applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16385 Filed 7–29–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Meetings With Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 31, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0731. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910–0731—Extension

The Family Smoking Prevention and 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 as described in ''Guidance on 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 meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. The original guidance issued in 2012 was revised for updating and clarity in July 2016.

In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in a meeting request;
- How and when to submit a request; and
- What information FDA recommends persons submit prior to a 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. FDA issued this guidance and the revisions consistent with FDA's good guidance practices regulations (21 CFR 10.115).

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 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 permission to market a modified risk tobacco product, 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. FDA is proposing that a meeting request include the FDA-assigned submission tracking numbers of relevant product version(s), if applicable, to allow for FDA to reference such information to better assess and respond to the issues and questions raised in the meeting request.

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.

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 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. If the 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.

In the **Federal Register** of February 2, 2022 (87 FR 5824), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was not PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers	65	1	65	10	650
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers	65	1	65	18	1,170
Total					1,820

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

On March 15, 2022, after publication of the 60-day notice, President Biden signed H.R. 2471—the Consolidated Appropriations Act, 2022. As a result, the Federal Food, Drug, and Cosmetic Act now includes specific language that makes clear FDA 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. We based our updated estimate on the number of bundled premarket tobacco product applications we might receive (15) assuming ⅓ of these submissions (5) will submit a meeting request. As such, we have increased our estimated respondents for meetings from 60 to 65. 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 now 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.

The total number of burden hours for this collection of information is estimated to be 1,820 hours (650 hours to prepare and submit meeting requests and 1,170 hours to prepare and submit information packages). Our estimated burden for the information collection reflects an overall decrease of 504 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years and our projections for the next 3 years.

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16388 Filed 7–29–22; 8:45 am]

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