United States Food and Drug Administration

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

OMB Control No. 0910-0731--EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us, or we) guidance. The guidance that includes this information collection is intended to assist tobacco manufacturers, importers, researchers, and investigators, and their representatives who seek meetings with the Office of Science within FDA's Center for Tobacco Products (CTP) relating to their plans to conduct research to inform the regulation of tobacco products or support the development or marketing of tobacco products. This guidance does not pertain to other types of meetings or meeting requests with CTP staff. The information collected will help FDA better understand issues discussed during these meetings. FDA issued this guidance and the revisions consistent with FDA's good guidance practices regulations (21 CFR 10.115).

The Federal Food, Drug, and Cosmetic Act (the 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, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) 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 meets with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate as described in FDA's guidance document entitled, "Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised)" (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. In the guidance, the agency discusses, among other things:

- What information FDA recommends persons include in such a meeting request;
- How and when to submit such a request; and
- What information FDA recommends persons submit prior to such a meeting.

I. 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 FDA 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 authorization 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 revising the guidance to include 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 as referenced in 5 CFR Part 2641.

II. 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.

We therefore request extension of OMB approval of the information collection provisions found in the guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. The guidance describes two collections of information: (1) the submission of a meeting request containing certain information, and (2) the submission of a meeting information package in advance of the meeting. The meeting request information will be used by the agency to determine the utility of the meeting, identify agency staff necessary to discuss proposed agenda items, and schedule the meeting. 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. For information that was previously submitted in a

meeting request, the information package should provide updated information that reflects the most current and accurate information available.

Because these meetings often represent important opportunities in the regulatory process, efficient, consistent procedures are important for the timely and effective conduct of such meetings. This guidance and the information collection are intended to provide consistent principles and procedures to promote well-managed meetings pertaining to tobacco product research and development

The respondents to this collection of information are from the private sector, which could include manufacturers, importers, researchers, and investigators of tobacco products who seek to meet with FDA to discuss their plans regarding the development or marketing of a tobacco product.

3. Use of Improved Information Technology and Burden Reduction

The agency has considered the possible impact of improved information technology and determined that, although improved technology may not reduce the burden significantly, electronic submission is available and may reduce some burden. Based on information related to other FDA information collections, we estimate that 90 percent of respondents will submit their meeting information packages electronically.

As discussed in the guidance document, electronic submission is not required, although we strongly encourage electronic submission via the CTP Portal Next Generation (CTP Portal NextGen) using FDA's eSubmitter tool. Instructions on obtaining a CTP Portal NextGen account are available at www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal-next-generation .

The CTP Portal NextGen web application requires that an organization request an Industry Account Manager (IAM) role be set up for an individual of the organization to act as an administrator for all of the organization's CTP Portal NextGen accounts. Once the IAM account is created by CTP, the IAM can create, manage, and set roles for all of the organization's employees' CTP Portal NextGen user accounts. Users may then prepare submissions on behalf of their organization using the FDA's eSubmitter tool for supported submission types and can send these submissions to CTP directly from CTP Portal NextGen. Instructions on requesting a free IAM account for CTP Portal NextGen are available at www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal-next-generation .

Alternatively, respondents can mail submissions to FDA, as instructed in the guidance document.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection does not fall disproportionately upon small businesses. Small businesses may submit these requests; however, the procedures for providing this information to

FDA are the same for businesses of all sizes. This information may be submitted by any manufacturer of tobacco products, either electronically or by paper submission.

FDA aids small business in dealing with the information submission recommendations of this collection of information by providing technical, nonfinancial assistance in submitting the information.

6. Consequences of Collecting the Information Less Frequently

FDA staff intends to participate in several meetings with industry and investigators who seek assistance relating to the research and development of particular tobacco products. Because these meetings often represent important opportunities for FDA and stakeholders to discuss future submissions, efficient, consistent procedures are important for the timely and effective conduct of such meetings. This guidance is intended to provide consistent principles and procedures to promote well-managed meetings pertaining to tobacco product research and development. If this information was not collected, FDA, industry, researchers, and investigators would not have productive and efficient meetings.

The guidance requests that respondents send meeting requests and information packages to FDA prior to meetings to ensure that meetings are conducted in a timely and efficient manner.

There are no legal obstacles to reducing the burden. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of June 27, 2025 (90 FR 27636). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Several laws govern the confidentiality of information submitted to CTP under the FD&C Act, including sections 301(j) and 906(j) of the FD&C Act (21 U.S.C. 331, 387f, and 387k), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552). Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions. Section 906(c) of the

FD&C Act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under several FD&C Act provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade secret information obtained by FDA under several FD&C Act provisions, outside of the Department of Health and Human Services (HHS), except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized Congressional request. Information provided by respondents under this information collection will be kept private and anonymous, except as otherwise required by law.
CTP consulted with FDA's Privacy office, which conducted a Privacy Impact Assessment (PIA). CTP received HHS approval on the PIA and was assigned PIA ID: FDA2107988.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the annual burden for this information collection as follows:

In the burden hour table below, we calculate a total of 20 annual respondents.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers.	20	1	20	12	240
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers.	20	1	20	18	360
Totals					600

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 preapplication meetings will be requested over the next 3 years (20 each year on average). This adjusted respondent estimate is based on recent historical meeting requests and reflects the projected requested meetings over the next 3 years.

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 240 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time 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 20 respondents will compile and submit meeting information packages annually at 18 hours per response. Based on FDA's experience, the agency expects that it will take respondents, collectively, 360 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.
In addition, this collection includes part of the burden previously attributed to "requests for meetings with CTP's Office of Science to discuss investigational plans" in information collection 0910-0768 (which covers the burden for tobacco products subject to the FD&C Act). Information collection 0910-0768 is being consolidated, since the above mentioned burden is accounted for in this collection, therefore avoiding overestimation of burden.

The total annual number of burden hours for this collection of information is estimated to be 600 hours (240 hours to prepare and submit meeting requests and 360 hours to prepare and submit information packages).

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for meeting requests and meeting information packages is $92,274. To reflect this estimate accurately, a composite wage was calculated from the 2024 BLS national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry (Department of Labor's Bureau of Labor Statistics (BLS) May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 312200 – Tobacco Manufacturing, data.bls.gov/oes/#/industry/312200). We use a mix of 50 percent management occupations (average hourly wage $76.92) and 50 percent legal occupations (average hourly wage $76.87). This mix yields a composite wage of $76.90 (=($76.92 x 50%) + ($76.87 x 50%). We double this to account for benefits and overhead, yielding an hourly wage of $153.79.

Table 2.—Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers, Importers, Researchers, and Investigators	600	$153.79	$92,274

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital, start-up, or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The estimated total annualized cost to the federal government for this information collection is $265,276. Our estimated cost reflects the allocation of one (1) federal full-time equivalent (FTE) employee who collects, processes, and files responses received. Using 2025 salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/pdf/DCB.pdf for a GS-13/ Step 4 employee, we calculate a total annual cost to the federal government of $132,638 ($132,638 x 1). We double this to account for benefits and overhead, yielding a total annual cost of $265,276.

15. Explanation for Program Changes or Adjustments

Program Changes

As described above, FDA is revising the guidance to include 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. Therefore, FDA has adjusted its meeting requests average burden per response estimate to reflect an increase of 2 hours per response to account for time needed to identify prior FDA employment.

Adjustments

FDA has adjusted its respondent estimates based on recent experience with this information collection. Based on recent meeting requests data, we have lowered our estimate of annual meeting requests and meeting information packages submitted from 65 to 20. We re-evaluated the occupational employment categories for staff creating the meeting requests and reviews. Based on recent experience, a composite wage estimage including 50 percent management and 50 percel legal occupations to capture the estimated annualized cost burden accurately. This resulted in a total respondent cost increase from $53,437.20 to $92,274.

Total Burden Impacts

Based on the combined impacts of program changes and adjustments describes above, FDA's estimated burden for the entire information collection reflects an overall annual decrease of 1,220 hours and 90 respondents (45 fewer respondents submitting meeting requests, and 45 fewer respondents submitting metting information packages). The total burden hours for the collection have been reduced from 1,820 hours to 600 total hours. FDA's estimated cost burden to the respondents has increased from $53,437.20 to $92,274 due to a re-assessment of staff occupational employment categories needed to create and review meeting requests and packages.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in this notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.