List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products

Reinstatement: OMB No. 0920-0210 OMB Expiration Date 01/31/2026

Supporting Statement A

Program Official/Contact
Leslie Norman
Public Health Analyst
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
P: 770/488-5469
Email: lan0@cdc.gov

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ATTACHMENTS

1a. Comprehensive Smoking Education Act of 1984 (15 U.S.C. 1335a)
1b. Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331-1341)
2. Certificate of Compliance for Manufacturers, Packagers, and Importers of Tobacco Products

3a. Notice of Change in Reporting Requirements
3b. Notice of Recommencement of Reporting Requirements
4. Federal Register Notice (2025)

5. Initial Federal Register Notice (1985)
6a. Guidelines to Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474
6b. Civil Penalties for Disclosure of Confidential Information (18 U.S.C. 1905)
7. Human Subjects Document Non-research Determination
8a. Recommended Cigarette Ingredient Report Format
8b. Request for Additional Information from Manufacturers, Packagers, and Importers of Tobacco Products

JUSTIFICATION SUMMARY

Goal of the project: This Information Collection Request (ICR) supports a reinstatement of the Congressionally mandated information collection, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products" (OMB control no. 0920-0210, exp. January 31, 2026).

Intended use of the resulting data: The information collection is used to certify tobacco industry compliance with the terms of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1335a (FCLAA).

Methods to be used to collect: To comply with the Act, manufacturers, packagers, and importers must submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacturing of cigarettes.

The subpopulation to be studied: The data collected does not contain data on human subjects. The data that are collected are required for submission by commercial cigarette manufacturers, packagers, or importers.

How data will be analyzed: HHS is authorized, but not required, to analyze submitted data and to submit a report to the Congress. Reports are only submitted at such times as the Secretary of HHS considers appropriate.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

This Information Collection Request (ICR) is for the reinstatement of a Congressionally mandated information collection, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products" (OMB control no. 0920-0210, exp. January 31, 2026). A 3-year approval is requested.

Section 7 of the Comprehensive Smoking Education Act of 1984 (Public Law 98-474) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of Health and Human Services with a list of ingredients added to tobacco in the manufacture of cigarettes, commonly known as the Ingredient Report (**Attachment 1a**). The requirements have been codified in section 1335a of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. Parts 1331-1341 (**Attachment 1b**), hereinafter referred to as FCLAA.

Section 1335a of FCLAA requires that each manufacturer, packager, or importer of cigarettes annually provide the HHS Secretary with a list of ingredients added to tobacco in the manufacture of cigarettes which does not identify the company that uses the ingredients or the brand of cigarettes that contain the ingredients. Subsection (b)(2)(A) requires that "[a]ny information provided to the Secretary . . . shall be treated as trade secret or confidential information…" In 1985, HHS delegated this authority to the National Clearinghouse for Smoking and Health, a unit within the Public Health Service that was a precursor to CDC's Office on Smoking and Health (OSH). After OSH was established, these activities continued to be carried out by OSH. Reports are due annually, to be received or postmarked by March 31.

A2. Purpose and Use of the Information Collection

The information collection is used to enable manufacturers, packagers, and importers to submit annually to HHS (through CDC/OSH) a list of ingredients added to tobacco in the manufacturing of cigarettes as required under the FCLAA.

In the past CDC has issued a Certificate of Compliance (**Attachment 2**) to each entity that submitted a report. However, moving forward CDC will no longer issue such a certificate. CDC will instead provide confirmation via email to regulated entities confirming receipt of ingredients.

In certain states, tobacco manufacturers and importers are required to provide proof of compliance with the cigarette ingredient reporting requirements of FCLAA to retail their products. These states either require annual submission of an HHS Certificate of Compliance or a letter from CDC confirming compliance for each brand. Moving forward CDC will now only issue letters confirming compliance upon request of regulated entities in states that have such requirements.

Also, to import cigarettes into the United States for introduction into domestic commerce, one must certify to U.S. Customs and Border Protection that the original manufacturer has complied with FCLAA's requirements. Again, CDC will issue letters confirming compliance upon request of regulated entities.

HHS has the authority under FCLAA to use the information submitted to conduct research on the health effects of ingredients added to tobacco in the manufacture of cigarettes. If and when the Secretary of HHS considers it appropriate, HHS will report to the Congress information regarding its current and proposed research relative to the health effects of the ingredients; information pertaining to any such ingredient which, in the judgment of the Secretary, poses a health risk to users of cigarettes; and any other information which the Secretary determines to be in the public interest.

Due to the impact of a reduction in force in OSH, CDC paused the collection of ingredient submissions and the issuance of certificates of compliance as of April 2025. In accordance with FCLAA and the provisions of H.R. 7148, Consolidated Appropriations Act, 2026, Div. B, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2026, Pub. L. No. 119-75 (2026), CDC proposes to restart requesting submissions now.

Of note, submissions and certificates were paused once before. On April 27, 2020, a Federal Register Notice was published Vol. 85, No. 81, pp. 23359-23360, **(Attachment 3a)**, to indicate CDC/OSH was temporarily pausing collection of ingredient submissions due to the public health response to COVID-19. Activities resumed with publication of a follow-up Federal Register Notice (Vol. 88, No. 188, p. 67296) on September 29, 2023 (**Attachment 3b**).

A3. Use of Improved Information Technology and Burden Reduction

To reduce burden to the respondents, only the minimum information necessary to comply with provisions of FCLAA is being requested. Respondents are not required to use a complex format or to complete a questionnaire. CDC receives the data reports via hard copy either by mail, courier, or fax. The mode of submission is chosen by the submitters at their convenience.

A4. Efforts to Identify Duplication and Use of Similar Information

In addition to FCLAA, regulated entities are required to report tobacco product information to the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (TCA). Therefore, FDA's Center for Tobacco Products (CTP) collects certain information under OMB Control No. 0910-0650 that is similar to this collection.

There are differences between the two statutes at issue, the FCLAA and the TCA. For one, FCLAA requires regulated entities to provide ingredient lists annually whereas TCA-mandated annual submissions need to list products. TCA also requires submission of ingredients only prior to a tobacco product's introduction into commerce and thereafter if certain changes are made to such product. Second, FCLAA allows for the submission of a list of ingredients in a way that does not identify the company which uses the ingredients or cigarettes which contain the ingredients. TCA, on the other hand, requires submission of all ingredients by quantity, brand, and sub-brand. Also, FDA collects user fees from each manufacturer and importer of regulated tobacco products which may only be used for the purpose of funding the costs for FDA to regulate tobacco products under the TCA. FDA cannot use other funds for performing these duties, nor use tobacco product user fees to perform duties falling outside the regulation of tobacco products under the TCA.

CDC hopes to create an arrangement with FDA to prevent a duplication of tobacco ingredient reporting to the federal government with one streamlined collection that satisfies the requirements of all relevant legislation. If and when that can be arranged, CDC will amend or close this ICR accordingly.

A5. Impact on Small Businesses or Other Small Entities

Some of the companies affected by the reporting requirements are small businesses. The burden on these companies has been considered. To ease potential burden on both small and large entities, the data collection process does not require respondents to use a cumbersome format or to complete an unwieldy form or questionnaire. Each respondent may select and use the response option that is most convenient for their organization.

A6. Consequences of Collecting the Information Less Frequently

FCLAA stipulates that respondents shall report ingredient information annually. If the data collection were less frequent, the collection and reporting provisions would not satisfy statutory requirements.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

There are no special circumstances for this request.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE
A 60-day Federal Register Notice was published in the *Federal Register* on September 9, 2025, Vol. 90, No. 172, pp. 43448-43449 **(Attachment 4)**. CDC did not receive any public comments in response to this federal register notice.

Part B: CONSULTATION
CDC is in ongoing discussions with FDA to identify a process to satisfy FCCLA requirements and appropriately review ingredient submissions while reducing duplication of work and burden to respondents across the two agencies. If and when a new process is determined, CDC will seek to change or close this information collection request.

A9. Explanation of Any Payment or Gift to Respondents

N/A

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

This ICR has been reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), who determined that the Privacy Act is not applicable because respondents are commercial entities, not individuals, and no personal information is being collected.

The authorizing legislation for this information collection requires HHS to establish written procedures to assure the confidentiality of the information provided. Consistent with these statutory provisions, HHS has developed strict procedures for treating and protecting relevant documents, including secured file storage, and strictly limiting access to the information. A copy of the HHS procedures is included in the 1985 Federal Register Notice provided in **Attachment 5**. In accordance with provisions in FCLAA, the collected information is to be treated as trade secret or confidential information subject to 5 U.S.C. 552 (b)(4) (Freedom of Information Act) and 18 U.S.C. 1905 (Criminal Code) **(Attachments 6a and 6b)** and shall not be revealed except as authorized in the statute. Data submissions are stored in a locked file cabinet at CDC when not in use and CDC maintains a separate database stored on a removable hard drive that connects to a singular desktop computer that is not connected to the CDC network or server. Submissions received by fax go to a dedicated fax machine housed in an office that remains locked when not in use.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This data collection does not involve research with human subjects and does not require IRB review and approval. There have been no changes since the original determination was made. There is no consent process comparable to participation in research **(Attachment 7)**.

A12. Estimates of Annualized Burden Hours and Costs

Table A12A: Estimated Annualized Burden (Hours)

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Cigarette Manufacturers, Packagers, and Importers	Ingredient Report	55	1	6.5	358

Table A12B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Annual Burden Hours	Average Hourly Wage Rate	Total Respondent Labor Cost
Cigarette Manufacturers, Packagers, and Importers	Ingredient Report	358	$75.99	$27,204

The estimated total annualized cost to respondents is $27,204, based on an average hourly wage of $75.99 per hour for compiling and reporting the response. The hourly wage was obtained from The Bureau of Labor Statistics, Occupational Employment Statistics, Occupational Employment and Wages, May 2024 (available at: Beverage and Tobacco Product Manufacturing: NAICS 312 : U.S. Bureau of Labor Statistics.

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs. The collection tool requires no special hardware or software and submission is free to respondents.

A14. Annualized Cost to the Federal Government

The estimated annualized cost to the government is $12,490. The table below describes itemized cost components. Wages were based on the 2026 OPM schedule for the Atlanta, Georgia area.

Table A14.-A. Estimated Annualized Federal Government Cost Distribution

Item	***Annualized Cost***
CDC Staffer (3% GS 14-1 FTE)	$3,990
Computing equipment and maintenance	$8,500
Total	$12,490

A15. Explanation for Program Changes or Adjustments

This ICR is a reinstatement. The hourly wage rate was updated for the respondents and CDC staff, and the need for a contractor was removed, but there was no change in burden hours per response.

A16. Plans for Tabulation and Publication and Project Time Schedule

Information collection occurs annually; ingredient information is to be submitted by March 31 of each year for ingredients used in the previous calendar year. Because the information collection occurs annually, in accordance with FCLAA, we request a maximum (3-year) clearance.

HHS is authorized, but not required, to analyze submitted data and to submit a report to the Congress. Reports are only submitted to Congress when requested. Requested reports only were prepared and submitted to Congress in February 1990, July 1990, and March 1993.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate. As discussed in Section A.3, respondents are required to report information but are not required to use a standardized form. The OMB approval number and expiration date are included on the

Recommended Cigarette Ingredient Reporting Format **(Attachment 8a)** which is available on the CDC website. This information and the burden estimate are also displayed on the Request for Additional Information from Manufacturers, Packagers, and Importers of Tobacco Products letter **(Attachment 8b**).

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.