with ''stimuli'', (3) removing the youth screener from the burden table because parents determine the eligibility of their youth aged 12–17 (18 to 20 in Alabama and Nebraska in accordance with state law), (4) removing the young adult screener from the burden table, which will not be needed because young adult panel members (18–20 years old) will only receive an email invitation to complete the survey, (5) updating the burden table to reflect that we will send direct invitations to young adult panel members (18–20 years old), (6) updating the permission, assent, and consents because of updated information on the expected sample breakdown from the sample vendor for the distribution of the sample who are 12–17 and 18–20, (7) removing the thank you email since that will not be a part of the data collection procedures, (8) updating the focus of the stimuli and survey because FDA will assess cigarettes, e-cigarettes, and other emerging tobacco products and (9) updating the annualized cost burden estimates based on current data. In addition to the implementation evaluation described above, we will conduct formative evaluation to assess perceptions to proposed stimuli and potential unintended consequences in order to inform the development of future messaging.

In addition to those changes described above since the publication of the 60-day **Federal Register** notice, on our own initiative for efficiency of Agency operations, we are revising the information collection request from a ''stand-alone'' to an umbrella generic. This change will enable FDA to rotate and test different modules of the MIA study on a monthly basis and collect mixed methods data in a timely and efficient manner.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12420 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–0956]

Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Certain Tobacco Products

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 collection provisions associated with warning plans for certain tobacco products.

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–0956 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Certain Tobacco Products.'' 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 including each proposed extension of an existing 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.

Warning Plans for Certain Tobacco Products

OMB Control Number 0910–0671—Revision

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Implementing regulations are found in 21 CFR subchapter K (21 CFR parts 1100 through 1150). Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402) requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. (15 U.S.C. 4402(a)(1)). The label statements specified in 15 U.S.C. 4402(a)(1) must be randomly displayed on packaging and randomly distributed ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA. (15 U.S.C. 4402(b)(3)(A)). Those labels must be rotated quarterly in advertisements for each brand of smokeless tobacco product, also ''in accordance with a plan'' and subject to approval by FDA. (15 U.S.C. 4402(b)(3)(A)). Similarly, all cigar packages and advertisements bear one of six required warning statements, which must be displayed on packaging and advertising for each brand of cigars ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA. (21 CFR 1143.5).

To implement statutory requirements for smokeless tobacco products, warning plans are reviewed by FDA, upon submission by respondents. (21 U.S.C. 4402(b)(C)(3)). FDA published a draft guidance entitled ''Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products'' on September 9, 2011, which describes the information and format to be submitted for smokeless plans (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-warning-plans-cigarettes-and-smokeless-tobacco-products*). Submitters may also visit a web page that describes the smokeless tobacco labeling and warning statement requirements (*https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/smokeless-tobacco-labeling-and-warning-statement-requirements*). Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan. Warning plans can be submitted either electronically or in paper format. The Center for Tobacco Products (CTP) Portal, available at *https://ctpportal.fda.gov/ctpportal/login.jsp,* provides a secure online system for electronically submitting documents and receiving messages from CTP.

FDA published a draft guidance for cigar warning plans entitled ''Submission of Warning Plans for Cigars'' in August of 2018, which describes the information and format to be submitted for cigar plans (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-certain-labeling-and-warning-statement-requirements-cigars-and-pipe-tobacco*). However, the U.S. District Court for the District of Columbia issued an order vacating the health warning requirements for cigars and pipe tobacco set forth in 21 CFR 1143.3 and 1143.5 (§§ 1143.3 and 1143.5) and remanding the Final Deeming Rule's warning requirements for cigars and pipe tobacco back to the Agency. See Order, *Cigar Ass'n of Am.* v. *U.S. Food and Drug Admin.,* No. 1:16–cv–01460 (D.D.C. September 11, 2020). Although the requirement has been vacated, cigar and pipe tobacco firms may choose to voluntarily comply with these health warning provisions.

Based on FDA's experience over the years, FDA retains the estimate of 60 hours to complete an original rotational warning plan. FDA estimates that preparing and submitting a supplement to an approved plan will take half this time (30 hours).

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
Submission of original rotational plans for health warning statements for smokeless tobacco products	1	1	1	60	60
Supplement to approved plan for smokeless tobacco products	2	1	2	30	60
21 CFR part 1143 Cigar Warning Plans	1	1	1	1	1

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