E 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information entitled, "Required Warnings for Cigarette Packages and Advertisements."

DATES: Either electronic or written comments on the collection of information must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-6076 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Required Warnings for Cigarette Packages and Advertisements." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted

as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.

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 and cigars, 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 to the nearest whole number.

FDA estimates that 51 recordkeepers will keep a total of about 76.5 (rounded to 77) 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 and cigars, 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 3,981 hours annually (3,150 hours for reporting + 231 hours for recordkeeping). We have adjusted our burden estimate, 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 respondents and a corresponding decrease of 7,386 annual hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Brian Fahey,

Associate Commissioner for Legislation.

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