FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j)(1)(A)(i) and 910(a) of the FD&C Act for an SE application.

FDA estimates that 683 respondents will prepare and submit 683 section 905(j)(1)(A)(i) SE Reports each year. In addition, anyone submitting an SE Report is required to submit an environmental assessment (EA) under 21 CFR 25.40. The burden for environmental reports has been included in the burden per response for each type of SE report. Based on FDA's experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours to prepare an environmental assessment for a SE Report. Thus, FDA estimates that it will take a manufacturer approximately 300 hours per report to prepare an SE Report and the EA for a new tobacco product, which is a total of 204,900 hours each year.

In addition, we estimate receiving 456 Full SE Bundled Reports at 90 hours per submission for a total of 41,040 hours each year.

FDA estimates that it will receive 239 Product Quantity Change SE Reports each year and that it will take a manufacturer approximately 87 hours to prepare this report for a total of 20,793 hours. This includes time to prepare the environmental assessment, which FDA believes will take less time due to the typically more limited modification(s) included in a Product Quantity Change SE Report. We estimate receiving 192 Product Quantity Change Bundled SE Reports each year at approximately 62 hours per submission for a total of 11,904 hours; this number excludes the time for the initial SE Report, which was previously accounted for.

Therefore, FDA estimates the annual burden for submission of SE information will be 278,637 hours. This is an increase of 106,759 hours from the currently approved burden. We attribute this increase to an increase in the number of SE Reports we expect related to Deemed products (*e.g.,* based on the initial registration and listing information).

Dated: May 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11657 Filed 6–4–19; 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; Submission for Office of Management and Budget Review; 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) 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 July 5, 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 0910–0684. 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.

Exemptions From Substantial Equivalence Requirements for Tobacco Products

OMB Control Number 0910–0684—Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was signed 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))). 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 (21 U.S.C. 387e(j)(3)) 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.

FDA's 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).

In the **Federal Register** of September 13, 2018 (83 FR 46501) FDA published a 60-day notice requesting public comment on the proposed collection of information. Two PRA related comments were received, which inquired about how FDA formulated the PRA estimates. In response to the questions related to the PRA estimates, these estimates are based on our experience. To date, the annual number of exemption requests has been lower than the estimate of 812 respondents in this notice (*https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=%20CTP-OS-total-exemption-from-SE-since-Program-Inception*), but the Agency expects that the number of exemption requests could increase as applicants begin to submit such requests for tobacco products subject to the final deeming rule. The estimated number of respondents is intended to reflect that potential. As noted in the comments, the exemption request is anticipated to take less time than the other premarket applications, and FDA believes that 24 hours average burden per response reflects the experience to date.

Along with commenting on the PRA estimates, these comments also state that the Agency should provide additional details on exemption requests and develop categories of exemptions. FDA appreciates these comments but notes that consideration of such new processes is outside the scope of the present information collection. FDA will continue to consider these comments as appropriate in future rulemakings.

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))					19,488

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
§ 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
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: May 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11658 Filed 6–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: Preventing Opioid Use Disorder in Older Adolescents and Young Adults (ages 16–30) (UG3/UH3 Clinical Trial Required).

Date: June 11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: Coordinating Center to Support NIDA Preventing Opioid Use Disorder in Older Adolescents and Young Adults (ages 16–30) Initiative (U24 Clinical Trial Not Allowed).

Date: June 12, 2019.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard,