4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

# Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents--21 CFR 1140 (OMB Control Number 0910-0312)--Renewal

This is a request for a renewal 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 including subpart C (which included 897.24) and 897.32(c) be removed 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 (formerly 897.30) 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 (formerly 897.32) states 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:

| | | |
|---|---|---|
| 21 CFR 1140.30 | Reporting | Directs persons to notify FDA if they intend to use a form of advertising that is not originally described in the March 19, 2010, final rule. |
| 21 CFR 1140.32 | Disclosure | Requires firms to use black text on white backgrounds in labeling and advertising. |
| 21 CFR 1140.32 | Recordkeeping | 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.

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 |
| Total | | | | | 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 Record-keepers | No. of Records per Record-keeper | Total Annual Records | Average Burden per Record-keeping | Total Hours |
|---|---|---|---|---|---|
| 1140.32 (Format and content requirements for labeling and advertising) | 1 | 1 | 1 | 1 | 1 |
| Total | | | | | 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 (previously 897.30) 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 (previously 897.32) 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: September 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-23833 Filed 09/27/2012 at 8:45 am; Publication Date: 09/28/2012]