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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 Barrett, 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.

Required Warnings for Cigarette Packages and Advertisements -

21 CFR Part 1141

OMB Control Number 0910-0877-Extension

This information collection supports Food and Drug Administration (FDA) regulations and guidance. Tobacco products are 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 amended section 4 of 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 2020

final rule specifies the 11 new textual warning label statements and accompanying color graphics.

Section 4(c) of the FCLAA and 21 CFR 1141.10(g) 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 requirements, cigarette plans will be reviewed by FDA upon submission by respondents. FDA published an updated guidance document in September, 2024, entitled "Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)" 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.

Litigation is pending regarding the validity of the final rule. See R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al., No. 6:20-cv-00176 (E.D. Tex.), 25-40137 (5th Cir.); and Philip Morris USA Inc. et al. v. United

States Food and Drug Administration et al., No. 2:24-cv-00143 (S.D. Ga.). FDA will provide updates regarding submission of cigarette plans as they are available. Visit FDA's website https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements for updates.

In the *Federal Register* of December 19, 2025, FDA published a 60-day notice requesting public comment on the proposed information collection and associated burden estimates. FDA received two PRA related public comments on the 60-day notice for this information collection. One commenter supported the extension, agreed that the collection is necessary for FDA's public health mission, and found the burden estimates reasonable. The second commenter supported the required warnings but questioned whether FDA's collection of "consumer data" was necessary and expressed concern about potential burden.

(Comment) One commenter supported the proposed extension of this information collection, stating that the collection appears necessary for FDA's public health mission and implementation of statutorily required warning plans. The commenter also indicated that the burden estimates are reasonable and appropriately reflect recent submission trends.

(FDA Response) FDA agrees that this information collection is necessary to implement statutory and regulatory requirements for cigarette packages and advertisements, including the submission of warning plans required under section 4 of the Federal Cigarette Labeling and Advertising Act and 21 CFR 1141.10(g). FDA's burden estimates are based on the Agency's experience with similar submissions and available

data on industry activity. Based on this comment, FDA has not made any changes to the burden estimates or methodology.

(Comment) The second commenter supported the requirement for cigarette health warnings but questioned whether FDA's collection of "consumer data" is necessary and expressed concern about potential burden associated with such data collection.

(FDA Response) FDA agrees that this information collection is necessary to support required warnings for cigarette packages and advertisements. However, FDA disagrees with the commenter's concern regarding "consumer data." This information collection does not involve the collection of data from consumers. Rather, it requires manufacturers, distributors, and certain retailers to submit plans describing how they will comply with statutory and regulatory requirements for the display and rotation of required warnings. The burden estimates reflect only the reporting and recordkeeping activities associated with preparing, submitting, and maintaining these plans. Based on this comment, FDA has not made any changes to the burden estimates or methodology.

FDA considered all comments received in response to the 60-day notice and determined that no revisions to the information collection or burden estimates are warranted.

FDA's burden estimates, discussed below, reflect consideration of the comments received in response to the 60-day notice as well as updated data on recent submission activity. These burden estimates reflect only industry reporting and recordkeeping activities associated with plan submission and maintenance, and do not include any collection of information from individual consumers. The following estimates reflect

only the reporting and recordkeeping burden for manufacturers, distributors, and retailers associated with preparing, submitting, and maintaining cigarette warning plans.

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

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

21 CFR Part 1141 and Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Original Submission (Initial Plan)	17	1	17	150	2,550
Supplement	8	1	8	75	600
Total					3,150

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

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless, consolidated under OMB control number 0910-0671) and 2023 Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) data.

FDA estimates up to 17 entities are affected annually. We estimate these 17 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 2,550 hours. We estimate that about half of respondents will submit a supplement each year. FDA estimates it will take respondents half the time per response to prepare and submit a supplement to an approved plan. We estimate receiving 8 supplements per year at 75 hours per response for a total of 600 hours. FDA estimates that the total annual hours for submitting initial plans and supplements will be 3,150. Based on a review of the information collection since our last request for OMB approval, our reporting burden estimate has reduced from 11,100 to 3,150 hours annually.

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 21 CFR 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[1,2]

21 CFR Part 1141 and Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (hours)	Total Hours
Original Submission (Initial Plan) Records	51	1.5	77	3	231
Total					231

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

FDA estimates that 51 recordkeepers will keep a total of about 77 (rounded) records at 3 hours per record for a total of 231 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless, consolidated under OMB control number 0910-0671). 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. 3501-3520). 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)).

FDA estimates that the total burden for this information collection is 3,381 hours annually (3,150 hours for reporting + 231 hours for recordkeeping). Independently of the public comments received, FDA has adjusted its burden estimate based on updated submission data, which has resulted in a decrease to the currently approved burden. Our estimated reporting burden for the information collection reflects an overall decrease of 76 annual responses and a corresponding decrease of 7,986 annual hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years. These updated estimates are consistent with the scope of this information collection as described above and do not reflect any changes made in response to public comments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-10187 Filed: 5/20/2026 8:45 am; Publication Date: 5/21/2026]