

United States Food and Drug Administration
ESTABLISHING THAT A TOBACCO PRODUCT WAS COMMERCIALY MARKETING IN
THE UNITED STATES AS OF FEBRUARY 15, 2007

OMB Control Number 0910-0775 -- EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration 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. 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.

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, FDA estimates that based on our data, approximately 99 percent of the respondents 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 CTP Portal NextGen. The CTP Portal NextGen web application requires that an organization request an Industry Account Manager (IAM) role be set up for an individual of the organization to act as an administrator for all of the organization's CTP Portal NextGen accounts. Once the IAM account is created by CTP, the IAM can create, manage, and set roles for all of the organization's employees' CTP Portal NextGen user accounts. Users may then prepare submissions on behalf of their organization using the FDA's eSubmitter tool or web forms provided in CTP Portal NextGen for supported submission types and can send these submissions to CTP directly from CTP Portal NextGen. Instructions on requesting a free IAM account for CTP Portal NextGen are available at <https://www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal-next-generation>. 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 collection does not fall disproportionately upon small businesses. This information may be submitted by any manufacturer of tobacco products, either electronically or by paper submission. Of the 113 manufacturers that may potentially provide Pre-Existing Tobacco Product submissions, we use Census Bureau 2021 Statistics of U.S. Business data (<https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html>) on establishments with 500 or fewer employees (the closest reported threshold to 350 employees) to estimate that 95 may be small businesses. 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 June 27, 2025 (90 FR 27632), 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 FDA2107988.

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	500	1	500	5	2,500
Total					2,500

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 2,500 hours annually to respond to this collection of information.

12b. Annualized Reporting Cost Burden Estimate

FDA assumes that a Pre-Existing Tobacco Product submission will likely involve the work of tobacco manufacturing management occupations and legal occupations. Referencing 2023 Bureau of Labor Statistics national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry, FDA has estimated that the wage is \$153.96 per hour. This wage represents a mix of 50 percent management (11-0000, \$73.88/hour) and 50 percent legal occupations (23-0000, \$80.08/hour) and is doubled to account for benefits and overhead.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco manufacturers	2,500	\$153.96	\$384,900

FDA estimates the reporting cost to respondents is \$384,900. This figure was derived by multiplying the total reporting burden hours from Table 1 (2,500) by an hourly rate of \$153.96.

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 2.5 full-time equivalent employees (50 percent of the time of 5 full-time employees) who collect, process, and file responses related to requests for a Pre-Existing Tobacco Product status review. Using 2025 Grade 13 Step 4 salary and wage data for the Washington DC-Metropolitan area found at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/html/DCB.aspx> and doubling for benefits and overhead, we calculate a total cost of \$663,190 ($\$132,638 \times 2 \times 2.5$).

15. Explanation for Program Changes or Adjustments

Program Change Burden: None

Adjustments Burden: The burden adjustment is related to and overall decrease in the expected number of respondents. The number of hours per response has remained the same. As a result of this adjustment, we recorded a decrease to the currently approved burden.

Total Burden: Our estimated burden for the information collection reflects an overall decrease of 2,500 hours and a corresponding decrease of 500 responses. The number of submissions FDA received to establish marketing as of February 15, 2007 has decreased and we have therefore revised the number of respondents to the information collection based on this data.

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

Consistent with established practice the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.