(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).

Guidelines for Maintaining and Releasing Privileged Information Obtained in Accordance With Sec. 4 (b) (2) (a) of Public Law 99-252 (15 U.S.C. 4403)

1. Purpose

These Guidelines establish minimum requirements to maintain, protect and release documents that contain privileged information regarding ingredients in **smokeless tobacco** products. The Guidelines establish individual responsibility for the accountability and protection of privileged information on ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products and the quantity of nicotine in each such product. The Comprehensive **Smokeless Tobacco** Education Act of 1986 (Pub. L. 99-252 (15 U.S.C. 4403)) requires manufacturers, packagers, and importers of **smokeless tobacco** products to submit such information annually to the Secretary of Health and Human Services.

2. Policy

Employees of the Department of Health and Human Services shall take such action as may be necessary to assure implementation of statutory requirements to safeguard privileged information. In accordance with Public Law 99-252 (15 U.S.C. 4403 (b) (2)), HHS shall treat the lists of ingredients added to **tobacco** in the manufacture of **smokeless tobacco** products as trade secret or confidential information. HHS shall not reveal the information except as authorized by the statute. Privileged information shall be released to Congress only as provided in section 4 (b) of Public Law 99-252 (15 U.S.C. 4403 (b)) and to employees of the Department authorized to review the information in carrying out their official duties under Public Law 99-252 (15 U.S.C. 4403 (b) (2)). All other requests for the privileged information shall be denied.

If HHS receives a request for the privileged information under the Freedom of Information Act, the Freedom of Information Officer shall deny the request in accordance with the provisions of 5 U.S.C. 552 (b) (3) and 552 (b) (4), section 4 (b) (2) (A) of Public Law 99-252 (15 U.S.C. 4403 (b) (2)), which require the protection of confidential or trade secret information.

3. Statutory Requirements

Statutory requirements for safeguarding the subject privileged information are as follows:

a. Sections 4 (b) (2) of Public Law 99-252 (15 U.S.C. 4403 (b) (2)) (Comprehensive **Smokeless Tobacco** Health Education Act of 1986) 5 U.S.C. 552 (b) (4) (Freedom of Information Act).

4. Definitions

a. Document Control Officer. This Officer is the Departmental official designated in writing as having responsibility for the Department's control of privileged information pertaining to the **smokeless tobacco** product ingredients. The Document Control Officer shall be the Director, office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC).

b. Privileged Information. As used in this Guideline, privileged information refers to (i) any information provided to HHS in accordance with section 4 (a) (1) of Public Law 99-252 (15 U.S.C. 4403 (a) (1)), and
(ii) any other materials derived from the information provided.

c. Secure Files Area. A room or rooms that are locked during non duty hours.

d. Secure Files Containers. Any equipment that is locked when unattended and that cannot be hand carried (e.g., Power Files and Lektrievers, filing cabinets and shelf units, credenzas, desk, pedestals, etc.,).

5. Responsibilities

The Document Control officer shall:

(1) Provide written guidance to HHS organizational components regarding the action necessary to assure compliance with the provisions of these Guidelines.

(2) Maintain and verify the operation of an effective document control system.

(3) Assure adherence to the requirements these Guidelines establish.

(4) Investigate reports of overdue documents.

6. Persons Authorized to Have Access to Privileged Information

The following may be granted access to privileged information under the conditions specified:

a. Department Employees. Upon written authorization from the Document Control Officer, regular or special employees of the Department are permitted access to privileged information needed to perform their official duties. Any employee permitted such access shall, prior to receiving privileged information, read and execute a Commitment to Protect Confidential Information form.

b. In accordance with section 4(b) (2) (B) of Public Law 99-252 (15 U.S.C. 4403 (b) (2) (B)), the Department shall provide privileged information submitted under that Act to a duly-authorized committee or subcommittee of Congress upon its written request. When documents are so released, the Department, at the same time, shall provide written notice of the release to the person who provided the privileged information.

Users of files containing privileged information are responsible for complying with these HHS Guidelines and other accountability procedures that the Document Control Officer establishes to protect the files.

7. Document Accountability

The Document Control Officer shall authorize, in writing, the release of the privileged information. Persons accessing the privileged information shall execute a Commitment to Protect Confidential Information form and provide personal identification to verify their identity.

a. Charge-Outs. When privileged information documents are charged out, the recipient shall sign a Commitment to Protect Confidential Information form. This form, which includes identifying information and anticipated date of return, also shall serve as a document receipt form. The person who certifies to accept and protect the privileged information is responsible for the file documents received. Receipts shall be kept current so that documents can be located readily.

b. Control, Follow-up, and Verification of Locations. The Document Control Officer shall require the return of each document by the return date stipulated on the receipt. If use of the document is necessary for an additional period, the Document Control Officer may authorize an extension and shall document the files accordingly. When the privileged information documents are returned, the actual date of return shall be recorded on the receipt form.

c. Report of Lost Documents. Individuals who have received privileged information documents shall notify the Document Control officer in writing when privileged information files cannot be located. The notification shall include:

(1) The name and organizational location of the individual authorized to possess the documents at the time of loss;

(2) The identification and description of each missing file;

(3) A summary of the efforts made to locate the missing file.

8. Document Protection

Document protection shall include the following:

a. During Non-Working Hours. All privileged information must be locked in an approved secure files area or in an approved secure files container during non-working hours.

b. During Working Hours. When not in actual use by an authorized employee, privileged information shall be protected by using the protective measures required for non-working hours.

9. Transfer of Privileged Information

Method of Transmission. The preferred method is person-to-person transmission. When this is not practical, the privileged information is to be sent through the U.S. Registered Mail system, unless a written exception has been obtained on an individual basis from the Document Control Officer.

10. Document Reproduction

Privileged information documents will be reproduced only as required for the performance of official business, and only by those persons so authorized by the Document Control Officer.

11. Document Disposition

The documents provided to the Department in accordance with Section 4 (a) (1) of the Comprehensive **Smokeless Tobacco** Health Education Act of 1986 (15 U.S.C. 4403 (a)(1)) shall be maintained in accordance with the Records Control Schedule of the Centers for Disease Control and Prevention (CDC).

12. Violation

Misuse or loss of privileged information constitutes a violation of statutory provisions and HHS rules for controlling and protecting such information. Employees failing to comply with the provisions of these Guidelines or other established document control procedures are subject to action commensurate with the seriousness of the violation.

Attachment A--Commitment to Protect Confidential Information on the Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco** Products

Whereas access to confidential information in the files of the Public Health Service is required in the performance of official duties, I_____ on this_____ day of _____19___, hereby agree that I shall not further release, publish, copy, or disclose such information, and that I shall protect such information in accordance with the provisions of 5 U.S.C. 552 (b) (4), and the Public Health Service guide for the Control of Confidential Information on the Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco** Products.

I understand the provision of 5 U.S.C. 552 (b) (4), and the PHS guide, and that I am subject to penalties prescribed by law for any violations thereof.
Signed: .....
Date: .....
Witnessed by:.....
Date: .....

Attachment B--Receipt for Confidential Information in the Manufacture of **Smokeless Tobacco** Products

To: Director, Office on Smoking and Health, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia 30341-3724. From: .....

Receipt of the following privileged information is hereby acknowledged: File<SUP>#--Description of Information--Anticipated Date of Return.
Date: .....
Signature:.....

Attachment C--Authority to Remove Confidential Information on the Ingredients Added to **Tobacco** in the Manufacture of **Smokeless Tobacco** Products

_____(name) of _____ (government agency or office) is hereby granted the authority to have the following privileged information in his/her personal possession from _____(hours), _____ (date) to _____ (hours), _____ (date).

Describe Privileged Information:
Document Number: Title.
This information will be used for:

Authorized by: .....
Director, Office on Smoking and Health

Date: .....

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