

ATTACHMENT 9

**FEDERAL REGISTER NOTICE
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(Federal Register: February 1, 1994]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice Regarding Requirement for Submission of List of Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco Products**

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice implements the requirement of the Comprehensive **Smokeless Tobacco** Health Education Act of 1986 (Public Law 99-252) that each person who manufactures, packages, or imports **smokeless tobacco** shall provide the Secretary of Health and Human Services (HHS) annually with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. (This statute also requires reporting to HHS the nicotine content of **smokeless tobacco** products. The nicotine reporting requirement will be implemented at a later date.)

DATES: The first ingredient list is due on April 4, 1994, and shall identify all ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products marketed on December 31, 1993. Beginning in 1994 and each subsequent calendar year, the ingredient list will be due on December 31, and shall identify any changes in the ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products at any time during the previous twelve months.

ADDRESSES: The list shall be submitted to: Michael P. Eriksen, Sc.D., Director, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Atlanta, GA 30341-3724.

FOR FURTHER INFORMATION CONTACT: Michael P. Eriksen, Sc.D., Director, Office on Smoking and Health, (404) 488-5701.

SUPPLEMENTARY INFORMATION: Section 4(a) of Public Law 99-252 (15 U.S.C. 4403(a)) requires manufacturers, packagers, and importers of **smokeless tobacco** products to provide the Secretary of HHS annually with a list of all ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products. This statute also stipulates that the list need not identify the company which uses the ingredients or the brand of **smokeless tobacco** which contains the ingredients.

The implementation procedures HHS has established for submitting the ingredient information require respondents to report each ingredient by chemical name and Chemical Abstract Service (CAS) Registry Number. This format for reporting ingredients is consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products, including cigarettes.

The statute permits a person or group of persons required to submit an ingredient list to HHS to designate an individual or entity to provide information on their behalf. In such case, HHS

procedures require the designated individual or entity to identify for HHS the person or group of persons on whose behalf the ingredient list is being submitted.

HHS has established strict procedures for assuring the confidentiality of the information submitted in accordance with section 4 (b) (2) (C) of Public Law 99-252 (15 U.S.C. 4403 (b) (2) (c)). The information will be treated as trade secret or confidential information subject to 5 U.S.C. 552 (b) (4). Access to the information will be limited to those authorized by the Secretary in carrying out their official duties and to duly-authorized committees or subcommittees of the Congress that submit a written request for the information.

Information Collection Provisions:

This Notice contains information collections which have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980 and assigned the control number 0920-0338. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and record keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco** Products.

Description: The Comprehensive **Smokeless Tobacco** Health Education Act of 1986 requires HHS to collect this information. HHS is authorized to conduct research on the potential health effects of the ingredients, and to report to the Congress as appropriate.

Description of Respondents: Businesses or Other For-Profit Organizations.

Estimated Annual Reporting and Recordkeeping Burden: The Office on Smoking and Health (OSH) contacted five **smokeless tobacco** manufacturers, through the law firm of Patton, Boggs and Blow, which will submit ingredient information in order to estimate the annualized cost for reporting ingredient information to the Department of Health and Human Services. The estimated average cost to industry for this three year period is \$4,314. This is based on an annualized estimated cost of \$1,438 per company with an annual estimated cost range of \$250 to \$3500 per company per year. The estimated cost to the government for this collection and storage over a three year period is \$18,000.00. This cost is based on an annualized estimated cost of \$6,000.00 for collection and storage.

There are 11 manufacturers, packagers, and importers of **smokeless tobacco** products in the U.S. In November 1992, OSH contacted five companies, through the law firm of Patton, Boggs and Blow, which will submit ingredient information to the Department of Health and Human Services, regarding the estimated response burden to the industry. Patton, Boggs and Blow reported that the annual response burden for each company it represents ranges from 4 to 30 manhours, with an average burden of 15 hours per company.

Dated: January 25, 1994.

Walter R. Dowdle,

Deputy Director, Centers for Disease Control and Prevention (CDC).