4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0190]

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

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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 Smokeless Tobacco Products

OMB Control Number 0910-0671--Extension

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) 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 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 (https://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 (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. Warning plans can be submitted either electronically or in paper format. 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.

Based on our experience with the information collection over the past 3 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).

In the *Federal Register* of May 9, 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.

We estimate 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 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.

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. 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. Therefore, we have decreased our estimate burden by 360 hours.

Dated: October 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-22615 Filed: 10/17/2022 8:45 am; Publication Date: 10/18/2022]