REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS

OMB CONTROL NO. 0910-0312
SUPPORTING STATEMENT

EXTENSION

1. Circumstances Making the Collection of Information Necessary

This is a request for an extension of OMB approval of the information collection requirements contained in the Food and Drug Administration's (FDA's) regulations for cigarettes and smokeless tobacco containing nicotine. The regulations, which 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. 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 described in § 1140.30(a)(1).

2. Purpose and Use of the Information Collection

Federal law directed the Agency to reissue regulations pertaining to the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. The Agency intends to use the information in this collection to determine whether a party is meeting its regulatory obligations.

Respondents to this collection of information are businesses or other for-profit institutions who advertise the availability and sale of tobacco products.

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.

As noted in the FDA guidance entitled "Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco," the recordkeeping and disclosure requirements under section 1140.32 are not being enforced.

3. Use of Improved Information Technology and Burden Reduction

The Agency has considered the possible impact of improved information technology and determined that although improved technology may not reduce the burden significantly, electronic submission is available and may reduce some burden. Based on information related to other FDA information collections, we expect that 80 percent of respondents would take advantage of electronic submission.

In addition, the Agency has regulations regarding electronic signatures and records that may ultimately facilitate submission of information and, consequently, reduce the burden under this rule.

4. Efforts to Identify Duplication and Use of Similar Information

Because of the unique nature of the information to be collected, duplication of information is unlikely. The information to be submitted is only generated by, in the possession of, or determined by the manufacturer and, in some cases, distributors and retailers.

The Agency examined other federal tobacco-related statutes and regulations implemented by the Department of Agriculture (USDA), the Department of Health and Human Services (DHHS), the Department of the Treasury (Bureau of Alcohol, Tobacco, and Firearms (BATF)), the Federal Trade Commission (FTC), and the General Services Administration (GSA). FDA used computer databases and libraries to identify and to study tobacco-related statutes and regulations, and, during the rulemaking, consulted staff at DHHS, BATF, and the FTC. FDA determined that the disclosure, reporting, and recordkeeping requirements described in this document are not duplicative of requirements in other statutes and regulations.

For example, many USDA statutes and regulations concern tobacco classification and tobacco plants; BATF and Treasury statutes and regulations address tax issues and contraband cigarettes; FTC statutes and regulations involve warning statements on packages and advertising practices; and GSA statutes and regulations focus on cigarette and smokeless tobacco sales on federal property.

The Agency is also aware of regulations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA). The SAMHSA rule concerns tobacco regulation for substance abuse prevention and treatment block grants and focuses on States and State efforts to reduce tobacco use by young people. In contrast, FDA's rule focuses on manufacturers, distributors, and retailers. The SAMHSA rule reflects a statutory requirement that States have laws prohibiting the sale of tobacco products as a condition of receipt of certain grants and that States enforce those laws and meet certain negotiated rates of compliance.

5. Impact on Small Businesses or Other Small Entities

The disclosure, reporting, and recordkeeping requirements on small businesses should not be burdensome.
The reporting requirements in § 1140.30 affect small businesses if they decide to use a form of advertising or labeling not specified in § 1140.30 or if they decide to advertise in an "adult" publication. The list of permitted forms of advertising and labeling in § 1140.30 is very comprehensive, so FDA does not anticipate that many small businesses will notify the Agency of their intent to use a form of advertising or labeling that is not specified in § 1140.30.

6. Consequences of Collecting the Information Less Frequently

The regulations reissued under the Tobacco Control Act require respondents to respond to the data collection occasionally; for example, if they need to provide notice of a different medium under § 1140.30. The frequency of response depends on what type of advertising is used, its frequency, and the type of media used to display the advertising. If this information is collected less frequently, FDA will be unable to enforce advertising provisions under section 102 of the Tobacco Control Act

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection methods are consistent with the guidelines of 5 CFR 1320.5. There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of January 12, 2016 (81 FR 1428). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA did not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Section 101 of the Family Smoking Prevention and Tobacco Control Act protects certain information from disclosure (see Public Law 111-31, June 22, 2009).
Information provided by respondents will be kept private and anonymous, except as otherwise required by law.

This collection of information does not require IRB approval.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of the Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The burden hour estimates for this rule are 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.

FDA estimates that the total time required for this collection of information is 300 hours..

Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1140.30 (Scope of permissible forms of labeling and	300	1	300	1	300

advertising)					
Total					300

12b. Annualized Cost Burden Estimate

The costs of this collection of information is $7,989 (300 hours x $26.63), which is the seasonally adjusted average Bureau of Labor and Statistics March 2016 hourly and weekly earning wage.

Respondent	Total Burden Hours	Hourly Wage Grade	Total Costs
Tobacco Industry	300	$26.63	$7,989
Total			$7,989

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection. With respect to § 1140.30, the Agency expects no estimated capital or annual costs. (The provision provides for the possibility that a person may seek to use a form of advertising that is not listed in § 1140.30, and should notify FDA if they intend to use a medium not mentioned in § 1140.30.)

14. Annualized Cost to the Federal Government

The anticipated cost to government is the equivalent of one full-time equivalent (FTE) employee to collect, process, and file the responses received related to § 1140.30 for a total cost of $116,000.

15. Explanation for Program Changes or Adjustments

The estimated burden hours have been reduced from 302 hours to 300 hours. The reduction is due to FDA's removal of the two 1-hour place holders for burden in § 1140.32, which is not being enforced.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected will not be used for statistical purposes.

17. Reason Display of OMB Expiration Date is Inappropriate

The Agency is not seeking approval to not display the expiration date of OMB approval for these information collections.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.