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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0338]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

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. 2/28/2014) – Extension – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from the use of smokeless tobacco products and other forms of tobacco use through programs of information, education and research.

Since 1994, as required by the Comprehensive Smokeless Tobacco Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 et seq., Pub. L. 99-252), CDC has collected information about the ingredients used in smokeless tobacco products and their nicotine content. Respondents are commercial smokeless tobacco product manufacturers, packagers, or importers (or their designated representatives), who are required by the CSTHEA to submit ingredient reports to HHS on an annual basis. The legislation also authorizes HHS to undertake research, and to report to Congress, as deemed appropriate, about the health effects of these ingredients.

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 currently 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.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. The information collection is subject to strict confidentiality provisions and electronic mail submissions are not accepted. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

OMB approval is requested for three years. There are no changes to information collection procedures, the estimated burden per response, or the estimated number of respondents. The total estimated annualized burden hours are 22,269. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers	SLT Nicotine and Ingredient and Report	13	1	1,713

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