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 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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Submission of this ICR has been approved by the
HHS/Assistant Secretary for Planning and Evaluation

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Part B. Collections of Information Employing Statistical Methods

List of Attachments

Attachment 1:	Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. ' 4401 et seq.; Public Law 99-252), relevant portions
Attachment 2a:	Federal Register Notice (2013)
Attachment 3:	Initial Federal Register Notice (1985)
Attachment 4a-1:	SLT Nicotine Report Guidelines
Attachment 4a-2:	SLT Ingredient Report Guidelines
Attachment 4b:	Reminder Notification Postcard to Manufacturers, Packagers and Importers
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:	HHS/CDC/OSH Tobacco Ingredient Reporting Web Page
Attachment 6b:	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 8a:	Guidelines to Control and Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474
Attachment 8b:	Civil Penalties for Disclosure of Confidential Information (18 U.S.C. ‘ 1905)
Attachment 9:	Federal Register Notice (1994)
Attachment 10:	CDC/OSH and FDA Review of Data Collections and Strategies to Reduce Duplicative Collections
Attachment 11a:	Public Comment #1, FRN published 10/31/2013
Attachment 11b:	CDC Response to Public Comment #1

Attachment 12a: Public Comment #2, FRN published 10/31/2013

Attachment 12b: 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. OSH reviews and revises the mailing list of smokeless tobacco product manufactures, packagers, and importers by comparing it to lists available from the tobacco industry, the Federal Trade Commission, and the National Association of Attorneys General, and updates the files as new companies submit ingredient lists.

2. Procedures for the Collection of Information

Each commercial entity is required to submit information about the ingredients in each product in its smokeless tobacco product line. The information must conform to the specifications established by the Nicotine Report Guidelines (**Attachment 4a-1**) and the Ingredient Report Guidelines **(Attachment 4a-2**), 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 also be submitted 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.

The original submission deadline was December 31. 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**.

Currently, information for each calendar year is submitted no later than March 31 of the following year. CDC/OSH distributes a postcard reminder (**Attachment 4b**) to each manufacturer or designated representative in advance of the annual deadline. OSH may follow up by sending a request for additional information (**Attachment 4c**) if a submission contains incomplete entries or possible errors.

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 required for state-based commercial activity.

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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