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 Extension (Reinstatement)

Supporting Statement Part A

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

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February 21, 2012

Resubmitted December 20, 2012

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This Information Collection Request (ICR) supports continuation of 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, exp. September 30, 2012.

The revision request includes the following changes: an increase in the estimated number of respondents from 11 respondents of the prior ICR to 13 for the current ICR and a corresponding increase in the total burden hours from 18,843 to 22,269. There are no changes to information collection procedures or the estimated burden per response. OMB approval is requested for three years.

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 P.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 (SLT) 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**. Section 4403 relates specifically to ingredient reporting.

The legislative requirements for reporting were first published in the Federal Register in 1985 (**Attachment 3**, Federal Register, Vol. 50, p. 49617-49619, December 3, 1985). At that time, each potential respondent received a letter requesting the information specified in the legislation. 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.

Prior approval to collect smokeless tobacco ingredient and nicotine information was granted by OMB on March 17, 2011. At which time, OMB approved the total burden

estimate of 18, 843 hours was based on 11 respondents. The estimates in the current revision request are being increased to 13 respondents and 22,269 burden hours (an increase of 2 respondents and 3,426 burden hours). The increase in the estimated number of respondents is based on the actual number of responses received by OSH for the most recent complete reporting period (2010).

Privacy Impact Assessment

Overview of the Data Collection System

Respondents are commercial manufacturers, packagers, and importers (collectively called "commercial entities" throughout this ICR) of smokeless tobacco (SLT) products. In many cases, commercial entities submit the required information to CDC through their designated representative, such as legal counsel. Respondents are required to report both the ingredients in, and the nicotine content of, their SLT product lines, but are not required to complete a complex form or a specific questionnaire. CDC accepts SLT Nicotine and Ingredient Reports in any format that meets the legislation's reporting requirements. Guidelines for the SLT Ingredient Report are included as **Attachment 4a-1**, and guidelines for the SLT Nicotine Report are included as **Attachment 4a-2**. Typically, commercial entities submit information for multiple products in summary (aggregate) form. Nicotine and ingredient reports for new products are due at the time of first importation. Thereafter, nicotine and ingredient reports are due annually on March 31. Respondents are required to submit a new list or a statement that there are no changes to their previously submitted ingredient report, along with the original submission, every year. Since 2003, an annual post card reminder **(Attachment 4b**) has been mailed to respondents to notify them of reporting requirements.

Items of Information Collected

Commercial entities are required to provide CDC with an itemized list of all ingredients in each SLT product. 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. In addition, respondents are required to submit information about the nicotine content of their products. Nicotine content is determined on the basis of a standard laboratory protocol for analyzing SLT product samples. The laboratory protocol was revised and re-published in 2009 (see **Attachment 5**, Federal Register, Vol. 74, No. 4, pp. 712-719, January 7, 2009). As of 2010, nicotine data reports provided to CDC reflected the minor change in the nicotine analysis protocol.

This information collection involves information in identifiable form (IIF). For each commercial entity required to report, 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 Direct at Children Under 13 Years of Age

Since 2003, background information about the requirements of the law, nicotine and ingredient reporting requirements, and instructions have been available to commercial entities through an OSH web site, http://www.cdc.gov/tobacco/basic_information/tobacco_industry/reporting/instructions/index.htm (see **Attachments 6a** and **6b**).

Thirteen respondents reported information during the prior OMB approval period (March 2010 – September 2012). Thirteen respondents are expected to participate in the period of this extension.

2. Purpose and Use of the Information Collection

This information collection will continue to be used for purposes described here and in previous submissions. These purposes include support of compliance with CSTHEA and preparing responses to requests for information from Congress and other entities.

This information collection is used to certify commercial entities' compliance with the terms of the Comprehensive Smokeless Tobacco Health Education Act of 1986 and to support research on the health effects of smokeless tobacco products.

Submission of the ingredient and nicotine 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 7**) to each commercial entity or its representative. The respondent subsequently files a copy of the certificate with the tobacco tax administrator (usually the State Attorney General) in each state in which the commercial entity operates. The Certificate of Compliance from CDC is part of the commercial entity's initial application to sell SLT 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 Smokeless Tobacco Health 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.

Privacy Impact Assessment

HHS is required to treat the information as trade secret and confidential. The authorizing legislation established Guidelines to Control and Protect Documents that contain Privileged Information Obtained in Accordance with the mandate (see **Attachment 8a**). A copy of the statutory provisions describing penalties for disclosure of confidential information is provided in **Attachment 8b**.

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 Health Education Act is being requested. The CSTHEA requires annual reporting. Due to the confidentiality concerns related to the proprietary nature of the information collected, electronic data collection methods are not used.

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 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.

Recently, FDA obtained OMB approval for the Tobacco Health Document information collection (FDA 0910-0654, exp. 10/31/2013). This information collection relates to new provisions in section 904(a)(4) of the Family Smoking Prevention and Tobacco Control Act. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 904 to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d), establishing requirements for tobacco product ingredient submissions. Section 904(a)(1) of the act requires each tobacco product manufacturer or importer, or agent thereof, 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, by brand and by quantity in each brand and sub-brand. For tobacco products on the market as of June 22, 2009, the list of ingredients was submitted by December 22, 2009. For tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days

prior to delivery for introduction into interstate commerce. Section 904(c) of the act also requires submission of information whenever any additive, or the quantity of any additive, is changed.

On March 17, 2011, the Office of Management and Budget (OMB) approved the extension of the ICR 0920-0210 for 18 months to expire on 09/30/2012 with the following terms of clearance: "Approved without change for 18 months consistent with the understanding that CDC will work with FDA's Center for Tobacco Products to identify duplication of tobacco ingredient collections. No later than one year from the date of this approval, CDC will submit a brief report to OMB identifying redundancies in the data collections along with strategies for eliminating duplication and reducing burden on respondents."

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 (**Attachement10**). 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 collection and sharing of information will improve the overall utility of data collected. This will allow the agencies to verify the reliability and accuracy of the data, given CDC's year-by-year program and ability to serve as an annual quality assurance check for FDA monitoring of tobacco product changes by manufacturers. The HHS agencies would benefit from the ability to share information received under the FCLAA, CSTHEA, and FSPTCA legislation.

The information collection conducted by FDA is not a substitute for the legislatively mandated report of the Federal Cigarette Labeling and Advertising Act (FCLAA) submitted to CDC/OSH.

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 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 FRN and Efforts to Consult Outside the Agency

a) Federal Register Notification

On 03/01/2012, a Notice was published in the Federal Register Notice (Volume 77 No. 41, pp. 12595-12596) **(Attachment 2)**. The Centers for Disease Control and Prevention received two public comments in response to publication of the Notice.

CDC has received public comments in response to the Federal Register Notice was published on March 1, 2012 (**Attachment 11**).Two comments have been received and CDC has responded to the public comments (**Attachment 12**).

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.

The tobacco industry is required to provide 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 provides 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 to from the Tobacco Tax and Trade Bureau, which utilizes a HHS Certification of Compliance.

b) Other Consultations

In 1989 and 1990, consultations were held with the designated legal counsel and representatives 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.

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In 2010, Stacy Saunders of Wind River Tobacco Company 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 Information Collection Review Office, who determined that the Privacy Act is not applicable. Respondents are commercial entities, not individuals. Each responding commercial entity is represented by a contact person; however, no personal information is being collected. All information is filed and retrieved by name of the responding commercial entity or the attorney representing the respondent, 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 8a**. 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 8b)**, 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 Smokeless Tobacco Health Education Act of 1986.

12. Estimates of Annualized Burden Hours and Costs

Information for each SLT product must conform to the specifications established by the SLT Ingredient Report Guidelines (**Attachment 4a-1**) and the SLT Nicotine Report Guidelines (**Attachment 4a-2**). Commercial entities are not required to submit specific forms. The majority of respondents submit a combined ingredient/nicotine report, and for this reason, the burden estimate is a combined total for both ingredient and nicotine data elements. In some cases, a legal firm represents one or more commercial entities. Information for each reporting year is submitted by mail no later than March 31 of the following year. An annual reminder postcard (**Attachment 4b**) is distributed to each known commercial entity or its designated representative. CDC may follow up with a request for additional information (**Attachment 4c**) if a submission contains incomplete entries or possible errors. Due to concerns about the confidentiality of electronic submissions, electronic information collection methods are not used.

Ingredient and reporting for smokeless tobacco products is more complex than ingredient reporting for cigarette products. First, there is a broad range of SLT products, and ingredients must be reported for each product (including each formulation of the product, e.g., chew, pouch, etc.) and each combination of formulation and flavoring, etc.). Second, the burden estimate includes time for determining the nicotine content of samples through laboratory analysis.

The burden estimate for the period of this extension request is based on experience with the information collection in the prior approval period. In 2011, OSH contacted 13 respondents that import, manufacture or package smokeless tobacco products. Each company submitted a list of ingredients and sample by March 31, 2012. The total annual response burden reported for all 13 companies was 22,269 hours at a total cost of $14,807. 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	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total Burden (in hours)**
Smokeless Tobacco Product Manufacturers, Packagers, and Importers	SLT Nicotine and Ingredient Report	13	1	1,713	22,269

b) Estimated Annualized Costs to Respondents

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

Type of Respondents	**Number of Respondents**	**Number of Responses per Respondent**	**Average Cost per Response**	**Total Cost**
Smokeless Tobacco Product Manufacturers, Packagers, and Importers	13	1	$1,139	$14,807

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

There is no change to the estimated burden per response, which is 1,713 hours.

In the previous OMB approval period, the total burden estimate of 18,843 hours was based on 11 respondents. The estimates in the current Extension request are being increased to 13 respondents and 22,269 burden hours (an increase of 2 respondents and 3,426 burden hours). The increase in the estimated number of respondents is based on the actual number of responses received by OSH for the most recent, complete reporting period (2010).

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.