this collection contact Daniel Kidane at (301–786–0000.)

Dated: August 14, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–17731 Filed 8–16–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3104]

Optimizing the Use of Postapproval Pregnancy Safety Studies; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Optimizing the Use of Postapproval Pregnancy Safety Studies'' convened by the Duke-Margolis Center for Health Policy and supported by a cooperative agreement between FDA and Duke-Margolis. This workshop will include discussions of designs of postapproval pregnancy safety studies for drug and biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and experiences with implementing these studies. The workshop also will include discussion of considerations for further development of a framework that describes how data from different types of postapproval pregnancy safety studies might optimally be used when it has been determined that this data should be collected.

DATES: The public workshop will be held in person and virtually on September 18, 2023, from 10 a.m. to 4 p.m., Eastern Daylight Time, and on September 19, 2023, from 10 a.m. to 2:30 p.m. Either electronic or written comments on this public workshop must be submitted by November 30, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in person at the National Press Club, 529 14th St. NW, Washington, DC 20045 and virtually using the Zoom Platform. The link for the public workshop will be sent to registrants upon registration for virtual attendance.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered for the subsequent workshop report describing the proposed framework, which will be published by October 2, 2024. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on November 30, 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–3104 for ''Optimizing the Use of Postapproval Pregnancy Safety Studies.'' 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. 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: Commander Vicky Chan, Food and Drug Administration, CDER, 10903 New Hampshire Ave., Bldg. 22, Rm. 3404, Silver Spring, MD 20993, 301–796–1639, *Vicky.Chan@fda.hhs.gov* or Anne Taylor, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911, *Anne.Taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, approximately 5.5 million pregnancies occur each year (Ref. 1). Half of individuals who are pregnant use at least one drug or biological product to treat chronic (*e.g.,* diabetes, seizure disorders, or asthma), acute (*e.g.,* infection) or serious medical conditions (Ref. 2). Typically at the time of initial market approval, there are limited to no human data on the safety of drug or biological products used during pregnancy. As a result, for most products, human pregnancy safety data are collected after a product is available on the market (*i.e.,* postapproval).

In May 2019, FDA published a draft Guidance for Industry entitled ''Postapproval Pregnancy Safety Studies'' (available at *https://www.fda.gov/media/124746/download*), which discusses the strengths and limitations of postapproval study types including studies based on registry data and cohort studies using electronic health records or claims data. However, more research is needed to better understand the key considerations for determining the optimal postapproval study designs to obtain timely evidence to ensure the safe use of drug and biological products in pregnant individuals. The public workshop is a preliminary discussion with stakeholders to inform FDA's further development of a framework and also meets a performance goal under the FDA User Fee Reauthorization Act of 2022, in accordance with the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII Commitment Letter), which is available at *https://www.fda.gov/media/151712/download.* Specifically, the PDUFA VII Commitment Letter outlines the commitment of a public workshop to discuss postapproval pregnancy safety studies to facilitate determination of ideal study designs.

II. Topics for Discussion at the Public Workshop

The public workshop will include the following topics for discussion:

1. FDA's considerations for constructing a framework describing how data from different types of post-market pregnancy safety studies might optimally be used.
2. Stakeholders' perspectives on opportunities to optimize postapproval pregnancy safety study types and designs.
3. Design considerations and potential approaches to bridge knowledge gaps in developing the framework, including understanding how the Sentinel Initiative (*i.e.,* Sentinel System and Biologics Effectiveness and Safety (BEST)) may address these gaps.
4. Stakeholders' perspectives on considerations for FDA's proposed framework.

Meeting updates, the agenda, and background materials (if any) will be made available at *https://duke.is/nj5kg* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for this hybrid public workshop, please visit the following website: *https://duke.is/nj5kg.* Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by 10 a.m. Eastern Daylight Time, September 18, 2023. Early registration is recommended due to limited seating; therefore, FDA may limit the number of participants from each organization. Registrants will receive a confirmation email when they have been registered.

If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, 202–621–2800, *margolisevents@duke.edu,* no later than 5 p.m. Eastern Time, September 5, 2023.

Requests for Oral Comments: During online registration, you may indicate if you wish to speak during a public comment session. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request a time for joint commentary. All requests to make oral comments must be received by 11:59 p.m. Eastern Time on September 5, 2023. FDA will determine the amount of time allotted to each commenter and the approximate time each comment is to begin and will select and notify participants by September 11, 2023.

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.* It may be viewed by the Dockets Management Staff.

IV. References

The following references marked with an asterisk (*) have been placed on display at the Dockets Management Staff (see **ADDRESSES**) 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.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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. Centers for Disease Control and Prevention, National Center for Health Statistics. ''U.S. Pregnancy Rates Drop During Last Decade.'' Hyattsville (MD); 2023 April 12, Available from: *https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2023/20230412.htm.*

2. Mitchell, A.A, S.M. Gilboa, M.M. Werler, et al. ''Medication Use During Pregnancy, with Particular Focus on Prescription Drugs: 1976–2008.'' *American Journal of Obstetrics & Gynecology* 2011;205:51.e1–8.

Dated: August 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17718 Filed 8–16–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment; Biographical Sketch Form for Use With Applications to the Maternal and Child Health Bureau Research Grants OMB No. 0906—Reinstatement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.