U.S. Food and Drug Administration
Center for Tobacco Products
Meetings With Industry and Investigators on the Research and Development of Tobacco Products

0910-0731

SUPPORTING STATEMENT

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 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.

The Federal Food, Drug, and Cosmetic Act (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 will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate. We developed the guidance document entitled, "Meetings with Industry and Investigators on the Research and Development of Tobacco Products", (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products). This guidance is intended to assist persons who seek guidance 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 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 an MRTP, or 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 and responsibilities;
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.

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

We request 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

This 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 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. If this information was not collected, FDA, industry, researchers, and investigators would not have productive and efficient meetings.

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 would 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 using FDA's eSubmitter tool. Instructions on obtaining a CTP Portal account are available at https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal

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 submission of meeting requests and information packages by small businesses should not be burdensome. Small businesses may submit these requests; however, the procedures for providing this information to FDA are the same for businesses of all sizes and are not overly burdensome.

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.

Respondents need to 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 reduce 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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of Feburary 2, 2022, (87 FR 5824) requesting public comment on the proposed collection of information. FDA received one comment that was not PRA related.

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

Section 101 of the Family Smoking Prevention and Tobacco Control Act protects certain information from disclosure (see Public Law 111-31, June 22, 2009). Information provided by respondents 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 privacy impact assessment and was assigned PIA ID 2060831.

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'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 65 preapplication meetings will be requested.

The hours per response for combining and sending meeting request letters are estimated at 10 hours each, and the total burden hours for meeting requests are expected to be 650 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.

FDA estimates that 65 respondents will compile meeting information packages and submit to FDA at 18 hours per response. Based on FDA's experience, the Agency expects that it will take respondents, collectively, 1,170 hours to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information, including identifying prior FDA submissions for the product or relevant versions of the product, that generally would already have been generated for the planned research and/or product development.

This estimate now includes meeting requests from manufacturers of products containing non tobacco nicotine (NTN). On March 15, 2022, President Biden signed H.R. 2471 – the Consolidated Appropriations Act, 2022 on March 15, 2022. As a result, the Federal Food, Drug, and Cosmetic Act (FD&C Act) now includes specific language that makes clear the U.S. Food and Drug Administration has the authority to regulate tobacco products containing nicotine from any source. Our estimate for this collection now includes meeting requests from manufacturers of products containing non tobacco nicotine (NTN). We based our updated estimate on the number of bundled PMTA applications we might receive (15), and assuming 1/3 of these submissions (5) will submit a meeting request.

The total number of burden hours for this collection of information is estimated to be 1,1820 hours (650 hours to prepare and submit meeting requests and 1,170 hours to prepare and submit information packages).

Table 1.--Estimated Annual Reporting Burden[1]

Meeting requests and information packages	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.	65	1	65	10	650
Meeting Information Packages					

Table 1.--Estimated Annual Reporting Burden[1]

Meeting requests and information packages	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Combining and submitting meeting information packages for manufacturers, importers, and researchers.	65	1	65	18	1,170
Totals					1,820

12b. Annualized Cost Burden Estimate

The costs of this collection of information are $55,437.20 (1,820 x $30.46), which is the seasonally adjusted average Bureau of Labor Statistics (BLS) May 2020 average (mean) hourly wage for all occupations (https://www.bls.gov/oes/2020/may/naics4_312200.htm) (NAICS 312200) - Tobacco Manufacturing.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers, Importers, Researchers, and Investigators	1,820	$30.46	$53,437.20

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

There are no additional capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Our estimated cost to the Federal government reflects the allocation of 1 full-time equivalent (FTE) employee who collect, process, and file responses received. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for a GS-13/4 employee, we calculate a total cost of $117,505 ($117,505 x 1).

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 504 hours and 18 respondents. Additionally based on new authority for NTN products twe added 5 respondents. We attribute this adjustment to the number of meeting requests received the last few years and the number of requests projected for the next few years.

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 that 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.