DATES: Fax written comments on the collection of information by August 26, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0264. 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.

Export of Medical Devices; Foreign Letters of Approval

OMB Control Number 0910–0264—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or Agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of March 11, 2019 (84 FR 8727), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval—801(e)(2)	33	1	33	3	99	$8,250

[1] There are no capital costs associated with this collection of information.

We have adjusted our burden estimate by decreasing the number of respondents by 5, which has resulted in a corresponding decrease of 15 hours to the currently approved hour burden and $1,250 to the total operating and maintenance costs. This adjustment is based on a decrease in the number of submissions we received over the last few years.

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15790 Filed 7–24–19; 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; Submission for Office of Management and Budget Review; 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) 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: Fax written comments on the collection of information by August 26, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0768. 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.

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

OMB Control Number 0910–0768—Extension

The Tobacco Control Act, enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (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.

When the deeming final rule published, FDA revised the following information collections that added deemed products to these collections: Tobacco Product Establishment Registration and Submission of Certain Health Information (OMB control number 0910–0650); Tobacco Health Document Submission (OMB control number 0910–0654); Exemptions from Substantial Equivalence Requirements (OMB control number 0910–0684); Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product (OMB control number 0910–0673); Electronic Importer's Entry Notice (OMB control number 0910–0046); Exports: Notification and Recordkeeping Requirements (OMB control number 0910–0482); and Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (OMB control number 0910–0775).

In the **Federal Register** of April 22, 2019 (84 FR 16673), FDA published a 60-day notice requesting public comment on the extension of collection of information ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act.'' FDA received one comment that was Paperwork Reduction Act (PRA) related.

The commenter noted that they would like to see the associated collections that the deeming rule revised. FDA appreciates the comment addressing the associated deemed product information collections. FDA notes that in the PRA section of the deeming final rule (81 FR 28973 at 29076) all the revised OMB information collection control numbers and their revised burdens were all listed. Per the comment, we have added a listing of all the collections the final rule revised.

The commenter also notes that the burdens associated with deemed products are not all included in this notice even though the notice ''appears intended to present a comprehensive set of burden estimates and analyses for information collection activities associated with . . . the Deeming Rule.'' FDA notes that this notice is not intended to cover all information collection reviews associated with the deeming rule. Instead, this notice only covers the information collections that did not already have an approved collection prior to the deeming final rule. For the collections that existed prior to the deeming final rule, FDA added the new associated deeming-related burdens to these previously approved OMB control numbers. We also note that some of the estimates from the PRA section of the deeming rule may have changed since the final rule published. If any estimates have changed, these changes have been published in the **Federal Register** through the process associated with renewing PRA collections.

The comment also mentions the omission of the burden associated with the submission of harmful and potentially harmful constituents (HPHC) listings. FDA notes that we have not yet sought OMB approval of the burden associated with listing and reporting HPHCs for deemed products. On March 8, 2019, FDA revised the ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule'' guidance (*https://www.fda.gov/media/105346/download*) and the related Small Entity Compliance Guide entitled ''FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-deems-certain-tobacco-products-subject-fda-authority-sales-and-distribution-restrictions-and*). This revision extends the HPHCs reporting compliance date to a date that is 6 months after the publication date of a final guidance regarding HPHC reporting under section 904(a)(3) of the FD&C Act (21 U.S.C. 287d(a)(3)) and 9 months after that publication date for small tobacco product manufacturers. For products entering the market after the publication date of the final guidance, manufacturers must submit their HPHC report 90 days prior to marketing the products under section 904(a)(3).

In the preamble to the final deeming rule, FDA indicated that it intends to

issue guidance regarding HPHC reporting (and later a testing and reporting regulation under section 915 of the FD&C Act (21 U.S.C. 387o)) with enough time for manufacturers to report, given the original 3-year compliance period. At this time, FDA has not published a final HPHC reporting guidance and as a result, we are providing a revised compliance date based on when a final HPHC reporting guidance is issued.

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 (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

[1] 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 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 is 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 is 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, § 1143.3(c) 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.

TABLE 2—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
Certification Statement	5	1	5	20	100
Total Exemptions From the Required Warning Statement Requirement					100

[1] 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. 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 [1]

Cigar warning plan	Number of respondents	Number 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
Total Cigar Warning Plan					1,200

[1] 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) are 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 in 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 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 [1]

Activity	Number of respondents	Number 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

[1] 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: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15791 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0349]

National Offshore Safety Advisory Committee

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The National Offshore Safety Advisory Committee and its Subcommittee will meet in Katy, Texas to discuss Committee matters relating to the safety of operations and other matters affecting the offshore oil and gas industry. All meetings will be open to the public.

DATES:

Meetings: The National Offshore Safety Advisory Committee and its Subcommittee will meet on Tuesday, September 10, 2019 and on Wednesday, September 11, 2019. The Use of Offshore Supply Vessels and Other Non-Purpose Built Vessels for Restoration/Recovery Activities Subcommittee will meet on Tuesday, September 10, 2019 from 1 p.m. to 4 p.m. The full Committee will meet on Wednesday, September 11, 2019, from 8 a.m. to 6 p.m. (All times are Central Time). Please note that these meetings may close early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received by Committee members before the meetings, submit your written comments no later than August 27, 2019.

ADDRESSES: All meetings will be held at DNV GL USA Facility, 1400 Ravello Drive, Katy, Texas 77449.

For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meetings, but if you want Committee members to review your comment before the meetings, please submit your comments no later than August 27, 2019. We are particularly interested in the comments in the ''Agenda'' section below. You must include ''Department of Homeland Security'' and docket number USCG–2019–0349. Written comments may also be submitted using the Federal eRulemaking Portal at *http://www.regulations.gov.* If you encounter technical difficulties with comments submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. For more information about the privacy and docket, review the Privacy and Security Notice for the Federal Docket Management System at *https://www.regulations.gov/privacyNotice.*

Docket Search: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* and insert ''USCG–2019–0349)'' in the ''Search'' box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Commander Myles Greenway, Designated Federal Officer of the National Offshore Safety Advisory Committee, Commandant (CG–OES–2), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE, Stop 7509, Washington, DC 20593–7509; telephone (202) 372–1410, fax (202) 372–8382 or email: *myles.j.greenway@uscg.mil,* or Mr. Patrick Clark, telephone (202) 372–1358, fax (202) 372–8382 or email *patrick.w.clark@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is in compliance with the *Federal Advisory Committee Act,* (Title 5 U.S.C. Appendix). The National Offshore Safety Advisory Committee provides advice and recommendations to the Department of Homeland Security on matters relating to activities directly involved with or in support of the exploration of offshore mineral and