tobacco product may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i))).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

In the **Federal Register** of October 17, 2018 (83 FR 52488), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, they were not PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act sections or action	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	1,000	1	1,000	5	5,000

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

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the grandfathered status of a tobacco product under the guidance is not required and also on the number of grandfathered submissions received from 2011 to June 2018. We estimate submissions have increased due to the effective date of the deeming rule. FDA has stated that, for deemed combustible products that were on the market as of August 8, 2016, it does not intend to initiate enforcement for failure to have premarket authorization until August 8, 2021. FDA has also stated that, for deemed noncombustible products that were on the market as of August 8, 2016, it does not intend to initiate enforcement for failure to have premarket authorization until August 8, 2022. Because interested persons are seeking information on the grandfathered status of tobacco products in advance of these dates, FDA expects a drop in the number of grandfathered submissions following those dates. The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 5,000 hours annually to respond to this collection of information.

Our estimated burden for the information collection reflects an overall increase of 4,235 hours. We attribute this adjustment to an updated number of submissions received through this approval and the number of submissions expected in the next 3 years.

Dated: May 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11659 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–2011–D–0147]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence 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 (PRA).

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 0910–0673. 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.

Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

OMB Control Number 0910–0673—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, among other things, a chapter granting FDA 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, generally 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 (21 U.S.C. 387j(a)(2)(A)) before the product may be introduced into commercial distribution (section 910 of the FD&C Act).

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) of the FD&C Act (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) (''the Deeming final rule'').

The FD&C Act authorizes three premarket pathways for a new tobacco product to legally enter the market. Submission of a section 905(j)(1)(A)(i) report intended to demonstrate substantial equivalence and, in response, an order from the Agency finding that the new tobacco product is substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act, is one pathway. Under section 905(j)(1)(A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i)), a tobacco product manufacturer must show that a new tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary of Health and Human Services has previously determined, under subsection (a)(3) of section 910, is substantially equivalent and that it is in compliance with the requirements of the FD&C Act. The comparison product chosen by the tobacco product manufacturer is referred to by FDA as the predicate tobacco product.

The guidance document associated with this collection of information contains recommendations on preparing reports intended to demonstrate substantial equivalence to a predicate tobacco product as required under section 905(j)(1)(A)(i) of the FD&C Act. FDA's guidance entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' (December 2016) may be accessed at *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm*. In that guidance, FDA recommends that certain modifications might be addressed in a ''Product Quantity Change Report,'' which is a more streamlined Substantial Equivalence (SE) Report for certain modifications that should be easier for manufacturers to prepare.

In the **Federal Register** of September 6, 2018 (83 FR 45251), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received seven comments that were PRA related. Commenters noted that the burden estimates seem low given current experience and rounds of review by FDA, but that FDA could reduce the current burden by increasing transparency in the SE process by issuing a rulemaking related to SE. These comments concerned the burdens related to the SE program and noted that lack of a rule related to the SE pathway has contributed to that burden. In addition, commenters stated that lack of clarity on the content of SE Reports, including the lack of clarity regarding the information that might be needed when a new tobacco product has ''same characteristics'' or ''different characteristics,'' contributes to that burden.

We believe that recent activities undertaken by FDA will help address these concerns and support maintaining the current estimates, which are averages of burden across a number of years. Specifically, in October 2018, FDA held a public workshop that provided industry stakeholders with additional information on SE content and process (*https://www.fda.gov/TobaccoProducts/NewsEvents/ucm615443.htm*). More recently, FDA issued a notice of proposed rulemaking related to the content and format of SE Reports (84 FR 12740, April 2, 2019), which would establish the required content of SE Reports and explain FDA review practices. This proposed rule also provides potential approaches to addressing same characteristics and different characteristics, along with examples, and considerations FDA may evaluate in determining whether difference(s) in characteristics cause the new tobacco product to raise different questions of public health. FDA is seeking comment on that proposed rule.

In addition, we note that several of the commenters are cigar industry stakeholders who indicated that submissions may be higher for cigar products than our current estimates reflect, and we acknowledge that future collections may be further refined to reflect changes in numbers of submissions due to more SE submissions for cigar products related to the Deeming final rule.

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	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	683	1	683	300	204,900
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	456	1	456	90	41,040
Product Quantity Change SE Report	239	1	239	87	20,793
Product Quantity Change Bundled SE Report	192	1	192	62	11,904
Total					278,637

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

FDA's estimates are based on experience with SE Reports, initial updated deemed registration and listing data, interactions with the industry, and information related to other regulated products. The estimated number of SE Reports is expected to increase from an annual average of 979 to 1,570.

When groups of full or product quantity change SE Reports have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

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]

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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.