used, tar and nicotine content, flavoring used, size of the cigarette, filtration on the cigarette, or packaging.

(9) The term "Secretary" means the Secretary of Health and Human Services.

(Pub. L. 89–92, §3, July 27, 1965, 79 Stat. 282; Pub. L. 91–222, §2, Apr. 1, 1970, 84 Stat. 88; Pub. L. 93–109, §2, Sept. 21, 1973, 87 Stat. 352; Pub. L. 98–474, §6(b), Oct. 12, 1984, 98 Stat. 2204; Pub. L. 99–92, §11(b), Aug. 16, 1985, 99 Stat. 403.)

AMENDMENTS

1985—Pars. (8), (9). Pub. L. 99-92 added par. (8) and redesignated former par. (8) as (9).

1984—Par. (8). Pub. L. 98-474 added par. (8).

1973—Subsec. (7). Pub. L. 93-109 added subsec. (7).

 $1970\mathrm{-Subsec.}$ (3). Pub. L. $91\mathrm{-}222$ inserted provisions defining "State".

EFFECTIVE DATE OF 1973 AMENDMENT

Pub. L. 93-109, §4, Sept. 21, 1973, 87 Stat. 352, provided that: "The amendment made by this Act [amending this section and section 1335 of this title] shall become effective thirty days after the date of enactment [Sept. 21, 1973]."

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–222 effective Jan. 1, 1970, except where otherwise specified, see section 3 of Pub. L. 91–222, set out in part as a note under section 1331 of this title

§ 1333. Labeling

(a) Label requirements

(1) In general

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 cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children

WARNING: Cigarettes cause fatal lung disease.

WARNING: Cigarettes cause cancer.

WARNING: Cigarettes cause strokes and heart disease.

WARNING: Smoking during pregnancy can harm your baby.

WARNING: Smoking can kill you.

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

WARNING: Quitting smoking now greatly reduces serious risks to your health.

(2) Placement; typography; etc.

Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word "WARNING" shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size,

provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white 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 (c).

(3) Does not apply to foreign distribution

The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

(4) Applicability to retailers

A retailer of cigarettes shall not be in violation of this subsection for packaging that—

- (A) contains a warning label;
- (B) is supplied to the retailer by a licenseor 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) Advertising requirements

(1) In general

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

(2) Typography, etc.

Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word "WARNING" shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). 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. 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. The label statements shall be in English, except that—

(A) 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

(B) 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) Matchbooks

Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

(4) Adjustment by Secretary

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 (including smoke 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 cigarette 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) Marketing requirements

(1) Random display

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.

(2) Rotation

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

(3) Review

The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

(A) will provide for the equal distribution and display on packaging and the rotation

required in advertising under this subsection; and

(B) 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.

(4) Applicability to retailers

This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if 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 and subsection (b).

(d) 1 Graphic label statements

Not later than 24 months after June 22, 2009, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.

(d) 1 Change in required statements

The Secretary through a rulemaking conducted under section 553 of title 5 may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

(e) Tar, nicotine, and other smoke constituent disclosure

(1) In general

The Secretary shall, by a rulemaking conducted under section 553 of title 5, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

(2) Resolution of differences

Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memoran-

¹ So in original. There are two subsecs. designated (d).

dum of understanding between the Secretary and the Federal Trade Commission.

(3) Cigarette and other tobacco product constituents

In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(4) Retailers

This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.

(Pub. L. 89–92, §4, July 27, 1965, 79 Stat. 283; Pub. L. 91–222, §2, Apr. 1, 1970, 84 Stat. 88; Pub. L. 98–474, §4(a), Oct. 12, 1984, 98 Stat. 2201; Pub. L. 99–92, §11[(a)], Aug. 16, 1985, 99 Stat. 402; Pub. L. 99–117, §11(d), Oct. 7, 1985, 99 Stat. 495; Pub. L. 111–31, div. A, title II, §§201(a), 202(b), 206, June 22, 2009, 123 Stat. 1842, 1845, 1849.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(4), (d), and (e)(3), 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, §201(a), amended section generally. Prior to amendment, section related to cigarette labeling requirements.

Subsec. (d). Pub. L. 111–31, $\S 202(b)$, added subsec. (d) relating to change in required statements.

Subsec. (e). Pub. L. 111–31, §206, added subsec. (e).

1985—Subsec. (c). Pub. L. 99–92 designated existing provisions as par. (1), substituted "Except as provided in paragraph (2), the" for "The label", and added par. (2).

Subsec. (c)(2)(A). Pub. L. 99–117 substituted "brand style" for "brand" in provisions preceding cl. (i).

1984—Pub. L. 98-474 amended section generally, designating existing provisions as subsec. (a), expanding choice of warnings to be placed on cigarette packaging and further expanding scope of places that must contain warnings to include advertisements and outdoor billboards, and adding subsecs. (b) to (d).

1970—Pub. L. 91–222 substituted "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health" for "Caution: Cigarette Smoking May Be Hazardous to Your Health."

EFFECTIVE DATE OF 2009 AMENDMENT

Pub. L. 111–31, div. A, title II, §201(b), June 22, 2009, 123 Stat. 1845, provided that: "The amendment made by subsection (a) [amending this section] shall take effect

15 months after the issuance of the regulations required by subsection (a) [final rule issued June 22, 2011, eff. Sept. 22, 2012; see 76 F.R. 36628]. 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 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a)."

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–92, 11(c), Aug. 16, 1985, 99 Stat. 403, provided that:

"(1) The amendments made by subsection (a) [probably refers to undesignated par. preceding subsec. (b), amending this section] shall take effect October 12, 1985, except that—

"(A) on and after the date of the enactment of this Act [Aug. 16, 1985] a manufacturer or importer of cigarettes may apply to the Federal Trade Commission to have the label rotation specified in section 4(c)(2) of the Federal Cigarette Labeling and Advertising Act [subsec. (c)(2) of this section], as amended by subsection (a), apply to its brand styles of cigarettes and the Commission may take action on such an application, and

"(B) a manufacturer or importer of cigarettes may elect to have the amendments apply at an earlier date or dates selected by the manufacturer or importer.

porter. "(2) The Federal Trade Commission may, upon application of a manufacturer or importer of cigarettes with an approved application under section 4(c)(2) of the Federal Cigarette Labeling and Advertising Act [subsec. (c)(2) of this section], as amended by subsection (a), extend the effective date specified in paragraph (1) to January 11, 1986. The Commission may approve an application for such an extension only if the Commission determines that the effective date specified in such paragraph (1) would cause unreasonable economic hardship to the applicant. Section 4 of the Federal Cigarette Labeling and Advertising Act [this section], as in effect before October 12, 1985, shall apply with respect to a manufacturer or importer with an application approved under this paragraph."

EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98-474, §4(b), Oct. 12, 1984, 98 Stat. 2203, provided that: "The amendment made by subsection (a) [amending this section] shall take effect upon the expiration of a one-year period beginning on the date of the enactment of this Act [Oct. 12, 1984]."

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–222, §3, Apr. 1, 1970, 84 Stat. 90, provided in part that: "Section 4 of the amendment made by this Act [amending this section] shall take effect on the first day of the seventh calendar month which begins after the date of the enactment of this Act [Apr. 1, 1970]."

§ 1334. Preemption

(a) Additional statements

Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 387c(a)(2) of title 21 or section 387t(a) of title 21, no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package.