GUIDANCE ON MEETINGS WITH INDUSTRY AND INVESTIGATORS ON THE RESEARCH AND DEVELOPMENT OF TOBACCO PRODUCTS

0910-[NEW]

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 staff of 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 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 tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market particular products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) where 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.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

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 an 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, and they could be 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 take advantage of submitting 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. While small businesses may be expected to submit these requests, the procedures for providing this information to FDA remain the same for businesses of all sizes and are not overly burdensome.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond occasionally, when they need to schedule a meeting with FDA.

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 such 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 the FEDERAL REGISTER of May 25, 2012, (77 FR 31368), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one response containing PRA-related comments. The comment indicated that the guidance should clarify that meeting request times will vary depending on the type of submission to be discussed and the meeting information package requirements should be tailored to the submission type.

In response, the estimated burden hours for both meeting requests and meeting information package requirements have been calculated by FDA and are based on an average number of hours for each type of submission over a 3-year period. The meeting information requirements are also averaged together and are not individually split into submission types for this collection. The commenter also provided comments that were not PRA-related and are beyond the scope of this document.

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 to be received over the next 3 years. In year 1 of this collection, FDA estimates that 50 preapplication meetings will be requested. In year 2, FDA estimates that 100 meetings will be requested, especially as applications and reports for substantial equivalence, etc., are received and acted upon. Once the public knows more about submitting these applications in year 3, the request for meetings is expected to drop back to the year 1 rate of 50 per year. Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting request requests in table 1 to be 67 (50 year 1 requests + 100 year 2 requests + 50 year 3 requests divided by 3). 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 670 hours (10 hours preparation/mailing times 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 67 respondents each preparing copies of their information package and submitting them to FDA, for a total of 1,206 hours annually. 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 1,206 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 1,876 hours (670 hours to prepare and submit meeting requests and 1,206 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.	67	1	67	10	670
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers.	67	1	67	18	1,206
Collection Totals					1,876

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

12b. Annualized Cost Burden Estimate

The costs of this collection of information is $49,526 (1,876 x $26.40), which is the seasonally adjusted average Bureau of Labor Statistics (BLS) June 2011 hourly wage.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers, Importers, Researchers, and Investigators	1,876	$26.40	$49,526

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

This is a new information collection.

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.