4160-01-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:

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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 is a request for an extension of OMB approval of 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 (previously codified at 21 CFR part 897) are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 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--which included striking subpart C (with § 897.24) and § 897.32(c) from the reissued rule (section 102(a)(2)(B). The reissued final rule was published in the Federal Register on March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30, which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the

regulations. Disclosure requirements for § 1140.32 state that the advertising must use black text on a white background, but that this particular requirement does not apply to adult newspapers, magazines, periodicals, or other publications. Recordkeeping requirements under § 1140.32 indicate that competent and reliable survey evidence is required to determine whether a particular publication is an "adult" publication.

The requirements are as follows:

- Reporting--§ 1140.30 directs persons to notify FDA if they intend to use a form of advertising that is not described in § 1140.30(a)(1).
- Disclosure--§ 1140.32 requires firms to use black text on white backgrounds in labeling and advertising.
- Recordkeeping--§ 1140.32 indicates that firms advertising in "adult" magazines or publications may need survey evidence demonstrating that the publication meets the criteria for an "adult" publication.

For the disclosure and recordkeeping requirements under § 1140.32, FDA has decided to use its discretionary enforcement and has placed placeholders of 1 burden hour for disclosure and 1 burden hour for reporting because FDA does not intend to enforce the requirements for this section for the next 3 years.

In the Federal Register of September 28, 2012 (77 FR 59622), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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)	300	1	300	1	300

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1140.32 (Format and content requirements for labeling and advertising)	1	1	1	1	1

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

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
1140.32	1	1	1	1	1

[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 pharmaceutical advertising and cigarette and smokeless tobacco product advertising expenditures. The burden collection does not include reporting burdens associated with providing established names on labels and statements of intended use because section 102 of the Tobacco Control Act required that these provisions be struck from the reissued final rule (previously included in §§ 897.24 and 897.32(c)).

Section 1140.30 requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to 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. FDA estimates that approximately 300 respondents

will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice.

For the recordkeeping and disclosure requirements, § 1140.32 requires competent and reliable survey evidence to establish whether a newspaper, magazine, periodical, or other publication qualifies as an "adult" publication. Section 1140.32 also requires the use of a black text on a white background for labeling and advertising. The respondent and hourly burden for recordkeeping and disclosure under this section (2 burden hours total) reflect placeholders for the number of manufacturers who would keep records under this section.

During the next 3 years, FDA does not intend to enforce the recordkeeping and disclosure requirements of § 1140.32 and has revised the burden to act as a placeholder in the event FDA exercises its authority to enforce the requirements of this section in the future.

FDA estimates that the total time required for this collection of information is 302 hours.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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