translated report is an accurate representation of the original GLP study report.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Translation of GLP Study Reports: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 58 for good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.regulations.gov,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25859 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4996]

Advancing Drug Development for the Prevention of Spontaneous Preterm Birth; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Advancing Drug Development for the Prevention of Spontaneous Preterm Birth.'' The meeting will be convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting is intended to gather industry, family, clinician, researcher, ethicist, professional society, and other stakeholder input on the impact of preterm birth on families and on society, as well as on the ethical, regulatory, and clinical trial considerations surrounding the drug development for the prevention of spontaneous preterm birth.

DATES: The public meeting will be held on January 23 and 24, 2024, from 1 p.m. to 4:30 p.m. Eastern Time each day. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public meeting will be held virtually via Zoom.

FOR FURTHER INFORMATION CONTACT: Luke Durocher, Duke-Margolis Center for Health Policy, *margolisevents@duke.edu,* 202–621–2800; or Christina Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2078.

SUPPLEMENTARY INFORMATION:

I. Background Information

In the United States in 2021, 1 in every 10 infants was born prematurely (before 37 weeks of pregnancy). Infants born too early have higher rates of death and disability, resulting in a significant public health concern. The exact mechanisms and risk factors associated with spontaneous preterm birth are not fully understood, resulting in a dearth of interventions demonstrated to be effective and safe.

FDA endorses an informed and balanced approach to gathering data supporting the safe and effective use of drugs and biological products for the prevention of spontaneous preterm birth. Currently, there is a significant medical need for such therapies, as there are no FDA approved therapies for reducing the risk of neonatal morbidity/mortality resulting from spontaneous preterm birth. Input from this meeting will help provide guidance on the development of therapies for the prevention of spontaneous preterm birth.

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including clinicians, patients, family, researchers, ethicists, professional societies, and other stakeholders) to provide input on key topics, including:

- The current understanding of spontaneous preterm birth, including the epidemiology of the condition, etiologies, and pathophysiology
- Ethical and regulatory considerations and challenges associated with the development of therapeutics for the prevention of spontaneous preterm birth
- Impact of preterm birth on families and society
- Assessing efficacy and safety in clinical programs for therapeutics for spontaneous preterm birth prevention
- Dose-finding and clinical trial design considerations

For more information on the meeting topics and discussion questions, visit *https://duke.is/g/gde6.* Duke-Margolis will publish a discussion guide outlining background information and current thinking on the topic areas to this website approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the virtual public meeting, please visit the following website: *https://duke.is/g/gde6.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free. Persons interested in attending this virtual public meeting must register. Early registration is recommended. Registrants will receive confirmation once they have been accepted. If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, at *margolisevents@duke.edu* or at 202–621–2800.

Streaming Webcast of the Public Meeting: This virtual public meeting will be webcast via Zoom and the archived video footage will be available at the event website. The link for registration is the same as above: *https://duke.is/g/gde6.* Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will not be available.

Dated: November 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25816 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4965]

Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; 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 or the Agency) is announcing the following public workshop entitled ''Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice.'' The purpose of the public workshop is to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs. This workshop is being conducted to meet the performance goal of convening a public workshop on complex innovative design (CID) included in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The workshop may also inform a draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products. In conjunction with the workshop, FDA is seeking comments on the use of CID to inform regulatory decision making, including high-level case examples of CIDs and approaches that can advance the use of these designs. The public workshop will be held on March 5, 2024, from 9 a.m. to 3:30 p.m. Eastern Time.

DATES: Either electronic or written comments on this public workshop must be submitted by April 5, 2024. 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., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002. 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.* The public workshop will use an online platform for the webcast.

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 April 5, 2024. 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–4965 for ''Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop; Request for Comments.'' 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: Tuan Pham, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 3670, Silver Spring, MD 20993–0002, 301–348–1595, *CID.Meetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: