

DEPARTMENT OF HEALTH AND HUMAN SERVICES
AGENCY: Department of Health and Human Services (HHS).

50 FR 9617

December 3, 1985

Notice Regarding Requirement for Submission of List of Ingredients Added to Tobacco in Cigarettes
ACTION: Notice.

SUMMARY: This notice implements the requirement of the Federal Cigarette Labeling and Advertising Act that each person who manufactures, packages, or imports cigarettes shall annually provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of cigarettes.

DATES: The lists are required to be provided to HHS April 2, 1986, and annually thereafter by December 31, beginning with December 31, 1986.

ADDRESS: The list shall be submitted to: Director, Office on Smoking and Health, Park Building, Room 1-10, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Donald R. Shopland, Acting Director, Office on Smoking and Health, (301) 443-1575.

SUPPLEMENTARY INFORMATION: Section 5(a) of Pub. L. 98-474 added a new section 7 to the Federal Cigarette Labeling and Advertising Act. That Section requires manufacturers, importers, and packagers of cigarettes to provide the Secretary of HHS annually with a list of all ingredients added to tobacco in the manufacture of cigarettes. The list shall not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients.

The list shall be provided reporting each ingredient by chemical name and chemical abstract service (CAS) registry number. A person or group of persons required to provide a list may designate an individual or entity to provide the list on their behalf. In such case, the designated individual or entity shall identify the person, or group of persons on whose behalf the list is submitted.

In accordance with section 7, procedures for assuring confidentiality of the information are available. A copy of these procedures may be obtained by written request to the address stated above. The information submitted will be treated as trade secret or confidential information subject to 5 U.S.C. 552(b)(4) and 18 U.S.C. 1905. Access to the information will be limited to those authorized by the Secretary in carrying out their official duties and, upon their request, to duly authorize committees or subcommittees of the Congress.

Dated November 4, 1985.

TEXT: James O. Mason,

Acting Assistant Secretary for Health.

Dated November 25, 1985.

Margaret M. Heckler,

Secretary of Health and Human Service.

Guidelines To Control and Protect Documents That Contain Privileged Information Obtained in Accordance With Sec. 5(a) of Pub. L. 98-474

1. Purpose

This guide establishes minimum requirements to control and protect those documents that contain privileged information. Its objective is to establish individual responsibility for the accountability and protection of privileged information provided to the Secretary, Department of Health and Human Services, specifically that information on the ingredients added to tobacco in the manufacture of cigarettes as called for under Pub. L. 98-474. This document is directed at setting forth specific conditions governing access to privileged information, including trade secret data.

2. Policy

The Department of Health and Human Services recognizes that trust placed in it under the requirements of the Federal Statutes with respect to safeguarding privileged information. Employees of the Department of Health and Human Services shall take such action as may be necessary to preclude a breach of this trust. Privileged information shall be released only to employees of the Department as described herein, unless otherwise authorized by law or by the source of the information. Any Freedom of Information Act request for information obtained by the Department under section 5(a) of Pub. L. 98-474 shall be referred to the Freedom of Information Officer of the Public Health Service. In accordance with the provisions of 5 U.S.C. 552(b)(3) and 552(b)(4), 18 U.S.C. 1905, section 7(b)(2)(A) of Pub. L. 98-474, and 42 CFR 5.71, the Freedom of Information Officer shall deny any such requests. Any request for such information that is not submitted under the Freedom of Information Act shall be referred to the Director of the Office on Smoking and Health. With the exception of duly authorized request by a committee or subcommittee of Congress made in accordance with section 7(b)(2)(B) of Pub. L. 98-474, any such request shall be denied.

3. Statutory Requirements

Statutory requirements for safeguarding privileged information entrusted to the Department of Health and Human Services are contained in the following:

- a. Section 7(b)(2)(A) of the Federal Cigarette Labeling and Advertising Act.
- b. Section 1905, Title 18 U.S.C. Crimes and Criminal Procedure (18 U.S.C. 1905).
- c. Section 552(b)(4), Title 5, U.S.C.

4. Definitions

- a. Document Control Officer. That individual who has been designated in writing as having the responsibility for the organization's secret document control. The Document Control Officer shall be the Director, Office on Smoking and Health.
- b. Privileged Information. As used in this Guide, privileged information refers to(i) any information provided to the Department of Health and Human Services in accordance with section 7 of the Federal Cigarette Labeling and Advertising Act, as added by section 5(a) of Pub. L. 98-474, the Comprehensive Smoking Education Act, and (ii) any other materials derived from the information provided.
- c. Secure Files Area. A room of 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 Director, Office of Smoking and Health shall:

- (1) Advise, in writing, appropriate constituent units of the Department of Health and Human Services of the action they must take in order that the provisions of this Guide will be met.
- (2) Maintain and verify the operation of an effective document control system.
- (3) Assure adherence to the requirements established by this guide.
- (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 authorization from the Director of the Office on Smoking and Health in the form of Attachment C, regular or special employees of the Department are permitted access to information needed in the performance of their official duties. Any employee permitted such access shall, prior to receiving privileged information, read and execute a Commitment to Protect Confidential Information, in the form of Attachment A.
- b. In accordance with the provisions set forth in section 7 of the Federal Cigarette Labeling and Advertising Act, as added by Pub. L. 98-474, the Department will make available the list submitted under that Act to a committee or subcommittee of Congress upon a duly authorized request by such committee or subcommittee and shall, at the same time, notify the person who provided the list of such request. Such notice shall be in writing, and the Department will take reasonable measures to ensure that the notice is transmitted to such person as promptly as possible.

Users of files containing privileged information are responsible for complying with established procedures of accountability as prescribed by the Document Control Officer and for protecting borrowed files in accordance with this Guide.

7. Document Accountability

Persons accessing privileged information shall present to the Document Control Office appropriate authorization as indicated by attachment "C" of this Guide, an executed Commitment to Protect Confidential Information in the form of Attachment A, and an acceptable means of personal identification.

- a. Charge-Outs. When privileged information documents are charged out, the signature of the recipient will be obtained on a receipt bearing the document number and other identifying information. The receipt shall be in the form of Attachment B. **RESPONSIBILITY FOR THE FILE REMAINS WITH THE PERSON WHOSE NAME APPEARS ON THE RECEIPT.** Receipts shall be kept current so that the document can be readily located.
- b. Control Followup and Verification of Locations. The Document Control Officer shall require the return of each document at the conclusion of the period stipulated on the receipt. If use of the document is necessary for an additional period, the Director will prepare a new authorization in the form of Attachment C and the employee will sign a new receipt in the form of Attachment B.

c. Report of Lost Documents. The Director, Office on Smoking and Health shall immediately be notified in writing when privileged information files cannot be located after a search has been made. The notification shall include:

(1) The identification and description of each missing file,

(2) The name and organizational location of the individual to whom the files were last charged,

and (3) A summary of the efforts that have been made to locate the missing file.

8. Document Protection

Document protection shall include the following:

a. 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.

b. 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.

9. Transfer of Privileged Information

Method of Transmission. The preferred method is person to person transmission. When this is not practicable, 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 Director, Office on Smoking and Health.

10. Document Reproduction

Privileged information documents will be reproduced only as required in the performance of official business, and only by the Director, Office on Smoking and Health.

11. Document Disposition

The documents provided to the Department in accordance with Section 7, of the Federal Cigarette Labeling and Advertising Act, as added by section 5(a) of Pub. L. 98-474, the Comprehensive Smoking Education Act shall be maintained in accordance with the Office of the Assistant Secretary for Health, Public Health Service Records Control Schedule, section 3, Special Staff Programs.

12. Violation

The loss or misuse of privileged information may seriously hamper the Department of Health and Human Services in the conduct of its mission. Employees failing to comply with the provisions of this Guide or of established control systems are subject to action commensurate with the seriousness of the violation,-including disciplinary action and criminal penalties under *18 U.S.C. 1905*.

Attachment A -- Commitment To Protect Confidential Information on the Ingredients Added to Tobacco in the Manufacture of Cigarettes

Whereas access to confidential information in the files of the Public Health Service is required in the performance of official duties, I XXXXXX, on this XX day of XXXX 19 X, 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 18 *U.S.C. 1905*, 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 Cigarettes.

I understand the provisions of 18 *U.S.C. 1905*, 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, on the Ingredients Added to Tobacco in the Manufacture of Cigarettes

To: Director, Office on Smoking and Health, Office of the Assistant Secretary for Health, Rockville, Maryland 20857

From:

Receipt of the following privileged information is hereby acknowledged:

File #

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 Cigarettes

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

Described Privileged Information:

Document Number:

Title:

This information will be used for:

Authorized by:

Director, Office on Smoking and Health

Date:
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