

Annual Submission of the Ingredients Added to and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.

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Supporting Statement B

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ATTACHMENTS

1. Comprehensive Smokeless Tobacco Health Education Act of 1986 15 U.S.C. ' [4401 seq.; Public Law 99-252]
2. Federal Register Notice (2021)
3. Smokeless Tobacco Submission Requirement (1994)
- 4a. Recommended Smokeless Tobacco Ingredient Reporting Format
- 4b. Recommended Smokeless Tobacco Nicotine Data Reporting Format
- 4c. Request for Additional Information from Manufacturers, Packagers, and Importers of Smokeless Tobacco Products
- 4d. Human subjects document non-research determination
5. Federal Register Notice Revisions to the Laboratory Protocol to Measure (2009)
- 6a. OSH Comprehensive Smokeless Tobacco Health Education Act Web Page
- 6b. OSH Tobacco Ingredient and Nicotine Reporting Instructions Web Page
7. Certificate of Compliance to Manufacturers, Packagers, and Importers of Smokeless Tobacco Products
- 8a. Guidelines to Control Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474
- 8b. Civil Penalties for Disclosure of Confidential Information (18 U.S.C. 1905)
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 smokeless tobacco product 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 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 should 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. All submissions must be received on letterhead belonging to the manufacturer 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. 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.

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 Comprehensive Smokeless Tobacco Health Education Act (CSTHEA). Within the April 2020 Federal Register Notice, CDC/OSH stated that due to the unforeseen circumstances related to COVID-19, OSH was rendered unable to **Annual Submission of the Ingredients Added to and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.**

accept any ingredient submissions or to issue Certificates of Compliance. This same language was provided on OSH’s website under the webpage entitled [Tobacco Ingredient and Nicotine Reporting | CDC.](#)

If a submission contains incomplete entries or possible errors, CDC may follow up by sending a request for additional information (**Attachment 4c**). Upon receipt of the required information, OSH sends a Certificate of Compliance to the manufacturer (**Attachment 7**).

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.

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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