

Tobacco Products
Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product
Guidance Document

Extension

0910-0673

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) 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.

2. Purpose and Use of the Information Collection

Two 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 to a predicate tobacco product.

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.

FDA recently issued guidance entitled, “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.” In that guidance, FDA is recommending that certain modifications might be addressed in either a “Same Characteristics SE Report” or “Product Quantity Change Report,” which are more streamlined SE reports.

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.

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 March 5, 2015 (80 FR 11989).

FDA received one comment. The commenter expressed a concern that small manufacturers have the burden of conducting testing without a definitive guide on what will constitute substantial equivalence. FDA has carefully considered the burden associated with the submission of an SE report. The information needed to demonstrate

substantial equivalence is dependent on the new product and the predicate product that the manufacturer identifies. Nevertheless, to assist manufacturers in preparing SE reports, FDA has issued guidance documents and participated in outreach such as webinars to provide manufacturers with information. Moreover, manufacturers seeking to demonstrate substantial equivalence may also contact FDA to seek the Agency's input on the specific types of information that the Agency believes will be necessary to support the manufacturer's section 905(j) report. The commenter also supported FDA's development of more streamlined SE Reports but challenged "new requirements on label changes," and requested that FDA promulgate a rule on categorical exclusions (environmental assessments). Although these comments are outside of the scope of this PRA collection, FDA intends to consider them as part of the Agency's other regulatory efforts as appropriate.

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

The guidance document associated with this collection of information will contain recommendations on preparing reports intended to demonstrate substantial equivalence to a predicate tobacco product and compliance with the FD&C Act as required under section 905(j)(1)(A)(i). 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 Act, is one means for a new tobacco product to legally enter the market. FDA also recently issued guidance entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions." In that guidance, FDA is recommending that certain modifications might be addressed in either a "Same Characteristics SE Report" or "Product Quantity Change Report," which are more streamlined SE reports for certain changes that should be easier for manufacturers to prepare.

FDA estimates the burden for this information collection as follows:

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

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)	75	1	75	300	22,500
Product Quantity Change SE Report	125	1	125	87	10,875
Same characteristics SE Report	100	1	100	47	4,700
Totals					38,075

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

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.

Based on current information, FDA estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be “full” substantial equivalence (SE) reports that take a manufacturer approximately 300 hours to prepare.

FDA estimates that it will receive 100 Same Characteristics SE Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 38,075 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

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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	38,075	\$86.20	\$3,282,065

FDA estimates the reporting cost to respondents is \$3,282,065. This figure was derived by multiplying the total reporting burden hours (38,075) 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

The burden for this collection of information has not changed from the burden shown in the current inventory.

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.