United States Food and Drug Administration

Center for Tobacco Products

Warning Plans for Certain Tobacco Products

OMB Control No. 0910-0671—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 (FDA) regulation and guidance. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). Implementing regulations are found in 21 CFR subchapter K (21 CFR parts 1100 through 1150)).

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 Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements (15 U.S.C. 4402(a)(1)). The warning statements specified in 4402(a)(1) must be randomly displayed on packaging and randomly distributed "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by FDA (15 U.S.C. 4402(b)(3)(A)). Those statements must be rotated quarterly in advertisements for each brand of smokeless tobacco product, also "in accordance with a plan" submitted to and approved by FDA (15 U.S.C. 4402(b)(3)(B)).

To implement statutory requirements for smokeless tobacco products, warning plans are reviewed by FDA, upon submission by respondents (21 U.S.C. 4402(b)(3)(C)). FDA published draft guidance entitled "Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products" on September 9, 2011, which describes the information and format to be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 (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 (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. Warning plans can be submitted either electronically or in paper format. The Center for Tobacco Products (CTP) Portal Next Generation (NextGen), available at ctpportal-

ng.fda.gov/portal/, provides a secure online system for electronically submitting documents and receiving messages from CTP.

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

The 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 as amended by the Tobacco Control Act, to determine whether the companies' plans provide for the equal distribution and random display of warning statements on packaging and the quarterly rotation of warning statements in advertising. Section 3 requires that warning statements be randomly displayed in each 12-month period, in as equal number of times as possible, on each brand of smokeless tobacco products, and be randomly distributed in all areas of the United States where the product is marketed, in accordance with an FDA approved plan. Section 3 also requires that warning statements be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with an FDA approved plan.

This information is collected from private sector for-profit businesses. This collection of information will be requested of 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.

3. Use of Improved Information Technology and Burden Reduction

Warning plans can be submitted either electronically or in paper format. Based on recent submissions for smokeless products, FDA estimates approximately 20 percent of respondents will submit their warning plans electronically.

Electronic submission of information is completed via the Center for Tobacco Products (CTP) Portal Next Generation (NextGen) using FDA's eSubmitter tool. The CTP Portal NextGen, available at ctpportal-ng.fda.gov/portal/, provides a secure online system for electronically submitting documents and receiving messages from CTP. 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 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 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 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 www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal-next-generation. Once approved, the user can send all submissions to CTP using the eSubmitter

tool and CTP Portal. Alternatively, respondents can mail submissions to FDA, as instructed in the guidance documents referenced in Section 1 above.

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

All domestic manufacturers and importers of tobacco products subject to regulation under chapter IX of the FD&C Act are affected by this rule, including small businesses. It is likely that about 85 percent of the affected entities would be considered small tobacco product manufacturers under the definition included in section 900 of the FD&C Act.[1]

The requirement for submission of warning plans for certain tobacco products does not fall disproportionately upon small businesses. The Smokeless Tobacco Act, as amended, 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. If necessary, FDA provides an alternative paper submission for those individuals who are unable, or choose not to, use the electronic portals. 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.

CTP has issued draft guidance to assist small businesses and other persons required to submit warning plans under the Smokeless Tobacco Act, as amended, which is described and linked in Section 1 above.

6. Consequences of Collecting the Information Less Frequently

Section 3 of the Smokeless Tobacco Act, as amended, (15 U.S.C. 4402) requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. (15 U.S.C. 4402(a)(1)). The warning statements specified in 4402(a)(1) must be randomly displayed on packaging and randomly distributed "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA. (15 U.S.C. 4402(b)(3)(A)). For a particular brand, the original rotational warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. But the original rotational warning plan must be approved by FDA before any entity manufactures, packages, sells, offers to sell, distributes, or imports for sale of any brand of smokeless tobacco product. Because warnings must be randomly displayed on packages, and rotated quarterly in advertisements, for smokeless tobacco products in accordance with an approved warning plan, a

[1] This estimate is based on counts of tobacco product manufacturer and importer EINs from 2023 TTB data and Census Bureau 2021 Statistics of U.S. Business data (www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html) on establishments with 500 or fewer employees (the closest reported threshold to the small tobacco product manufacturer 350 employee threshold).

new warning plan or supplement to an approved warning plan must be submitted and approved before distributing or displaying packages and advertisements for a new brand.

The consequence of collecting this 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

FDA published a 60-day notice for public comment in the Federal Register of July 3, 2025 (FR 90 29559). Two comments were received that were not PRA related.

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 Department of Health and Human Services approval on the privacy impact assessment (PIA) underneath PIA ID: FDA2107988.

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 3 respondents annually.

Table 1.—Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours

Submission of original rotational plans for health warning statements for smokeless tobacco products	1	1	1	60	60
Supplement to approved plan for smokeless tobacco products	2	1	2	30	60
Total					120

Based on FDA's experience over the years, FDA retains the estimate of 60 hours to complete an original rotational warning plan. FDA estimates that preparing and submitting a supplement to an approved plan will take half this time (30 hours).

FDA estimates a total of 1 respondent will submit a new original smokeless tobacco warning plan per year, which will take approximately 60 hours to complete, for a total of 60 burden hours. Additionally, FDA estimates a total of 2 respondents will submit a supplement to an approved smokeless tobacco warning plan per year, taking approximately 30 hours to complete per response, for a total of 60 burden hours. Thus, the total annual burden for the collection for smokeless tobacco warning plans is estimated to be 120 hours.

FDA has adjusted its burden estimate, which has resulted in a decrease of 60 hours and 2 respondents to the currently approved burden. This adjusted burden estimate is based on historical trends for smokeless tobacco warning plans. As of this OMB submission, FDA has received a total of 47 original smokeless warning plans, and a total of 33 supplements. Generally, after receiving the initial influx of original smokeless warnings plans, the number of annual warning plan submissions has decreased, and FDA does not expect submissions to increase at this time.

The total annual burden for this collection is estimated to be 120 hours.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for submitting rotational warning plans is $16,070.40. To reflect this estimate accurately, a composite wage was calculated from the 2024 BLS national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry (data.bls.gov/oes/#/industry/312200). We used a mix of 80 percent management occupations (average hourly wage $76.92) and 20 percent office/administrative time (average hourly wage $27.10).

This mix yielded a composite hourly wage of $66.96 (=($76.92 x 80%)+($27.10 x 20%)). We doubled this to account for benefits and overhead, yielding an hourly wage of $133.92.

Table 2.—Estimated Annualized Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco industry: management and office/administrative (composite wage)	120	$133.92	$16,070.40

Total	$16,070.40

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

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

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this collection is $132,638. Our estimated cost to the federal government reflects the allocation of 50 percent of a full-time equivalent (FTE) employee to administer the requirements. Using 2025 Grade 13 Step 4 salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/pdf/DCB.pdf and doubling to account for benefits and overhead, we calculate a total cost of $132,638 ($132,638 x 0.50 x 2).

15. Explanation for Program Changes or Adjustments

Program Change Burden

N/A

Adjustment Burden

FDA estimates a total of 2 respondents will submit a supplement to an approved smokeless tobacco warning plan, a decrease from the previously approved 4 respondents, based on 2022–2024 trends for smokeless tobacco warning plans. FDA is not adjusting the assumption that it will take approximately 30 hours to complete and submit a supplement to an approved smokeless tobacco warning plan.

Total Burden

FDA adjustments result in reducing the total annual burden hours associated with the supplement to an approved smokeless tobacco warning plan from 120 hours to 60 hours. The FDA has adjusted its burden estimate, which has resulted in a decrease of 60 hours and 2 respondents compared to the currently approved burden.

The total burden hours for the collection have been reduced from 180 hours to 120 total hours.

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.