formation required of a tobacco product manufacturer under this subsection.

(c) Time for submission

(1) In general

At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on June 22, 2009, the manufacturer of such product shall provide the information required under subsection (a).

(2) Disclosure of additive

If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

(3) Disclosure of other actions

If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

(d) Data list

(1) In general

Not later than 3 years after June 22, 2009, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

(2) Consumer research

The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after June 22, 2009, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

(e) Data collection

Not later than 24 months after June 22, 2009, the Secretary shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

(June 25, 1938, ch. 675, §904, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1790.)

PRIOR PROVISIONS

A prior section 904 of act June 25, 1938, was renumbered section 1004 and is classified to section 394 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.

§ 387e. Annual registration

(a) Definitions

In this section:

(1) Manufacture, preparation, compounding, or processing

The term ''manufacture, preparation, compounding, or processing'' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

(2) Name

The term ''name'' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) Registration by owners and operators

On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration pursuant to this subsection shall occur.

(c) Registration by new owners and operators

Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

(d) Registration of added establishments

Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

(e) Uniform product identification system

The Secretary may by regulation prescribe a uniform system for the identification of tobacco

products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

(f) Public access to registration information

The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

(g) Biennial inspection of registered establishments

Every establishment registered with the Secretary under this section shall be subject to inspection under section 374 of this title or subsection (h), and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

(h) Registration by foreign establishments

Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 381(a) of this title.

(i) Registration information

(1) Product list

Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 387g of this title or which is subject to section 387j of this title, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 387g of this title, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

(2) Consultation with respect to forms

The Secretary shall consult with the Secretary of the Treasury in developing the forms to be used for registration under this section to minimize the burden on those persons required to register with both the Secretary and the Tax and Trade Bureau of the Department of the Treasury.

(3) Biannual report of any change in product list

Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

(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—