4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0429]

# Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products." This guidance describes FDA's current policies and recommendations with respect to Agency meetings with tobacco manufacturers, importers, researchers, and/or investigators relating to their plans to conduct research to inform the regulation of tobacco products, or support the development or marketing of tobacco products. The guidance is intended to assist persons seeking a meeting with FDA to discuss the research and development of tobacco products. This guidance does not pertain to other types of meetings or meeting requests with Center for Tobacco Products (CTP) staff.

DATES: Submit either electronic or written comments on this guidance at any time. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] (see section III. Paperwork Reduction Act of 1995 in this document).

ADDRESSES: Submit written requests for single copies of the guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" to the Center

for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments, including comments on the proposed collection of information, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the guidance:

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With regard to the proposed collection of information:

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SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products." This guidance is intended to assist tobacco manufacturers, importers, researchers, and investigators, and their representatives who seek meetings with staff of FDA's 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 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 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.

## II. Significance of Guidance

FDA is issuing this guidance as a level 2 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115). The guidance represents the Agency's current thinking on "Meetings with Industry and Investigators on the Research and Development of Tobacco Products." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320(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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this 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 on 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.

Guidance for Industry: Meetings with Industry and Investigators on the Research and Development of Tobacco Products

This guidance is intended to assist persons seeking to have a meeting with FDA on the research and development of tobacco products. This guidance document discusses, among other things: What information FDA recommends that persons include in a meeting request, how and when to submit a request, and what information FDA recommends that persons submit prior to the meeting.

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.

A. Meeting Requests

Section IV.E of 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. Under 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, etc.) (if applicable);
3. Product use (indicate for consumer use or for further manufacturing);
4. Contact information for individual or company requesting the meeting;

5. The type of meeting being requested;

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 draft list of the specific objectives/outcomes expected from the meeting;

8. A preliminary proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s);

9. A draft list of specific questions, grouped by discipline;

10. A list of all individuals (including titles and responsibilities) who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator;

11. The approximate date on which supporting documentation (i.e., the meeting information package) likely will be received by FDA; and

12. Suggested dates and times for the meeting (note that generally a meeting will be scheduled for approximately 1 to 1.5 hours).

This information 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.

B. 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 section IV.K of the guidance, FDA recommends that meeting information packages generally

include updated information from the meeting request (see items 1 through 8 in section III.A of this document) and:

1. Chemistry, manufacturing, and control data summary (as applicable);

2. Preclinical data summary (as applicable);

3. Clinical data summary (as applicable);

4. Behavioral and product use data summary (as applicable);

5. User and nonuser perception data summary (as applicable); and

6. 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 followup and baseline and followup 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.

## C. Description of Respondents

The respondents to this collection of information are 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.

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

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.

FDA's estimate of the number of respondents for meeting requests in table 1 of this document is based on the number of meeting requests to be received over the next 3 years. In the first year 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 of this document 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 of this document 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 (67 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).

## IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## V. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at http://www.regulations.gov or http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.

Dated:May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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