e: 6750-01-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 ("PRA"), the Federal Trade Commission ("FTC" or "Commission") is seeking public comments on its proposal to seek Office of Management and Budget ("OMB") clearance for information collection requirements contained in the Federal Cigarette Labeling and Advertising Act, which requires the FTC to review plans for the rotation of health warnings on cigarette packaging and advertising. The proposed clearance request will be submitted to OMB for review following this opportunity for public comment. The current clearance expires on January 31, 2024, and the FTC intends to seek OMB renewal for three years.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "Surgeon General's Cigarette Health Warnings: Paperwork Comment, FTC File No. P854505" on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, N.W., Suite CC-5610 (Annex J), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Shira Modell, General Attorney, Division of Advertising Practices, Bureau of Consumer Protection, (202) 725-2162, smodell@ftc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.* (2006 ed.) ("FCLAA"), prohibits cigarette manufacturers and importers from manufacturing, packaging, importing for sale, or distributing cigarettes within the United States unless the packages bear one of four statutorily-prescribed Surgeon General's health warnings. 15 U.S.C. 1333(a). Cigarette advertising by any of these entities must also bear statutorily-prescribed health warnings. *Id*. Section 1333(b) sets forth the location and format requirements for the health warnings on both packaging and advertising.

The FCLAA further provides that the health warnings "shall be rotated by each manufacturer or importer . . . quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Federal Trade Commission." 15 U.S.C. 1333(c)(1).

The FCLAA does provide an alternative to the requirement of quarterly rotation on cigarette packaging for manufacturers and importers whose sales satisfy two criteria.[1] These manufacturers and importers can seek approval to display the Surgeon General's warnings on a particular cigarette brand style[2] "an equal number of times within the twelve-month period beginning on the date of the approval by the Commission of the application" (hereinafter referred to as "equalization"). 15 U.S.C. 1333(c)(2)(C). In order to qualify for equalization, the sales of a manufacturer or importer must meet the following two criteria:

(i) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than one-fourth of 1 percent of all the cigarettes sold in the United States in such year, and

(ii) more than one-half of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of clause (i).

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[1] There is no comparable alternative to quarterly rotation for cigarette advertising.

[2] The statute defines "brand style" as "a variety of cigarettes distinguished by the tobacco used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging." 15 U.S.C. 1332(8).

15 U.S.C. 1333(c)(2)(A). A manufacturer or importer can seek permission to equalize the display of the warnings on some of its brand styles, even if other brand styles do not qualify for equalization and are therefore subject to quarterly rotation.

Pursuant to the FCLAA, cigarette manufacturers and importers submit plans to the Commission explaining how they intend to comply with the statutory requirement to display the Surgeon General's warnings on their packaging.[3] If the company will be rotating the warnings on a quarterly basis, its plan must identify each of its brands and brand styles and include a schedule (or other explanation) showing the warning that will be assigned to each brand during each quarter of the year. The company must also specify when in the manufacturing process it will consult its rotation schedule for that particular brand in order to assign the appropriate quarterly warning.

If the company wishes to use the option provided by section 1333(c)(2) and display the four warnings an equal number of times during the year on the packaging of certain brand styles, its plan must provide information sufficient to show that its sales satisfy both of the criteria in 15 U.S.C. 1333(c)(2)(A). It must also explain how it will ensure that all four warnings will be equally displayed during the one-year period beginning on the date the plan is approved—for example, by using printing plates that produce an even number of all four warnings simultaneously on each print run. Finally, because the statute authorizes approval for equalization only for one year, *see* 15 U.S.C. 1333(c)(2)(C), the manufacturer or importer must submit a new plan annually demonstrating that its sales continue to qualify for equalization.

Manufacturers and importers who intend to engage in advertising must provide the Commission with a rotation schedule for the four statutorily-prescribed warnings for each brand

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[3] Manufacturers and importers must also submit samples of actual packaging for any new cigarette brands or brand styles, or samples of new packaging for existing brands or brand styles. However, this requirement is not subject to clearance under the Paperwork Reduction Act ("PRA"). Such packaging samples do not constitute "information" for purposes of the PRA because they merely constitute "samples of . . . physical objects." *See* 5 CFR 1320.3(h)(2). Accordingly, the burden associated with the submission of any such samples is not reflected in the Commission's burden analysis below.

they intend to advertise. They also must provide an example of each of the warning statement formats they will use, which vary based on the size of their advertisement,[4] and specify how they will determine which warnings will appear on different kinds of advertisements and how they will handle advertisements that feature more than one of the company's brands.

Since the information collection is statutorily prescribed, the need for OMB clearance was not necessarily apparent.[5] Nonetheless, the FTC recently decided to obtain OMB clearance for this statutorily-mandated information collection. Accordingly, on July 28, 2023, the FTC obtained OMB's approval of an expedited provisional clearance for this information collection (OMB Control Number: 3084-0175, Title: Information Collection under the Federal Cigarette Labeling and Advertising Act), and, under 5 CFR 1320.13(d), a waiver of the requirement to publish a notice of the emergency clearance request. As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before submitting the information collection to OMB for its nonprovisional clearance.

B. Burden Statement

Affected Public: Private Sector: Businesses and other for-profit entities.

Estimated Annual Burden Hours: 336.

Estimated Annual Labor Costs: $23,382.

Estimated Annual Non-Labor Costs: $0.

I. Estimated Burden Hours

FTC staff's estimate of the burden hours is based on the time required for an applicant to prepare a plan seeking the Commission's approval for display of the Surgeon General's health

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[4] The formats and sizes of the warnings that the Commission uses to enforce the requirements for advertisements are set forth in acetate exhibits. Electronic versions of the acetates with the required warning statement formats are available on the Commission's website.

[5] An agency's failure to obtain OMB clearance for a statutorily-mandated information collection requirement does not appear to excuse a respondent's failure to comply with the requirement. *Accord* 5 CFR 1320.6(e) (establishing that, for purposes of information collection requirements that are imposed by statute, an agency's failure to comply with the requirements of the PRA does not amount to a defense against the assessment of a penalty); *U.S. v. Ionia Management S.A.*, 498 F. Supp. 2d 477, 489 (D. Conn. 2007) (discussing that, for purposes of information collection requirements that are imposed by statute, an agency's failure to comply with the requirements of the PRA does not excuse a person's failure to comply with the requirement).

warnings on its packages and advertising (assuming it plans to engage in advertising). During the period from 2020 to 2022, the Commission approved a total of 124 plans. In 2022, all 44 of the plans approved by the Commission included a request for equalization of the warning labels on at least some brand styles, and thus, the submission of sales information for those brand styles.

Manufacturers and importers who are approved for quarterly rotation of the warnings on their packaging do not have to submit new plans unless and until they intend to add new brands or brands styles or new types of advertising to their existing plans. As explained above, manufacturers and importers that are approved to use the alternative to quarterly rotation on their packaging must refile each year so the Commission can assess whether they remain eligible to equalize the warnings. They also must file new plans if they add new brands or brand styles to their existing plans; once the company has obtained approval for its initial plan, however, it should need less time in subsequent years to prepare those updates. Moreover, the sales information required to prove eligibility for the alternative to quarterly rotation is readily available to the applicant.

FTC staff recognizes that preparation of a plan by a manufacturer or importer that has not previously submitted one will take somewhat more time than either preparation of essentially the same plan with updated sales figures in subsequent years, or preparation of a very similar plan that modifies a previously-approved plan (*e.g.*, adding new brand styles). However, plans can be short (*e.g.*, 2-page) letters, and numerous examples of plans already approved by the Commission are available on the Commission's website. Thus, as an approximation, FTC staff believes that, on average, each submission will take respondents 8 hours to prepare and submit. As FTC staff receives, on average, 42 responses related to the FCLAA's information collection requirements per year, this yields an annual burden of 336 hours (42 responses × 8 hours per response).

2. *Estimated Annual Labor Costs*

FTC staff's experience is that most of the plans it receives are submitted by, or on behalf of, relatively small companies (as evidenced by the fact that all of the plans received in 2022 included requests for label equalization). Roughly half of the plans are submitted by non-legal company personnel, the other half by attorneys. FTC staff is assuming an average $69.59/hour wage, based on mean hourly wages listed by the U.S. Bureau of Labor Statistics 2022 Occupational Employment and Wage Statistics for lawyers ($80.11) and general and operations managers ($59.07).[6] Using this figure, this yields a burden of $23,382 per year (336 hours × $69.59).

3. Estimated Annual Non-Labor Costs

FTC staff believes that the capital or other non-labor costs associated with the information requests are minimal.

C. Request for Comment

Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) whether the disclosure and recordkeeping requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (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.

For the FTC to consider a comment, we must receive it on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Your comment, including your name and your state, will be placed on the public record of this proceeding, including the *https://www.regulations.gov* website.

If you file your comment on paper, write "Surgeon General's Cigarette Health Warnings:

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[6] This is derived from the average of the U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics (May 2022) hourly wages for lawyers/legal services ($80.11) and general and operations managers ($59.07), as roughly half of the plans submitted to the Commission are signed by attorneys and half by non-attorneys. https://www.bls.gov/oes/current/oes_stru.htm (Tables 23-1011, 11-1021).

Paperwork Comment, FTC File No. P854505" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, N.W., Suite CC-5610 (Annex J), Washington, DC 20580.

Because your comment will become publicly available at *https://www.regulations.gov*, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including, in particular, competitively sensitive information, such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must (1) be filed in paper form, (2) be clearly labeled "Confidential," and (3) comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov*, we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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