



4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0338]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 22, 2018 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

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 No. 0920-0338 exp. 12/31/2018) - Reinstatement without Change - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Smokeless tobacco products (SLT) are associated with many health problems. Using smokeless tobacco: can lead to nicotine addiction; causes cancer of the mouth, esophagus, and pancreas; is associated with diseases of the mouth; can increase risks for early delivery and stillbirth when used during pregnancy; can cause nicotine poisoning in children; and may increase the risk for death from heart disease and stroke.

The CDC's Office on Smoking and Health (OSH) has the primary responsibility for the HHS smoking and health program. As required by the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 et seq., P. L. 99-252), CDC collects 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 product. HHS has delegated responsibility for implementing the required information collection to CDC's OSH. Respondents are manufacturers, packagers, or importers (or their

representatives) of smokeless tobacco products. Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies that are required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report. Respondents may submit the required information to CDC through a designated representative. The information collection is subject to strict confidentiality provisions.

Ingredient reports for new SLT products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to CDC by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Annual submission reports are mailed to Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS S107-7, Atlanta, GA 30341-3717.

Upon receipt and verification of the annual nicotine and ingredient report, CDC issues a Certificate of Compliance to the respondent. As deemed appropriate by the Secretary of HHS, HHS is authorized to use the information to report to Congress the health effects of ingredients, research activities related to the health effects of ingredients, and other information that the Secretary determines to be of public interest.

There are no costs to respondents other than their time. OMB approval is requested for three years.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers	SLT Nicotine and Ingredient and Report	11	1	1,713

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[FR Doc. 2019-02496 Filed: 2/14/2019 8:45 am; Publication Date: 2/15/2019]