

(j) Report preceding introduction of certain substantially equivalent products into interstate commerce

(1) In general

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

(A) the basis for such person's determination that—

(i) the tobacco product is substantially equivalent, within the meaning of section 387j of this title, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 387j of this title, is substantially equivalent and that is in compliance with the requirements of this chapter; or

(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this chapter, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

(B) action taken by such person to comply with the requirements under section 387g of this title that are applicable to the tobacco product.

(2) Application to certain post-February 15, 2007, products

A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009, shall be submitted to the Secretary not later than 21 months after June 22, 2009.

(3) Exemptions

(A) In general

The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 387j of this title, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

(i) such modification would be a minor modification of a tobacco product that can be sold under this chapter;

(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be

appropriate for protection of the public health; and

(iii) an exemption is otherwise appropriate.

(B) Regulations

Not later than 15 months after June 22, 2009, the Secretary shall issue regulations to implement this paragraph.

(June 25, 1938, ch. 675, §905, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1792.)

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (b), is div. A of Pub. L. 111-31, June 22, 2009, 123 Stat. 1776. 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 905 of act June 25, 1938, was renumbered section 1005 and is classified to section 395 of this title.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in an amendment by div. A of Pub. L. 111-31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111-31, set out as a note under section 387 of this title.

§ 387f. General provisions respecting control of tobacco products

(a) In general

Any requirement established by or under section 387b, 387c, 387e, or 387i of this title applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 387g of this title, section 387j of this title, section 387k of this title, or subsection (d) of this section, and any requirement established by or under section 387b, 387c, 387e, or 387i of this title which is inconsistent with a requirement imposed on such tobacco product under section 387g of this title, section 387j of this title, section 387k of this title, or subsection (d) of this section shall not apply to such tobacco product.

(b) Information on public access and comment

Each notice of proposed rulemaking or other notification under section 387g, 387h, 387i, 387j, or 387k of this title or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is¹ based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

(c) Limited confidentiality of information

Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 387c, 387d, 387g, 387h, 387i, 387j, 387k, or 374 of this title, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this subchapter, or when relevant in any proceeding under this subchapter.

(d) Restrictions

(1) In general

The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

(2) Label statements

The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

(3) Limitations

(A) In general

No restrictions under paragraph (1) may—

(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

(B) Matchbooks

For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

(4) Remote sales

(A) In general

The Secretary shall—

(i) within 18 months after June 22, 2009, promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification; and

(ii) within 2 years after June 22, 2009, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products.

(B) Relation to other authority

Nothing in this paragraph limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection.

(e) Good manufacturing practice requirements

(1) Methods, facilities, and controls to conform

(A) In general

In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as pre-

¹ So in original. Probably should be "are".

scribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this subchapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

(B) Requirements

The Secretary shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A);

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices; and

(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

(2) Exemptions; variances

(A) Petition

Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this subchapter;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Secretary shall prescribe.

(B) Referral to the Tobacco Products Scientific Advisory Committee

The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) Approval

The Secretary may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this subchapter; and

(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this subchapter.

(D) Conditions

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this subchapter.

(E) Hearing

After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) Compliance

Compliance with requirements under this subsection shall not be required before the end of the 3-year period following June 22, 2009.

(f) Research and development

The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

(June 25, 1938, ch. 675, §906, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1795.)

PRIOR PROVISIONS

A prior section 906 of act June 25, 1938, was renumbered section 1006 and is classified to section 396 of this title.

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in an amendment by div. A of Pub. L. 111-31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111-31, set out as a note under section 387 of this title.

§ 387f-1. Enforcement action plan for advertising and promotion restrictions**(a) Action plan****(1) Development**

Not later than 6 months after June 22, 2009, the Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall develop and publish an action plan to enforce restrictions adopted pursuant to section 387f of this title, as added by section 101(b) of this division, or pursuant to section 387a-1(a) of this title, on promotion and advertising of menthol and other cigarettes to youth.

(2) Consultation

The action plan required by paragraph (1) shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

(3) Priority

The action plan required by paragraph (1) shall include provisions designed to ensure enforcement of the restrictions described in paragraph (1) in minority communities.

(b) State and local activities**(1) Information on authority**

Not later than 3 months after June 22, 2009, the Secretary shall inform State, local, and tribal governments of the authority provided to such entities under section 1334(c) of title 15, as added by section 203 of this division, or preserved by such entities under section 387p of this title, as added by section 101(b) of this division.

(2) Community assistance

At the request of communities seeking assistance to prevent underage tobacco use, the Secretary shall provide such assistance, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

(Pub. L. 111-31, div. A, title I, § 105, June 22, 2009, 123 Stat. 1841.)

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

With respect to any time periods specified in div. A of Pub. L. 111-31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section 387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111-31, set out as a note under section 387 of this title.

§ 387g. Tobacco product standards**(a) In general****(1) Special rules****(A) Special rule for cigarettes**

Beginning 3 months after June 22, 2009, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) Additional special rule

Beginning 2 years after June 22, 2009, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) Revision of tobacco product standards

The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) Tobacco product standards**(A) In general**

The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) Determinations**(i) Considerations**

In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;