

those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

“(45) The Federal Trade Commission was created to protect consumers from unfair or deceptive acts or practices, and to regulate unfair methods of competition. Its focus is on those marketplace practices that deceive or mislead consumers, and those that give some competitors an unfair advantage. Its mission is to regulate activities in the marketplace. Neither the Federal Trade Commission nor any other Federal agency except the Food and Drug Administration possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention and Tobacco Control Act [div. A of Pub. L. 111-31, see Short Title of 2009 Amendment note set out under section 301 of this title].

“(46) If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance.

“(47) In August 2006 a United States district court judge found that the major United States cigarette companies continue to target and market to youth. *USA v. Philip Morris, USA, Inc., et al.* (Civil Action No. 99-2496 (GK), August 17, 2006).

“(48) In August 2006 a United States district court judge found that the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998. *USA v. Philip Morris, USA, Inc., et al.* (Civil Action No. 99-2496 (GK), August 17, 2006).

“(49) In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. *USA v. Philip Morris, USA, Inc., et al.* (Civil Action No. 99-2496 (GK), August 17, 2006).”

#### PURPOSE

Pub. L. 111-31, div. A, § 3, June 22, 2009, 123 Stat. 1781, provided that: “The purposes of this division [see Short Title of 2009 Amendment note set out under section 301 of this title] are—

“(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;

“(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

“(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public dis-

closure, and amount of ingredients used in such products;

“(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products;

“(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

“(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

“(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

“(8) to impose appropriate regulatory controls on the tobacco industry;

“(9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

“(10) to strengthen legislation against illicit trade in tobacco products.”

#### MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

Pub. L. 111-31, div. A, § 6, June 22, 2009, 123 Stat. 1783, provided that:

“(a) DELAYED COMMENCEMENT OF DATES FOR SECRETARIAL ACTION.—

“(1) IN GENERAL.—Except as provided in subsection (c), with respect to any time periods specified in this division [see Short Title of 2009 Amendment note set out under section 301 of this title] (or in an amendment made by this division) that begin on the date of enactment of this Act [June 22, 2009], within which the Secretary of Health and Human Services is required to carry out and complete specified activities, the calculation of such time periods shall commence on the date described in subsection (b).

“(2) LIMITATION.—Subsection (a) shall only apply with respect to obligations of the Secretary of Health and Human Services that must be completed within a specified time period and shall not apply to the obligations of any other person or to any other provision of this division (including the amendments made by this division) that do not create such obligations of the Secretary and are not contingent on actions by the Secretary.

“(b) DATE DESCRIBED.—The date described in this subsection is the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387s] (as added by section 101).

“(c) EXCEPTION.—Subsection (a) shall not apply to any time period (or date) contained—

“(1) in section 102 [21 U.S.C. 387a-1], except that the reference to ‘180 days’ in subsection (a)(1) of such section shall be deemed to be ‘270 days’; and

“(2) in sections 201 through 204 [amending sections 1333, 1334, and 4402 of Title 15, Commerce and Trade, and enacting provisions set out as notes under sections 1333 and 4402 of Title 15] (or the amendments made by any such sections).

“(d) ADJUSTMENT.—The Secretary of Health and Human Services may extend or reduce the duration of one or more time periods to which subsection (a) applies if the Secretary determines appropriate [sic], except that no such period shall be extended for more than 90 days.”

#### § 387a. FDA authority over tobacco products

##### (a) In general

Tobacco products, including modified risk tobacco products for which an order has been is-

sued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V.

**(b) Applicability**

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

**(c) Scope**

**(1) In general**

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under subchapter V or any other subchapter.

**(2) Limitation of authority**

**(A) In general**

The provisions of this subchapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

**(B) Exception**

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this subchapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

**(C) Rule of construction**

Nothing in this subchapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

**(d) Rulemaking procedures**

Each rulemaking under this subchapter shall be in accordance with chapter 5 of title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act [21 U.S.C. 387a-1(a)].

**(e) Center for tobacco products**

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and

Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

**(f) Office to assist small tobacco product manufacturers**

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

**(g) Consultation prior to rulemaking**

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

(June 25, 1938, ch. 675, §901, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1786.)

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (c)(1), is div. A of Pub. L. 111-31, June 22, 2009, 123 Stat. 1776. Section 101(a) of title I of the Act amended section 321 of this title. Section 102 of title I of the Act enacted section 387a-1 of this title. Section 103 of title I of the Act amended sections 331, 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacted provisions set out as notes under sections 331, 333, and 387c of this title. Title II of the Act amended sections 1333, 1334, 4402, and 4406 of Title 15, Commerce and Trade, and enacted provisions set out as notes under sections 1333 and 4402 of Title 15. Title III of the Act enacted section 387t of this title. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

PRIOR PROVISIONS

A prior section 901 of act June 25, 1938, was renumbered section 1001 and is classified to section 391 of this title.

**§ 387a-1. Final rule**

**(a) Cigarettes and smokeless tobacco**

**(1) In general**

On the first day of publication of the Federal Register that is 180 days or more after June 22, 2009, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9<sup>1</sup> of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387 et seq.], as added by section 101 of this division; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5 and all other provisions of law relating to rulemaking procedures.

**(2) Contents of rule**

Except as provided in this subsection, the final rule published under paragraph (1),<sup>2</sup> shall

<sup>1</sup> So in original. Probably should be "chapter IX".

<sup>2</sup> So in original. The comma probably should not appear.