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.

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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/*