Tobacco Products

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

Guidance Document

0910-NEW

Agency Emergency Processing Request for OMB Approval

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.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the Paperwork Reduction Act (PRA) (44 U.S.C. 3507(j) and 5 CFR 1320.13). The FD&C Act, as amended, requires an order (order after review of a premarket application) before a new tobacco product may be commercially marketed. For new tobacco products introduced into interstate commerce after February 15, 2007 and before March 22, 2011, the law provides an alternative to obtaining this order. Manufacturers of these tobacco products may submit a report under section 905(j) demonstrating that their new tobacco product is substantially equivalent to a predicate tobacco product. If they submit this report before March 23, 2011, manufacturers may continue to market their tobacco products unless FDA issues an order finding that the product is not substantially equivalent to the predicate product. FDA is requesting emergency clearance for the proposed collection of information to meet deadlines specified in the Tobacco Control Act.

FDA intends to issue a guidance document with recommendations on preparing reports under section 905(j), including recommendations for demonstrating substantial equivalence (section 910(a)). Manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007 and prior to March 22, 2011 must submit a report no later than March 22, 2011, or the products can no longer be legally marketed (section 910(a)(2)(B) of the FD&C Act). It is important that this guidance be available in advance of March 23, 2011, to assist manufacturers in preparing 905(j) reports.

2. Purpose and Use of the Information Collection

This is a new collection of information. The information collected under the FD&C Act will enable FDA to determine if a new tobacco product, including a tobacco product that has been on the market since February 15, 2007, is substantially equivalent to a predicate tobacco product. The guidance discusses premarket statutory requirements that include certain submissions to be made to FDA no later than March 22, 2011. This guidance document is being implemented immediately without prior public comment under § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline.

The guidance document associated with this collection of information provides recommendations and information related to the submission and review of reports under section 905(j) of the FD&C Act, as amended, including recommendations for demonstrating substantial equivalence to predicate tobacco products. Section 905(j) authorizes FDA to establish the form for the submission of information related to substantial equivalence (21 USC 387e(j)). In the future, FDA intends to initiate a rulemaking that would establish requirements and standards for substantial equivalence under sections 905(j) and 910 of the Act (the provisions relating to reports intended to demonstrate substantial equivalence). The guidance is intended to assist persons submitting reports under section 905(j) of the Act. It explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence, and provides recommendations on the form and content of section 905(j) reports. The guidance also provides information on FDA's review of 905(j) reports. Because manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007 and prior to March 22, 2011 must submit a report no later than March 22, 2011, or the tobacco product can no longer be legally marketed, it is important that this guidance be available in advance of March 23, 2011 to assist manufacturers in preparing section 905(j) reports.

For 905(j) reports for tobacco products first marketed between February 15, 2007 and March 22, 2011 (many of which are from small manufacturers) that are submitted prior to March 23, 2011, FDA intends to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their initial submissions, provided these manufacturers submit a 905(j) report by the statutory deadline. FDA intends to determine what constitutes a reasonable period of time on a case by case basis.

3. Use of Improved Information Technology and Burden Reduction

FDA has suggested that respondents to this collection of information submit their 905(j) reports for substantial equivalence electronically, although they may submit their request 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 electronically.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. The Tobacco Control Act is the only legislation which requires premarket review of new tobacco products and allows the submission of reports to establish substantial equivalence to a predicate tobacco product. The FDA is the only Federal agency responsible for the collection of such 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 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 requests for substantial equivalence in paper form for those individuals who are unable, or choose not, to submit electronically. 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) of the FD&C Act by providing technical, nonfinancial assistance in submitting this information.

6. Consequences of Collecting the Information Less Frequently

The Tobacco Control Act requires the submission of reports under section 905(j) of the FD&C Act if the manufacturer of tobacco products wishes to demonstrate substantial equivalence to an existing predicate tobacco product. In its report, the manufacturer must show that its 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. Reports expected to be submitted once by manufacturers of a single product wishing to demonstrate substantial equivalence, and occasionally by manufacturers of multiple products wishing to demonstrate substantial equivalence. Collecting this information less frequently would not meet the FD&C Act requirements for submission of these reports.

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

This section is not applicable.

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

On December 15, 2010, FDA met with OMB to discuss emergency approval by OMB to allow the immediate availability of this guidance document. OMB agreed to allow immediate availability of the guidance document to help ensure that interested parties have clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline. The information collection in the guidance document will be approved for no more than 180 days. During that time period, FDA will publish regular 60 Day and 30 Day notices in the Federal Register in preparation for OMB approval of this collection of information for a three year period.

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) 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.

12a. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden for this information collection as follows:

FDA has based the estimates of hourly burden on information related to other regulated products and FDA's expectations regarding the tobacco industry's use of the 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) and 910(a) of the FD&C Act. FDA estimates that it will receive 150 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 54,000 hours. FDA's estimates are based on staff expertise and interaction with industry.

Estimated Annual Reporting Burden

FD&C Act Sections	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
905(j) and 910(a)	150	1	150	360	54,000
Total					54,000

12b. 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.

The estimated cost for this collection of information is $4,654,800 (150 respondents x 360 hours x $86.20).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco manufacturers[1]	54,000	$86.20	$4,654,800

[1]Specifically, those tobacco manufacturers who are submitting reports under section 905(j) of the FD&C Act to demonstrate substantial equivalence of their product to an existing, predicate tobacco product.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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 = $696,000

Full time Equivalents = 6
Annual Cost per FTE=$116,000
Annual Cost = $696,000

15. Explanation for Program Changes or Adjustments

This is a new collection.

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.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.