the uniform system for identification of tobacco products prescribed under section 387e(e) of this title as the Secretary by regulation requires;

(7) if, in the case of any tobacco product distributed or offered for sale in any State—

(A) its advertising is false or misleading in any particular; or

(B) it is sold or distributed in violation of section 387f(d)(5) of this title or of regulations prescribed under section 387f(d) of this title;

(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

(B) a brief statement of—

(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

(9) if it is a tobacco product subject to a tobacco product standard established under section 387g of this title, unless it bears such labeling as may be prescribed in such tobacco product standard; or

(10) if there was a failure or refusal—

(A) to comply with any requirement prescribed under section 387d or 387h of this title; or

(B) to furnish any material or information required under section 387i of this title.

(b) Prior approval of label statements

The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 387k of this title. No advertisement of a tobacco product published after June 22, 2009, shall, with respect to the language of label statements as prescribed under section 1333 of title 15 and section 4402 of title 15 or the regulations issued under such sections, be subject to the provisions of sections 52 through 55 of title 15.

(June 25, 1938, ch. 675, §903, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1788; amended Pub. L. 116–94, div. N, title I, §603(d)(3), Dec. 20, 2019, 133 Stat. 3124.)

Editorial Notes

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 903 of act June 25, 1938, was renumbered section 1003 and is classified to section 393 of this title.

Another prior section 903 of act June 25, 1938, was renumbered section 1004 and is classified to section 394 of this title.

AMENDMENTS

2019—Subsec. (a)(7)(B). Pub. L. 116–94 inserted ''section 387f(d)(5) of this title or of'' after ''violation of''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 111–31, div. A, title I, §103(q)(5), (6), June 22, 2009, 123 Stat. 1840, provided that:

''(5) PACKAGE LABEL REQUIREMENTS.—The package label requirements of paragraphs (3) and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387c(a)] (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act [June 22, 2009]. The package label requirements of paragraph (2) of such section 903(a) for cigarettes shall take effect on the date that is 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333[(d)]), as amended by section 201 of this division. The package label requirements of paragraph (2) of such section 903(a) for tobacco products other than cigarettes shall take effect on the date that is 12 months after the date of enactment of this Act. The 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 903(a)(2), (3), and (4) and section 920(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387t(a)].

''(6) ADVERTISING REQUIREMENTS.—The advertising requirements of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387c(a)(8)] (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act [June 22, 2009].''

§ 387d. Submission of health information to the Secretary

(a) Requirement

Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

(1) Not later than 6 months after June 22, 2009, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 1333(e) of title 15.

(3) Beginning 3 years after June 22, 2009, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 3 years after June 22, 2009, the manufacturer, importer, or agent shall comply with regulations promulgated under section 387*o* of this title in reporting information under this paragraph, where applicable.

(4) Beginning 6 months after June 22, 2009, all documents developed after June 22, 2009 that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

(b) Data submission

At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

An importer of a tobacco product not manufactured in the United States shall supply the information 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.)

Editorial Notes

PRIOR PROVISIONS

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

Statutory Notes and Related Subsidiaries

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