4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0305]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 0910-0768. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0768--Extension

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Implementing regulations are found in 21 CFR subchapter K (parts 1100 through 1150 (21 CFR parts 1100 through 1150)). This information collection supports the reporting, recordkeeping, and third-party disclosure requirements associated with statutory requirements applicable to tobacco products and set forth in Agency regulations. Section 910(a)(1) of the FD&C Act defines a "new tobacco product" as a tobacco product that was not commercially marketed in the United States on February 15, 2007, or a modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. An order under section 910(c)(1)(A)(i) of the FD&C Act is required prior to marketing a new tobacco product. This requirement applies unless the product has been shown to be substantially equivalent to a valid predicate product or is exempt from substantial equivalence (21 CFR 1107.1).

Section 910(b) of the FD&C Act states that a premarket tobacco application (PMTA) (part 1114) shall contain full reports of all investigations of health risks; a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product; a full description of methods of manufacturing and processing (which includes a listing of all manufacturing, packaging, and control sites for the product); an explanation of how the product complies with applicable tobacco product standards; samples of the product and its components; and labeling.

FDA also encourages persons who would like to study their new tobacco product to meet with the Office of Science (OS) in the Center for Tobacco Products (CTP) to discuss their

investigational plan. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss agenda items. Details regarding the process for requesting a meeting with OS and how FDA will respond may be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products.

FDA efforts regarding issuance of a final guidance for Harmful and Potentially Harmful Constituent reporting (and later a testing and reporting regulation under section 915 of the FD&C Act) is ongoing, and the guidance document will be issued consistent with our good guidance practice regulations found in 21 CFR 10.115, which provide for public comment at any time.

In the *Federal Register* of April 28, 2022 (87 FR 25280) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (PMTA application) and 21 CFR 25.40 Environmental Assessments	200	3.75	750	1,713	1,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan	27	1	27	10	270
21 CFR part 1143 Cigar Warning Plans	1	1	1	1	1
Total					1,285,021

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

FDA estimates an average burden per respondent of 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. We assume, on average, an additional 213 hours is necessary to prepare an environmental assessment in accordance with the requirements of 21 CFR 25.40, for a total of 1,713 hours per PMTA application. This average represents a wide range of hours that will be required for these

applications under different circumstances, with a small number requiring more hours (e.g., as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (e.g., as few as 50 hours for applications for products that are very similar to other new products). A PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 electronic nicotine delivery systems (ENDS) Liquids and 108 ENDS Delivery Systems).

FDA anticipates that the 27 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. This number has been reduced based on the average number of meeting requests received over the past 3 years. To request this meeting, applicants should compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 270 hours to compile and request a meeting with OS. We have revised the hours per response to be consistent with the meetings information collection for originally regulated products (OMB control number 0910-0731).

Based on the September 2020 order vacating the health warning requirements for cigars and pipe tobacco (set forth in 21 CFR 1143.3 and 1143.5) and remanding the Final Deeming Rule's warning requirements for cigars and pipe tobacco, we have removed the burden associated with this activity. We have included 1 token hour of burden associated with the requirements in part 1143 to acknowledge that the requirement remains in the regulations.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. The total estimated burden for this information collection is 1,285,021 reporting hours and 778 annual responses. Our estimated burden for the information collection reflects an overall decrease of 2,779 hours and a corresponding decrease of 262 responses. We attribute this adjustment to updated information in the number of meeting requests with CTP's

Office of Science to discuss investigational plans, the removal of burden for the cigar warning plans, the removal of the small-scale manufacturer reporting, and have therefore revised the estimated burden and number of respondents to the information collection.

Dated: October 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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