2019 public health emergency, we revised the Agency guidance document to provide recommendations for recordkeeping applicable to any pandemic, not just influenza, including recommendations for planning, notification, and documentation for continuity of operations for firms that report postmarketing adverse events during any pandemic.

For operational efficiency, on March 20, 2023, OMB approved the addition of burden attributable to provisions related to postmarketing safety reporting for combination products as outlined in part 4, subpart B, and previously included in OMB control number 0910–0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of a combination product that includes a drug product, is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103 (21 CFR 4.103). Relatedly, 21 CFR 4.104 explains how and where to submit reports for combination products, and 21 CFR 4.105 provides for associated recordkeeping. For combination products that are administered as drug products with a constituent part, adverse event reports are submitted to the drug application under 21 CFR part 314, and constituent applicants are notified of the AER under § 4.103. These provisions are also described in the guidance document ''Postmarketing Safety Reporting for Combination Products'' (July 2019), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-safety-reporting-combination-products.*

Our estimates of the number of respondents and the total annual responses are based on reports submitted to the Agency. This information collection incorporates revisions to include the two guidances for industry regarding submission of adverse event reports (''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic'' and ''Providing Submissions in Electronic Format—Postmarketing Safety Reports'') and adjustments to include 15-day alert reports from applicants, manufacturers, distributors, and packers that were not recorded previously in this information collection. We also believe adjustments in the information collection reflect anticipated fluctuations in burden after pandemic conditions, adjustments by reporters' and changes in electronic reporting methodologies use of updated technology including updates and redefinitions of reporting software, and changes of company business practices over time. All reports and followup reports must be submitted to FDA in electronic format. Waivers of the electronic requirements are available. As a result of these revisions and adjustments, including the additional reports, the inclusion of guidance document recommendations and the consolidation of the burden from OMB control number 0910–0834 (previously added to this information collection March 2023), the total burden hours of the information collection have increased by 61,614,921 hours and 2,546,112 responses as compared to the previous renewal. While no changes have been made to the estimates in the 60-day notice, due to a clerical error, we are clarifying in this notice that the total burden hour increase is slightly lower (a difference of 198 burden hours and 89 responses).

Dated: January 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01151 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–0001]

Optimizing Pregnancy Registries; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Optimizing Pregnancy Registries.'' The purpose of the public workshop is to discuss challenges in designing and implementing pregnancy registries and to consider innovative approaches to improve the design and conduct of pregnancy registries to inform the safety of drug and biological products during pregnancy. This public workshop is being held in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation program.

DATES: The public workshop will be held on March 27, 2025, from 9 a.m. to 4 p.m. eastern time and on March 28, 2025, from 9 a.m. to 12 p.m. eastern time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Room 1503), Silver Spring, MD 20993 and online. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, 301–796–6169, *OPRWorkshop@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Historically, pregnant individuals have been excluded from drug and biological product development. At the time of initial approval of a drug or biological product, there are generally limited data on the safety of the product when used during pregnancy. Therefore, postapproval pregnancy safety studies are needed to evaluate the safety of a product in the postapproval setting and to inform safety-related product labeling and clinical care.

Under the latest reauthorization of the Prescription Drug User Fee Act, FDA made a commitment to develop a framework describing how to optimally use data from different types of postapproval pregnancy safety studies. On September 18–19, 2023, FDA and the Duke-Margolis Institute for Health Policy convened a public workshop to discuss the design of postapproval pregnancy safety studies for drug and biological products.[1] Participants and interested parties discussed ways these studies can be optimized and different approaches that can be taken to bridge knowledge gaps in developing the framework. Although data were presented that suggest that pregnancy registry studies are an important source of pregnancy safety information, interested parties noted challenges with conducting single-drug, single-sponsor pregnancy registries, including low enrollment and long lag time to study completion. Similar to the Pregnant Women and Lactating Women recommendations,[2] interested parties identified the need to optimize disease-

[1] *https://healthpolicy.duke.edu/events/optimizing-use-postapproval-pregnancy-safety-studies.*

[2] *https://www.nichd.nih.gov/about/advisory/PRGLAC.*

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.