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

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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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 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. 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 total estimated annualized burden to respondents.

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 Notice, 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.

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 every year. Since 2003, an annual post card reminder **(Attachment 4b**) has been mailed to respondents to notify them of reporting requirements.

Thirteen respondents are expected to participate in the period of this Extension.

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**).

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

The current collection of smokeless tobacco ingredients and nicotine data analysis (OMB No 0920-0338, exp. 02/28/2014) is mandated by the Comprehensive Smoking Education Act

and the Comprehensive Smokeless Tobacco Education Act. Approval for CDC to submit this Extension request has been obtained from the HHS/Assistant Secretary for Planning and Evaluation (ASPE). Although FDA also has an ingredient reporting mechanism the differences in periodicity of the CDC reporting system make the CDC reporting system unique and valuable.

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.

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 10**). 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 0920-0338 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 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, FDA obtained OMB approval for the 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 (OMB #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 smokeless tobacco products and nicotine analysis that could potentially fulfill the current legislative requirements.

OMB approval is being requested for three years.

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 Notice

On October 31, 2013, a Notice was published in the Federal Register (Volume 78, No. 211, pp. 65323-65324) **(Attachment 2)**.

CDC received two public comments in response to the Federal Register Notice. The first public comment is included as **Attachments 11a** and CDC's response is included as **Attachment 11b**). The second public comment is included as **Attachment 12a** and CDC's response is included as **Attachment 12b**).

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 2012, Stacy Saunders of Wind River Tobacco Company was contacted to provide an estimate of person-hours and financial resources for this information collection. In 2012, Barry Boren was contacted to provide an estimate of person-hours and financial resources for this information collection. In 2012, 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 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 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 2012, OSH contacted 13 respondents that import, manufacture or package smokeless tobacco products. Each company submitted a list of ingredients by March 31, 2013. The total annual response burden reported for all 13 respondents was 22,269. The average annual response burden for each company was 1,713 hours. 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

The average cost for compiling each report, per respondent, is estimated at $1,139. The total estimated annualized cost to respondents is $14,807.

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.

The estimates in the current Extension request have not changed from the previous year of 13 respondents and 22,269 burden hours. The estimated number of respondents is based on the actual number of responses received by OSH for the most recent, complete reporting period (2013).

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.