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) 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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0312. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, 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.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents--21 CFR 1140.30

OMB Control Number 0910-0312--Extension

This is a request for an extension of OMB approval for the information collection requirements contained in FDA's regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21 CFR part 1140 are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions including that subpart C (which included 21 CFR 897.24) and 21 CFR 897.32(c) be removed from the reissued rule (section 102(a)(2)(B)). The reissued final rule was published in the *Federal Register* of March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30 (21 CFR 1140.30), which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations and not originally described in the March 19, 2010, final rule. Section 1140.30 requires manufacturers, distributors, and retailers to (1) observe certain format and content requirements for labeling and advertising and (2) notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising.

In the *Federal Register* of May 17, 2019 (84 FR 22496), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related. The commenter stated that this program is ineffective and has no effect on whether Americans smoke. FDA disagrees. Section 1140.30 is intended to help protect children and adolescents by reducing the appeal of cigarettes and smokeless tobacco to them. Section 1140.30, in part, contains a comprehensive list of permissible forms of advertising and labeling; in the unlikely event that a person wishes to use a form of advertising or labeling that is not described in § 1140.30, the section directs respondents to notify FDA of the form of advertising or labeling they intend to use.

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

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1140.30--Scope of permissible forms of labeling and advertising	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 industry-prepared data and information regarding cigarette and smokeless tobacco product advertising expenditures.

FDA estimates that approximately 25 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, FDA estimates that the total time required for this collection of information is 25 hours.

We have adjusted our burden estimate to approximately 25 notifications annually, which more accurately reflects the current number of submissions under this regulation. This is a

decrease to the currently approved burden. The decrease in notifications is not unexpected given that the regulation applies to cigarettes and smokeless tobacco and many of the alternative media notifications have been made in previous years.

Dated: October 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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