Request for an Emergency Exception
Supporting Statement

1. Necessity for Collecting the Information

The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq*. ("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. Additionally, cigarette advertising is also prohibited unless it bears statutorily-prescribed health warnings.

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). Accordingly, the Commission collects information from manufacturers and importers that identifies the cigarette brands and brand styles for which approval is sought and establishes how the applicant intends to comply with the statutory warning requirements for packaging and advertising (if it intends to engage in advertising). *See* 15 U.S.C. 1333(a).

The FCLAA does provide an exception to the requirement of quarterly rotation on cigarette packages. Specifically, manufacturers and importers whose sales the previous fiscal year satisfied two criteria can apply to the Commission for permission to display the Surgeon General's warnings "an equal number of times within the twelve-month period beginning on the date of the approval by the Commission of the application." 15 U.S.C. 1333(c)(2)(C). Accordingly, the Commission collects sales information from these applicants. Moreover, because eligibility for "equalization" of the Surgeon General's warnings on packaging is based upon the company's sales for the prior fiscal year, manufacturers and importers who choose this route must submit information to the FTC annually showing that they continue to meet the statutory criteria. *See* 15 U.S.C. 1333(c)(2)(C).

2. Use of the Information

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. The Commission also uses the sales information provided by companies applying for label "equalization" to determine whether those applicants meet the statutory requirements for this alternative to quarterly rotation.

3. Consideration to Use Improved Information Technology to Reduce Burden

Surgeon General's health warning plans can be submitted electronically and nearly all of the plans received by the Commission are submitted that way.

4. Efforts to Identify Duplication/Availability of Similar Information

The Commission is not aware that the information being collected concerning compliance with the FCLAA's health warning requirements is currently duplicated elsewhere. Although the U.S. Food and Drug Administration issued an industry guidance document entitled "Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)" in July 2021 that reviewed the requirements that cigarette packaging and advertising plans will have to address when the nine new health warnings set forth in the 2009 Family Smoking Prevention and Tobacco Control Act go into effect, that guidance is nonbinding as a result of a federal court ruling vacating FDA's "Required Warnings for Cigarette Packages and Advertisements" rule in December 2022.

5. Efforts to Minimize Burden on Small Businesses

A portion of the respondents will be small entities. However, the information being collected is minimal and even the sales information that applicants for "equalization" must submit if they seek this option is readily available within the business.

6. Consequences of Conducting Collection Less Frequently

The Commission collects information only once from cigarette manufacturers and importers who rotate the warning statements on a quarterly basis, unless they decide to add new cigarette brands or brand styles or revised packaging for existing brand styles, or new advertising to their previously-approved plans.

In addition to a plan showing how the manufacturer or importer intends to comply with the statutory warning requirements, the Commission also collects sales information annually from manufacturers and importers who choose to equalize. As manufacturers and importers are only eligible for equalization when their sales figures for the previous fiscal year fall below certain statutorily-defined thresholds, this information collection is necessary in order for the FTC to assess whether the manufacturer or importer meets the statutory requirements for equalization. The Commission also collects information from these entities concerning new cigarette brands, brand styles and packaging and new advertising before those cigarettes and advertising enter the market.

Less frequent collection of this sales information would significantly impair the FTC's ability to evaluate whether these companies are eligible for equalization. As a result, the companies would either be unable to sell their products (because they lack a plan approved by the Commission, as required by the FCLAA) or they would have to change to quarterly rotation. Less frequent collection of information as to new packaging or advertising would mean that the companies could not introduce new packages or advertising to the marketplace.

7. Circumstances Requiring Collection Inconsistent with Guidelines

This collection of information is consistent with the provisions of FCLAA.

8. Consultation Outside the Agency

Special circumstances exist that require an emergency clearance pursuant to 5 C.F.R. § 1320.13(a). First, without the information, the FTC is unable to determine whether cigarette manufacturers and importers are complying with the statutory requirements for cigarette packaging. For this reason, any interruption in the FTC's ability to carry out its statutory mandate will likely result in public harm. *See* 5 C.F.R. § 1320.13(a)(2)(i). Second, because the FTC is already collecting the information in accordance with its statutory mandate, "[t]he use of normal clearance procedures is reasonably likely to . . . disrupt the collection of information." *See* 5 C.F.R. § 1320.13(a)(2)(iii). Finally, the collection of information is needed prior to the expiration of established time periods and is essential to the mission of the agency. *See* 5 C.F.R. § 1320.13(a)(1).

9. Payments or Gifts to Respondents

Not applicable.

10. & 11. Assurances of Confidentiality and Matters of a Sensitive Nature

The Commission does post approved plans on its website but it redacts any sales information submitted by applications for health warning label equalization.

12. Burden Estimate

The estimated burden of collecting this information is as follows:
an average of 41 approved plans each year from 2020-2022 = 41 total annual responses
x (8 hours average per manufacturer/importer)
= 328 annual hours for manufacturers/importers
x $50.90/hour for personnel[1]
$16,695 annual labor cost for manufacturers/importers.

13. Estimated Capital or Other Non-Labor Costs

The Commission believes that there are no current start-up costs or other capital costs associated with the information collection.

[1] This is derived from the average of the U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics (May 2022) hourly wages for attorneys ($65.26) and business operation specialists ($36.53), 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, 13-1199).

14. Estimated Cost to the Federal Government

The Commission estimates that review and approval of health warning plans takes 0.2 federal work years, for a cost of $26,039 based on OPM's 2023 pay table.

15. Program Changes or Adjustments

None.

16. Statistical Use of Information

The proposed collection does not employ statistical methods.

17. Display of Expiration Date for OMB Approval

Not applicable.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

Not applicable. No exceptions are being requested on the certification statement.