

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2018-N-3263]

Request for Nominations for Voting Members on the Tobacco Products Scientific Advisory Committee**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Tobacco Products Scientific Advisory Committee, Office of Science, Center for Tobacco Products.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before November 13, 2018 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after November 13, 2018 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSportal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, the primary contact is:* Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373 (choose option 5), email: TPSAC@fda.hhs.gov.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at: <https://www.fda.gov/AdvisoryCommittees/default.htm>.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Criteria for Voting Members

The Committee consists of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. The Committee includes nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members include seven members who are physicians, dentists, scientists, or healthcare professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. The nine voting members also include one member who is an officer or employee of a State or local government or of the Federal Government, and one member who is a representative of the general public. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or

contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 7, 2018.

Leslie Kux,*Associate Commissioner for Policy.*

[FR Doc. 2018-19921 Filed 9-12-18; 8:45 am]

BILLING CODE 4164-01-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-1588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exemptions From Substantial Equivalence Requirements for Tobacco Products**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 exemptions from substantial equivalence requirements for tobacco products.

DATES: Submit either electronic or written comments on the collection of information by November 13, 2018.

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 November 13, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2018. 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-2013-N-1588 for "Exemptions From Substantial Equivalence Requirements for Tobacco Products." 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.

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.

Exemptions From Substantial Equivalence Requirements for Tobacco Products

OMB Control Number 0910-0684—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, the new tobacco product must undergo premarket review by FDA. FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution (section 910 of the FD&C Act (21 U.S.C. 387j)).

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe

tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976, May 10, 2016) (“the final deeming rule”).

FDA has established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act in § 1107.1 (21 CFR 1107.1) of the Agency’s regulations. As described in § 1107.1(a), FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, from the requirement of demonstrating substantial equivalence if the Agency determines that: (1) The modification would be a minor modification of a tobacco product that can be sold under the FD&C Act; (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and (3) an exemption is otherwise appropriate.

Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product and that the manufacturer must submit the request and all information supporting it to FDA. The request must be made in an electronic format that FDA can process, review, and archive (or a written request must be made by the manufacturer explaining in detail why the manufacturer cannot submit the request in an electronic format and requesting an alternative means of submission to the electronic format).

An exemption request must contain: (1) The manufacturer’s address and contact information; (2) identification of the tobacco product(s); (3) a detailed explanation of the purpose for the modification; (4) a detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive; (5) a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act; (6) a detailed explanation of why a report under section 905(j)(1) of the FD&C Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; (7) a certification (*i.e.*, a signed statement by a responsible official of the company) summarizing the supporting evidence and providing the rationale for the official’s determination that the modification does not increase the tobacco product’s appeal to or use by minors, toxicity, addictiveness, or abuse liability; (8) other information justifying an exemption; and (9) an environmental assessment (EA) under part 25 (21 CFR part 25) prepared in accordance with the requirements of § 25.40.

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement for every major Federal action

that will significantly affect the quality of the human environment.

The FDA NEPA regulations are contained in part 25. All applications for exemption from substantial equivalence require the submission of an EA. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

The information required by § 1107.1(b) is submitted to FDA so FDA can determine whether an exemption from substantial equivalence to the product is appropriate for the protection of the public health. Section 1107.1(c) states that FDA will review the information submitted and determine whether to grant or deny an exemption based on whether the criteria in section 905(j)(3) of the FD&C Act are met. FDA may request additional information if necessary to make a determination and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.

Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, a report must be submitted to FDA that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary of Health and Human Services (the Secretary) under section 905(j)(3).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section and activity	Number of respondents	Number of responses per respondent ²	Total annual responses	Average burden per response (in hours)	Total hours
§ 1107.1(b) Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request Including § 25.40 Preparation of an Environmental Assessment					
21 CFR 1107.1(b)—Preparation of tobacco product exemption from substantial equivalence request and 21 CFR 25.40—Preparation of an environmental assessment	812	1	812	24	19,488
Total Hours (§ 1107.1(b))					19,218
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request					
21 CFR 1107.1(c)—Preparation of additional information for tobacco product exemption from substantial equivalence request	244	1	244	3	732

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

21 CFR section and activity	Number of respondents	Number of responses per respondent ²	Total annual responses	Average burden per response (in hours)	Total hours
Total Hours (§ 1107.1(c))	732
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)					
Abbreviated report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	1217	1	1217	3	3,651
Total Hours (section 905(j)(1)(A)(ii) of the FD&C Act	3,651
Total Hours Exemptions From Substantial Equivalence Requirements	23,871

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

FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours per response.

FDA further estimates that we will receive 244 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 732 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 3 hours to prepare, as required by section 905(j)(1)(A)(ii) of the FD&C Act, for a total of 3,651 hours.

This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all the modifications are covered by exemptions granted by the Secretary under section 905(j)(3). FDA estimates the total hours for exemptions

from Substantial Equivalence Requirements will be 23,871 hours.

FDA's estimates are based on full analysis of economic impacts and information gathered from other FDA-regulated products. Based on a review of the currently approved information collection, we have made no adjustments to our burden estimate.

Dated: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Forms for Use With Applications to the Maternal and Child Health Bureau Research and Training Grants, OMB No. 0906—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the

public regarding the burden estimate below or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than November 13, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Forms for Use with Applications to the Maternal and Child Health Bureau Research and Training Grants, OMB No. 0906-xxxx—New.

Abstract: HRSA currently utilizes the National Institute of Health's (NIH) Biographical Sketch and Public Health Service (PHS) Inclusion Enrollment forms (0925-0001) for HRSA's SF424 Research & Related application package research grants. In order to update the forms to meet HRSA's needs, HRSA plans to remove the NIH-specific references and obtain its own OMB control number for the collection of this information.

Need and Proposed Use of the Information: HRSA's Maternal and Child Health Bureau (MCHB) plans to modify the Biographical Sketch and the