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

Reinstatement: OMB No. 0920-0210 OMB Expiration Date 04/30/2022

Supporting Statement, A

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JUSTIFICATION SUMMARY

Goal of the project: This Information Collection Request (ICR) supports an Extension of the Congressionally mandated information collection, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products" (OMB control no. 0920-0210, exp. April 30, 2022).

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) supports Reinstatement without Change of a Congressionally mandated information collection, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products" (OMB control no. 0920-0210, exp. April 30, 2022). A 3-year approval is requested.

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**). Responsibility for collecting ingredient information has been delegated to CDC. The legislation also authorizes HHS to undertake research, and to report to Congress, as deemed appropriate, on the health effects of the ingredients. 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 as FCLAA.

The original submission deadline was December 31 of each year. In 1994, HHS published an additional Federal Register Notice (November 8, 1994, vol. 59, p. 55669-55670) that changed the due date from December 31 to March 31. A copy of this notice is provided in **Attachment 8**.

A2. Purpose and Use of the Information Collection

The information collection is used to certify tobacco industry compliance with the terms of FCLAA. To comply with FCLAA, manufacturers, packagers, and importers must submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacturing of cigarettes. The submission must be received on letterhead from the manufacturer or designated representative. Reports may be submitted via mail or facsimile, but all faxed lists should be followed up with a mailed original. In addition, data may be submitted to CDC by mailing a thumb drive. Electronic mail submissions are not accepted. Upon receipt and verification of the required information, CDC sends a Certificate of Compliance (**Attachment 6**) to each entity that submitted a report.

Tobacco manufacturers and importers are required to provide proof of compliance with the cigarette ingredient reporting requirements of FCLAA in nearly every state in which their products are retailed. Most states specifically require annual submission of an HHS Certificate of Compliance or a letter from CDC confirming compliance for each brand. 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. The Certificate of Compliance from CDC can serve as proof of compliance.

HHS also 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. 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.

Items of Information to be Collected

The Ingredient Report provides an itemized list of all ingredients in each cigarette product. CDC requires the list of ingredients to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number. This is consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. To the best of CDC's knowledge, laboratory analysis is not available that would provide a complete representation of the ingredients added to tobacco in the manufacture of cigarettes. Laboratory analysis in lieu of the Ingredient Report is not acceptable. This information collection involves information in identifiable form (IIF). For each manufacturer or designated representative, the name and contact information of a contact person is collected. No personal information about the contact person is collected.

Since 2003, background information about FCLAA, ingredient reporting requirements and instructions for reporting have been posted on CDC's public web site, http://www.cdc.gov/tobacco/basic_information/tobacco_industry/reporting/instructions/index.htm (see **Attachments 5a and 5b**).

There is no website content directed at children less than 13 years of age.

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. Respondents are required to submit a new list or a statement that there are no changes to their previously submitted ingredient report every year.

To date, data submissions are received via courier, mail, or facsimile to ensure confidentiality of the information included. At present, CDC is working to assess the feasibility of establishing an electronic means to receive information while adhering to confidentiality requirements.

A4. Efforts to Identify Duplication and Use of Similar Information

No other information collection activity of the Federal government or private sector has compiled the information necessary to certify compliance with FCLAA.

As stated in the previous terms of clearances for the Center for Disease Control (OMB Control No.'s: 0920-0210) and FDA's Center for Tobacco Products (CTP) (OMB Control No. 0910-0650), the data to be collected overlap in terms of the similar tobacco product ingredient collections being conducted. However, at this time, the CTP data cannot currently be used by CDC due to both logistical reasons and restrictions on the use of information collected.

FCLAA contains certain requirements that differ from the statutory requirements for submission of information in the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (TCA). For instance, FCLAA requires ingredient lists to be provided annually whereas the TCA only mandates annual submissions detailing lists of products, but not ingredients. In addition, the TCA only requires submission of ingredients prior to a tobacco product's delivery for introduction into commerce and thereafter if certain changes are made to such product. Further, 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. The 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.

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 those 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 27, 2021, vol. 86 No.184, pp. 53308-53309 **(Attachment 2)**.

CDC did not receive any public comments in response to this federal register notice.

Part B: CONSULTATION

Table 1. External Consultations

No individuals/entities were consulted for purposes of this OMB submission. Please note, however, that consultations were held in 1989 and 1990 to inform a prior OMB submission to assist with estimating the approximate time burden for complying with the requirements pursuant to FCLAA. All burden estimates remain the same as those provided in previous OMB submissions.

Table 2. Consultations within CDC

Name	Title	Affiliation	Phone	Email	Role
Kathy Gallagher	Public Health	OSH, Policy	678-733-5349	khg5@cdc.gov	Project Officer

Ruth Hayes	Contractor	Katmai Government Services, OSH, Policy Unit	770-488-5743	aro5@cdc.gov	Data Collection

A9. Explanation of Any Payment or Gift to Respondents

No payment or remuneration will be provided to respondents.

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.

Respondents are commercial entities, not individuals. No personal information is being collected. All information is filed and retrieved by name of the cigarette manufacturer or the attorney representing the manufacturer, therefore, the information does not fall under the purview of the Privacy Act.

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 3**. 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 7a and 7b)** and shall not be revealed except as authorized in the statute.

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

IRB Approval

This data collection does not involve research with human subjects and does not require IRB review and approval. There is no consent process comparable to

participation in research **(Attachment 4c)**.

Sensitive Questions

The proposed information collection is sensitive in that the industry has expressed concern about possible unintentional or unauthorized release of the ingredient information that the law requires to be reported. The sensitive information must be collected in order to meet the requirements of FCLAA.

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	$71.59	$25,629

The estimated total annualized cost to respondents is $25,629, based on an average hourly wage of $71.59 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 2020 (available at: https://www.bls.gov/oes/current/oes231011.htm)

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 is free to respondents.

A14. Annualized Cost to the Federal Government

The estimated annualized cost to the government is $66,250. The table below describes itemized cost components.

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

Item	***Annualized Cost***
CDC Supervisor (3% FTE)	$3,250
Contractor for data collection, data management, communications and logistical support related to compilation of data and quality assurance.	$54,500
Computing equipment and maintenance	$8,500
Total	$66,250

A15. Explanation for Program Changes or Adjustments

This ICR is an extension: There is no change in burden. The hourly wage rate was updated for the respondents, but there was no change in burden hours or number of respondents.

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.

Of note, on April 27, 2020, a Federal Register Notice was published Vol. 85, No. 84, pp. 23359-23360, **(Attachment 9)**, to indicate the CDC was extending the March 31st deadline for submissions required under the Federal Cigarette Labeling

and Advertising Act (FCLAA). Within the April 2020 Federal Register Notice, CDC stated that due to the unforeseen public health response to COVID-19 and related issues, CDC was and remains unable to accept any ingredient submissions or to issue Certificates of Compliance. This same language was inserted on CDC's website under the webpage entitled Tobacco Ingredient and Nicotine Reporting | CDC.

HHS is authorized, but not required, to analyze submitted data and to submit a report to the Congress. Reports 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 4a)** which is available on the CDC website. This information and the burden estimate are also displayed on the needs additional information letter **(Attachment 4b**).

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.