Tobacco Products

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

Guidance Document

0910-0673

Revision Request

SUPPORTING STATEMENT

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.

On December 30, 2010, OMB granted FDA emergency approval for a period of 180 days under section 3507(j) of the Paperwork Reduction Act (PRA) (44 U.S.C. 3507(j) and 5 CFR 1320.13) for the proposed collection of information contained in the guidance document described below. This request for revision asks for OMB approval for a three year collection period.

The FD&C Act, as amended, requires FDA to issue an order (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 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 with recommendations on 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 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 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.

It is important that the guidance document be available to assist manufacturers in preparing their 905(j)(1)(A)(i) substantial equivalence reports.

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

2. Purpose and Use of the Information Collection

This is an extension of an existing collection of information. 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 from the private sector, and are 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 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% 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, as amended by the Tobacco Control Act, is the only legislation which requires premarket review of new tobacco products and allows 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 Tobacco Control 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 business 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

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 that published in the FEDERAL REGISTER on January 24, 2011 (76 FR 4116). FDA received 1 comment. The commenter indicated that it thought the substantial equivalence requirements were “burdensome to industry in the extreme”, that FDA’s estimate of the number of reports to be received was too low, and that the current burden hours to complete each report was unrealistic. Although the commenter asserted that the burden hours were too low and unrealistic, no alternative estimates were provided.

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 the Freedom of Information Act (FOIA) (5 U.S.C. 552) and FDA's implementing regulations. 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 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. *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
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, comments regarding the submission of 905(j)(1)(A)(i) substantial equivalence reports, and comments on the 60-day information collection notice published in the Federal Register on January 24, 2011 (76 FR 4116). 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. FDA estimates that it will receive 1,000 section 905(j)(1)(A)(i) substantial equivalence 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. *Reporting 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.

Table 2
Estimated Annual Reporting Cost

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 a 2,080 annual work hours and at an annual salary rate of $179,296.

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

1

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 = 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 increased by 306,000 hours (from 54,000 to 360,000 hours) since it was approved on an emergency basis by OMB on December 30, 2010. The increase in burden was due primarily to the fact that the agency has revised the number of reports it expects to receive from 150 to 1,000 annually. The burden estimate for the number of reports is expected to increase by 306,000 hours (from 54,000 to 360,000 hours) because of information received through interactions with industry, comments received regarding the submission of 905(j)(1)(A)(i) substantial equivalence reports, and comments on the 60 Day Federal Register information collection request for comments published on January 24, 2011 (76 FR 4116).

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 for 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.