

(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.)

Editorial Notes

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).

Statutory Notes and Related Subsidiaries

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 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.)

Statutory Notes and Related Subsidiaries

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