4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0977]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 0910-0312. 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.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents--21 CFR Part 1140

OMB Control Number 0910-0312--Revision

This information collection supports FDA regulatory requirements contained in part 1140 (21 CFR part 1140) authorized under Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 9) and associated Agency guidance. Regulations in part 1140 establish permissible forms of labeling and advertising for cigarettes or smokeless tobacco and include reporting requirements directing persons to notify FDA if they intend to use a form of advertising or labeling that is not addressed in the regulations. Section 1140.30(a)(2) (21 CFR 1140.30(a)(2)) requires tobacco product manufacturers, distributors, and retailers to notify FDA if they intend to use advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in the regulations. The notifications must be made 30 days prior to the use of such mediums.

We allow electronic and written submission of these notifications. Respondents can mail notifications as prescribed in section 1140.30(a)(2) to FDA. Instructions providing clarification on how to format the notification may be found in the guidance document entitled "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (2010) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-regulations-restricting-sale-and-distribution-cigarettes-and-smokeless-tobacco-protect).

In the *Federal Register* of June 27, 2022 (87 FR 38160), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited. Subsequent to publication of the 60-day notice, we identified the associated guidance as an information collection instrument.

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

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

21 CFR Section/Guidance Document Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1140.30(a)(2)--Notification of other advertising or labeling medium	25	1	25	1	25

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

The burden hour estimates for this collection of information were based on submissions regarding cigarette and smokeless tobacco product advertising expenditures.

FDA estimates that approximately 25 respondents will submit an annual notice of alternative advertising or labeling, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, the total estimated time required for this collection of information is 25 hours. Based on a review of the information collection and the number of notifications received since 2018, we have made no adjustments to our burden estimate.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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