NDAs and the collections of information and (2) the submissions required by section 760 of the FD&C Act for nonprescription human drug products marketed without an approved application have been approved under OMB control number 0910–0230. The collections of information in 21 CFR part 600 for biological drug products have been approved under OMB control number 0910–0308. The collections of information pertaining to the electronic submission of adverse event reports in 21 CFR parts 310, 314, and 329 have been approved under OMB control number 0910–0645. The collections of information pertaining to submissions required for outsourcing facilities under section 503B of the FD&C Act have been approved under OMB control number 0910–0800. The collections of information in 21 CFR part 4 pertaining to postmarketing safety information sharing by constituent part applicants for combination products have been approved under OMB control number 0910–0834.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09065 Filed 4–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0305]

Agency Information Collection Activities; Proposed Collection; 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, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act.''

DATES: Submit either electronic or written comments on the collection of information by June 27, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 27, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 27, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–0305 for ''Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezzuto, Office of Operations, Food and Drug

Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing 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 of 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.

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 (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 (21 U.S.C. 387j(a)(1)) 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) (21 CFR 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. The following web page details the process for requesting a meeting with OS and how FDA will respond: *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.

We estimate 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 (in hours)	Total hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (PTMA 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
§ 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 §§ 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 one token hour of burden associated with the requirements in § 1143 to acknowledge 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: April 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09072 Filed 4–27–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3758]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 May 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 0910–0814. 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.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910–0814—Revision

This information collection supports Agency regulations in 21 CFR part 312, subpart I, Expanded Access to Investigational Drugs for Treatment Use; associated guidance; and Form FDA 3926, Individual Patient Expanded Access Investigational New Drug Application (IND). The regulations govern the use of investigational new drugs, biologics, and approved drugs if availability is limited by a risk evaluation and mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The goal of the expanded access program is to facilitate the availability of such products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. The regulations provide that certain criteria be met, establish content and format requirements for associated reporting, and require that submissions include a cover sheet.

Although we continue to account for burden associated with the submission of expanded access requests for individual patients, we are revising the information collection to also account for burden attendant to other expanded access submissions, including commercial investigational new drug applications (INDs) that involve large groups of patients enrolled for treatment use of the investigational drug (§§ 312.300 through 312.320 (21 CFR 312.300 through 312.320)), currently approved under OMB control number 0910–0014. Because of FDA's long history of facilitating expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions, our efforts in this regard are ongoing.

Form FDA 3926 was developed to assist respondents to the information collection. Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians who want to request expanded access as prescribed in the applicable regulations. To supplement the form instructions, we issued guidance, most recently updated in October 2017, entitled ''Individual Patient Expanded Access Applications: Form FDA 3926,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/*