

GUIDANCE ON 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 approval request is for a Food and Drug Administration (FDA) guidance for industry entitled “Meetings with Industry and Investigators on the Research and Development of Tobacco Products.” 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. 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 and FDA-assigned Submission Tracking Number (if applicable);
2. Product category (e.g., cigarettes, smokeless tobacco) (if applicable);

3. Product use (indicate for consumer use or for further manufacturing);
4. Contact information for the authorized point of contact for the company requesting the meeting;
5. 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;
6. 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;
7. A preliminary list of the specific objectives/outcomes expected from the meeting;
8. A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item;
9. A preliminary list of specific questions, grouped by discipline (e.g., Chemistry, Clinical, Nonclinical);
10. 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;
11. The date on which the meeting information package will be received by FDA; and
12. 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.

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.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is intended to assist tobacco manufacturers, importers, researchers, and/or investigators who seek meetings with CTP regarding their research and development plans related to tobacco products.

Because of the unique nature of the information to be collected, duplication of information is highly unlikely. Meeting requests and information packages submitted by potential respondents are not duplicative, and every response should be different.

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 September 12, 2018, (83 FR 46174) requesting public

comment on the proposed collection of information. Three comments were received however none were PRA related.

9. Explanation of Any Payment or Gift to Respondents

FDA did not provide any payment or gift to respondents.

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.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked.

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 shown in table 1 is based on the number of meeting requests received and expected to be received over the next 3 years. FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting requests each year, as shown in table 1, to be 83.

The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by this guidance to be submitted with a meeting request is estimated to be approximately 10 hours each, and the total burden hours are 830 hours (10 hours preparation/ mailing x 67 average respondents per year). 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's estimate of the number of respondents for compiling meeting information packages in table 1 is based on 83 respondents each preparing copies of their information package and submitting them to FDA. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package as recommended by the guidance, is estimated to be approximately 18 hours per information package. Based on FDA's experience, the Agency expects that it will take respondents 1,494 hours of time (67 respondents times 18 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 2,324 hours (830 hours to prepare and submit meeting requests and 1,494 hours to prepare and submit information packages).

Table 1.--Estimated Annual Reporting Burden¹

| 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. | 83 | 1 | 83 | 10 | 830 |
| Meeting Information Packages | | | | | |
| Combining and submitting meeting information packages for manufacturers, importers, and researchers. | 83 | 1 | 83 | 18 | 1,494 |
| Totals | | | | | 2,324 |

12b. Annualized Cost Burden Estimate

The costs of this collection of information is \$77,319 (2,324 x \$33.27), which is the seasonally adjusted average Bureau of Labor Statistics (BLS) May 2017 average (mean) hourly wage for all occupations¹.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|--------------------|--------------------|------------------|------------------------|
| Manufacturers, | 2,324 | \$33.27 | \$77,319 |

¹ http://www.bls.gov/regions/mid-atlantic/news-release/occupationalemploymentandwages_washingtondc.htm

| | | | |
|---|--|--|--|
| Importers, Researchers, and Investigators | | | |
|---|--|--|--|

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

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

14. Annualized Cost to the Federal Government

The anticipated cost to the government is the equivalent of one full-time equivalent (FTE) employee to collect, process, and file the responses received for a total cost of \$116,000.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 16 respondents and 448 hours. We attribute this adjustment to an increase in the number of industry meetings as the premarket tobacco product application compliance deadlines will come due in the next 3 years. Additionally, the cost burden has increased by 18,750 due to the burden adjustment and updated wage rates.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected will not be used for statistical purposes.

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

The Agency is not seeking approval to exclude the display of the expiration date of OMB approval for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.