



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; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0671. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 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.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

(OMB Control Number 0910-0671)--Extension

The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). 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 3(b)(3)(A) of the Smokeless Tobacco Act 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.

This information collection-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.

Based on the Federal Trade Commission's (FTC's) previous experience with the submission of warning plans and FDA's experience, FDA estimates that there are 52 companies affected by this information collection. To account for the entry of new smokeless tobacco companies that may be affected by this information collection, FDA is conservatively estimating the total number of annual respondents to this collection of information to be 100.

When the FTC requested an extension of their approved warning plan information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

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

Table 1.--Estimated Annual Reporting Burden¹

Activity	Numbers of Respondents	Numbers of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Capital Costs
Submission of rotational plans for health warning statements	100	1	100	60	6,000	\$1,200

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

FDA estimates a total of 100 respondents will respond to this collection of information and take 60 hours to complete a rotational warning plan for a total of 6,000 burden hours. In addition, capital costs are based on 100 respondents mailing in their submission at a postage rate of \$12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone).

Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to FDA to be \$1,200.

In the Federal Register of February, 19, 2016 (81 FR 8505), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was PRA related comment was received.

(Comment) The comment believes that warning plans should not be renewed every year, but should remain in force as long as necessary after their approval

(Response) FDA does not require that a previously FDA-approved warning plan be resubmitted. FDA reviews and approves warning plans only once, unless a submitter seeks to change the distribution or display of warnings on packages or rotation of warnings in advertisements, in which case the submission would be considered a supplement. The purpose of FDA's proposed extension is to account for the entry of new smokeless tobacco product brands and advertising onto the market place.

Dated: July 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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