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 without Change

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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- **Goal of the Reinstatement without Change:** This Information Collection Request (ICR) supports Reinstatement without Change 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. December 31, 2018).

- **Intended use of the resulting data:** The information collection is used to certify tobacco industry compliance with the terms of the Comprehensive Smokeless Tobacco Health Education Act 15 U.S.C. 4403.

- **Methods to be used to collect data:** To comply with the Act, manufacturers, packagers, and importers must submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and a specification of the quantity of nicotine contained in each product. Upon receipt and verification of the required information, CDC sends a Certificate of Compliance to each entity that submitted a report.

  There are no changes to the information collected and the estimated burden per response. However, there is a change in the number of respondents. The respondents dropped from 13 to 11, which decreases the overall estimated annualized burden to respondents. The reasons for the decrease could be any number of things (e.g., companies could have closed or merged).

- **Respondents:** Respondents are commercial Smokeless Tobacco Products manufacturers, packagers, or importers.

- **How data will be analyzed:** The Department of Health and Human Services (HHS) is authorized, but not required, to analyze submitted data and to submit a report to the Congress. Reports are

A. JUSTIFICATION

1. Circumstances making the Collection of Information Necessary

Smokeless tobacco products (SLT) are associated with many health problems. Using smokeless tobacco: can lead to nicotine addiction; causes cancer of the mouth, esophagus, and pancreas; is associated with diseases of the mouth; can increase risks for early delivery and stillbirth when used during pregnancy; can cause nicotine poisoning in children; and, may increase the risk for death from heart disease and stroke.

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. OSH promotes tobacco control interventions, including actions to prevent youth from starting to use tobacco, smoke-free environments, programs to help tobacco users quit, and steps to eliminate tobacco-related health disparities in different population groups.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. '4401 et seq. or P.L. 99-252), hereinafter referred to as CSTHEA, requires each person who manufactures, packages, or imports smokeless tobacco products to

annually 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 SLT Nicotine 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 statute is provided in **Attachment 1**. Section 4403 relates specifically to ingredient reporting.

The legislative requirements for reporting were published in the Federal Register in 1994 (**Attachment 3a**, Federal Register, Vol 59, Number 21, Tuesday, February 1, 1994). In November 1994, HHS published an additional Federal Register Notice that changed the due date for reporting to March 31 (**Attachment 3b**, Federal Register, Volume 59, Number 215, Tuesday, November 8, 1994).

Annually, OSH sends a certificate of compliance letter to each entity that has submitted the required information. The letter includes a reminder of responsibilities related to future reporting. If a submission contains incomplete entries or possible errors, CDC will follow up by sending a request for additional information **(Attachment 4c)**.

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. Respondents are required to report both the ingredients in, and the nicotine content of, their SLT products. CDC accepts SLT Nicotine and Ingredient Reports in any format that meets the legislation's reporting requirements. The recommended format for the SLT Ingredient Report are included as **Attachment 4a.** The recommended format for the SLT Nicotine Report are included as **Attachment 4b**. Typically, commercial entities submit information for multiple products in summary (aggregate) form, often through a designated entity such as legal counsel. The submission must be received on letterhead from the commercial entity or its designated representative. Reports may be submitted via mail or facsimile, but all faxed lists should be followed up with a mailed original. 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.

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.

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.

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

There is no website content directed at children less than 13 years of age.

2. Purpose and Use of the Information Collection

This information collection is used to certify tobacco industry compliance with the terms of the CSTHEA. To comply with the Act, manufacturers, packagers, and importers must submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and a specification of the quantity of nicotine contained in each smokeless tobacco product. Upon receipt and verification of the required information, CDC sends a Certificate of Compliance (**Attachment 7**) to each entity that submitted a report.

To import smokeless tobacco products into the United States for introduction into domestic commerce, one must certify to U.S. Customs and Border Protection that the original manufacturer has complied with the Act's requirements. The Certificate of Compliance from CDC can serve as proof of compliance.

HHS also has the authority under the Act to use the information submitted to conduct research on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products. When the Secretary considers it appropriate, 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 not have the means to comply with requirements of the CSTHEA.

Privacy Impact Assessment

Safeguards implemented by CDC are consistent with Section 4403 of CSTHEA, which required HHS to establish written procedures assuring the confidentiality of information provided. These Guidelines were included in the 1994 Federal Register Notice (**Attachment 3a**). A copy of the statutory provisions describing penalties for disclosure of confidential information is provided in **(Attachment 8)**.

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 CSTHEA 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 CSTHEA.

As stated in the previous terms of clearance for the Center for Disease Control (OMB Control No.: 0920-0338) and FDA's Center for Tobacco Products (OMB Control No. 0910-0650), the data to be collected overlap in terms of the similar tobacco product ingredient collections being conducted. However, at this time, the CTP data cannot currently be used by CDC due to both logistical reasons and restrictions on the use of information collected.

The CSTHEA contains certain requirements that differ from the statutory requirements for submission of information in the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (TCA). For instance, the CSTHEA requires ingredients to be provided annually whereas the FD&C Act only mandates annual submissions detailing lists of products, but not ingredients. Rather, the FD&C Act only requires submission of ingredients prior to a Tobacco product's delivery for introduction into commerce and thereafter if certain changes are made to such product. Further, the CSTHEA allows for the list submission of ingredients in a way that does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients. The FD&C Act, on the other hand, requires submission of all ingredients by quantity, brand, and sub-brand. The CSTHEA also contains specific requirements concerning

written procedures assuring confidentiality, physical possession of information, as well as storage requirements. The FD&C Act does not require that level of specificity.

The similarities and differences between the CSTHEA and the FD&C Act are highlighted in the table below. Overall, while there is some similarity between the two data collections, each system is uniquely different enough that these information collection requests do not constitute redundancy.

Key Distinctions Between CDC and FDA's Data Collection

	Comprehensive Smokeless Tobacco Health Education Act	**Tobacco Control Act**
HHS Program Administration	CDC	FDA
Smokeless Tobacco Data Collected: Ingredients	Yes; however, no quantities collected; brands and subbrands are not specified. Also, reporting not required for tobacco types/brands.	Yes; quantities are collected; brands and subbrands are specified. Reporting is required for tobacco types/brands.
Smokeless Tobacco Data Collected: Nicotine	Yes; quantities are collected; brands and subbrands are specified	Yes; quantities are collected; brands and subbrands are specified
Timeline of Collection	Annual, regardless of changes to product	Baseline collection when tobacco product is first introduced to market, with additional disclosure to FDA upon any changes to product
Confidentiality Provisions and Information Sharing	Information submitted is considered trade secret and confidential. Disclosures permitted only as authorized by legislation.	Information submitted is considered confidential and may contain trade secrets. Other disclosures as permitted to other officers or employees concerned with carrying out the tobacco control provisions of the FD&C Act or when relevant in a proceeding under the tobacco control provisions of the FD&C Act

CDC and FDA continue to discuss ways we can avoid duplication within our current constraints.

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

CSTHEA 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.

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 08/22/2018, a Notice was published in the Federal Register (Volume 83, No. 163, pp. 42503-42505) **(Attachment 2)**. CDC received a total of two public comments, both of which are included in this Information Collection Request. Of the two public comments received, one was submitted by Altria Client Services (**Attachment 9a**). Given the substantive and detailed nature of this comment submitted, CDC provided a direct response to Altria Client Services' Senior Vice President for Regulatory Affairs. The text of CDC's correspondence sent in response to this public comment is included in this Information Collection Request (**Attachment 9b)**. The second public comment was received from an anonymous source (**Attachment 10a**). The nature of this public comment was determined to be outside the scope of this information request and therefore a response from CDC was not warranted (**Attachment 10b**).

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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

A. Privacy Act Determination. This ICR has been reviewed by the NCCDPHP ADS and ISSO, 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 Guidelines for Maintaining and Releasing Privileged Information in Accordance With Sec. 4 (b) (2) (a) of Public Law 99-252, is included in the 1994 Federal Register Notice, **Attachment 3a**. In accordance with provisions in the CSTHEA, 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 8)**, and shall not be revealed except as authorized in the statute.

C. Nature of Response. Response is required.

11. Institutional Review Board (IRB) and 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 CSTHEA.

The reporting requirements for manufacturers are established by the CSTHEA. 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.

12. Estimates of Annualized Burden Hours and Costs

Information for each reporting year is submitted by mail no later than March 31 of the following year. Information for each SLT product must conform to the specifications established by the SLT Ingredient Report Guidelines (**Attachment 4a**) and the SLT Nicotine Report Guidelines (**Attachment 4b**). 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. If a submission contains incomplete entries or possible errors CDC may follow up with a request for additional information (**Attachment 4c**). Annually, OSH sends a certificate of compliance letter to each entity that has submitted information that meets the requirements of the CSTHEA. The letter includes a reminder related to future reporting (**Attachment 7**).

The burden estimate is based on experience with the information collection in the prior approval period. Ingredient and reporting for smokeless tobacco products are 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 total annual response burden reported for all 11 companies is estimated at 18,843 hours at a total cost of $12,529. The average annual response burden for each company is estimated at 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.

There are no changes to the information collected and the estimated burden per response. However, there is a change in the number of respondents. The respondents dropped from 13 to 11 which decreases the overall estimated annualized burden to respondents. The reasons for the decrease could be any number of things (e.g., companies could have closed or merged).

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	11	1	1,713	18,843

b) Estimated Annualized Costs to Respondents

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

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Cost per Response	Total Cost
Smokeless Tobacco Product Manufacturers, Packagers, and Importers	SLT Nicotine and Ingredient Report	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 $79,750. The table below describes itemized cost components.

Item	Estimated Annualized Cost
CDC Supervisor (3% FTE)	$3,250
Contractor for data collection, data management, communications and logistical support related to compilation and analysis of ingredient reports	$54,500
Computing equipment and maintenance	$22,000

Total	$79,750

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 22,269 hours was based on 13 respondents. The estimates in the current Reinstatement without Change request have changed due to a reduction in reports received in the most recent, complete reporting period (2018).

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 CSTHEA, 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.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

As discussed in Section A.3, respondents are required to report information but are not required to use a standardized form. The OMB approval number, expiration date and burden estimate are displayed on the recommended formats for reporting (**Attachments 4a and 4b**) which are available on the CDC website. This information is also displayed on the needs additional information letter (**Attachment 4b**).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.