

## EFFECTIVE DATE

Pub. L. 99-252, § 11, Feb. 27, 1986, 100 Stat. 35, 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

Pub. L. 99-252, § 1, Feb. 27, 1986, 100 Stat. 30, 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, sell, offer to sell, distribute, 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 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 [21 U.S.C. 301 et seq.]. 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.

**(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.

(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.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(4) and (d), is act June 25, 1938, ch. 675,

52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2009—Pub. L. 111-31, § 204(a), amended section generally. Prior to amendment, section consisted of subsecs. (a) to (f) relating to smokeless tobacco warning labels and television and radio advertising.

Subsec. (d). Pub. L. 111-31, § 205(a), amended section as amended by Pub. L. 111-31, § 204, by adding subsec. (d).

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), 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) shall be treated as a trade secret or confidential information subject to section 552(b)(4) of title 5 and shall not be re-