List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products

OMB Control No. 0920-0210

Request for Reinstatement with 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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Submission of this ICR has been approved by the
HHS/Assistant Secretary for Planning and Evaluation (ASPE)

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List of Attachments

Attachment 1a:	Comprehensive Smoking Education Act of 1984 (15 U.S.C. ‘ 1335a; Public Law 98-474)
Attachment 1b:	Federal Cigarette Labeling and Advertising Act (15 U.S.C. ‘ 1331-1341)
Attachment 2:	Federal Register Notice (2018)
Attachment 3:	Initial Federal Register Notice (1985)
Attachment 4a:	Recommended Cigarette Ingredient Report Format
Attachment 4b:	Request for Additional Information from Manufacturers, Packagers and Importers of Tobacco Products
Attachment 5a:	HHS/CDC/OSH Web Page on the Comprehensive Smokeless Tobacco Education Act
Attachment 5b:	HHS/CDC/OSH Web Page on Tobacco Ingredient Reporting
Attachment 6:	Certificate of Compliance for Manufacturers, Packagers and Importers of Tobacco Products
Attachment 7:	Statutory Provisions on Confidentiality (18 U.S.C. ‘ 1905, 5 U.S.C. ‘ 552)
Attachment 8:	Federal Register Notice, November 8, 1994, Vol. 59, pp. 55669-55670
Attachment 9a:	Public Comment #1, FRN published 8/21/2018
Attachment 9b:	CDC Response to Public Comment #1
Attachment 10a:	Public Comment #2, FRN published 8/21/2018
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 cigarette manufacturers, distributors, and importers in the U.S. (referred to collectively as "manufacturers" in this Information Collection Request).

2. Procedures for the Collection of Information

Each manufacturer, distributor, or importer is required to submit information about the ingredients in each product in its cigarette product line. The information must conform to the specifications established by the Recommended Cigarette Ingredient Report Format (**Attachment 4a**), however, manufacturers are not required to submit specific forms. Typically, manufacturers submit a summary report to CDC by mail or fax 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 manufacturer or 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 8**.

Currently, information for each calendar year is submitted no later than March 31 of the following year. OSH may follow up by sending a request for additional information (**Attachment 4b**) 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 6**).

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 filed 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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