

**Guidance for Industry on Establishing That a Tobacco Product Was Commercially
Marketed in the United States As of February 15, 2007**

0910-0775 - Revision

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 chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 201(rr) of the FD&C Act, as amended, defines a tobacco product as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” Section 910 of the FD&C Act (21 U.S.C. 387j) sets out premarket requirements for new tobacco products. The term “new tobacco product” is defined as (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products. Grandfathered tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A grandfathered tobacco product may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A(i) of the FD&C Act (21 U.S.C. 387e(j)(1)A(i))).

FDA interprets the phrase “as of February 15, 2007,” as meaning that the tobacco product was commercially marketed in the United States on February 15, 2007. The guidance associated with this collection of information recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially

marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

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

This is collection of information, and the information collected under these provisions of the FD&C Act will enable FDA to respond to a manufacturer’s request for an FDA determination if the product may be considered “grandfathered” and not subject to premarket review. A product that is grandfathered may also serve as a predicate tobacco product in a 905(j) (substantial equivalence) report.

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 demonstrate that their tobacco product was commercially marketed in the United States as of February 15, 2007. Although the evidence to demonstrate the product was commercially marketed in the United States as of February 15, 2007, can be submitted in electronic or paper format, 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 review of new tobacco products and allows the submission of evidence intended to establish the tobacco product was commercially marketed as of February 15, 2007. The FDA is the only Federal agency responsible for the collection of information related to premarket review of tobacco products. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

The information submission recommendations do not fall disproportionately upon small businesses. This information may be submitted by any manufacturer of tobacco products, either electronically or by paper submission. 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 recommendations of this collection of information by providing technical, nonfinancial assistance in submitting the information.

6. Consequences of Collecting the Information Less Frequently

The guidance recommends that those manufacturers that wish to have a FDA determination as to the status of their product may submit this information. The information for this collection is expected to be submitted on an occasional basis. Collecting the information less frequently may prevent FDA from being able to respond to requests from manufacturers that want a FDA determination on the status of their product.

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 of the proposed rule that published in the FEDERAL REGISTER of April 25, 2014 (79 FR 23142). FDA has responded to the comments received in the preamble to the final rule, and the supporting statement for the Deeming information collections under OMB control number 0910-0768.

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 sections 910 and 905 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 how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007, and therefore may be considered a grandfathered product not be subject to premarket review.

FDA estimates the burden for this information collection as follows:

12a. Hour Burden Estimate

Existing Burden

Table 1.--Estimated Annual Reporting Burden

FD&C Act Sections or Action	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	150	1	150	5	750
Total					750

New Deeming Burden

Table 2.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cigar Manufacturers (including large and small cigars and importers)	1	1	1	5	5
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	5	5
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Including Importers)	1	1	1	5	5
Total Hours Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007					15

² At publication of the proposed rule, this collection was not yet approved by OMB. On September 8, 2014, OMB approved the information collection for 3 years.

Final Burden Chart (Existing and Deeming Burden Combined)

Table 3.--Estimated Annual Reporting Burden

FD&C Act Sections or Action	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	153	1	153	5	765
Total					765

Based on FDA's experiences to date, and given that stand-alone grandfather submissions are purely voluntary, FDA does not anticipate that many manufacturers will make such submissions per the new deeming rule, but this option is available. As such, we assigned an extra one respondent annually per type of product. FDA estimates it will take a manufacturer approximately 5 hours to complete and submit for FDA review the evidence required by this collection of information for a total of 15 hours. FDA now estimates that it should take approximately 765 hours annually (153 responses times 5 hours for each response) to respond to this collection of information.

12b. Reporting Cost Burden Estimate

FDA also notes that preparation of a request 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	765	\$86.20	\$65,943

FDA estimates the reporting cost to respondents is \$65,943. This figure was derived by multiplying the total reporting burden hours (765) 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

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 = \$812,000

Full-time equivalents (FTEs) = 7

Annual cost per FTE=\$116,000

Annual cost = \$812,000

15. Explanation for Program Changes or Adjustments

The new collections of information under this control number were previously submitted to OMB at the proposed rule stage under the deeming rule information collection (0910-0768). After discussions with OMB about the final rule submission, it was decided that the collections associated with existing control numbers would be submitted under their respective approvals.

The burden for this collection of information is expected to increase by 15 reporting hours due to an expected increase in the number of tobacco respondents. This adjustment is a result FDA extending the Agency's "tobacco product" authorities in the FD&C Act 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.

The estimated number of respondents will increase by 3 (from 150 to 153 respondents). The annual responses will also increase by 3 (from 150 to 153). The increase of 15 hours equals to a total of 765 total burden from the previously OMB approved burden estimate of 750 hours.

Action	No. Respondents	Total Annual Response	Hours Per Response	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007 (Existing)	150	150	5	750
Submit evidence of commercial marketing in the United States as of February 15, 2007 (Deeming)	3	3	5	15
Submit evidence of commercial marketing in the United States as of February 15, 2007 (Final)	153	153	5	765

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.