U.S. Food and Drug Administration
Tobacco Products
Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product
Guidance Document

OMB Control No. 0910-0673

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 new chapter granting FDA important new 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, requires FDA to issue an order under section 910(c)(1)(A)(i) (order after review of a premarket application) 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 their new tobacco product is substantially equivalent to a predicate tobacco product.

FDA has issued a guidance document containing recommendations for preparing substantial equivalence reports under section 905(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 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.

For the purposes of 905(j)(1)(A)(i) substantial equivalence 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) issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act). 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. This final rule extends the Agency's "tobacco product" authorities to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements. FDA is taking this action to reduce the death and disease from tobacco products.

2. Purpose and Use of the Information Collection

Guidance documents are available to assist manufacturers in preparing their section 905(j)(1)(A)(i) substantial equivalence reports. The information collected under this provision of the FD&C Act will enable FDA to make the findings required by section 910(a)(2)(A)(i) of the FD&C Act, including determining if a new tobacco product (as defined by section 910(a)(1) of the FD&C Act) is substantially equivalent (see section 910(a)(a3)(A)).

The respondents to this collection of information are private sector business and other for-profit institutions who manufacture tobacco products.

3. Use of Improved Information Technology and Burden Reduction

FDA has suggested that respondents to this collection of information submit their section 905(j)(1)(A)(i) substantial equivalence reports in an electronic format, although they may submit their report in paper, if needed. FDA estimates that based on its past experience with submittal of this type of information, approximately 99 percent of the respondents will submit the information in an electronic format.

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 information submission requirements in section 905(j)(1)(A)(i) do not fall disproportionately upon small businesses. The FD&C Act allows for the submission of this information from all manufacturers of tobacco products. FDA is also allowing for the alternative submittal of reports for substantial equivalence in paper form for those individuals who are unable, or choose not, to submit in an electronic format. FDA 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.

In the guidance entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions." FDA is recommending that certain modifications might be addressed in a "Product Quantity Change Report," which is a more streamlined SE report.[1]

FDA aids small businesses in dealing with the information submission requirements of section 905(j)(1)(A)(i) of the FD&C Act by providing technical, nonfinancial assistance in submitting this information as required by section 901(f) of the FD&C Act.

6. Consequences of Collecting the Information Less Frequently

The Tobacco Control Act requires the submission of reports under section 905(j)(1)(A)(i) of the FD&C Act if the manufacturer of a new tobacco product wishes to demonstrate substantial equivalence to an existing predicate tobacco product. In its report, the manufacturer 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 substantial equivalence reports, and would mean that a manufacturer would need to submit a premarket application under section 910(b) of the FD&C Act.

[1] A recent decision in the United States District Court for the District of Columbia found that a modification to an existing tobacco product's label does not result in a "new tobacco product." (Philip Morris USA Inc. v. United States Food and Drug Administration, No. 15-cv1590 (APM), (D.D.C. Aug. 16, 2016)). As such, products with a modified label are not required to receive premarket authorization. Thus, this information collection reflects the fact that manufacturers need not submit SE applications for label changes, which were previously included in the collection as "same characteristics SE reports."

Respondents to this collection of information include those manufacturers 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 in order for a new tobacco product to enter the market. Instead, manufacturers would 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

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of September 6, 2018 (83 FR 45251), FDA received 7 comments that were PRA related. 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. 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.

   We believe that recent activities undertaken by FDA will help address these concerns and also support maintaining the current estimates, which are averages of burden across a number of years. For example, in October 2018, FDA held a public workshop which provided industry stakeholders with additional information on SE content and process (https://www.fda.gov/TobaccoProducts/NewsEvents/ucm615443.htm). And 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.

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 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

FDA estimates the burden for this information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No.. of respondents	No. 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

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 (21 U.S.C. 387j(a)) 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 account for.

Therefore, FDA estimates the annual burden for submission of SE information will be 278,637 hours.

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 manufacturers	278,637	$86.20	$24,018,509

FDA estimates the reporting cost to respondents is $24,018,509. This figure was derived by multiplying the total reporting burden hours 278,637 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

We have estimated an increase of 106,759 hours and 591 respondents from the currently approved burden. We attribute this adjustment 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).

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.