DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

June 27, 2025—Agency Information Collection Activities; Proposed Collection; Comment Request; Meetings With Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) 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 the information collection contained in FDA's guidance titled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised).''

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 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 August 26, 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–2012–D–0429 for ''Guidance on Meetings with Industry and Investigators on the Research and Development of 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.

Meetings With Industry and Investigators on the Research and Development of Tobacco Products

OMB Control Number 0910–0731—Extension

This information collection supports FDA guidance. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce.

To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate as described in FDA's guidance titled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised)'' (September 2022; *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products-revised*). This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products.

This guidance describes two collections of information: (1) the submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance and the revisions consistent with FDA's good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name;
2. FDA-assigned Submission Tracking Number(s) of prior submissions (*e.g.,* premarket applications, meeting requests) for the product and relevant product version(s) (if applicable);
3. Product category (*e.g.,* cigarettes, smokeless tobacco) (if applicable);
4. Product use (indicate for consumer use or for further manufacturing);
5. Contact information for the authorized point of contact for the company requesting the meeting;
6. The topic of the meeting being requested (*e.g.,* a new tobacco product application, an application for permission to market a modified risk tobacco product, or proposed investigational use of a new tobacco product);
7. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
8. A preliminary list of the specific objectives/outcomes expected from the meeting;
9. A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item;
10. A preliminary list of specific critical questions, grouped by discipline (*e.g.,* chemistry, clinical, nonclinical);
11. A list of all individuals who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator, including titles, responsibilities, and if applicable, identification of prior FDA employment;
12. The date on which the meeting information package will be received by FDA; and
13. Suggested format of the meeting (*e.g.,* conference call, in-person meeting at FDA offices, video conference, or written response) and suggested dates and times for the meeting. Meetings are usually scheduled for 1 hour. FDA is proposing the inclusion of a new recommendation that a meeting request identify prior FDA employment for any individual who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator, if applicable. This information would indicate if the individual is subject to certain post-government employment restrictions.

This information contained in the meeting request will be used by the Agency to: (1) determine the utility of the meeting, (2) identify Agency staff necessary to discuss proposed agenda items, and (3) schedule the meeting.

Meeting Information Packages: An individual submitting a meeting information package to FDA in advance of a meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the individual or FDA to be discussed at the meeting. As stated in the guidance, FDA recommends that meeting information packages generally include updates of information that was submitted with the meeting request and, as applicable:

1. Product composition and design data summary;
2. Manufacturing and process control data summary;
3. Nonclinical data summary;
4. Clinical data summary;
5. Behavioral and product use data summary;
6. User and nonuser perception data summary; and
7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):
   a. Study objective(s);
   b. Study hypotheses;
   c. Study design;
   d. Study population (inclusion/exclusion criteria, comparison group(s));
   e. Human subject protection information, including Institutional Review Board information;
   f. Primary and secondary endpoints (definition and success criteria);
   g. Sample size calculation;
   h. Data collection procedures;
   i. Duration of follow up and baseline and follow up assessments, and
   j. Data analysis plan(s).

The purpose of the meeting information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. If the meeting information package was previously submitted in the meeting request, it should be revised, as applicable, so that the information reflects the most current and accurate information available.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers; Guidance section III.E	60	1	60	12	720
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers; Guidance section III.K	60	1	60	18	1,080
Total					1,800

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

FDA's estimate of the number of respondents for meeting requests in table 1 is based on the number of meeting requests received and projected over the next 3 years. FDA estimates that 60 meetings will be requested over the next 3 years. We have revised this estimate from 65 respondents to 60 respondents.

The hours per response for combining and sending meeting request letters are estimated at 12 hours each, and the total burden hours for meeting requests are expected to be 720 hours. We have revised the average burden per response from 10 hours to 12 hours. Based on FDA's experience, the Agency expects it will take respondents 720 hours to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting, including identifying prior FDA employment for any individual who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator.

FDA estimates that 60 respondents will compile and submit meeting information packages at 18 hours per response, and the total burden hours for submitting meeting information packages are expected to be 1,080 hours. We have revised this estimate from 65 respondents to 60 respondents. Based on FDA's experience, the Agency expects that it will take respondents, collectively, 1,080 hours to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information, that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 1,800 hours (720 hours to prepare and submit meeting requests and 1,080 hours to prepare and submit information packages).

Our estimated burden for the information collection reflects an overall decrease of 20 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years and our projections for the next 3 years.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11948 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2253]

Medical Device User Fee Amendments; Stakeholder Meetings on the Medical Device User Fee Amendments of Fiscal Years 2028 to 2032 Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Medical Device User Fee Amendments (MDUFA). The statutory authority for MDUFA expires September 30, 2027. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings on or before July 28, 2025. Stakeholder meetings will be held monthly. It is anticipated that they will commence by October 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *MDUFAVIReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA White Oak campus, 10903 New Hampshire Ave., Silver Spring, MD 20993 and virtually using the Microsoft Teams platform. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to *https://www.dhs.gov/real-id/real-id-faqs.*

FOR FURTHER INFORMATION CONTACT: Nia Benjamin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–5424, *MDUFAVIReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of