Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

0910-0775

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) guidance. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Section 201(rr) of the FD&C Act, as amended, defines a tobacco product as "any product made or derived from tobacco or containing nicotine from any source 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 and provides for the submission of applications for review for those 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).

To assist new tobacco product manufacturers with requirements in section 910 of the FD&C Act, we developed the guidance document entitled, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007). The guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. The guidance document includes a description of the types of evidence FDA recommends that the manufacturer submit to demonstrate that a 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 guidance document also provides instruction on how to submit a request for a Pre-Existing Tobacco Product status review (Section III.B.).

FDA refers to tobacco products that were commercially marketed (including those products in test markets) in the United States as of February 15, 2007, as Pre-Existing Tobacco Products[1]. 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. Pre-Existing 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 Pre-Existing Tobacco Product that was commercially marketed (other than solely for test marketing) in the United States as of February 15, 2007, 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))). Therefore, a tobacco product that was solely in a test market as of February 15, 2007, despite being a Pre-Existing tobacco product, cannot serve as a predicate tobacco product.

We request OMB approval of the information collection provisions found in the guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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 a Pre-Existing Tobacco Product and not subject to premarket review. A Pre-Existing Tobacco Product that was commercially marketed (other than solely for test marketing) in the United States as of February 15, 2007, may also serve as a predicate tobacco product in a 905(j) (substantial equivalence) report. Therefore, a tobacco product that was solely in a test market as of February 15, 2007, despite being a Pre-Existing Tobacco Product, cannot serve as a predicate tobacco product.

The respondents to this voluntary 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

The guidance document includes a description of the types of evidence FDA recommends that respondents to this collection of information submit to 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,

[1] FDA changed the term from "grandfathered tobacco product" to "Pre-Existing Tobacco Product" in the recently published final SE (86 FR 55224) and PMTA (86 FR 55300) rules because it more appropriately describes these products by using the more precise term "Pre-Existing" in place of "grandfathered."

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.

As discussed in the guidance document, electronic submission is not required, although we strongly encourage electronic submission via the FDA's Electronic Submissions Gateway (ESG) using FDA's eSubmitter tool. The FDA ESG system requires users to apply for a free account before submitting data, a process which can take one to three weeks to complete. Once approved, the user can send all submissions to CTP using the eSubmitter tool and FDA ESG. Instructions on obtaining an ESG account are available at https://www.fda.gov/industry/electronicsubmissions-gateway/create-esg-account. Alternatively, respondents can mail submissions to FDA, as instructed in the guidance document.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

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 an 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 an 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

   In the Federal Register of December 09, 2021 (86 FR 70139), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There are no incentives, payments or gifts associated with this information collection.

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.

    CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. CTP received HHS approval on the privacy impact assessment and was assigned PIA Unique Identifier P-7465194-382822.

11. Justification for Sensitive Questions

    This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

    The guidance document associated with this collection of information contains recommendations on how a manufacturer may establish, by submitting evidence, that a tobacco product was commercially marketed in the United States as of February 15, 2007, and therefore may be considered a Pre-Existing Tobacco Product not subject to premarket review.

FDA estimates the burden for this information collection as follows:

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity; Guidance Document Section III. B	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	1,000	1	1,000	5	5,000
Total					5,000

FDA's estimate of the number of respondents is based on the fact that submissions are voluntary and also on the number of Pre-Existing Tobacco Product submissions received. The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 5,000 hours annually to respond to this collection of information.

12b. Annualized 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	5,000	$86.20	$431,000

FDA estimates the reporting cost to respondents is $431,000. This figure was derived by multiplying the total reporting burden hours (5,000) by an hourly rate of $86.20. This hourly rate is based on 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

    Our estimated cost to the Federal government reflects the allocation of 7 full-time equivalents (FTEs) employees who collect, process, and file responses related to requests for a Pre-Existing Tobacco Product status review. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for a GS-13/4 employee, we calculate a total cost of $822,535 ($117,505 x 7).

15. Explanation for Program Changes or Adjustments

    Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

    This information collected will not be published or tabulated.

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

    There are no exceptions to the certification.