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

Extension
(Without Change)

SUPPORTING STATEMENT

0910-0673

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.

This request for extension asks for OMB approval for a 3-year collection period.

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.

FD&C Act Section 905(j)(1)(A)(i). 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.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

A guidance document is available to assist manufacturers in preparing their section 905(j)(1)(A)(i) substantial equivalence reports. The information collected under these provisions 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 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 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 December 27, 2013 (78 FR 78974). Six comment submissions were received, some of which included multiple comments. Two of the six comment submissions were in favor of FDA's regulation of tobacco products. Three comment

submissions were considered to contain PRA-related comments and three comment submission were not considered to contain PRA-related comments. The three comment submissions not considered to contain PRA-related comments are beyond the scope of the Federal Register notice.

(Comment) One commenter supported FDA in its mission to regulate tobacco products for the benefit of public health and safety and indicated that language in the guidance be strengthened to assist in FDA reviews. The commenter also suggested that the respondents provide additional information to minimize future Freedom of Information Act (FOIA) requests.

(Response) FDA agrees that the request in this collection of information is necessary to fulfill the requirements of the FD&C Act. The type of data for a given new product may vary depending on whether the characteristics of the product are the same or different from a predicate tobacco product, and the information is needed to allow FDA to make informed decisions when reviewing a substantial equivalence application.

(Comment) Several commenters indicated that FDA has improperly implemented the substantial equivalence provisions of the statute (the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA)), and maintain that FDA is asking for reports that are neither authorized nor relevant to a substantial equivalence determination.

(Response) FDA disagrees with the comment. The information FDA is requesting is related to new products using the substantial equivalence pathway to assist FDA in making a determination of whether a product is substantially equivalent.

(Comment) Several commenters asserted that FDA was not asking for enough information, while other commenters asserted that FDA was asking for too much information.

(Response) FDA believes that the collection of information is necessary and the burden estimates are appropriate and reflect the amount of time a respondent would need to prepare a substantial equivalence submission

(Comment) One commenter noted that under FDA's interpretation, every new, including modified, product automatically will be evaluated. Other commenters questioned FDA's implementation and Congress' intent of the FSPTCA and its definition of substantial equivalence and new products.

(Response) The FD&C Act as amended by the FSPTCA establishes the definition of "new tobacco product" and the premarket pathways, of which substantial equivalence is one. FDA believes the information collection estimates are appropriate and reflect estimates of the time it would take to put together and report the information needed in a substantial equivalence submission required by the statute.

(Comment) One commenter stated that the commenter believes that SE reports should be exempt from environmental assessment requirements.

(Response) The National Environmental Policy Act (NEPA) and FDA implementing regulations require environmental assessment requirements.

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 estimates the burden for this information collection as follows:

12a. Annualized Hour Burden Estimate

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

FD&C Act Sections	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
905(j)(1)(A)(i) and 910(a)	1,000	1	1,000	360	360,000

[1]

Total					360,000

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. FDA estimates that it will receive 1,000 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 360,000 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	360,000	$86.20	$31,032,000

FDA estimates the reporting cost to respondents is $31,032,000. This figure was derived by multiplying the total reporting burden hours (360,000) 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.