4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0956]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Warning Plans for Certain Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0671. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Warning Plans for Certain Tobacco Products

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. 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 a 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 web page 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, available at

ctpportal.fda.gov/ctpportal/login.jsp, provides a secure online system for electronically submitting documents and receiving messages from CTP.

In the *Federal Register* of July 3, 2025 (FR 90 29559), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments that were not PRA related.

FDA estimates the burden of this collection of information as follows:

Table 1.-- Estimated Annual Reporting Burden[1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	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

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

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).

Regarding smokeless tobacco warning plans, FDA estimates a total of one 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 two respondents will submit a supplement to an approved smokeless tobacco warning plan, taking approximately 30 hours to complete per response, for a total of 60 burden hours. Thus, the total burden for this collection 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. Since publication of the 60-day notice, we removed the cigar warning plan burden from this collection.

Brian Fahey

Associate Commissioner for Legislation

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