DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0375, FDA–2013–N–1147, FDA–2010–N–0083, FDA–2013–N–0115, FDA–2013–N–1588, and FDA–2016–N–1593]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Agreement for Shipments of Devices for Sterilization	0910–0131	9/30/2025
Environmental Impact Considerations	0910–0322	9/30/2025
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	9/30/2025
Manufactured Food Regulatory Program Standards	0910–0601	9/30/2025
Tobacco Products, Exemptions From Substantial Equivalence Requirements	0910–0684	9/30/2025
Medical Device Accessories	0910–0823	9/30/2025

Dated: October 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22762 Filed 10–19–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2455]

Advancing Real-World Evidence Program

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the Advancing Real-World Evidence (RWE) Program to fulfill FDA's commitment under the seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII), incorporated as part of the FDA User Fee Reauthorization Act of 2022.

DATES: The Advancing RWE Program will proceed from the date of this notice through September 30, 2027. Sponsors may submit meeting requests for the program through March 31, 2027.

ADDRESSES: For additional information about the Program, please refer to FDA's web page at *https://www.fda.gov/drugs/development-resources/advancing-real-world-evidence-program.*

FOR FURTHER INFORMATION CONTACT: Nahleen Lopez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6360, Silver Spring, MD 20993–0002, 240–402–2659, *Nahleen.Lopez@fda.hhs.gov,* with the subject line ''Advancing RWE Program''; or Stephen Ripley, 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, *Stephen.Ripley@fda.hhs.gov,* with the subject line ''Advancing RWE Program.''

SUPPLEMENTARY INFORMATION:

I. Background

In connection with the seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII), incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to establishing the ''Advancing Real-World Evidence (RWE) Program,'' which seeks to identify approaches for generating RWE that meet regulatory requirements in support of labeling for effectiveness (*e.g.,* new indications, populations, dosing information) or for meeting post-approval study requirements. FDA is establishing and publicly communicating the Advancing RWE Program to satisfy this commitment. The Advancing RWE Program provides sponsors who are selected into the Program the opportunity to meet with Agency staff—before protocol development or study initiation—to discuss the use of RWE in medical product development. The Advancing RWE Program is an optional pathway for sponsors submitting RWE proposals; established procedures to engage with the Agency will continue to be available.

Meetings under the Advancing RWE Program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) during fiscal years 2023 to 2027. Oncology applications will include participation from the Oncology Center of Excellence. FDA will grant up to four meetings between CDER or CBER and a sponsor selected into the Advancing RWE Program to discuss approaches for generating RWE that can meet regulatory requirements. To promote awareness of characteristics of RWE that can support regulatory decisions, study designs discussed through the program may be presented by FDA in a public forum (*e.g.,* in a guidance or public workshop).

The Advancing RWE Program website includes current program eligibility criteria; format, content, and instructions for submission of initial and followup meeting requests; and information regarding a required disclosure agreement. The Program's website address is *https://www.fda.gov/drugs/development-resources/*

advancing-real-world-evidence-program.

II. Paperwork Reduction Act of 1995

This notice refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information resulting from formal meetings between sponsors or applicants and FDA have been approved under OMB control number 0910–001. The collections of information in 21 CFR part 312 (investigational new drug applications) have been approved under OMB control number 0910–0014.

Dated: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22795 Filed 10–19–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1400]

Complex Innovative Design Paired Meeting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The seventh iteration of the Prescription Drug User Amendments (PDUFA VII), included as part of the FDA User Fee Reauthorization Act of 2022, highlights the goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. The Food and Drug Administration (FDA or Agency) is announcing the continuation of the paired meeting program established under the sixth iteration of PDUFA that affords sponsors, who are selected, the opportunity to meet with Agency staff to discuss the use of complex innovative trial design (CID) approaches in medical product development. Meetings under the program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) during fiscal years 2023 to 2027. For each sponsor whose meeting request is granted, two meetings will be held between the sponsor and CDER or CBER that will provide an opportunity for medical product developers to discuss their CID proposals. To promote innovation in this area, trial designs developed through the paired meeting program may be presented by FDA (*e.g.,* in a guidance or public workshop) as case studies, including trial designs for drugs that have not yet been approved by FDA.

DATES: The CID Paired Meeting Program will proceed from October 1, 2022, through September 30, 2027. Sponsors may submit meeting requests for the program through June 30, 2027. Either electronic or written comments about this meeting program must be submitted by November 3, 2022.

ADDRESSES: You may submit comments about the CID paired meetings program 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 November 3, 2022. 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–2022–N–1400 for ''Complex Innovative Design Paired Meeting Program.'' 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:

CDER: Scott Goldie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New