



## FEDERAL TRADE COMMISSION

### Agency Information Collection Activities; Submission for OMB Review; New Collection

**AGENCY:** Federal Trade Commission (“FTC” or “Commission”).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (“PRA”), the Federal Trade Commission (“FTC” or “Commission”) is submitting to the Office of Management and Budget (“OMB”) its proposal to seek OMB clearance for information collection requirements contained in the Federal Cigarette Labeling and Advertising Act (“FCLAA”). The FCLAA requires the FTC to review plans for the rotation of health warnings on cigarette packaging and advertising. The current provisional 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 30 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. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review - Open for Public Comments” or by using the search function.

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

### **SUPPLEMENTARY INFORMATION:**

#### **A. Background**

The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.* (2006 ed.) (“FCLAA”) tasks the FTC with reviewing the rotation of statutorily-prescribed Surgeon

General's health warnings on cigarette packaging and in advertisements, and requires the FTC to collect certain information from manufacturers, packagers, and importers importing for sale, distributing, or advertising cigarettes in the United States.

Because this information collection requirement is statutorily prescribed, OMB clearance was not required for the requirement to submit information to be effective.<sup>1</sup> Nonetheless, the FTC recently decided to obtain OMB clearance for this statutorily mandated information collection. Accordingly, on July 28, 2023, the FTC obtained from OMB (i) 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 (ii) a waiver under 5 CFR 1320.13(d) of the requirement to publish a notice of the emergency clearance request. On September 6, 2023, the FTC published a *Federal Register* notice with a 60-day comment period soliciting comments from the public concerning the proposed collections of information (hereinafter, "*Federal Register* Notice"). See 88 FR 60941 (September 6, 2023). In response to this *Federal Register* Notice, the FTC received four responsive, non-duplicative comments.<sup>2</sup>

## **B. Comments**

Three of the four comments express the commenters' strong support for the information collection, noting that the collection of the information is useful and necessary for the purpose of the promotion of public health.<sup>3</sup> One of the four comments expresses concerns pertaining to the

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<sup>1</sup> An agency not having obtained OMB clearance for a statutorily-mandated information collection requirement does not excuse a respondent's failure to comply with the requirement. *U.S. v. Ionia Management S.A.*, 498 F. Supp. 2d 477, 489 (D. Conn. 2007); accord 5 CFR 1320.6(e) (where information collection requirements are imposed by statute, an agency's not having complied with the requirements of the PRA is not a defense against the assessment of a penalty).

<sup>2</sup> See *Comment FTC-2023-0056-0007*, <https://www.regulations.gov/comment/FTC-2023-0056-0007> (Sept. 27, 2023) [hereinafter *Comment from Anonymous*]; *Comment FTC-2023-0056-0009*, <https://www.regulations.gov/comment/FTC-2023-0056-0009> (Nov. 6, 2023) [hereinafter *State AGO Comment*]; *Comment FTC-2023-0056-0006*, <https://www.regulations.gov/comment/FTC-2023-0056-0006> (Sept. 23, 2023) [hereinafter *JD Comment*]; *Comment FTC-2023-0056-0010*, <https://www.regulations.gov/comment/FTC-2023-0056-0010> (Nov. 6, 2023) [hereinafter *ITG Brands & Commonwealth Brands Comment*].

<sup>3</sup> See *State AGO Comment*; see also *JD Comment*; *Comment from Anonymous*.

information collection.<sup>4</sup> In the remainder of this section, the Commission provides summaries of the four comments and the Commission's responses to the comments.

### *I. Individual Commenters*

*Comments:* Two of the four comments the Commission received express strong support for the information collection, and explain that the commenters had personally witnessed the effects of tobacco addiction on others.<sup>5</sup>

*Response:* The Commission shares the commenters' concern about the importance of informing consumers about the health risks associated with cigarette smoking through display of the Surgeon General's health warnings on cigarette packaging and advertising.

### *II. Comment by State Attorneys General*

*Comment:* The Offices of the Attorneys General for the States of Maryland, Arizona, Arkansas, California, Colorado, Connecticut, Hawaii, Illinois, Montana, Missouri, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Washington (hereinafter, collectively referred to as "State AGOs") submitted a joint comment, noting that the information collection ("FCLAA information collection") is useful and necessary for the purpose of the promotion of public health, and aids State governments in their regulation of cigarette manufacturers seeking to sell cigarettes in the States.<sup>6</sup> The State AGOs note that most States publish a directory of cigarette brands that have been approved for sale in their respective States, and require manufacturers to submit certain information, including approval letters from the FTC showing that the manufacturers have submitted plans that the FTC found to be compliant with the FCLAA.<sup>7</sup> According to the State AGOs, the submission of the approval letters (1) promotes public health by ensuring that cigarette brands a manufacturer seeks to sell in the State will bear required health warnings that alert consumers to the risks cigarettes pose to

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<sup>4</sup> See *ITG Brands & Commonwealth Brands Comment*.

<sup>5</sup> See *JD Comment*; *Comment from Anonymous*.

<sup>6</sup> See *State AGO Comment*.

<sup>7</sup> *State AGO Comment* (citing Md. Code Ann., Bus. Reg. sections 16-501 to -508 ; Ohio Rev. Code Ann. section 1346.05 *et seq.*; 35 Pa. Stat. Ann. sections 5702.101 *et seq.*; S.C. Code Ann. sections 11-48-30; Tenn. Code Ann. sections 67-4-2601 *et seq.*).

the smoker's health and the health of people nearby; (2) informs States about the cigarette brands a manufacturer intends to sell during the upcoming year; (3) serves as a tool for States to verify that cigarettes listed on their directory of approved brands are, in fact, legal for sale in the United States; and (4) provides a level of assurance to the reviewing States that a manufacturer is a business that is in good standing, capable of meeting its regulatory obligations with different government agencies, and committed to operating legally.

*Response:* The FTC appreciates the comment, which underscores the necessity of this information collection.

*I. Comment by ITG Brands, LLC, and Commonwealth Brands, LLC*

*Comment:* ITG Brands, LLC, submitted a public comment on behalf of itself and its affiliate, Commonwealth Brands, LLC, voicing the following concerns pertaining to this information collection.

First, the two cigarette companies assert that the Notice's apparent position that rotation plans must identify brand styles by name exceeds FTC's statutory authority and is unnecessary. According to the two cigarette companies, the text of 15 U.S.C. 1333© only requires that rotation plans sufficiently explain how cigarette manufacturers will comply with their quarterly or simultaneous rotation obligations. The two cigarette companies assert that because the text of 15 U.S.C. 1333(c)(1) does not employ the term "brand style," the statute does not suggest that any element of a rotation plan must be brand-specific. In support of this argument, they note that, in 1985, the FTC approved a number of rotation plans that include language continuing to permit those cigarette manufacturers to introduce new brands and brand styles without having to seek prior approval or submit sample packaging.

Second, the two cigarette companies argue that the *Federal Register* Notice's apparent position that cigarette manufacturers must submit packaging for new brands and brand styles and packaging changes for existing brand styles, exceeds the FTC's statutory authority and is unnecessary. Noting that 15 U.S.C. 1333(c) does not specify that cigarette manufacturers must

submit “packages” to the FTC for approval, the two cigarette companies contend that Congress would have expressly required cigarette manufacturers to submit “packages,” if it had intended them to do so. The two companies assert that FTC appears to be using the rotation plan requirement of 15 U.S.C. 1333(c) to enforce the warning label requirements of paragraphs (a) and (b) of 15 U.S.C. 1333, although 15 U.S.C. 1333(c) only requires manufacturers to submit a plan ensuring compliance with the subsection’s rotation requirements. According to the two cigarette companies, 15 U.S.C. 1333(c) does not require the plan to cover the manufacturer’s compliance with paragraphs (a) and (b) of 15 U.S.C. 1333. The two cigarette companies argue that “the FTC seems to recognize this by its treatment of the major tobacco companies, as on information and belief the FTC has not required them to submit sample packaging before implementing packaging changes since 1985.”

Third, the two cigarette companies assert that the information collection imposes a substantial burden on cigarette manufacturers beyond the burden stated in the *Federal Register* Notice. The two companies contend that the Commission’s analysis fails to account for the costs cigarette manufacturers incur as a result of submitting packaging for the agency’s review and that even the collection activities accounted for in the burden analysis are drastically underestimated.

For example, the two cigarette companies assert that the submission of “revised packaging and plan documents involves . . . far more than the 8 hours that the FTC estimates, with a more accurate estimate based on ITG and Commonwealth’s experience requiring up to 20 to 40 hours per submission.” The companies’ estimate includes, among other things, the time spent making printing arrangements for packaging samples and addressing any changes requested by the FTC.

The two companies also assert that, due to the fact that the FTC requires cigarette manufacturers to submit actual packaging samples, rather than PDFs of packaging samples, the introduction of new brand styles requires a special print run from an outside printing company.

According to the two companies, samples of actual packaging for new products are often not available until shortly before the intended launch of such products and require up to three months of lead time for printing “and additional expense for printing a complete sample set from \$8,000 to \$25,000 per variant.” The two cigarette companies state that the aggregate burden in time and expense resulting from this is substantial when cigarette companies introduce several new brand styles a year. Moreover, the companies assert that, since the plans of Philip Morris and RJR/Lorillard permit those manufacturers to introduce new brands and brand styles without having to seek prior approval or submit sample packaging, other cigarette companies—such as ITG Brands, LLC, and Commonwealth Brands, LLC—experience a substantial competitive burden as a result of this delay.

Fourth, the two cigarette companies argue that the FTC should minimize these burdens by (1) allowing all manufacturers to adopt rotation plans that permit the introduction of new brands or brand styles without further submission to the Commission as long as the rotation plan explains how the warnings on such new products will be appropriately rotated, and (2) no longer requiring manufacturers to submit “every packaging change [to the FTC] for review and approval.” The two cigarette companies contend that doing so would be consistent with the regulations the U.S. Food and Drug Administration (“FDA”) has issued in light of the pending transfer of statutory authority concerning the display of health warnings. The two companies claim that in a final rule, titled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,” the FDA took the position that, “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) ... and incorporate any new brands into their approved plan, so long as no other changes are made to the plan.”<sup>8</sup>

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<sup>8</sup> *ITG Brands & Commonwealth Brands Comment* (citing 85 FR 15638 (Mar. 18, 2020)).

*Response:* The two companies are correct that section 1333(c)(1) does not explicitly mention brand styles. However, section 1333(b)(1), which addresses the format of packaging warnings, specifically states that the health warning statements must be in “conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.” Accordingly, to ensure that the Surgeon General’s health warnings on cigarette packs and cartons are conspicuous, since at least 1991, the Commission has required manufacturers and importers to submit health warning plans for all new cigarette brands and brand styles, and has reviewed the packaging submitted with those plans by the manufacturers and importers before that packaging is sent out into the marketplace. As a practical matter, no other system would efficiently effectuate Congress’s intent that the warnings be conspicuous on cigarette packaging.

Moreover, section 1333(c)(2) of the FCLAA does expressly use the term “brand style” with respect to a manufacturer or importer that is applying for permission to use the alternative to quarterly rotation. Section 1333(c)(2)(A) sets forth the requirements that must be met to qualify for the alternative “with respect to a brand style of cigarettes,”<sup>9</sup> including that the number of cigarettes “of **such** brand style” sold in the previous fiscal year is less than one-quarter of 1 percent of all cigarettes sold in the U.S. that year.

The Commission believes it has the authority under FCLAA to review the format of packaging warnings in order to ensure that the Act’s statutory requirements are satisfied. Paragraph (a)(1) of section 1333 sets forth the requisite wording of the four packaging warnings, and paragraph (b)(1) of section 1333 sets forth the aforementioned format requirements applicable to the “label statements” required by paragraph (a)(1). Paragraph (c)(1) of section 1333 then refers to the “label statements” specified in paragraph (a)(1), and provides that the label statements are required to be rotated “on packages of **each brand** of cigarettes manufactured by the manufacture or importer” in accordance with a plan approved by the Commission that ensures “that all of the labels required . . . will be displayed by the

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<sup>9</sup> 15 U.S.C. 1333(c)(2)(A) (emphasis added).

manufacturer or importer.”<sup>10</sup> Read together, these provisions provide the basis for the Commission to require that manufacturers and importers submit packaging samples to ensure that the rotation plan meets the statutorily prescribed rotation and formatting requirements. In order to do so for new brands and brand styles, the Commission must have the ability to require cigarette manufacturers and importers to submit updated rotation plans and packaging samples.

With regard to the companies’ argument that the information collection imposes a substantial burden on cigarette manufacturers beyond the burden stated in the *Federal Register* Notice, the Commission notes the following. First, “[s]amples of products or of any other physical objects,” which, by definition, includes packaging samples, do not constitute “information” for purposes of the PRA,<sup>11</sup> and any costs related to the preparation and submission of any such samples should not be included in a burden analysis prepared for purposes of the PRA.<sup>12</sup>

Second, the companies’ estimate that, in the context of the introduction of new brands and brand styles, the preparation and submission of an amended plan takes approximately 20 to 40 hours—*i.e.*, up to a full workweek—is likely not reflective of the industry average. The amendment of an existing rotation plan to add a new brand or brand style is generally relatively quick and simple, and cigarette manufacturers can use their existing approved rotation plans as templates. A company with an approved plan for rotating the warnings quarterly on its packaging must merely identify the new brand style being added to that plan and submit the packaging for that new brand style;<sup>13</sup> if the company wishes to add a new brand to its plan, it must also identify the warning that will be assigned to that brand during each quarter of the year.

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<sup>10</sup> See 15 U.S.C. 1333(c)(1) (emphasis added).

<sup>11</sup> See 5 CFR 1320.3(c) (“Collection of information means . . . the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties or the public *of information* by or for an agency . . .”) (emphasis omitted) (emphasis added), CFR 1320.3(h)(2) (“‘Information’ does not generally include . . . [s]amples of products or of any other physical objects.”).

<sup>12</sup> See 5 CFR 1320.3(b)(1) (defining the term “burden” as “the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide *information* to or for a Federal agency”) (emphasis added).

<sup>13</sup> The Commission’s insistence on actual packaging, rather than just artwork, reflects its experience that colors can be different in artwork than in final packaging, and that those differences can affect whether the warnings are conspicuous.

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, it must provide information sufficient to show that its sales satisfy both of the criteria in 15 U.S.C. 1333(c)(2)(A), provide packaging, and explain—again, as it has done previously—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).

Third, the two cigarette companies' estimate includes activities that do not result from a collection of information. Specifically, because, as indicated above, the submission of the samples does not constitute a collection of information for purposes of the PRA,<sup>14</sup> the two cigarette companies' estimate erroneously includes time spent making printing arrangements.<sup>15</sup> Furthermore, when a plan submitted to the Commission cannot be approved in its original form, FTC staff usually provides the cigarette manufacturer with specific, individualized guidance as to the changes necessary for Commission approval. As the PRA exempts "request[s] for facts or opinions addressed to a single person" and "[f]acts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections of information,"<sup>16</sup> the time spent incorporating requested changes into the companies' proposals should not be reflected in the burden estimate for this information collection.<sup>17</sup>

Fourth, the Commission questions the companies' assertion that the preparation of their plans requires the assistance of outside counsel. For the years 2017 through 2021—the most recent years for which the two companies' plans are on the public record—their plans were all signed by in-house counsel. Although some manufacturers and importers do use outside counsel

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<sup>14</sup> See *supra* note 13.

<sup>15</sup> See *supra* note 15.

<sup>16</sup> See 5 CFR 1320.3(h)(6), (9).

<sup>17</sup> See *supra* note 15.

to file their plans, they presumably do so because it makes more sense from a business perspective than using in-house personnel.

The companies also fail to explain why the submission to the Commission of the packaging that they intend to use for new products requires a significant lead time for printing that would not otherwise be incurred. Even if the Commission were to allow manufacturers to adopt rotation plans that permit the introduction of new brands or brand styles without further submission to the Commission, manufacturers and importers would nonetheless have to create, print, and then review any packaging for new varieties or redesigned packaging for existing varieties for compliance with the FCLAA's format requirements.<sup>18</sup> The two companies also fail to explain why the expense associated with the preparation of sample packaging by an outside printing company would not still be incurred if the companies were to review their own new packaging for compliance with FCLAA (rather than submit them to the Commission for approval).

The companies also argue that the fact that they are required to seek Commission approval prior to the introduction of new brand styles or packaging causes them to suffer a "substantial competitive burden." However, consideration of whether the requirement imposes a competitive burden is beyond the scope of a burden analysis under the PRA, which defines the term "burden" more narrowly.<sup>19</sup> Furthermore, the two companies' final argument—that is, that requiring Commission approval for the introduction of new brand styles is inconsistent with the approach that the FDA proposed in light of the pending transfer of statutory authority concerning the display of health warnings<sup>20</sup>—is equally beyond the scope of this notice. The FDA's proposed approach is based on the Family Smoking Prevention and Tobacco Control Act, Pub.

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<sup>18</sup> As noted *supra* note 13, the preparation and submission of packaging samples does not constitute a collection of information for purposes of the PRA, and, thus, should be disregarded for purposes of this burden analysis.

<sup>19</sup> For a definition of the term "burden," see 44 U.S.C. 3502(2) and 5 CFR 1320.3(b)(1).

<sup>20</sup> *ITG Brands & Commonwealth Brands Comment* (citing 85 FR 15638 (Mar. 18, 2020)).

L. No. 111-31, tit. II, sec. 201 (June 22, 2009) (hereinafter, “FSPTCA”), which differs from the FCLAA in significant aspects.<sup>21</sup>

Accordingly, as the Commission does not find the two companies’ arguments to be convincing, the Commission declines to adjust the estimates that were included in its expedited provisional clearance request and approved by OMB on July 28, 2023.

### **C. Overview of Information Collection**

*Title of Collection:* Information Collection under the Federal Cigarette Labeling and Advertising Act.

*OMB Control Number:* 3084-0175.

*Type of Review:* Extension without change of currently approved collection.

*Abstract:* The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.* (2006 ed.) (“FCLAA”), requires cigarette manufacturers, packagers, and importers to place one of four statutorily-prescribed Surgeon General’s health warnings on cigarette packaging and in advertisements, on a rotational basis in accordance with plans reviewed and approved by the FTC. Each manufacturer, packager, and importer (hereinafter, also referred to as “respondents”) wishing to import for sale or distribute cigarettes in the United States is required to submit a plan to the FTC that (1) explains how the respondent intends to comply with the statutory requirement to display the statutorily-prescribed health warnings on its packaging, (2) identifies each of the respondent’s brands and brand styles, (3) includes a schedule (or other explanation) showing the warnings that will be assigned to each brand during each quarter of the year, and (4) specifies when in the manufacturing process the respondent will consult its rotation schedule for that particular brand in order to assign the appropriate quarterly warning. Respondents wishing to engage in advertising of cigarettes in the United States are required to submit to the FTC a plan

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<sup>21</sup> For example, the FSPTCA provides precise details as to the size, font, location, and color of the nine warning statements that will ultimately replace the current four Surgeon General’s warnings. *See* 15 U.S.C. 1333(a)(2) (2009 ed.). Additionally, only the FCLAA specifically requires the annual submission of information demonstrating that the manufacturer or importer continues to qualify for equalization of the health warnings.

that (1) includes a rotation schedule for the four statutorily-prescribed health warnings for each brand the respondent intends to advertise, (2) specifies how the respondent will determine which health warnings will appear on different kinds of advertisements, and (3) specifies how the respondent will handle advertisements that feature more than one of the respondent's brands.

The FCLAA also provides for an alternative method for displaying the required health warnings on packaging—that is, equalization. Specifically, manufacturers, packagers, and importers may seek the FTC's approval to display the health warnings on a particular cigarette brand style an equal number of times. In order to obtain approval for equalization, respondents must submit an additional plan to the FTC that establishes (1) that their sales satisfy the statutory-prescribed requirements for equalization, and (2) how the respondent will ensure that all four health warnings will be equally displayed during the one-year period following the plan's approval (*e.g.*, by using printing plates that produce an even number of all four warnings simultaneously on each print run). Respondents seeking to equalize must submit new plans annually to demonstrate that their sales continue to qualify for equalization.

The Commission uses the information to assess—as it is required to do under the FCLAA—whether a manufacturer or importer will display the Surgeon General's health warnings in compliance with the governing statutory provisions in the FCLAA.

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

*Estimated Annual Burden Hours:* 328.

*Estimated Annual Labor Costs:* \$16,695.

*Estimated Annual Non-Labor Costs:* \$0.

#### **D. Request for Comment**

Pursuant to OMB regulations, 5 CFR part 1320, which implement the PRA, 44 U.S.C. 3501 *et seq.*, the FTC is providing this second opportunity for public comment while submitting to OMB its request for clearance for the information collection requirements contained in the

FCLAA. For more details about the requirements and the basis for the calculations summarized above, see 88 FR 60941.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone’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 ensuring 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 “[t]rade secret or any commercial or financial information which is . . . privileged or confidential”—as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2)—including, in particular, competitively sensitive information, such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

**Josephine Liu,**

*Assistant General Counsel for Legal Counsel.*

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