TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					121

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimated total burden for warning plans for certain tobacco products is 121 hours, since FDA is revising this collection to incorporate the burden for cigar warning plans previously received under OMB control number 0910–0768 (which covers the burden for tobacco products subject to the Federal Food, Drug, and Cosmetic Act). Based on a 2020 order vacating the health warning requirements for cigars and pipe tobacco (set forth in §§ 1143.3 and 1143.5) and remanding the Final Deeming Rule's warning requirements for cigars and pipe tobacco, FDA has replaced the burden previously attributed to this activity with a placeholder of 1 hour, acknowledging that the regulation remains effective.

In regard to smokeless tobacco warning plans, FDA estimates a total of one respondent will submit a new original smokeless tobacco warning plan per year, which will take approximately 60 hours to complete, for a total of 60 burden hours. Additionally, FDA estimates a total of two respondents will submit a supplement to an approved smokeless tobacco warning plan, taking approximately 30 hours to complete per response, for a total of 60 burden hours. Thus, the total burden for the collection for smokeless tobacco warning plans is estimated to be 120 hours.

FDA has adjusted its burden estimate, which has resulted in a decrease of 60 hours and 2 respondents to the currently approved burden. This adjusted burden estimate is based on historical trends for smokeless tobacco warning plans. To date, FDA has received a total of 47 original smokeless warning plans, and a total of 33 supplements. However, from 2022–2024, FDA only received one original smokeless tobacco warning plan and a total of two supplements. Generally, after receiving the initial influx of original smokeless warnings plans, the number of annual warning plan submissions has decreased, and FDA does not expect submissions to increase at this time.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12413 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0308]

Agency Information Collection Activities; Proposed Collection; Comment Request; Emerging Drug Safety Technology Meeting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Emerging Drug Safety Technology Meeting (EDSTM) Program.

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 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 September 2, 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–2025–N–0308 for '' Emerging Drug Safety Technology 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emerging Drug Safety Technology Meeting Program

OMB Control Number—New

The pharmaceutical industry is expanding its use of artificial intelligence (AI) and other emerging technologies across the drug product lifecycle. FDA is interested in accelerating its understanding of the research, development, and use of AI and other emerging technologies in the area of pharmacovigilance, including their performance characteristics. The EDSTM program is a means by which applicants and other relevant parties who meet the eligibility and selection criteria for participation, can meet with the Center for Drug Evaluation and Research (CDER) to share information about their use of AI and other emerging technologies, and its potential application in pharmacovigilance (PV).

The initial phase of the EDSTM program was announced in the **Federal Register** on June 11, 2024 (89 FR 49179). CDER has received several meeting requests and inquiries from the pharmaceutical industry and other relevant parties, eager to share their latest applications of AI in PV. The requests represent a diverse set of AI use cases that are of interest to the Agency. Given the current level of interest in the program expressed by respondents, FDA anticipates an increase in the number of meetings granted to expand the Agency's understanding of how AI-enabled tools and other emerging technologies are being used for pharmacovigilance.

The goal of the EDSTM program is to facilitate mutual learning and discussion on the opportunities and challenges with using emerging technologies in PV. If selected for a meeting, application holders and/or other relevant parties will meet with CDER staff to discuss their research, development, and/or use of AI and other emerging technologies in PV. FDA plans to leverage these learnings to help inform potential regulatory and policy approaches relating to the use of AI and other emerging technologies in PV. EDSTMs will collect information for the following purposes: (1) serve as the central point of contact for dialogue between industry and CDER on the use of AI and other emerging technologies in PV; (2) enable knowledge management and transfer within FDA specific to the context of use for AI or other emerging technologies in PV; and (3) further thinking about policy and application of potential regulatory approaches within the landscape of AI and other emerging technologies.

Respondents include select applicants (applicant) with an approved new drug application or biologics license application and/or other relevant parties supporting industry's PV activities (*e.g.,* academia, contract research organizations (CROs), PV vendors, software developers). Respondents will provide an initial submission to FDA detailing their meeting proposal. We estimate this will require 10 hours to prepare. If selected for participation in the EDSTM, the respondent will need to prepare and deliver a 20–50 minute presentation, which will require an additional burden of 30 hours. FDA estimates 25 organizations will submit requests to present at EDSTMs per year, and a total of 12 meetings will be held per year.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Industry request to give presentation at EDSTM	25	1	25	10	250
Industry preparing and delivering presentation to EDSTM after the request has been granted	12	1	12	30	360
Total	25		37		610

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12418 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–N–5451, FDA–2024–N–2177, FDA–2024–N–3379, FDA–2021–N–1333]

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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
Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements	0910–0435	2/29/2028
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food and Food for Animals	0910–0751	2/29/2028
Laboratory Accreditation for Analyses of Foods	0910–0898	2/29/2028
Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases	0910–0906	2/29/2028

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12415 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0348]

Agency Information Collection Activities; Proposed Collection; Comment Request; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with the Center for Devices and Radiological Health Appeals Processes.

DATES: Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be