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

OMB Control No. 0920-0210

Request for Reinstatement with Change

Supporting Statement Part A

Submitted by:

Office on Smoking and Health
National Center of Chronic Disease Prevention
and Health Promotion
Centers for Disease Control and Prevention
Department of Health and Human Services

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Submission of this ICR has been approved by the
HHS/Assistant Secretary for Planning and Evaluation (ASPE)

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SUMMARY

- **Goal of the Reinstatement:** This Information Collection Request (ICR) supports Reinstatement with 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. December 31, 2018).

- **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.

- **Methods to be used to collect data:** 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. Upon receipt and verification of the required information, CDC sends a Certificate of Compliance to each entity that submitted a report.

  There are no changes to the information collected, the estimated burden per response, or the estimated annualized burden to respondents. However, there is a change in the number of respondents. The respondents dropped from 77 to 55. The reasons for the decrease could be any number of things (e.g., companies could have closed or merged).

- **Respondents:** 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 submitted at such times as the Secretary of HHS considers appropriate.

1. Circumstances Making the Collection of Information Necessary

   Cigarette smoking is the leading preventable cause of premature death and disability in our Nation. Each year more than 480,000 deaths occur as the result of cigarette smoking-related diseases.

   The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. OSH promotes tobacco control interventions including actions to prevent youth from starting to use tobacco, smoke-free environments, programs to help tobacco users quit, and steps to eliminate tobacco-related health disparities in different population groups.

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

The legislative requirements for ingredient reporting were first published in the Federal Register in 1985 (**Attachment 3,** vol. 50, p. 49617-49619, published December 3, 1985).

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.**

Annually, OSH sends a certificate of compliance letter to each entity that has submitted the required information. The letter includes a reminder of responsibilities related to future reporting. If a submission contains incomplete entries or possible errors, CDC will follow up by sending a request for additional information **(Attachment 4b).**

Privacy Impact Assessment

Overview of the Data Collection System

Respondents are commercial cigarette manufacturers, packagers, or importers (collectively called "manufacturers" throughout this ICR). The information outlined in the Recommended Cigarette Ingredient Reporting Format (**Attachment 4a**) must be submitted for each product. Typically, manufacturers submit a summary report to CDC with the ingredient information for multiple products, often through a designated entity such as legal counsel. 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 CD, 3-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted.

Ingredient reports are due annually on March 31.

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 OSH'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.

2. Purpose and Use of Information Collection

The information collection is used to certify tobacco industry compliance with the terms of FCLAA. 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. 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 the Act 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 the Act's requirements. The Certificate of Compliance from CDC can serve as proof of compliance.

HHS also has the authority under the Act 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 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.

If this information is not collected, those who manufacture, package, or import cigarettes will not have the means to comply with requirements of FCLAA or many state laws.

Privacy Impact Assessment

Safeguards implemented by CDC are consistent with Section 1335a of FCLAA, which required HHS to establish written procedures assuring the confidentiality of information provided. These Guidelines were included in the 1985 Federal Register Notice (see **Attachment 3).** Penalties for disclosure of confidential information are outlined in 18 U.S.C., Crimes and Criminal Procedure, Chapter 93, Part 1905, (see **Attachment 7)**.

3. Use of Improved Information Technology and Burden Reduction

In order 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. Legal obstacles to reducing respondent burden through the use of electronic data collection methods include the confidential and proprietary nature of the ingredients, which makes it impracticable for companies to submit electronically.

4. 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 FD&C Act only mandates annual submissions detailing lists of products, but not ingredients. Rather, the FD&C Act 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 FD&C Act, on the other hand, requires submission of all ingredients by quantity, brand, and sub-brand. FCLAA also contains specific requirements concerning written procedures assuring confidentiality, physical possession of information, as well as storage requirements. The FD&C Act does not require that level of specificity.

Also important to note is that 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.

Information about the key distinctions between CDC and FDA's Data Collection are also highlighted below.

Key Distinctions Between CDC and FDA's Data Collection

	Federal Cigarette Labeling and Advertising Act	Tobacco Control Act
HHS Program Administration	CDC	FDA
Cigarette Data Collected: Ingredients	Yes; however, no quantities collected; brands and subbrands are not specified. Also, reporting not required for tobacco types/brands or reporting of ingredients used in paper and filters.	Yes; quantities collected; brand and subbrands are specified. Reporting is required for tobacco types/brands and reporting of ingredients used in paper and filters.
Cigarette Data Collected: Nicotine[1]	Not collected	Yes; quantities are collected, brands and subbrands are specified
Timeline of Collection	Annual, regardless of changes to product	Baseline collection when tobacco product is first introduced to market, with additional disclosure to FDA upon any changes to product
Confidentiality Provisions and Information Sharing	Information submitted is considered trade secret and confidential. Disclosures permitted only as authorized by legislation.	Information submitted is considered confidential and may contain trade secrets. Other disclosures as permitted to other officers or employees concerned with carrying out the tobacco control provisions of the FD&C Act or when relevant in a proceeding under the tobacco control provisions of the FD&C Act

CDC and FDA continue to discuss ways we can avoid duplication within our current constraints.

[1] FDA is also required to collect information on harmful and potentially harmful constituents (such as nicotine) by brand and sub-brand and notes that not every constituent is harmful/potentially harmful and therefore on the list. Since constituents are what are inhaled/absorbed/ingested by the person, some ingredients may also be constituents, other ingredients are not constituents (cigarette paper), and some constituents are not ingredients (e.g., lead since it comes from the tobacco itself or CO since it is produced by burning the tobacco). Thus, the reporting of harmful and potentially harmful constituents is also not duplicative of CDC ingredient reporting requirements

OMB approval is being requested for three years.

5. Involvement of Small Business 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.

6. 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; HHS and respondents submitting information less frequently would not be in compliance with the law.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this request.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Federal Register Notice

On 08/21/2018, a Notice was published in the Federal Register (Volume 83, No. 162, pp. 42299-42300) **(Attachment 2)**. CDC received a total of two public comments, both of which are included in this Information Collection Request. Of the two public comments received, one was submitted by Altria Client Services (**Attachment 9a**). Given the substantive and detailed nature of this comment submitted, CDC provided a direct response to Altria Client Services' Senior Vice President for Regulatory Affairs. The text of CDC's correspondence sent in response to this public comment is included in this Information Collection Request (**Attachment 9b)**. The second public comment was received from an anonymous source (**Attachment 10a**). The nature of this public comment was determined to be outside the scope of this information request and therefore a response from CDC was not warranted (**Attachment 10b**).

CDC and FDA continue to discuss ways we can avoid duplication within our current constraints.

B. Other Consultations

In 1989 and 1990, consultations were held with the designated legal counsel and representative for the major cigarette companies, the Federal Trade Commission, and the Oak Ridge National Laboratory regarding the data collection. There were no major problems that could not be resolved during consultation.

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The designated legal counsel has been contacted prior to each OMB submission and asked to provide a revised estimate of the respondent burden hours and cost to respondents. In 2018, Deborah Wolenberg at Altria Client Services and Barry Boren at Law Offices of Barry Boren were contacted to provide an estimate of person-hours and financial resources for this information collection.

9. Explanation of Any Payment or Gift to Respondents

No payment or remuneration will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

A. Privacy Act Determination. 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 business entities, not individuals. Each respondent entity is represented by a contact person; however, 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.

B. Safeguards. 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. These procedures have proven workable, effective, and acceptable to the companies required to report the confidential information. A copy of the HHS procedures is included in the 1985 Federal Register Notice provided in **Attachment 3**. In accordance with provisions in the 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) **(Attachment 7)**, and shall not be revealed except as authorized in the statute.

C. Consent. The reporting requirements for manufacturers are established by FCLAA. 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.

D. Nature of Response. Response is required.

11. Justification for 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.

12. Estimates of Annualized Burden Hours and Costs

Information for each calendar year is submitted no later than March 31 of the following year. Information for each cigarette product must conform to the specifications established by the Recommended Cigarette Ingredient Report Format (**Attachment 4a**), which is available on the CDC website. Manufacturers are not required to submit specific forms. If a submission contains incomplete entries or possible errors, CDC may follow up by sending a request for additional information (**Attachment 4b**). Annually, OSH sends a certificate of compliance letter (**Attachment 6**) to each entity that has submitted complete information. The letter includes a reminder related to future reporting. The burden estimate is based on experience with the information collection in the prior approval period. The average burden per response is estimated at 6.5 hours, the number of respondents is estimated at 55, and the total burden hours are estimated at 358.

a) Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Average of Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Cigarette	Ingredient	55	1	6.5	358

Manufacturers, Packagers, and Importers	Report				

b) Estimated Annualized Cost to Respondents

The estimated total annualized cost to respondents is $20,524, based on an average hourly wage of $57.33 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 2017 (available at: https://www.bls.gov/oes/current/oes231011.htm)

Type of Respondents	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Hourly Wage Rate**	**Total Cost**
Cigarette Manufacturers, Packagers, and Importers	Ingredient Report	55	1	6.5	$57.33	$20,524

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

a) Total Capital and Start-up Costs
None.

b) Total Operation and Maintenance
None.

14. Annualized Cost to the Government

The estimated annualized cost to the government is $79,750. The table below describes itemized cost components.

Item	Estimated 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	$22,000
Total	$79,750

15. Explanation for Program Changes or Adjustments

There is no change to the estimated burden per response, which is 6.5 hours.

In the previous OMB approval period, the total burden estimate of 501 hours was based on 77 respondents. The estimates in the current Reinstatement with Change Request has changed. The number of respondents dropped from 77 to 55, decreases the overall estimated annualized burden to respondents. The reasons for the decrease could be any number of things (e.g., companies could have closed or merged).

16. 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 were submitted to Congress in February 1990, July 1990, and March 1993.

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

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**).

18. Exceptions to Certification

There are no exceptions to the certification statement.