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

OMB Control No. 0920-0210

Request for Extension

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

This Information Collection Request (ICR) supports Extension of a Congressionally-mandated information collection, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products" (OMB control no. 0920-0210, exp. February 28, 2014). OMB approval is requested for three years.

There are no changes to information collection procedures, the number of respondents, the estimated burden per response, or the estimated annualized burden to respondents.

A. JUSTIFICATION

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 443,000 premature 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. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smoking Education Act of 1984 (15 U.S.C.' 1335a or P.L. 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 are also outlined in section 1335a of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. Parts 1331-1341 (**Attachment 1b**).

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). At that time, OSH wrote to the companies and trade associations known to be involved in the manufacture, packaging or distribution of cigarettes informing them of the requirements of the Comprehensive Smoking Education Act and the procedures established for submission of the ingredient lists. OSH also advised Covington and Burling, the designated legal counsel and representative for the major cigarette companies in the U.S., of the reporting requirements.

For subsequent data collections, OSH reviews and revises the mailing list of cigarette manufactures, packagers, and importers by comparing it to lists available from the tobacco industry, the Federal Trade Commission, the National Association of

Attorneys General and updating the files as new companies submit ingredient lists. CDC distributes a postcard notice **(Attachment 4b)** to each manufacturer, packager and importer, or respective attorney, reminding them of the reporting requirements and the due date. If a submission contains incomplete entries or possible errors, CDC may follow up by sending a request for additional information **(Attachment 4c).**

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.**

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 Ingredient Report (**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. 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 for new products are due at the time of first importation. Thereafter, 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.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Since 2003, background information about the Comprehensive Smoking Education Act, 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 compliance with the terms of the Comprehensive Smoking Education Act of 1984 and to support research on the health effects of tobacco smoking.

The tobacco industry is required to provide the HHS Certificate of Compliance to every State's Attorney General in which their tobacco product is retailed. Also, upon importation to the United States, the tobacco industry also provides the HHS Certificate of Compliance to U.S. Custom's Border Protection (CBP); in order for the tobacco industry to become established as a manufacturer or importer of tobacco products, it must gain a permit from the Tobacco Tax and Trade Bureau, which utilizes the HHS Certification of Compliance.

Submission of the Ingredient Report information to HHS (through CDC) is required to establish and document manufacturers' compliance with the legislative mandate. Upon receipt and verification of the required information, CDC sends a Certificate of Compliance (**Attachment 6**) to each manufacturer. The manufacturer subsequently files a copy of the certificate with the tobacco tax administrator (usually the State Attorney General) in each state in which the manufacturer operates. The Certificate of Compliance from CDC is part of the manufacturer's initial application to sell tobacco products in the state, and must be updated annually no later than April 30. A manufacturer, packager, or importer that fails to file the Certificate of Compliance with the state tax administrator is not eligible to sell or transfer products in that state or to import products through U.S. Customs.

HHS also uses the information collected to exercise its authority under the Comprehensive Education Act to conduct research on the health effects of ingredients added to tobacco in the manufacture of cigarettes. As authorized in the statute, 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 neither have means to comply with requirements of this law nor will CDC be able to effectively report on the health consequences of cigarette use.

Privacy Impact Assessment

Safeguards implemented by CDC are consistent with Section 1335a of the FCLAA, which required HHS to establish written procedures assuring the confidentiality of information provided (see **Attachment 7a,** Guidelines to Control and Protect Documents that Contain Privileged Information Obtained in Accordance with Sec.

5(a) of P.L. 98-474). Penalties for disclosure of confidential information are outlined in 18 U.S.C., Crimes and Criminal Procedure, Chapter 93, Part 1905, (see **Attachment 7b)**.

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 the Comprehensive Smoking Education Act 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

The current collection of cigarette ingredient information (OMB No. 0920-0210, exp. 02/28/2014) is required by the Comprehensive Smoking Education Act. Approval for CDC to submit this Extension request has been obtained from the HHS/Assistant Secretary for Planning and Evaluation.

In 1994, the four largest tobacco manufacturers released a public list of ingredients used in the manufacture of cigarette products. While this list provided information similar to that being requested, it only covered one year and did not provide Chemical Abstract Service numbers. Additionally, it did not cover all tobacco manufacturers.

As directed by OMB, CDC/OSH and FDA reviewed their data collections and discussed strategies to reduce or eliminate duplicative collections involving tobacco industry respondents. CDC submitted a follow-up report to OMB in July 2011 (**Attachment 9**). The findings are that although both CDC and FDA collect tobacco product ingredients and nicotine analysis data, key differences in the scope and detail of the information make these collections non-duplicative. Aligning the programmatic collections and sharing of information would improve the overall utility of data collected. This sharing of information would allow the agencies to verify the reliability and accuracy of the data, given CDC's annual statutory requirement and could serve as an annual quality assurance check for FDA in the monitoring of tobacco product changes by manufacturers. Thus, the HHS agencies would benefit from the ability to share information received under the FCLAA, CSTHEA, and FSPTCA legislation.

On February 5, 2013, OMB approved the extension of the ICR 0920-0210 for 12 months with an expiration date of Feb 28, 2014, with the following terms of clearance: "Approved without change for 1 year consistent with the understanding that CDC will work with FDA's Center for Tobacco Products to identify duplication of tobacco product ingredient collections. Within this year, CDC will work with FDA, OMB, and HHS to eliminate duplication and reduce burden on respondents. As part of this effort, HHS, including CDC and FDA, should determine why the existing collection of information by the Center for Tobacco Products (OMB Control Number

0910-0650, and a pending ICR titled Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act) would not eliminate the need for and the practical utility of CDC's annual collection of this information. HHS should also consider whether the authority delegated to CDC for this collection should be delegated to the Center for Tobacco Products."

In June 2013, CDC, FDA, and OMB met briefly in Washington, DC regarding the potential duplication of tobacco ingredient reporting efforts. FDA and CDC provided OMB with the background and summary information on the tobacco product ingredient reporting programs within HHS/CDC/OSH and FDAs' Center for Tobacco Products (CTP). Additional follow-up discussions involving CDC and FDA have also been held (FDA contact: Corinne Husten, telephone (301) 796-9210; email Corinne.Husten@fda.hhs.gov). As discussed:

a) The data collections are similar, but they are not duplicative.
b) Because CDC collects information yearly, CDC's data collection could be used as a quality check for FDA.
c) Tobacco companies rely on their compliance letters from CDC in order to sell their products in individual states.
d) Tobacco companies also rely on their compliance letters from CDC to present to Customs upon importation in the U.S.
e) States will not allow tobacco companies to sell their products in their state unless they have a compliance letter from CDC.
f) Statutes for each data collection would need to be substantially revised.
g) FDA's mandate does not allow them to collect the information that CDC is collecting.
h) FDA and CDC will continue to collaborate and discuss opportunities for programmatic collections to enhance the overall utility of both HHS' and FDA's programs.

Currently, there is an active OMB approval for FDA's Tobacco Health Document information collection (OMB #0910-0654, exp.12/31/2016). This clearance relates to new provisions in section 904(a)(4) of the Family Smoking Prevention and Tobacco Control Act. The Act requires each tobacco product manufacturer or importer, or its agent, to submit to FDA all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." This information collection is not a substitute for the required reporting to CDC/OSH because it was only collected this one time – in 2009.

FDA has been granted approval for the Tobacco Product Establishment Registration and Submission of Certain Health Information collection (OMB #0910-0650, exp. 10/31/2015). This clearance relates to Section 905 of the Family Smoking Prevention and Tobacco Control Act. The Act requires annual registration of any tobacco product manufacturer, preparer, compounder, or processor by December 31 annually via an electronic portal or paper form FDA 3741. Section 904(a)(1) of the act requires

each tobacco product manufacturer or importer to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product. This information collection is not a substitute for the required reporting to CDC/OSH because it was only collected this one time.

On 03/15/2013, FDA obtained OMB approval for the Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act (0910-0732, exp. 03/31/2016). This collection requires each tobacco product manufacturer or importer, or an agent, to report to FDA "all constituents, including smoke constituents, identified by FDA as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product." These entities must also provide similar information at least 90 days prior to introducing the product into interstate commerce. OMB approved this collection with the following terms of clearance: ***"During this approval, OMB instructed that the Center for Tobacco Products (CTP) must work with CDC over the next year to identify duplication within the tobacco product ingredient collections. As part of this effort, HHS, including CDC and FDA, should determine why this collection of information by the CTP would not eliminate the need for and the practical utility of CDC's annual collection of this information. HHS should also consider whether the authority delegated to CDC for this collection should be delegated to CTP."*** This information collection is not a substitute for the required reporting to CDC/OSH because it does not require a list of ingredients, only potentially harmful ones.

At the time of this OMB submission, under the Tobacco Control Act, user fees collected by FDA may only be used for the purpose of paying the costs of the activities for FDA to regulate tobacco products. FDA cannot use these funds for any other activity. The Tobacco Control Act does not include authority for FDA to provide tobacco manufacturers, importers and packagers with a Certificate of Compliance that allows them to be in compliance with State requirements for selling tobacco products, and/or to be imported in the United States. As noted above, states as well as Customs rely upon CDC Certification in order to allow tobacco companies to import and sell their products in the U.S. The three statutes authorizing CDC and FDA to collect this information would have to be substantially revised to allow the collection of all required product ingredient information by only one of the two agencies.

No other data collections exist that pertain to cigarette ingredients and could potentially fulfill the current legislative requirements.

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

The Comprehensive Smoking Education Act 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. Also, analysis of the potential health effects of the reported ingredients would likely be delayed.

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 October 31, 2013, a Notice was published in the Federal Register (Volume 78, No. 211, pp. 65324-65325) **(Attachment 2)**.

CDC received two public comments in response to this Federal Register Notice. The first comment is included as **Attachment 10a** and CDC's response is included as **Attachment 10b**. The second comment is included as **Attachment 11a** and CDC's response is included as **Attachment 11b**.

Currently, CDC/OSH and FDA are in communication and have complied with OMB's directive to strategize a plan to reduce duplicative collections involving tobacco industry respondents.

In early 2011, CDC and FDA collaborated on an analysis and review of their respective information collections. Although similarities exist, the process resulted in the determination that the data collections are non-duplicative due to key distinctions. These distinctions are summarized in **Attachment 9**.

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. 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.

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In 2010, Barry Boren at The Law Offices of Barry Boren was contacted to provide an estimate of person-hours and financial resources for this information collection. In 2010, Stuart Pape at Patton Boggs was contacted to provide an estimate of person-hours and financial resources for this information collection. In 2010, Deborah Wolenberg at Altria Client Services was contacted to provide an estimate of person-hours and financial resources for this information collection.

There were no major problems that could not be resolved during consultation.

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 provided in **Attachment 7a**. In accordance with provisions in the Comprehensive Smoking Education Act, 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 7b)**, and shall not be revealed except as authorized in the statute.

C. Consent. The reporting requirements for manufacturers are established by the Comprehensive Smoking Education Act. 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 the Comprehensive Smoking Education Act of 1984.

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 Ingredient Report (**Attachment 4a**); however, manufacturers are not required to submit specific forms. CDC distributes a postcard reminder (**Attachment 4b**) to each manufacturer or designated representative. If a submission contains incomplete entries or possible errors, CDC may follow up by sending a request for additional information (**Attachment 4c**). The burden estimate is based on experience with the information collection in the prior approval period. As before, the average burden per response is estimated at 6.5 hours, the number of respondents is estimated at 77, and the total burden hours are estimated at 501.

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 Manufacturers, Packagers, and Importers	Ingredient Report	77	1	6.5	501

b) Estimated Annualized Cost to Respondents

The estimated total annualized cost to respondents is $23,058, based on an average hourly wage of $46.07 per hour for compiling and reporting the response.

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Hourly Wage Rate	Total Cost
Cigarette Manufacturers, Packagers, and Importers	77	1	6.5	$46.07	$23,058

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 $140,000. The table below describes itemized cost components.

Item	Estimated Annualized Cost
CDC Supervisor (3% FTE)	$3,000
Contractor for data collection, data management, communications and logistical support related to compilation and analysis of ingredient reports	$100,000
Secure storage of confidential materials	$5,000
Computing equipment	$12,000
Support services provided by the HHS/CDC/National Center for Environmental Health for laboratory research on chemical substances added to tobacco products	$20,000
Total	$140,000

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 Extension request have not changed.

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 the Comprehensive Smoking Education Act, 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

The OMB expiration date is displayed on the reminder postcard (Attachment 4b) mailed to respondents, along with the OMB approval number and burden estimate. As discussed in Section A.3, respondents are required to report information but are not required to use a standardized form. OMB has previously approved display of the expiration date on the reminder postcard, in lieu of displaying the expiration date on a standardized data collection instrument.

18. Exceptions to Certification

There are no exceptions to the certification statement.