



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; Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 the information collection "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act)."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 "Deeming Tobacco Products To Be Subject to the FD&C 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.

- 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.gpo.gov/fdsys/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.

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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: 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 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.

#### Deeming Tobacco Products To Be Subject to the FD&C Act

##### OMB Control Number 0910-0768--Extension

The Tobacco Control Act, enacted on June 22, 2009, amended the FD&C Act and provided FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). Specifically, section 101(b) of the Tobacco Control Act amended the FD&C Act by adding chapter IX (21 U.S.C. 387 through 387u), which provides FDA with tools to regulate tobacco products. Section 901 of the FD&C Act (21 U.S.C. 387a) states that Chapter IX--Tobacco Products applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to this chapter.

The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. On May 10, 2016 (81 FR 28973) FDA issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the FD&C Act. This final rule extended FDA's "tobacco product" authorities under Chapter IX to all

tobacco products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).

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.

Section 910(b) of the FD&C Act states that a premarket tobacco application (PMTA) 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 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.

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

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

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 (the application) and 21 CFR 25.40 Environmental Assessments:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Electronic Nicotine Delivery Systems (ENDS) Liquids and Delivery Systems (Including Importers))	200	3.75	750	1,713	1,284,750
Total Hours Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application)					1,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Electronic Nicotine Delivery Systems (ENDS) Liquids and Delivery Systems (Including Importers))	200	1	200	4	800
Total Hours Request for Meeting with CTP's Office of Science to Discuss Investigational Plan					800
Total Hours "Applications for Premarket Review of New Tobacco Products"					1,285,550

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours 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 ENDS Liquids and 108 ENDS Delivery Systems).

For tobacco products already on the market at the time of the final rule, much of the information required to support a PMTA may be obtained from previously published research on similar products. Therefore, FDA expects that a large portion of applications may be reviewed with no or minimal new nonclinical or clinical studies being conducted to support an application. In contrast, nonclinical and clinical studies may be required for market authorization of a new product for which there is limited understanding of its potential impact on the public health. The range of hours involved to compile these two types of applications would be quite variable.

FDA anticipates that the 200 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. To request this meeting, applicants should compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 4 hours to compile this information, for a total of 800 hours additional burden.

Therefore, the total annual burden for submitting PMTA applications is estimated to be 1,285,550 hours. FDA's estimates are based on the corresponding information collection estimates that apply to tobacco products currently subject to the FD&C Act and an assumption that manufacturers would submit applications for the premarket review of tobacco products.

In § 1143.3(c) (21 CFR 1143.3(c)) an exemption is provided to the manufacturer of a product that otherwise would be required to include the warning statement in § 1143.3(a)(1) on its packages and in its advertisements, i.e., "WARNING: This product contains nicotine. Nicotine is an addictive chemical." This warning will be required to appear on at least 30



percent of the two principal display panels of the package and on at least 20 percent of the area of the advertisement.

To obtain an exemption from this requirement, a manufacturer would be required to certify to FDA that its product does not contain nicotine and that the manufacturer has data to support that assertion. For any product that obtains this exemption, the section requires that the product bear the statement: "This product is made from tobacco." The parties that package and label such products will share responsibility for ensuring that this alternative statement is included on product packages and in advertisements. Companies are permitted to obtain an exemption from this warning requirement in the event that such tobacco products are developed in the future.

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Certification Statement	5	1	5	20	100
Total Exemptions From the Required Warning Statement Requirement					100

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated average burden per response is based on currently approved information collection estimates. Although very few certifications are expected for tobacco products that do not contain nicotine, FDA estimates that the number of certification submissions could rise if the Agency decides in the future to address not only nicotine, but any other addictive substances.

The estimated hours listed in the burden table for certification submissions reflect the time needed to test the product for nicotine and to prepare and submit the self-certification request. FDA expects that these types of certifications will be rare and estimates that the Agency will receive on average five submissions per year.

FDA concludes that the labeling statements in §§ 1143.3(a)(1) and 1143.5(a)(1) and the alternative statement in § 1143.3(c) (i.e., "This product is made from tobacco") are not subject to

review by OMB because they do not constitute a "collection of information" under the PRA (44 U.S.C. 3501-3520). Rather, these labeling statements are a "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

Table 3.--Estimated Annual Reporting Burden<sup>1</sup>

Cigar Warning Plan	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Manufacturers, Importers, and Retailers	10	1	10	120	1,200
<b>Total Cigar Warning Plan</b>					<b>1,200</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The requirement for submission of warning plans for cigar products, and the specific requirements relating to the random display and distribution of required warning statements on cigar packaging and quarterly rotation of required warning statements in alternating sequence on cigar product advertising, appear in § 1143.5(c).

The six warnings for cigars (five specifically for cigars and the one addictiveness warning) will be required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed accordance with a warning plan submitted to and approved by FDA. For advertisements, the warning statements must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to and approved by FDA.

FDA published a final guidance in August 2018 (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM534739.pdf>) to assist manufacturers, importers, distributors, and retailers of cigars with the submission of warning plans. FDA will work with the submitters to ensure that the plans submitted meet the established criteria for approval under 21 CFR part 1143.

The warning statements on cigar packaging must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold and are required to be randomly distributed in all areas of the United States in which the product is marketed in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

FDA also requires that the required warning statements be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, regardless of whether the cigar is sold in product packaging. This rotation of warning statements in cigar advertisements also must be done in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

The burden estimates are based on FDA's experience with cigar warning plans, smokeless warning plans, and the associated information collection (OMB control number 0910-0671) as well as warning plans for cigarettes submitted to the Federal Trade Commission prior to the implementation of the Tobacco Control Act on June 22, 2009.

We estimate 10 entities will submit warning plans, and it will take an average of 120 hours per respondent to prepare and submit a warning plan for packaging and advertising for a total of 1,200 hours.

Table 4.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Small-Scale Manufacturer Reporting	75	1	75	2	150
Total Small-Scale Manufacturer Report					150

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Generally, FDA considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent

employees and has annual total revenues of \$5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with such manufacturer. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues. FDA does not believe many manufacturers who fit the criteria of a small-scale tobacco product manufacturer would submit the voluntary information.

FDA estimates that there are approximately 75 small-scale manufacturers who will voluntarily submit information. FDA believes it will take respondents 2 hours to voluntarily submit information regarding employment and revenues for a total of 150 hours.

The total estimated burden for this information collection is 1,286,950 reporting hours, and 1,040 annual responses. Our estimated burden for the information collection reflects an overall decrease of 39,050 hours and a corresponding decrease of 315 responses. We attribute this adjustment to updated information in the number of submissions we received over the last few years.

Dated: April 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.