Tobacco Products
Substantial Equivalence Reports for Tobacco Products
0910-0673
RIN 0910-AG89

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the 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. In May 2016, the FDA issued a final rule that deemed all tobacco products meeting the statutory definition of "tobacco product" to be subject to the FD&C Act, except accessories of these deemed tobacco products.

The FD&C Act requires FDA to issue an order under section 910(c)(1)(A)(i) (order after review of a premarket application, see section 910(b) of the FD&C Act) before a new tobacco product may be commercially marketed. An order under section 910(c)(1)(A)(i) is not required, however, if a manufacturer submits a report under section 905(j)(1)(A)(i) for the new tobacco product and FDA issues an order finding that the tobacco product is (1) substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, and (2) in compliance with the requirements of the FD&C Act. Manufacturers of these tobacco products may submit a report under section 905(j)(1)(A)(i) demonstrating 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 has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that it is in compliance with the requirements of this Act" (section 905(j)(1)(A)(i) of the FD&C Act). The comparison product chosen by the tobacco product manufacturer is referred to by FDA as the predicate tobacco product. (In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i), certain new tobacco products may use the exemption premarket pathway, see 21 CFR 1107.1.)

For the purposes of 905(j)(1)(A)(i) substantial equivalence reports (SE Reports), the new tobacco product is compared to a predicate tobacco product in determining substantial equivalence (section 910(a)(3)(A) of the FD&C Act). FDA interprets this to mean that a single predicate tobacco product should be used for comparison purposes, as FDA believes that a meaningful scientific comparison intended to determine whether the

characteristics of the products are the same or are different but present no different questions of public health cannot be made between a new tobacco product and multiple predicate products.

The Food and Drug Administration (FDA) is now issuing a proposed rule that would establish requirements for the content and format of SE Reports intended to establish the substantial equivalence of a tobacco product. The reports would be submitted in the form of SE Reports. The proposed rule would establish the information an SE Report must include so that FDA may make a substantial equivalence determination. In addition, the proposed rule would establish the general procedures FDA intends to follow when evaluating SE Reports, including procedures that would address communications with the applicant and the confidentiality of data in an SE Report.

2. Purpose and Use of the Information Collection

This proposed rule would establish requirements related to the content and format of SE Reports, including the information that SE Reports must contain. FDA is basing this proposed rule on the experience the Agency has in reviewing thousands of SE Reports since 2010. The respondents to this collection of information are private sector business and other for-profit institutions that manufacture tobacco products and submit SE Reports.

3. Use of Improved Information Technology and Burden Reduction

The proposed rule would require that respondents submit an SE Report in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA. FDA created two new forms for submission: FDA 3964 Tobacco Amendment and General Correspondence Report and FDA 3965 Tobacco Substantial Equivalence Report Submission. FDA estimates that based on its experience with submittal of this type of information, approximately 85 percent of the respondents will submit the information in an electronic format. Although FDA believes most respondents will submit electronically, to be conservative we estimate that 15% of applicants may submit a waiver to submit by paper.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. The FD&C Act is the only legislation that requires premarket review of new tobacco products and allows for the submission of reports intended to establish a new tobacco product's substantial equivalence to a predicate tobacco product. The FDA is the only Federal agency responsible for the collection of such premarket review information, and the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

The FD&C Act authorizes the submission of this information from all manufacturers of tobacco products that submit SE Reports (also "applicants"). Under the assumption that the percentage of tobacco product manufacturing establishments in the Tobacco Tax and Trade Bureau (TTB) data that are small is the same as the percentage of tobacco manufacturing firms that are small, then 164 small manufacturing establishments would be affected by this proposed rule. Similarly, we also expect that most of the importers affected by this rule would be small. Using the proportion of tobacco and tobacco product merchant wholesalers that are small, 214 small importers would be affected by this rule. The impact on these small entities is also dependent on how many SE Reports the entity would submit, and FDA provides its reporting and recordkeeping burdens at section 12 of this document. In certain scenarios, the proposed rule would also permit a certification instead of the submission of detailed information, which may further reduce the burden for smaller entities. FDA also continues to pursue means of reducing the reporting burden for both small and large respondents and will continue to employ the latest technology for receiving these submissions, consistent with the intent of the legislation.

6. Consequences of Collecting the Information Less Frequently

Section 905(j)(1)(A)(i) of the FD&C Act requires the submission of SE information to the FDA if the manufacturer of a new tobacco product wishes to demonstrate substantial equivalence to an existing predicate tobacco product. In its SE Report, the applicant must show that its new tobacco product is substantially equivalent to a predicate tobacco product and that the product is also in compliance with the requirements of the FD&C Act. Collecting the information less frequently would not meet the FD&C Act premarket requirements for submission of an SE Report, and would mean that an applicant would need to submit a premarket application under section 910(b) of the FD&C Act.

Respondents to this collection of information include those applicants who wish to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. If this information were not collected, FDA would be unable to make the findings required by section 910(a)(2)(A)(i) of the FD&C Act for a new tobacco product to enter the market. Instead, applicants generally could need to submit premarket applications under section 910(b) of the FD&C Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This section is not applicable. There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of April 2, 2019 (84 FR 12740).

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of SE Reports submitted under section 905(j)(1)(A)(i) of the FD&C Act are FOIA (5 U.S.C. 552) and FDA's implementing regulations under 21 CFR Part 20. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Existing Burden

Table 1.-- Existing Burden OMB Control Number 0910-0673[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)	410	1	410	300	123,000
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	250	1	250	90	22,500
Product Quantity Change SE Report	264	1	264	87	22,968

Activity	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Product Quantity Change Bundled SE Report	55	1	55	62	3,410
Totals					171,878

[1] This chart represents the currently OMB approved burden for the SE program.

Table 2.--Estimated Annual Reporting Burden
Draft Burden (Not yet OMB approved)

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					00

In the Federal Register of September 6, 2018 (83 FR 45251), FDA published a notice soliciting comments on the extension of the current SE program. The numbers above in table 2 represent the tentative revisions which have not yet been approved by OMB. These estimates revise the number of reports under OMB control number 0910-0673 and take into account updated registration and listing data. The previous estimate for reports was 979 and total burden hours were 171,878. This chart accounts for the tentative

increase in burden due to the expected rise in submissions other than any increases in burden due to the proposed rule, if finalized.

New Burden (per the rule)

Table 3.--Estimated Annual Reporting Burden

21 CFR Part	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3965 Tobacco Substantial Equivalence Report Submission.	1,570	1	1,570	.5	785
FDA 3964 Tobacco Amendment and General Correspondence	628	1	628	.083	52
Waiver from Electronic submission 1107.62 (b)	240	1	240	.25	60
Totals					0

Table 4.--Estimated Annual Recordkeeping Burden

21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping SE Report under 1107.18 1107.58	471	1	471	2.5	1,178

Final Combined Reporting Burden (tables 2 +3)

Table 5.--Estimated Annual Reporting Burden

21 CFR Part	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SE Report 1107.18	683	1	683	300	204,900
Bundled SE 1107.18	456	1	456	90	41,040
SE Report where applicant provides certification for identical characteristics 1107.18(g) and 1107.18 (l)(2)	239	1	239	87	20,793
SE Report where applicant provides certification for some identical characteristics (bundled) 1107.18 (g) and 1107.18 (l) (2)	192	1	192	62	11,904
FDA 3965 Tobacco Substantial Equivalence Report Submission.	1,570	1	1,570	.5	785
FDA 3964 Tobacco Amendment and General Correspondence Report	628	1	628	.083	52
Waiver from	240	1	240	.25	60

Table 5.--Estimated Annual Reporting Burden

21 CFR Part	Number. of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission 1107.62 (b)					
Totals					0

Table 6.--Estimated Annual Recordkeeping Burden

21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping SE Report under 1107.18 1107.58	471	1	471	2.5	1,178

FDA's estimates are based on experience with SE Reports, registration and listing data, interactions with the industry, and information related to other regulated products. As explained above, taking into account the updated registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570. That estimate is not expected to change as a result of the proposed rule, if finalized. When groups of full SE Reports or SE Reports that each contain a certification that some characteristics are identical 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 substantial equivalence pathway to market their products. Table 1 describes the annual reporting burden for compliance with the requirements to demonstrate substantial equivalence under the FD&C Act. We do not expect a large burden increase for this program, as, without the proposed rule, manufacturers would routinely submit SE Reports for new tobacco products, and the Agency believes most respondents are currently practicing most of the proposed requirements. FDA will revise this collection with the new burden. FDA requests public comments on the estimated burden associated with the requirements associated with this rule and whether there is any evidence, information, or data to support alternate burden estimates.

Table 3 describes the annual reporting burden as a result of the requirements proposed in §§ 1107.18 and 1107.19, implementing the substantial equivalence requirements of section 905(j)(1)(A)(i) and 910(a) of the FD&C Act. This proposed rule would require manufacturers to submit SE Reports electronically (proposed §1107.62). We estimate that it would initially take about 30 minutes per product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3964 will take 5 minutes as applicants can copy and paste from the first submission. Proposed 1107.62(b) also allows for waivers from the electronic format requirement. FDA estimates that 240 respondents or 15 percent of SE Reports (1,570) will submit a waiver.
Based on updated information, FDA estimates that it will receive 683 full initial SE Reports for a new tobacco product each year under proposed § 1107.18 that take a manufacturer approximately 300 hours to prepare. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report. We expect to receive 456 bundled SE Reports under proposed § 1107.18 (other than the initial SE Report in the bundle) at approximately 90 hours per response for a total of 41,040 hours.

In the absence of more specific information concerning SE Reports where applicants provide a certification for some identical characteristics under proposed § 1107.18(g) and 1107.18(l)(2), FDA estimates receiving 239 such SE Reports at 87 hours per response for a total of 20,973 hours. We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under proposed §§ 1107.18(g) and 1107.18(*l*)(2) (other than the initial SE Report in the bundle) at 62 hours per response for a total of 11,904 hours. Although we believe that the number of SE Reports that include a certification will increase because the proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time.

FDA has based these estimates on the full analysis of economic impacts and experience with the recently-revised existing information collection that applies to tobacco products. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under proposed § 1107.18(k). 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 preparing an environmental assessment for a full SE Report under proposed § 1107.18.

Generally, an applicant may withdraw its SE Report after submission (proposed § 1107.22), change the ownership of its SE Report (proposed § 1107.24), and amend its SE Report (proposed § 1107.20). The information required to grant these requests is already being collected, so we do not expect a change in burden.
FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 2.5 hours per record for a total of 1,178 recordkeeping hours.

FDA estimates that the burden for new requirements will increase this collection by 108,834 (107,656 + 1,178 recordkeeping). The burden for the submission of substantial equivalence information is estimated to total 280,712 hours (279,534 reporting and 1,178 recordkeeping). This proposed rule also refers to previously approved collections of information found in FDA regulations.

Proposed § 1107.40 references meetings that may be held with applicants who want to meet with FDA to discuss scientific and other issues. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products." The collections of information in the guidance referenced have been approved under OMB control number 0910-0731. In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i), certain new tobacco products may use the exemption premarket pathway, see 21 CFR 1107.1). The collections of information found in 21 CFR 1107.1 have been approved under OMB control number 0910-0684.

12b. Annualized Cost Burden Estimate

FDA also notes that preparation of a request for substantial equivalence will involve life, physical, and social science occupations, architecture and engineering occupations, and legal occupations. FDA has estimated that the wage per hour adjusted for benefits and overhead, is $86.20 per hour.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco product manufacturers	280,712	$86.20	$24,197,374.40

FDA estimates the cost to respondents is $24,197,374.40. This figure was derived by multiplying the total burden hours (280,712) by an hourly rate of $86.20. This hourly rate is based on 2,080 annual work hours and an annual salary rate of $179,296.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal government will incur the following costs:

Staff Costs
Total annual cost to the Federal government = $2,320,000
Full-time Equivalents (FTEs) = 20
Annual Cost per FTE=$116,000
Annual Cost = $2,320,000

15. Explanation for Program Changes or Adjustments

This is a new proposed rule. FDA estimates that the burden for new requirements will increase this collection by 2,075 hours (897 reporting + 1,178 recordkeeping). The new estimated total for this collection is 280,712.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption from display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.