

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

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Supporting Statement B

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ATTACHMENTS

- 1a. Comprehensive Smoking Education Act of 1984 (15 U.S.C. 1335a)
- 1b. Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331-1341)
2. Federal Register Notice (2021)
3. Initial Federal Register Notice (1985)
- 4a. Recommended Cigarette Ingredient Report Format
- 4b. Request for Additional Information from Manufacturers, Packagers, and Importers of Tobacco Products
- 4c. Human subjects document
- 5a. OSH Web Page on the Federal Cigarette Labeling Advertising Act
- 5b. OSH Web Page on Tobacco Ingredient Reporting
6. Certificate of Compliance for Manufacturers, Packagers, and Importers of Tobacco Products
- 7a. Guidelines to Control and Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474
- 7b. Civil Penalties for Disclosure of Confidential Information (18 U.S.C. 1905)
8. Federal Register Notice (1994)
9. Federal Register Notice (2020)

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. 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).

B2. Procedures for the Collection of Information

Each manufacturer is required to annually submit to HHS information about the ingredients in each product in its cigarette product line. The information should 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. Electronic mail submissions are not accepted.

The original submission deadline was December 31 of each year. 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**.

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 (**Attachment 6**).

Of note, on April 27, 2020, a Federal Register Notice was published Vol. 85, No. 84, pp. 23359-23360, (**Attachment 9**), to indicate the CDC/OSH was extending the March 31st deadline for submissions required under the Federal Cigarette Labeling and Advertising Act (FCLAA). Within the April List of Tobacco Ingredients Added in the Manufacture of Cigarette Products

2020 Federal Register Notice, CDC/OSH stated that due to unforeseen circumstances in light of COVID-19, OSH was rendered unable to accept any ingredient submissions or to issue Certificates of Compliance. This same language was inserted on OSH's website under the webpage entitled [Tobacco Ingredient and Nicotine Reporting | CDC.](#)

B3. 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.

B4. Tests of Procedures or Methods to be Undertaken

OSH plans to continue the data collection using previously filed information collection methods.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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