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 and Part B

Submitted by:

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ATTACHMENT 2: Statutory Provisions on Confidentiality (18 U.S.C. ‘ 1905, 5 U.S.C. ‘ 552)

ATTACHMENT 3: Reminder Notification Postcard to Manufacturers, Packagers and Importers of Tobacco Products

ATTACHMENT 4a: HHS/CDC/OSH Tobacco Ingredient Reporting Web Page

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ATTACHMENT 5: Federal Register Notice, August 16, 2007, Vol. 72, p. 19207

ATTACHMENT 6: Guidelines to Control and Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474

ATTACHMENT 7: Federal Register Notice, December 3, 1985, Vol. 50, p. 49617-49619

ATTACHMENT 8: Request for Additional Information from Manufacturers, Packagers and Importers of Tobacco Products

ATTACHMENT 9: Federal Register Notice, November 8, 1994, Vol. 59, p. 55669-55670

This Supporting Statement describes CDC's request to reinstate a Congressionally-mandated information collection, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products," OMB control no. 0920-0210, which expired and was discontinued August 31, 2007. There are no changes to the previously approved estimated number of respondents (143) or estimated burden hours (930). Changes effective with this reinstatement relate to the redesign of the HHS/CDC/Office on Smoking and Health web site, which hosts the Tobacco Ingredient and Nicotine Reporting web page for this clearance. Changes are being instituted to improve compliance with E-government (e-gov) specifications, to improve organization of web site material, and to incorporate new features benefiting web site usability.

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 440,000 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 Pub.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; this list of ingredients is due to the CDC annually by March 31, or the time of first importation for importers of new products. This 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 1**. HHS is required to treat the Ingredient Reports as proprietary information per the trade secret and privacy acts. A copy of the Statutory Provisions on Confidentiality is in **Attachment 2**.

The legislation requires annual reporting of all such ingredients. A reminder notice is sent to each cigarette manufacturer, packager, and importer requesting the ingredient additives. For the first year of this data collection, the legislative requirements were published in the Federal Register (1985) and each potential respondent was sent a request letter. For many companies, the initial reporting year was 1986. Beginning in 1988, a comprehensive request letter was sent to all respondents, but a notice was not published in the Federal Register. In 2003, a post card **(Attachment 3)** was mailed and a web site **(Attachment 4)** developed

to notify and provide information to manufacturers, importers and packagers of the requirements of the law and to provide instructions and information to facilitate reporting.

2. Purpose and Use of Information Collection

HHS 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. Also, 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.

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. CDC requires the list of ingredients 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. OMB previously approved this format for reporting of cigarette ingredients.

The legislation requires annual reporting. Respondents are not required, however, 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 reduce the burden of collecting this information 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 Comprehensive Smoking Education Act is the only statute to mandate ingredient reporting for cigarettes. No other information collection activity of the Federal government or private sector has compiled such information. The information required is trade secret and cannot be compiled unless the tobacco companies provide it to HHS as required by the Comprehensive Smoking Education Act.

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.

No other data collections pertain to the information being requested exists.

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 comport with 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) On August 16, 2007, a Federal Register Notice (Volume 72, pp. 46084-46085) was published on this collection **(Attachment 5)**. The Centers for Disease Control and Prevention received no public comments in response to the Federal Register Notice.

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 1993, James W. Fox, Jr. at Covington and Burling was contacted to provide a revised estimate of person-hours and financial resources for this information collection. In 1996, Joseph Doss at Covington and Burling was contacted to provide an updated estimate of person-hours and financial resources for this information collection.

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

c) Not applicable.

9. Explanation of Any Payment or Gift to Respondents

There are no plans to provide any form of payment or remuneration to respondents.

10. Assurance of Confidentiality Provided to Respondents

In the review of this application, it has been 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 company name or the

attorney representing the company, therefore, the information does not fall under the purview of the Privacy Act.

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 2)**, and shall not be revealed except as authorized in the statute. The law also 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. Copies of the HHS procedures are provided in **Attachment 6**.

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

The burden estimate for the period of this reinstatement 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 143, and the total burden hours are estimated at 930.

a) Estimated Annualized Burden Hours

Type of Respondents	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total Burden (in hours)**
Cigarette Manufacturers, Packagers, and Importers	143	1	6.5	930

b) Estimated Annualized Cost to Respondents

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	143	1	6.5	$47.56	$44,207

The estimated total annualized cost to respondents is $44,207, based on an average hourly wage of $47.56 per hour for compiling and reporting the response.

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 smokeless tobacco products	$20,000
Total	$140,000

15. Explanation for Program Changes or Adjustments

The requested burden is the same as in the prior approval period.

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 3) 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.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This data collection does not require the use of statistical methods to select respondents, as all relevant companies are required to respond.

Data collection procedures

HHS initially announced the information collection through a 1985 Federal Register Notice (December 3, 1985, vol. 50, p. 49617-49619) outlining provisions of the law and reporting requirements. A copy of the notice is provided in **Attachment 7**. 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. OSH sends a notice to each manufacturer, packager and importer, or respective attorney, reminding them of the reporting requirements and the due date. If an incomplete submission is received, OSH sends a request for additional information **(Attachment 8.)** 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 9**.