4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3065]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0877. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements--21 CFR Part 1141

OMB Control Number 0910-0877--Extension

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

On March 18, 2020, FDA issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements entitled "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements" (85 FR 15638; https://www.federalregister.gov/d/2020-05223). The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA) (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics.

Section 1141.10(g) (21 CFR 1141.10(g) and section 4(c) of the FCLAA sets forth 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 advertising and requires the submission of plans outlining how the cigarette packaging and advertising will comply with such requirements. FDA must review and approve cigarette plans in advance of any person displaying or distributing cigarette packages or advertisements for products that are required to carry the required warnings, and a record of the FDA-approved plan must be established and maintained by the tobacco product manufacturer.

To implement these statutory and regulatory requirements, cigarette plans will be reviewed by FDA upon submission by respondents. FDA published a guidance document on July 9, 2021, entitled "Submission of Plans for Cigarette Packages and Cigarette Advertisements" which describes cigarette plans information, format and submission (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-plans-cigarette-packages-and-cigarette-advertisements-revised).

Pursuant to section 201(b) of the Tobacco Control Act, FDA finalized the "Required Warnings for Cigarette Packages and Advertisements" rule with an effective date of June 18, 2021, 15 months after the date of publication. On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] The effective date of the final rule has been delayed in accordance with orders issued by the U.S. District Court for the Eastern District of Texas. Visit FDA's website at https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements for updates regarding the effective date of the rule and related timelines, including the recommended date for submitting cigarette plans for FDA review.

In the *Federal Register* of September 19, 2022 (87 FR 57206), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Part 1141 and Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Original Submission (Initial Plan)	59	1	59	150	8,850
Supplement	30	1	30	75	2,250
Total					11,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20-cv-00176 (E.D. Tex. filed April 3, 2020).

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 data.

FDA estimates 59 entities are affected. 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.

Section 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 part 1141 must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection requires that the FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Part 1141 and Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Original Submission (Initial Plan) Records	59	1.5	89	3	267
Total					267

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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 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. 3501-3521). 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)).

Since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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