

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

OMB Control No. 0920-0210

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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June 13, 2012

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List of Attachments

- Attachment 1a: Comprehensive Smoking Education Act of 1984 (15 U.S.C. ‘ 1335a; Public Law 98-474), relevant portions
- Attachment 1b: Federal Cigarette Labeling and Advertising Act (15 U.S.C. ‘ 1331-1341)
- Attachment 2: Federal Register Notice
- Attachment 3: Initial Federal Register Notice (1985)
- Attachment 4a: Ingredient Report Specifications
- Attachment 4b: Reminder Notification Postcard to Manufacturers, Packagers and Importers of Tobacco Products
- Attachment 4c: 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 7a: Guidelines to Control and Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474
- Attachment 7b: 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 9: CDC/OSH and FDA Review of Data Collections and Strategies to Reduce Duplicative Collections
- Attachment 10: Public Comments Received in Response to Publication of the Federal Register Notice
- Attachment 11: CDC Response to Public Comments

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). OSH reviews and revises the mailing list of cigarette 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 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 Ingredient Report (**Attachment 4a**), 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 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. 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 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 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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