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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-14-0338]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to CDC, LeRoy Richardson, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 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. 02/28/2014)—Extension—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The oral use of smokeless tobacco (SLT) products represents a significant health risk. Smokeless tobacco products contain carcinogens which can cause cancer and a number of non-cancerous oral conditions, as well as leading to nicotine addiction and dependence. Furthermore, SLT use is not a safe substitute for cigarette smoking. Adolescents who use smokeless tobacco are more likely to become cigarette smokers.

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH), has 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 through programs of information, education and research.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 et seq., Pub. L. 99-252) requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. CSTHEA further requires submission of the quantity of nicotine contained in each smokeless tobacco product. Finally, the legislation authorizes HHS to undertake research, and to report to Congress (as deemed

appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the required information collection to CDC's Office on Smoking and Health. 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 OSH by mailing a written report on the respondent's letterhead, which may be accompanied by a Compact Disc (CD), three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Annual submission reports are mailed to: Office on Smoking and Health, Attention: FCLAA Program Manager, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS F-79, Atlanta, GA 30341-3717. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no costs to respondents other than their time. Office of Management and Budget (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)	Total burden (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers.	SLT Nicotine and Ingredient Report	13	1	1,713	22,269

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**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Centers for Disease Control and  
 Prevention**

[60Day-14-0210]

**Proposed Data Collections Submitted  
 for Public Comment and  
 Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to CDC, LeRoy Richardson, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques

or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB No. 0920-0210, exp. 2/28/2014)—Extension—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Cigarette smoking is the leading preventable cause of premature death and disability in the United States. Each year, more than 443,000 premature deaths occur as the result of diseases related to cigarette smoking. 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 cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smoking Education Act of 1984 (CSEA, 15 U.S.C. 1336 or Pub. L. 98-474) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of cigarettes. The legislation also authorizes HHS to undertake research, and to report to the Congress (as deemed appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the CSEA's ingredient reporting requirements to CDC's OSH. OSH has collected ingredient reports on

cigarette products since 1986. Respondents are commercial cigarette manufacturers, packagers, or importers, or their designated representatives. Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted 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. The estimated burden per response is 6.5 hours. The total estimated annualized burden hours are 501.

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, which may be accompanied by a compact disk (CD), three-inch floppy disk, or thumb drive. Annual ingredient reports should be mailed to: Office on Smoking and Health, Attention: FCLAA Program Manager, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., MS F-79 Atlanta, GA 30341-3717. Electronic mail submissions are not accepted. Upon receipt and verification of the annual ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no costs to respondents other than their time. Office of Management and Budget (OMB) approval is requested for three years.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Cigarette Manufacturers, Packagers, and Importers .....	77	1	6.5	501