Subsec. (b). Pub. L. 108–237, § 107(2), inserted ", or a notice with respect to such standards development activity that identifies the standards development organization engaged in such activity and that describes such activity in general terms" before period at end of first sentence and "or available to such organization, as the case may be" before period at end of last sentence.

Subsec. (d)(2). Pub. L. 108–237, § 107(3), inserted ", or the standards development activity," after "venture".

Subsec. (e). Pub. L. 108–237, § 107(4), substituted "person or standards development organization that" for "person who" and inserted "or any standards development organization" after "on any person".

Subsec. (g)(1). Pub. L. 108–237, § 107(5), inserted "or standards development organization" after "person".

1993—Pub. L. 103–42, § 3(f)(1), substituted "joint venture" for "joint research and development venture" in section catchline.

Subsec. (a). Pub. L. 103–42, § 3(f)(2), (3), substituted "joint venture" for "joint research and development venture" and "October 11, 1984" for "the date of the enactment of this Act" and added par. (3).

Subsecs. (d)(2), (e). Pub. L. 103–42, § 3(f)(3), substituted "joint venture" for "joint research and development venture".

REPORTS ON JOINT VENTURES AND UNITED STATES COMPETITIVENESS

Section 4 of Pub. L. 103–42 provided that:

"(a) PURPOSE.—The purpose of the reports required by this section is to inform Congress and the American people of the effect of the National Cooperative Research and Production Act of 1993 [15 U.S.C. 4301 et seq.] on the competitiveness of the United States in key technological areas of research, development, and production.

"(b) ANNUAL REPORT BY THE ATTORNEY GENERAL.—In the 30-day period beginning at each 1-year interval in the 6-year period beginning on the date of the enactment of this Act [June 10, 1993], the Attorney General shall submit to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate—

"(1) a list of joint ventures for which notice was filed under section 6(a) of the National Cooperative Research and Production Act of 1993 [15 U.S.C. 4305(a)] during the 12-month period for which such report is made, including—

"(A) the purpose of each joint venture;

"(B) the identity of each party described in section 6(a)(1) of such Act; and

"(C) the identity and nationality of each person described in section 6(a)(3) of such Act; and

"(2) a list of cases and proceedings, if any, brought during such period under the antitrust laws by the Department of Justice, and by the Federal Trade Commission, with respect to joint ventures for which notice was filed under such section at any time.

"(c) TRIENNIAL REPORT BY THE ATTORNEY GENERAL.—In the 30-day period beginning at each 3-year interval in the 6-year period beginning on the date of the enactment of this Act [June 10, 1993], the Attorney General, after consultation with such other agencies as the Attorney General considers to be appropriate, shall submit to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate a description of the technological areas most commonly pursued by joint ventures for production for which notice was filed under section 6(a) of the National Cooperative Research and Production Act of 1993 [15 U.S.C. 4305(a)] during the 3-year period for which such report is made, and an analysis of the trends in the competitiveness of United States industry in such areas.

"(d) REVIEW OF ANTITRUST TREATMENT UNDER FOREIGN LAWS.—In the three 30-day periods beginning 1 year, 3 years, and 6 years after the date of the enactment of this Act [June 10, 1993], the Attorney General, after consultation with such other agencies as the Attorney General considers to be appropriate, shall submit to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate a report on the antitrust treatment of United States businesses with respect to participation in joint ventures for production, under the law of each foreign nation any of whose domestic businesses disclosed its nationality under section 6(a)(3) of the National Cooperative Research and Production Act of 1993 [15 U.S.C. 4305(a)(3)] at any time."

§ 4306. Application of section 4303 protections to production of products, processes, and services

Notwithstanding sections 4303 and 4305 of this title, the protections of section 4303 of this title shall not apply with respect to a joint venture's production of a product, process, or service, as referred to in section 4301(a)(6)(D) of this title, unless—

(1) the principal facilities for such production are located in the United States or its territories, and

(2) each person who controls any party to such venture (including such party itself) is a United States person, or a foreign person from a country whose law accords antitrust treatment no less favorable to United States persons than to such country's domestic persons with respect to participation in joint ventures for production.

(Pub. L. 98–462, § 7, as added Pub. L. 103–42, § 3(g), June 10, 1993, 107 Stat. 119.)

CHAPTER 70—COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION

Sec.
4401. Public education.
4402. Smokeless tobacco warning.
4403. Ingredient reporting.
4404. Enforcement, regulations, and construction.
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§ 4401. Public education

(a) Development

(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this chapter;

(C) conduct and support research on the effect of smokeless tobacco on human health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(2) In developing programs, materials, and announcements under paragraph (1) the Secretary

shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

(b) Assistance

The Secretary of Health and Human Services may provide technical assistance and may make grants to States—

(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco,

(2) to assist in the distribution of such programs, materials, and announcements throughout the States, and

(3) to establish 18 as the minimum age for the purchase of smokeless tobacco.

(Pub. L. 99–252, § 2, Feb. 27, 1986, 100 Stat. 30.)

EFFECTIVE DATE

Section 11 of Pub. L. 99–252 provided that:

"(a) IN GENERAL.—Except as provided in sections 3(f) and 5(b) [sections 4402(f) and 4404(b) of this title] and subsection (b), this Act [enacting this chapter and amending section 342 of Title 21, Food and Drugs] shall take effect one year after the date of enactment of this Act [Feb. 27, 1986].

"(b) EXCEPTION.—Sections 2, 3(b), 3(c), 3(d), 3(e), 4(b), 7, 8, 9 [sections 4401, 4402(b) to (e), 4403(b), and 4406 to 4408 of this title], and 10 [amending section 342 of Title 21] shall take effect on the date of the enactment of this Act [Feb. 27, 1986]."

SHORT TITLE

Section 1 of Pub. L. 99–252 provided that: "This Act [enacting this chapter and amending section 342 of Title 21, Food and Drugs] may be cited as the 'Comprehensive Smokeless Tobacco Health Education Act of 1986'."

§ 4402. Smokeless tobacco warning

(a) General rule

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this chapter, one of the following labels:

"WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

"WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES".

(2) It shall be unlawful for any manufacturer, packager, or importer of smokeless tobacco products to advertise or cause to be advertised (other than through the use of outdoor billboard advertising) within the United States any smokeless tobacco product unless the advertising bears, in accordance with the requirements of this chapter, one of the labels required by paragraph (1).

(b) Label format

The Federal Trade Commission shall issue regulations requiring the label statement required by subsection (a) of this section to appear—

(1) in the case of the smokeless tobacco product package—

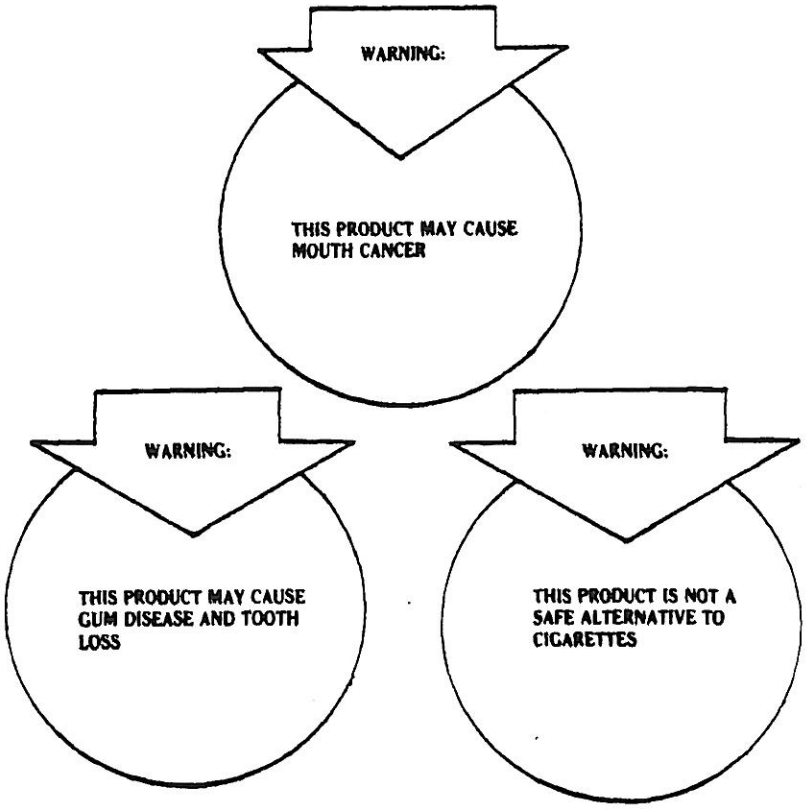
(A) in a conspicuous and prominent place on the package, and

(B) in a conspicuous format and in conspicuous and legible type in contrast with all other printed material on the package, and

(2) in the case of advertising subject to subsection (a)(2) of this section—

(A) in a conspicuous and prominent location in the advertisement and in conspicuous and legible type in contrast with all other printed material in the advertisement,

(B) in the following format:



(C) the label statement shall appear in capital letters and the area of the circle and arrow shall be determined by the Federal Trade Commission.

(c) Label display

The Federal Trade Commission shall issue regulations requiring each label statement required by subsection (a) of this section to—

(1) in the case of a smokeless tobacco product package, be randomly displayed by each manufacturer, packager, or importer of a smokeless tobacco product in each 12-month period in as equal a number of times as is possible on each brand of the product and be randomly distributed in all parts of the United States in which such product is marketed, and

(2) in the case of any advertisement of a smokeless tobacco product, be rotated every 4 months by each manufacturer, packager, or importer of a smokeless tobacco product in an alternating sequence in the advertisement for each brand of the product.

(d) Plan

(1) Each manufacturer, packager, or importer of a smokeless tobacco product shall submit a plan to the Federal Trade Commission which specifies the method such manufacturer, packager, or importer will use to rotate, display, and distribute the statements required by subsection (a) of this section in accordance with the requirements of subsections (b) and (c) of this section.

(2) The Federal Trade Commission shall approve a plan submitted by a manufacturer, packager, or importer of a smokeless tobacco product under paragraph (1) if such plan provides for the rotation, display, and distribution on smokeless tobacco product packages and advertisements of the statements required by subsection (a) of this section in a manner which complies with this section and the regulations promulgated pursuant to this section.

(e) Application

This section does not apply to a distributor or a retailer of any smokeless tobacco product which does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(f) Television and radio advertising

Effective 6 months after February 27, 1986, it shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

(Pub. L. 99-252, § 3, Feb. 27, 1986, 100 Stat. 30; Pub. L. 111-31, div. A, title II, §§ 204(a), 205(a), June 22, 2009, 123 Stat. 1846, 1848.)

AMENDMENT OF SECTION

Pub. L. 111-31, div. A, title II, § 204, June 22, 2009, 123 Stat. 1846, provided that, effective 12 months after June 22, 2009, this section is amended to read as follows:

§ 4402. Smokeless tobacco warning

(a) General rule

(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or im-

port for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this chapter, one of the following labels:

WARNING: This product can cause mouth cancer.

WARNING: This product can cause gum disease and tooth loss.

WARNING: This product is not a safe alternative to cigarettes.

WARNING: Smokeless tobacco is addictive.

(2) Each label statement required by paragraph (1) shall be—

(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

(A) contains a warning label;

(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

(b) Required labels

(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

(C) The word "WARNING" shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital "W" of the word "WARNING" in the label statements.

(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

(G) The label statements shall be in English, except that—

(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

(4) The Secretary may, through a rulemaking under section 553 of title 5, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food,

Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

(c) Television and radio advertising

It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

Pub. L. 111–31, div. A, title II, § 205(a), June 22, 2009, 123 Stat. 1848, provided that this section, as amended by section 204, is further amended by adding at the end the following:

(d) Authority to revise warning label statements

The Secretary may, by a rulemaking conducted under section 553 of title 5, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

EFFECTIVE DATE OF 2009 AMENDMENT

Pub. L. 111–31, div. A, title II, § 204(b), June 22, 2009, 123 Stat. 1848, provided that: "The amendment made by subsection (a) [amending this section] shall take effect 12 months after the date of enactment of this Act [June 22, 2009]. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a)."

EFFECTIVE DATE

Subsec. (a) effective one year after Feb. 27, 1986, and subsecs. (b) to (e) effective Feb. 27, 1986, see section 11 of Pub. L. 99–252, set out as a note under section 4401 of this title.

§ 4403. Ingredient reporting

(a) In general

(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

(A) a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients; and

(B) a specification of the quantity of nicotine contained in each such product.

(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

(b) Report

(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

(C) any other information which the Secretary determines to be in the public interest.

(2)(A) Any information provided to the Secretary under subsection (a) of this section shall be treated as a trade secret or confidential information subject to section 552(b)(4) of title 5 and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

(i) shall take physical possession of the information and, when not in use by any person authorized to have access to such information, shall store it in a locked cabinet or file; and

(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.

(Pub. L. 99–252, § 4, Feb. 27, 1986, 100 Stat. 32.)

EFFECTIVE DATE

Subsec. (a) effective one year after Feb. 27, 1986, and subsec. (b) effective Feb. 27, 1986, see section 11 of Pub. L. 99–252, set out as a note under section 4401 of this title.

§ 4404. Enforcement, regulations, and construction

(a) Enforcement

(1) A violation of section 4402 of this title or the regulations promulgated pursuant to this chapter shall be considered a violation of section 45 of this title.

(2) Any person who is found to violate any provision of section 4402 or 4403(a) of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.