REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS
OMB CONTROL NO. 0910-0312
SUPPORTING STATEMENT

1. Circumstances That Make Information Collection Necessary

This is a request for a reinstatement 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 requires 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 § 897.24) and § 897.32(c) be removed from the reissued rule (§ 102(a)(2)(B)).

In accordance with the statutory mandate, the rule includes section 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 rule. Section 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. The rule indicates 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 described in the 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

2. Purpose of Information Collection

Federal law directs 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 this information to determine whether a party is meeting its regulatory obligations. Failure to collect this information may result in a product being declared misbranded.

Sections 1140.30 and 1140.32 (formerly §§ 897.30 and 897.32) are 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 rule directs persons to notify FDA if they intend to use a form of advertising or labeling that is not described in the rule. Section 1140.32 would reduce the appeal of cigarettes and smokeless tobacco to children and adolescents by requiring most advertisements to use black text on white backgrounds, without any colors or pictures. The text-only requirement does not apply to advertisements in "adult" publications, and § 1140.32 describes what constitutes an adult publication. By implication, firms wishing to advertise in "adult" publications may need to retain records to demonstrate that the publication is an "adult" publication within § 1140.32.

3. Use of Improved Information Technology

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% of respondents would take advantage of electronic submission.

Additionally, one should note that the agency has regulations regarding electronic signatures and records which may ultimately facilitate submission of information and, consequently, reduce the burden under this rule.

4. Efforts to Identify Duplication and Availability 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 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. Small Business Considerations

The disclosure, reporting, and recordkeeping requirements on small businesses should not be burdensome. Most cigarette manufacturers are not small businesses.

The reporting, disclosure, and recordkeeping requirements in §§ 1140.30 and 1140.32 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 the agency 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. Small businesses should also be able to implement the disclosure requirement in § 1140.32 (black text on white background) easily and without being disadvantaged; in fact, the requirement may even reduce advertising costs for small businesses because color advertisements are usually more expensive to produce.

As for § 1140.32 and the concept of "adult" publications, FDA notes that, of 101 magazines with tobacco advertisements in 1994, large companies published 79 of the magazines, and, in the remaining 22 publications, less than 3 percent of the total revenue was derived from tobacco advertisements. FDA believes that many magazines could avoid the "text only" restriction for cigarette and smokeless tobacco advertising by demonstrating low youth readership.

The agency has no estimates of the number of small businesses that advertise in magazines or other publications or the number that would develop records to show that a particular publication was an "adult" publication. Thus, the rule makes no special considerations for small businesses.

6. Consequences of Less Frequent Collection

The regulations required to be reissued by the Tobacco Control Act will require respondents to respond to the data collection occasionally; for example, if they need to provide notice of a different medium under § 1140.30.

7. Special Circumstances That Require Departures from 5 CFR 1320.5

The collection methods are consistent with the guidelines of 5 CFR 1320.5.

8. Efforts to Consult with Non-Agency Personnel

The burden hour estimates for this rule were based on industry-prepared data and information regarding pharmaceutical advertising and cigarette and smokeless tobacco product advertising expenditures. The estimates are identical to the estimates used in the previous information collection budget for these provisions.

9. Payment or Gifts

FDA did not provide any payment or gift to respondents.

10. Assurances of Confidentiality

Section 101 of the Family Smoking Prevention and Tobacco Control Act protects certain information from disclosure (see Public Law 111-31, June 22, 2009).

11. Additional Assurances of Privacy

No questions of a sensitive nature are asked.

12. Estimates of the Burden Collection

As stated earlier, the estimates are identical to those previously used by the agency and approved by OMB. The burden collection no longer reflects 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 sections 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 all known forms of advertising, but the agency has provided an estimate of 1 hour in the remote chance that a firm will provide such notice to FDA.

For the recordkeeping requirement, § 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. In the August 28, 1996, final rule, FDA estimated that 31 respondents may be affected and that a total of 100,000 hours would be needed for such surveys (see 61 FR at 44612). The 31 respondents reflects the number of manufacturers as reported in a 1992 U.S. census of tobacco product manufacturers, and the estimated total time for these surveys would be 100,000 hours (assuming 100 surveys (for the approximately 100 magazines in which tobacco manufacturers advertise) at 1,000 hours per survey) or approximately 3,226 hours per respondent (100,000 total hours/31 total respondents = 3,225.81 hours per respondent, rounded up to 3,226).

For the disclosure requirement, § 1140.32, in the August 28, 1996, final rule, FDA estimated that approximately 25,000 pieces of labeling or advertising would be affected. The agency derived these figures by using advertising expenditures by the cigarette and smokeless tobacco industries and by the pharmaceutical industry, applying the ratio of such expenditures against the 25,000 pieces of advertising that the agency receives from the pharmaceutical industry, and projecting that printed advertisements may increase due to the rule's effect on promotional activities (see 61 FR 44395, 44597 (Aug. 28, 1996)). FDA also estimated that the time required for such advertising is one hour based on the highest estimated time reported in industry comments on the proposed rule. In summary, FDA estimates there will be 1 respondent for the reporting requirement (1140.30), 31 respondents for the recordkeeping requirement (1140.32), and 25,000 respondents for the disclosure requirement (1140.32) for a total of 25,032 respondents.

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 advertising)	1	1	1	1	1

Total					1

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeping	Total Hours
1140.32 (Format and content requirements for labeling and advertising)	31	1	31	3226	100,006
Total					100,006

* O & M = operating and maintenance

Estimated Annual Third-Party Disclosure Burden

21 CFR Section	No. of Respondents	Annual Frequency Per Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
1140.32	25,000	1	25,000	1	25,000

13. Cost to Respondents

With respect to § 1140.30, the agency has no estimated capital or annual costs. The provision provides for the possibility that a person may seek permission to use a form of advertising that is not listed in § 1140.30, but FDA believes that § 1140.30 already covers all known forms of advertising.

The requirement of black text on a white background, in § 1140.32, would result in negligible costs, if not cost savings, to industry by eliminating the need for images and colors in labeling and advertisements. However, as for the need for survey evidence if a firm intends to advertise in an “adult” newspaper, magazine, or other periodical, the agency estimates that such evidence would result in approximately $96,774 in costs per respondent or 3 million in total costs (96,774 multiplied by 31 = 2,999,994, rounded up to 3,000,000).

14. Cost to the Federal Government

The agency expects its costs related to these burdens to be reduced from the costs projected in 1999, which ranged from $257,785 to $412,406, because the requirements of §§ 897.24 and 897.32(c) were struck. We predict that the lower range will more closely reflect the agency's costs. In addition, it anticipates only one notice under § 1140.30.

15. Reason for Changes in Burden

The estimated burden hours have been reduced from 205,001 hours to 125,007. The reduction reflects the removal of 21 CFR § 897.24, which was part of the 1999 information collection request for this rule, from this 2010 information collection request. The Tobacco Control Act struck this provision from the reissued final rule.

16. Plans for Statistical Use

Information collected will not be used for statistical purposes.

17. Approval for Not Displaying Expiration Date

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

18. Exception to the Certification Statement; Item 19, OMB Form 83-I

FDA is not requesting an exception to the certification statement identified in Item 19 "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I.