CENTER FOR TOBACCO PRODUCTS

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

OMB Control No. 0910-0312

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration (FDA, us or we) regulations and associated agency guidance. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t).

   Regulations in part 1140 establish permissible forms of labeling and advertising and include reporting requirements directing persons to notify FDA if they intend to use a form of advertising or labeling that is not addressed in the regulations. Section 1140.30 advises tobacco product manufacturers, distributors, and retailers: to notify FDA if they intend to use advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in the regulations.

   We therefore request OMB approval of the information collection provisions found in 21 CFR Part 1140 and the associated guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

   Federal law directed the FDA to issue regulations pertaining to the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. We intend 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 cigarette and smokeless 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," (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-concerning-certain-regulations-restricting-sale-and-distribution-cigarettes-and) the recordkeeping and disclosure requirements under section 1140.32 are not being enforced.

3. Use of Improved Information Technology and Burden Reduction

FDA allows electronic submissions, via FDA's Electronic Submissions Gateway, and written submissions. FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing. FDA estimates that 80% of the respondents will use electronic means to submit their plans.

Electronic submissions are made through our Electronic Submissions Gateway (ESG) using an "eSubmitter" tool developed by FDA. The FDA ESG system requires users to apply for a free account before submitting data, a process which can take one to three weeks to complete. Once approved, the user can send all submissions to CTP using the eSubmitter tool and CTP Portal or FDA ESG. Instructions for preparing tobacco product submissions are available via: https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions. Information collection associated with electronic records is currently approved in OMB control number 0910-0303.

Alternatively, respondents can mail notifications to FDA. Instructions providing clarification on how to format the notification may be found in the guidance document entitled "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-regulations-restricting-sale-and-distribution-cigarettes-and-smokeless-tobacco-protect).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

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 we do not anticipate that many small businesses will notify FDA 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

This information collection for submissions regarding cigarette and smokeless tobacco product advertising and labeling is statutorily mandated (Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) Section 102).

The regulations 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 or labeling.

If this information is collected less frequently, FDA will be unable to enforce advertising and labeling provisions under § 1140.30.

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

This section is not applicable. 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 the Federal Register of June 27, 2022 (87 FR 38160), FDA published a 60-day notice requesting public comment on the proposed collection of information. One non-PRA comment was received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of information submitted under section 102 of the FD&C Act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) and FDA's implementing regulations. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions.

CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. FDA's web and privacy policies are provided on all FDA internet (FDA.gov) pages the PIA provides further notice.[1] The Center for Tobacco Products (CTP)
Electronic Submissions system (eSub) is a suite of database-supported applications that facilitates the collection, logging, tracking, and retrieval of documents provided to the FDA by the tobacco industry and others (e.g., adverse experience reports from the general public). CTP uses this data to evaluate tobacco products, develop policy, and assess industry compliance with the Family Smoking Prevention and Tobacco Control Act. CTP received HHS approval on the privacy impact assessment for the Electronic Submissions system and was assigned PIA ID: 2060831.

[1] https://www.fda.gov/about-fda/about-website/website-policies#privacy

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1140.30(a)(2); Notification of other advertising or labeling medium	25	1	25	1	25

The burden hour estimates for this collection of information were based on submissions regarding cigarette and smokeless tobacco product advertising expenditures.

FDA estimates that approximately 25 respondents will submit an annual notice of alternative medium, and the Agency has estimated it should take 1 hour to provide such notice.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for this collection of information is $1,557.50. This estimate assumes that tobacco industry (all occupations) will account for the submissions regarding cigarette and smokeless tobacco product advertising or labeling at an average wage of $31.15 (Department of Labor's Bureau of Labor Statistics for Tobacco Manufacturers (May 2021: https://www.bls.gov/oes/current/naics4_312200.htm). We double this to account for benefits and overhead, yielding an hourly wage rate of $62.30.

21 CFR Section 1140.30	Total Burden Hours	Hourly Wage Rate	Total Costs
Tobacco Industry	25	$62.30	$ 1,557.50

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Our estimated cost to the Federal government reflects the allocation of one (1) full-time equivalent (FTE) employee to administer the requirements. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at https://www.opm.gov for a GS-13/4 employee, we calculate a total cost of $117,505 ($117,505 x 1).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection and the number of notifications received since 2018, we have made no adjustments to our burden estimate. FDA discovered an associated guidance that was not included as an information collection instrument; it is now included in ROCIS. The guidance provides clarification on how to format the notification.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.