based multi-product, multi-sponsor pregnancy registries.

This current public workshop is part of FDA's commitment to advance optimal approaches to efficient generation of high-quality human safety data for drug products used during pregnancy. The purpose of the workshop is to discuss current challenges in gathering safety data for drug and biological products used during pregnancy and to discuss approaches to optimize and improve pregnancy registries with key interested parties.

II. Topics for Discussion at the Public Workshop

The objective of the meeting is to discuss the following topics with interested parties:

- Current status of pregnancy registries and challenges in gathering data regarding the safety of drug and biological products used during pregnancy.
- Perspectives from interested parties (FDA, academia, industry, healthcare providers, and patients) on strategies to improve the design and conduct of pregnancy registries.
- Innovative approaches/models to facilitate the conduct of pregnancy registries, including disease-based multi-product, multi-sponsor pregnancy registries.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://lu.ma/bod9zouc.* Persons interested in attending this public workshop must register online by March 14, 2025, 11:59 p.m. eastern time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8:30 a.m. eastern time. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact the Optimizing Pregnancy Registries Workshop Planning Team at *OPRWorkshop@fda.hhs.gov* no later than March 14, 2025.

Virtual Streaming of the Public Workshop: This public workshop will also be streamed virtually via Zoom. Virtual attendees may register at the following website to receive the Zoom link: *https://lu.ma/bod9zouc.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov* (Docket No. FDA–2024–N–0001). It also may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01164 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2033]

Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics'' that appeared in the **Federal Register** of December 6, 2024. In the notice of availability for the draft guidance, FDA requested comments on the draft guidance. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance for industry published December 6, 2024 (89 FR 97011). Either electronic or written comments must be submitted by March 6, 2025.

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 March 6, 2025. 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–2024–D–2033 for ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' 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: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926 or 301–796–2500, *dat.doan@fda.hhs.gov;* James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567, *Paul.Kluetz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 6, 2024, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' The Agency has received requests for a 30-day extension of the comment period. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA has considered the requests and is extending the comment period for 30 days, until March 6, 2025. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments on this draft guidance.

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01179 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3595]

Agency Information Collection Activities; Proposed Collection; Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a notice that was published in the **Federal Register** of October 18, 2023.

DATES: The notice is withdrawn on January 17, 2025.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 18, 2023 (88 FR 71875), ''Agency Information Collection Activities; Proposed Collection; Comment Request: Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.'' FDA requested comment on the information collection associated with the proposed study entitled ''Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.''

Under the Paperwork Reduction Act of 1995, 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.

In the October 18, 2023, **Federal Register** notice, FDA proposed a new collection of information. However, FDA no longer intends to proceed with the proposed study due to circumstances and timing surrounding the execution of the study. Therefore, we are withdrawing the October 18, 2023 notice.

Dated: January 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01152 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5468]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Adverse Event and Product Experience Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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 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 associated with FDA's