

Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act” (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled “Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination” (61 Fed. Reg. 44619–45318 (August 28, 1996)).

(Pub. L. 111–31, div. A, title I, § 102, June 22, 2009, 123 Stat. 1830.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(1)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. Chapter 9 [IX] of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This division, referred to in subsec. (a)(2)(A), (5), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776, known as the Family Smoking Prevention and Tobacco Control Act. For complete classification of division A to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

The date of enactment of the Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (a)(2)(G), is the date of enactment of Pub. L. 111–31, which was approved June 22, 2009.

Section 103(q), referred to in subsec. (a)(6), is section 103(q) of Pub. L. 111–31, which enacted provisions set out as notes under sections 333 and 387c of this title.

CODIFICATION

Section was enacted as part of the Family Smoking Prevention and Tobacco Control Act and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

For provision deeming reference to “180 days” in subsec. (a)(1) to be “270 days”, see section 6 of Pub. L. 111–31, set out as a note under section 387 of this title.

§ 387b. Adulterated tobacco products

A tobacco product shall be deemed to be adulterated if—

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 387s of this title by the date specified in section 387s of this title or by the 30th day

after final agency action on a resolution of any dispute as to the amount of such fee;

(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 387g of this title unless such tobacco product is in all respects in conformity with such standard;

(6)(A) it is required by section 387j(a) of this title to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i) of this title; or

(B) it is in violation of an order under section 387j(c)(1)(A) of this title;

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 387f(e)(1) of this title or an applicable condition prescribed by an order under section 387f(e)(2) of this title; or

(8) it is in violation of section 387k of this title.

(June 25, 1938, ch. 675, §902, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1787.)

PRIOR PROVISIONS

A prior section 902 of act June 25, 1938, was renumbered section 1002. Subsec. (a) of section 1002 is set out as a note under section 301 of this title. Subsecs. (b) and (c) of section 1002 are classified to section 392 of this title. Subsec. (d) of section 1002 is set out as a note under section 392 of this title.

§ 387c. Misbranded tobacco products

(a) In general

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

(D) the statement required under section 387t(a) of this title,

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

(3) if any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it has an established name, unless its label bears, to the exclusion of any other non-