and reporting requirements under part 814 or part 820. It is the manufacturer's responsibility to ensure compliance with applicable laws and regulations administered by FDA.

During this voluntary Radiation Pilot Program, CDRH staff intends to be available to answer questions or concerns that may arise. The Radiation Pilot Program participants may comment on and discuss their experiences with the Center.

II. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231. The collections of information in part 820, regarding the Quality System Regulation, have been approved under OMB control number 0910–0073.

III. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, ''FDA Executive Summary Prepared for the November 6–7, 2019 meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee,'' available at: *https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-and-personal-use-devices-panel-medical-devices-advisory-committee.*

2. FDA, Sterilization for Medical Devices, available at: *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices.*

3. FDA, PMA Supplements and Amendments, available at: *https://www.fda.gov/medical-devices/premarket-approval-pma/pma-supplements-and-amendments.*

4. National Academies of Sciences, Engineering, and Medicine. 2021. Radioactive Sources: Applications and Alternative Technologies. Washington, DC: The National Academies Press. *https://doi.org/10.17226/26121.*

5. FDA, ''Statement on Concerns With Medical Device Availability Due to Certain Sterilization Facility Closures,'' available at: *https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.*

Dated: April 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07598 Filed 4–11–23; 8:45 am]

BILLING CODE 4164–01–P

determined to be acceptable as described in this pilot notice.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2515]

Olga L. Torres: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Olga L. Torres 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. Torres was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Ms. Torres 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 January 20, 2023 (30 days after receipt of the notice), Ms. Torres had not responded. Ms. Torres' 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 April 12, 2023.

ADDRESSES: Any application by Olga L. Torres 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 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–2022–N–2515. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' 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. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 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 for development or approval, of any drug product under the FD&C Act. On September 30, 2022, Ms. Olga L. Torres 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 obstruction of agency proceeding in violation of 18 U.S.C. 1505.

The factual basis for this conviction is as follows: as contained in the information, entered into the docket on October 28, 2021, and the Factual Proffer in support of her guilty plea, entered into the docket on January 13, 2022, Ms. Torres co-owned a business called Unlimited Medical Research, LLC (Unlimited Medical Research) that conducted clinical trials on behalf of pharmaceutical company sponsors. On or around October 25, 2013, on behalf of Unlimited Medical Research, Ms. Torres signed a contract with a contract research organization retained by a drug manufacturer (Sponsor) to conduct a clinical trial (Study) initiated by the Sponsor. The clinical trial was designed to study the safety and efficacy of an investigational asthma medication in children between the ages of 4 and 11 with persistent asthma. Dr. Yvelice Villaman-Bencosme was a licensed medical doctor who had been retained by Unlimited Medical Research to serve as the clinical investigator for the Study.

On or about February 6, 2017, Ms. Torres learned that FDA investigators intended to conduct a regulatory inspection of Dr. Villaman-Bencosme in her capacity as the clinical investigator for the Study at Unlimited Medical Research. Ms. Torres also learned that, as part of the inspection, FDA investigators would review records prepared and maintained by Unlimited Medical Research concerning the study. The FDA regulatory inspection began on or about February 6, 2017, and continued until on or about April 28, 2017. In or around February 2017, as part of the inspection, Ms. Torres was interviewed by FDA investigators. On or about February 24, 2017, while the regulatory inspection remained ongoing, Ms. Torres reviewed and signed an affidavit which summarized her interview. In that affidavit, Ms. Torres made a number of false statements for purposes of falsely portraying to FDA investigators that the Study had been conducted legitimately and honestly, when in fact it had not. For example, Ms. Torres falsely represented in her signed affidavit that subjects were seen at Unlimited Medical Research and that medical records prepared and maintained by Unlimited Medical Research, which had been provided to the FDA investigators during the course of the inspection, and which purported to document the participation of subjects in the Study, were accurate and complete. In fact, Unlimited Medical Research employees falsified case histories to portray persons as legitimate study subjects who attended scheduled study visits at Unlimited Medical Research, when in fact such persons were not subjects participating in the Study. Ms. Torres knew these statements were dishonest and were made with the specific intent to conceal the truth about the Study from the FDA investigators and thereby prevent FDA from recommending further regulatory enforcement action against Unlimited Medical Research or its staff.

Based on this conviction, FDA sent Ms. Torres by certified mail on December 9, 2022, 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. Torres 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 for development or approval, of any drug product under the FD&C Act. The proposal also offered Ms. Torres 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. Torres received the proposal on December 21, 2022. 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. Torres 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. Torres is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, applicable as of the date of this order (see **DATES**) (see section 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. Torres 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. Torres 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. Torres 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))).

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07670 Filed 4–11–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0918]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 of 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 activity associated with statutory and regulatory food labeling requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by June 12, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 12, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–0918 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations.'' 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.