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

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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150

OMB Control Number 0910–0131—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations at § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Contact information of the firms involved and the identification of the signature authority of the shipper and receiver, (2) instructions for maintaining accountability of the number of units in each shipment, (3) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (4) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (see § 801.150(a)(2)). The respondents to this collection of information are device manufacturers and contract sterilizers. FDA's estimate of the reporting burden is based on data obtained from industry in recent years. It is estimated that each of the firms subject to this requirement prepares an average of 37.5 written agreements each year. This estimate varies greatly, from 1 to 218, because some firms provide sterilization services on a part-time basis for only 1 customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Record retention, 801.150(a)(2)	218	37.5	8,175	0.50 (30 minutes)	4088

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest hour.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Agreement and labeling requirements, 801.150(e)	218	37.5	8,175	4	32,700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 27,778 hours and a corresponding increase of 6,175 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: March 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05402 Filed 3–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)

National Institute of Mental Health (NIMH); Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The purpose of the IACC meeting is to discuss business, agency updates, and issues related to autism spectrum disorder (ASD) research and services activities. The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting should notify the Contact Person listed below at least seven (7) business days in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocast website (*http://videocast.nih.gov/*).

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Date: April 13–14, 2022.

Time: Wednesday, April 13, 2022, 1:00 p.m. to 5:00 p.m. ET.

Meeting Access: Wednesday, April 13, 2022, *https://videocast.nih.gov/watch=44688.*

Time: Thursday, April 14, 2022, 1:00 p.m. to 5:00 p.m. ET.

Meeting Access: Thursday, April 14, 2022, *https://videocast.nih.gov/watch=44690*

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended.

Deadlines: Written/Virtual Public Comment Due *Date:* Friday, April 1, 2022, by 5:00 p.m. ET, Public Comment Guidelines, For public comment instructions, see below.

Contact Person: Ms. Rebecca Martin, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Bethesda, MD 20892–9669, Phone: 301–435–0886, email: *IACCPublicInquiries@mail.nih.gov.*

Public Comments

The IACC welcomes public comments from members of the autism community and asks the community to review and adhere to its Public Comment Guidelines. In the *2016–2017 IACC Strategic Plan,* the IACC listed the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen with open minds to the diverse views of people on the autism spectrum and their families, thoughtfully consider community input, and foster discussions where participants can comfortably offer opposing opinions.'' In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

As the IACC will be updating its Strategic Plan, comments related to issues that the community would like to see highlighted in the new IACC Strategic Plan are welcome. Comments may be submitted in writing via email to *IACCPublicInquiries@mail.nih.gov* or using the web form at: *https://iacc.hhs.gov/meetings/public-comments/submit/index.jsp* by 5:00 p.m. ET on Friday, April 1, 2022. A limited number of slots are available for individuals to provide a 2–3-minute summary or excerpt of their written comment to the Committee live during the virtual meeting using the virtual platform. For those interested in that opportunity, please indicate ''Interested in providing virtual comment'' in your written submission, along with your name, address, email, phone number, and professional/organizational affiliation so that OARC staff can contact you if a slot is available for you to provide a summary or excerpt of your comment via the virtual platform during the meeting. For any given meeting, priority for live virtual comment slots will be given to those who have not previously provided live virtual comments in the current calendar year. This will help ensure that as many individuals as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately in order to allow other comments and the rest of the meeting to proceed on schedule.

Public comments received by 5:00 p.m. ET on Friday, April 1, 2022, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, April 1, 2022, may be provided to the Committee either before or after