Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.

OMB Control No. 0920-0338

Request for Reinstatement with Change

Supporting Statement Part A and Part B

Submitted by:

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

Project Officer:

Sherrill E. Brady
Policy Team Leader
Telephone: 770-488-5474
Fax: 770-488-5767
E-Mail: Sbrady@cdc.gov

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ATTACHMENT 2: Civil Penalties for Disclosure of Confidential Information (18 U.S.C. ‘ 1905)

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

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

ATTACHMENT 4b: OSH Web Page on the Comprehensive Smokeless Tobacco Education Act

ATTACHMENT 5: Federal Register Notice, July 24, 2007, Vol. 72, p. 40296-7

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, "Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.," OMB control no. 0920-0338, which expired and was discontinued August 31, 2007. There are no changes to the previously approved estimated number of respondents (11) or estimated burden hours (18,838). 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 were 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

Oral use of smokeless tobacco products (SLT) represents a significant health risk which can cause cancer and a number of noncancerous oral conditions, and can lead to nicotine addiction and dependence. Furthermore, smokeless tobacco use is not a safe substitute for cigarette smoking.

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 Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. ' 4401 et seq. or Pub.L. 99-252) requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary of Health and Human Services with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products as well as the nicotine data report for each product. Commonly known as the Nicotine Data and Ingredient Report, this report is due to the CDC annually by March 31. This legislation also authorizes HHS to undertake research, and to report to the Congress, as deemed appropriate, on the health effects of SLT products. A copy of the relevant portion of the statute is provided in **Attachment 1**. HHS is required to treat the information as trade secret and confidential. A copy of the statutory provisions describing penalties for disclosure of confidential information is provided in **Attachment 2**.

The legislation requires annual reporting of all such ingredients. A reminder notice is sent to each smokeless tobacco products 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 developed to notify manufacturers, importers and packagers of the requirements of the law and to provide instructions and information to facilitate reporting (see **Attachments 4a** and **4b**).

Eleven respondents reported information during the prior OMB approval period (September 30, 2004 – August 31, 2007). Eleven respondents are expected to participate in the period of this reinstatement.

2. Purpose and Use of the Information Collection

HHS uses the information collected to exercise its authority under the Comprehensive Smokeless Tobacco Education Act to conduct research on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products. 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 smokeless tobacco products; 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 smokeless tobacco products will neither have means to comply with requirements of this law nor will CDC be able to effectively report on the health consequences of smokeless tobacco products 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 Smokeless Tobacco 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 smokeless tobacco products 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 Smokeless Tobacco Education Act is the only statute to mandate ingredient reporting for smokeless tobacco products. 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 Smokeless Tobacco Education Act.

In 1994, the four largest tobacco manufacturers released a public list of ingredients used in the manufacture of smokeless tobacco 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. Impact on 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 Smokeless Tobacco 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 FRN and Efforts to Consult Outside the Agency

a) Federal Register Notification
On July 24, 2007, a Federal Register Notice (Volume 72, p. 40296-7) 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 smokeless tobacco products 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.

Stanley L. Temko
Attorney
Covington and Burling
201 Pennsylvania Avenue, NW
P.O. Box 7566
Washington, D.C. 20044
Telephone: (202) 662-6000

(Designated legal counsel and representative for the major smokeless tobacco products companies in the U.S.)

Michael R. Guerin, Ph.D.
Organic Chemistry Section Head
Analytical Chemistry Division
Oak Ridge National Laboratory
P.O. Box 2008
Oak Ridge, Tennessee 37831-6120
Telephone: (615) 574-4862

Judith Wilkenfeld
Assistant Director
Division of Advertising Practices
Federal Trade Commission
Washington, D.C. 20580
Telephone: (202) 326-3150

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.

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

b) 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 Smokeless Tobacco 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 Smokeless Tobacco Health Education Act of 1986.

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. In 2006, OSH contacted 11 companies that import, manufacture or package smokeless tobacco products. Each company submitted a list of ingredients and sample by March 31, 2006. The total annual response burden reported for all 11 companies was 18,843 hours at a total cost of $12,529. The average annual response burden for each company was 1,713 hours at a cost of $1,139 per company. Because some respondents report on only one product or brand, and other respondents report on

20 or more products or brands, burden and cost for an individual respondent may differ from the overall averages.

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)**
Smokeless Tobacco Manufacturers, Packagers, and Importers	11	1	1,713	18,843

b) Estimated Annualized Costs to Respondents

Average cost for compiling each report, per respondent, is $1,139.

Type of Respondents	**Number of Respondents**	**Number of Responses per Respondent**	**Average Cost per Response**	**Total Cost**
Smokeless tobacco products Manufacturers, Packagers, and Importers	11	1	$1,139	$12,529

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 Costs 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

On March 23, 2005, OMB granted a change in burden hours from 72 to 18,838. No further changes to the burden estimate are proposed in this reinstatement.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collection occurs annually; smokeless tobacco ingredient and nicotine 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 Smokeless Tobacco 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 for Paperwork Reduction Act Submissions

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 smokeless tobacco products informing them of the requirements of the Comprehensive Smokeless Tobacco 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 smokeless tobacco products companies in the U.S., of the reporting requirements.

For subsequent data collections, OSH reviews and revises the mailing list of smokeless tobacco products 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 **(Attachment 3)**. Instructions for reporting ingredient information are posted on the HHS/CDC/OSH Tobacco Ingredient Reporting Web Page **(Attachment 4a)**. Additional information about reporting and compliance issues associated with the Comprehensive Smokeless Tobacco Education Act is also provided on the OSH web site **(Attachment 4b).** If a respondent submits an incomplete submission, 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**.