

U.S. Food and Drug Administration
Required Warnings for Cigarette Packages and Advertisements

0910-0877
RIN 0910-AI39
Final Rule

SUPPORTING STATEMENT PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

This rule is being issued in accordance with sections 201 and 202 of the Tobacco Control Act (Pub. L. 111-31, 123 Stat. 1776), which amend section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333). This rule is also being issued based upon FDA's authorities related to misbranded tobacco products under sections 903 (21 U.S.C. 387c); FDA's authorities related to records and reports under section 909 (21 U.S.C. 387i); and FDA's rulemaking and inspection authorities under sections 701 (21 U.S.C. 371), 704 (21 U.S.C. 374), and 905(g) (21 U.S.C. 387e(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In 2009, in enacting the Tobacco Control Act, Congress amended the FCLAA and directed FDA to issue new cigarette health warnings that would include a color graphic component depicting the negative health consequences of smoking to accompany the new textual warnings (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act).

The requirement for submission of plans for cigarette packages and advertisements, and the specific marketing requirements relating to the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in alternating sequence in cigarette product advertising, appear in § 1141.10(d)(5). A record of the FDA-approved plan must also be established and maintained.

2. Purpose and Use of the Information Collection

FDA asks that each plan cover both packaging and advertising to the extent applicable. The tobacco product manufacturer, distributor, or retailer should demonstrate how they plan to achieve the random and equal display and distribution of the required warnings on packages and the quarterly rotation of required warnings in advertisements. Required warnings for cigarettes must be randomly and equally displayed and distributed on packages, and rotated quarterly in advertisements, in accordance with an FDA-approved plan. FDA's review of a plan would only be for the purpose of determining compliance

with the regulatory criteria for approval of a plan, as set forth in §1141.10(g)(3). FDA requests that each plan include representative samples of packages and advertisements with each of the required warnings. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan, not a review of the content of the package labels and advertisements.

To facilitate FDA's review, FDA requests that cigarette plans be accompanied by a cover letter includes information such as:

- The date of the submission;
- The following subject line: "RE: CIGARETTE PLAN FOR CIGARETTES ("Original," "Amendment," or "Supplement");
- A list of any previous submissions made to FDA relating to the cigarette plan, identified by the Submission Track Number (STN) and the date of submission, if applicable;
- A statement as to whether the cigarette plan covers packaging only, advertising only, or both packaging and advertising;
- The name, address, and phone number of the person making the submission;
- The name of the most responsible official if the submitter is a company;
- Identification of the submitter as the manufacturer, distributor, or retailer of the tobacco products covered by the cigarette plan;
- The Data Universal Numbering System (D-U-N-S®) number of the person making the submission;
- The name, address, phone number, fax number, and email address of the individual authorized to act as the contact point for the cigarette plan;
- A list of all cigarette brands covered by the plan, preferably identifying cigarettes using the unique name and identifying number (e.g., SKU, catalog number, UPC) that was provided when the product was listed under section 905 of the FD&C Act (21 U.S.C 387e). Alternatively, if desired, a manufacturer may refer to "all brands in its product listing(s) under section 905(i) of the FD&C Act" and state that the cigarette plan incorporates any and all future brands listed with FDA. Likewise, a retailer may state, "all brands"; and
- If the submitter is a third party, FDA recommends that the cover letter also include a statement by an authorized official of the manufacturer, distributor, or retailer that the third-party agent is authorized to submit the cigarette plan on its behalf. If a statement is not included in the cover letter, FDA will confirm with the manufacturer, distributor, or retailer that the submitter is an authorized third-party agent before reviewing the plan.

FDA strongly encourages entities to submit their plans within five (5) months after the date of publication of the final rule and before advertising or commercially marketing a product that is subject to the rule. Packages and advertisements of cigarettes will be required to bear the required warnings beginning 15 months after the date of publication of the final rule. FDA intends to request an amendment to a plan under review if FDA needs clarification of information in the plan or other additional information to determine whether it could approve the plan. Any such amendments would likely increase the overall review time.

After FDA approval of an initial plan, a supplement to the approved plan should be submitted to FDA and approved before making changes to the random and equal display or distribution of required warnings on packages or the quarterly rotation of required warnings in advertisements. For a new brand, a new plan or a supplement to an approved plan would be required to be submitted and approved before displaying or distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warning statements for all brands.

The respondents to this collection of information are manufacturers, distributors, and certain retailers of cigarettes who will be required to submit plans for cigarette packages and advertisements to FDA. Respondents are for-profit businesses from the private sector.

3. Use of Improved Information Technology and Burden Reduction

FDA intends to allow 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 99% of the respondents will use electronic means to submit their plans.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. The Tobacco Control Act amends the FCLAA of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. Once this rule is finalized and becomes effective, FDA will be the only Federal agency responsible for the collection of plans for cigarette packages and advertising.

5. Impact on Small Businesses or Other Small Entities

We anticipate that small businesses are mostly affected by this information collection. Based on data obtained from 2017 TTB data, there were 32 active cigarette manufacturers and 27 active cigarette importers (total of 59). We estimate that about 30 small cigarette manufacturers and roughly 25 small cigarette importers (total of 55) could be affected by this rule.

In the *Federal Register* of December 30, 2019 (84 FR 71957), FDA issued a draft guidance document titled “Submission of Plans for Cigarette Packages and Cigarette Advertisements” to assist the entities affected by this information collection. This draft guidance document provides information to those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing recommendations related to those submissions, including information on what should be in a cigarette plan, who should submit a cigarette plan, and when to submit a cigarette plan.

6. Consequences of Collecting the Information Less Frequently

Collecting the information less frequently would impede FDA’s regulatory authority over tobacco product manufacturers and their products. Submission of a plan for cigarette packages and advertisements to FDA is required so FDA can review and ensure the plan complies with the requirements set forth in 21 CFR part 1141 and section 4 of the FCLAA.

FDA's review of a plan would only be for the purpose of determining compliance with the regulatory criteria for approval of a plan, as set forth in § 1141.10(g)(1) and (2). FDA requests that each plan include representative samples of packages and advertisements with each of the required warnings. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan, not a review of the content of the package labels and advertisements.

The consequence of collecting this collection of information less frequently would result in a decrease of the promotion of increasing understanding of the negative health consequences of smoking.

The required cigarette health warnings must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed throughout the United States in accordance with a plan approved by the FDA. If FDA does not receive and approve the plan, we would not be able to verify that manufacturers are randomly displaying and distributing the new cigarette health warnings in accordance with the requirements of the rule and section 4 of the FCLAA..

7. Special Circumstances Relating to 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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the *Federal Register* of August 16, 2019 (84 FR 42754). No PRA related comments were received.

9. Explanation of Any Payment or Gift to Respondents

There is no incentive offered to respond to this collection.

10. Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. Among the laws governing the disclosure of data submitted under this collection of information are the Freedom of Information Act (FOIA) (5 U.S.C. 552), section 101 of the Family Smoking Prevention and Tobacco Control Act (which protects certain information from disclosure see Public Law 111-31, June 22, 2009), and FDA’s implementing regulations at 21 CFR Part 20. 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.

This ICR does not request any personally identifiable information and does not include a form that requires a Privacy Act Statement.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.-- Estimated One-Time Reporting Burden

Type of Plan	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial plans	59	1	59	150	8,850
Supplements	30	1	30	75	2,250
Total					11,100

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless OMB control number 0910-0671 and cigars OMB control number 0910-0768) and 2017 Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) data.

As discussed in the regulatory impact analysis, based on 2017 TTB data FDA estimates 59 entities will be affected by the rule. We estimate these 59 entities will submit initial plans, and it will take an average of 150 hours per respondent to prepare and submit a plan for packaging and advertising for a total of 8,850 hours. We estimate that about half of respondents will submit a supplement. If a supplement to an approved plan is submitted, FDA estimates it will take half the time per response. We estimate receiving 30 supplements at 75 hours per response for a total of 2,250 hours. FDA estimates that the total hours for submitting initial plans and supplements will be 11,100.

§ 1141.10(g)(4) establishes that each tobacco product manufacturer required to randomly and equally display and distribute warnings on cigarette packages or quarterly rotate warnings in cigarette advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and this part must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy (or record) of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection requires that the record(s) be retained for a period of not less than 4 years from the date of FDA's approval of the plan.

Table 2.--Estimated Annual Recordkeeping Burden

Plan Records	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records	59	1.5	89	3	267
Total					267

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 3 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless OMB control number 0910-0671 and cigars OMB control number 0910-0768). Based on our estimates for the submission of one-time, initial plans and supplements (i.e., that all respondents will submit one-time, initial plans and about half of respondents will submit supplements to FDA-approved plans), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA estimates that the total burden for this information collection is 11,367 hours (11,100 reporting + 267 recordkeeping).

FDA concludes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB because they do not constitute a "collection of information" under the PRA (44 U.S.C. 3501-3520). Rather, these labeling statements are a "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for submitting plans is \$2,307,595. This estimate assumes that management or attorneys will account for 80 percent of the estimated 11,367 hours required to draft initial plans, at an hourly billing rate of \$250 per hour, and that clerical support will account for the remaining time (20 percent) at an hourly billing rate of \$15. [Management and Attorneys' time (11,367 hours x 0.80 = 9,094 hours; 9,094 x \$250 = \$2,273,500) + Clerical time (11,367 hours x 0.20 = 2,273 hours; 2,273 x \$15 = \$34,095) = \$2,273,500.]

Activity	Total Burden	Hourly Wage Rate	Total Respondent
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	Hours		Costs
Submitting plans and records (Management and Attorneys)	9,094	\$250.00	\$2,273,500
Submitting plans and records (Clerical)	2,273	\$15	34,095
Total			0

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.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal Government will incur the following costs:

Staff Costs

Total annual cost to the Federal Government = \$1,740,000

Full-time Equivalents (FTEs) = 15

Annual Cost per FTE=\$116,000

FDA estimates that the equivalent of 15 full-time equivalent employees (FTEs) would be required annually.

The salary rate of \$116,000 includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency's current estimates of staff expenses. FDA estimates the total annualized cost to the government is \$1,740,000.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.