

United States Food and Drug Administration
Center for Tobacco Products
Warning Plans for Smokeless Tobacco Products
OMB Control No. 0910-0671
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 (FDA, us or we) guidance. 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 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402) as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section (b)(3)(A) of 15 U.S.C. 4402 requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA.

To implement these statutory requirements, warning plans are reviewed by FDA, upon submission by respondents. FDA published draft guidance entitled "Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products" on September 9, 2011, which describes the information and format to be submitted for smokeless plans (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-warning-plans-cigarettes-and-smokeless-tobacco-products>).

Submitters may also visit a webpage that describes the smokeless tobacco labeling and warning statement requirements (<https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/smokeless-tobacco-labeling-and-warning-statement-requirements>). Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan.

We therefore request extension of OMB approval of information collection provisions as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

This information collection for the submission to FDA of warning plans for smokeless tobacco products--is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal

distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended.

This collection of information is being collected from private sector for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

Warning plans can be submitted either electronically or in paper format. FDA estimates 90 percent of the expected respondents to this collection of information will submit their warning plans electronically.

Electronic submission of information is completed via the FDA's Electronic Submissions Gateway (ESG) or Center for Tobacco Products (CTP) Portal using FDA's eSubmitter tool. The Center for Tobacco Products (CTP) Portal, available at <https://ctpportal.fda.gov/ctpportal/login.jsp>, provides a secure online system for electronically submitting documents and receiving messages from CTP. 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. Instructions on obtaining an ESG account are available at <https://www.fda.gov/industry/electronic-submissions-gateway/create-esg-account>. Once approved, the user can send all submissions to CTP using the eSubmitter tool and FDA ESG or CTP Portal. 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 requirement for submission of warning plans does not fall disproportionately upon small businesses. The Smokeless Tobacco Act requires the submission of this information from manufacturers, distributors, importers, and retailers that manufacture, package, sell, offer to sell, distribute or import for sale or distribution smokeless tobacco products within the United States. Retailers may be exempt from this requirement under certain circumstances.

CTP has issued draft guidance to assist small businesses and other persons required to submit warning plans under the Smokeless Tobacco Act.

6. Consequences of Collecting the Information Less Frequently

Submission of warning plans for smokeless tobacco products to FDA is required so FDA can review and ensure the plan complies with the requirements set forth in the Smokeless Tobacco Act. The consequence of collecting this collection of information less frequently could result in a product being misbranded or adulterated.

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

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 May 09, 2022 (87 FR 27644), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments that were not PRA related 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 (PIA) underneath PIA ID: 2060831.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

In the burden hour table below, we calculate a total of 5 respondents.

Table 1.--Estimated Annual Reporting Burden¹

Activity	Numbers of Respondents	Numbers of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of initial rotational plans for health warning statements	1	1	1	60	60
Supplement to approved plan	4	1	4	30	120
Total					180

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our experience with the information collection over the past three years, we retain our estimate of 60 hours to complete an initial rotational plan. We estimate half this time for preparing and submitting a supplement to an approved plan (30 hours).

FDA estimates a total of 1 respondent will submit a new original warning plan yearly and take 60 hours to complete a rotational warning plan for a total of 60 burden hours. In addition, FDA estimates a total of 4 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 120 hours. The total burden for this collection is estimated to be 180 hours.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for submitting rotational warning plans is \$19,926. This estimate assumes that tobacco manufacturing management will account for 80 percent of the estimated 180 hours required to draft initial plans, at an average wage of \$63.81 per hour, and that office/administrative support will account for the remaining time (20 percent) at an average wage of \$21.51 (Department of Labor's Bureau of Labor Statistics for Tobacco Manufacturers (May 2021: https://www.bls.gov/oes/current/naics4_312200.htm). We double this to account for benefits and overhead, yielding an hourly wage rate of \$127.62 for management and \$43.02 for office/administrative support.

[Management time (180 hours x 0.80 x \$127.62 = \$18,377.28) + office/administrative time (180 hours x 0.20 x \$43.02 = \$1,548.72) = \$19,926.]

Respondent	Total burden hours	Hourly wage rate	Total costs
Tobacco industry: management	144	\$127.62	\$ 18,377.28
Tobacco industry: office/administrative	36	\$43.02	\$ 1,548.72
Total			\$ 19,926

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

There are no other annual cost burdens to respondents or record keepers resulting from the collection of information.

14. Annualized Cost to the Federal Government

Our estimated cost to the Federal government reflects the allocation of 50 percent of a full-time equivalent (FTE) employee to administering the requirements. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at <https://www.opm.gov> for a GS-13/4 employee, we calculate a total cost of \$58,752.50 (\$117,505 x .50).

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. The total estimated burden for this information collection is 180 burden hours, and 5 annual responses. Our estimated burden for the information collection reflects an overall decrease of 360 hours and a corresponding decrease of 9 responses. After receiving the

initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised.

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.