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 B

Submitted by:

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

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Table of Contents

List of Attachments

Attachment 1:	Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. ' 4401 et seq.)
Attachment 2:	Federal Register Notice (2018)
Attachment 3a:	Initial Federal Register Notice (1994)
Attachment 3b:	Federal Register Notice (1994)
Attachment 4a:	Recommended Smokeless Tobacco Ingredient Reporting Format – Comprehensive Smokeless Tobacco Health Education Act
Attachment 4b:	Recommended Format for Smokeless Tobacco Nicotine Data Reporting - Comprehensive Smokeless Tobacco Health Education Act
Attachment 4c:	Request for Additional Information from Manufacturers, Packagers and Importers of Smokeless Tobacco Products
Attachment 5:	Federal Register Notice, Revisions to the Laboratory Protocol to Measure the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States (2009)
Attachment 6a:	CDC/OSH Tobacco Ingredient and Nicotine Reporting Instructions Web Page
Attachment 6b:	CDC/OSH Web Page on the Comprehensive Smokeless Tobacco Health Education Act
Attachment 7:	Certificate of Compliance to Manufacturers, Packagers and Importers of Smokeless Tobacco Products
Attachment 8:	Disclosure of Confidential Information (18 U.S.C. ‘1905)
Attachment 9a:	Public Comment #1, FRN published 8/22/2018
Attachment 9b:	CDC Response to Public Comment #1
Attachment 10a:	Public Comment #2, FRN published 8/22/2018
Attachment 10b:	CDC Response to Public Comment #2

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

This data collection does not require the use of statistical methods to select respondents. Responses are required from all smokeless tobacco product manufacturers, distributors, and importers in the U.S. (referred to collectively as "commercial entities" in this Information Collection Request), or designated representative.

2. Procedures for the Collection of Information

Each commercial entity is required to submit annually to HHS 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 such product. The information must conform to the specifications established by the Recommended Smokeless Tobacco Ingredient Reporting Format (**Attachment 4a**) and the Recommended Smokeless Tobacco Nicotine Data Reporting Format **(Attachment 4b**), however, manufacturers are not required to submit specific forms. Typically, manufacturers submit a summary report to CDC by mail with the ingredient information for multiple products, often through a designated entity such as legal counsel. The submission must be received on letterhead belonging to the commercial entity or its designated representative. Reports may be submitted by mail or via 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.

If a submission contains incomplete entries or possible errors, CDC may follow up by sending a request for additional information (**Attachment 4c**).
Upon submission and verification of its complete ingredient list, OSH sends a Certificate of Compliance to the manufacturer, distributor, or importer (**Attachment 7**).

3. Methods to Maximize Response Rates and Deal with No Response

Response is required. Failure to respond will result in legal non-compliance, and inability of manufacturers, packagers, and importers to obtain the Certificate of Compliance.

4. Tests of Procedures or Methods to be Undertaken

Not applicable. OSH plans to continue the data collection using previously fielded information collection methods.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Design of the Information Collection

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Information Collection

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