

collection of the data or other information designated by the Secretary as necessary to protect the public health.

**(j) Withdrawal of authorization**

The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 387g of this title;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

**(k) Subchapter IV or V**

A product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to subchapter IV or V.

**(l) Implementing regulations or guidance**

**(1) Scientific evidence**

Not later than 2 years after June 22, 2009, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including

ongoing assessments of consumer perception;

(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

(F) establish a reasonable timetable for the Secretary to review an application under this section.

**(2) Consultation**

The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

**(3) Revision**

The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

**(4) New tobacco products**

Not later than 2 years after June 22, 2009, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 387j of this title and which the applicant seeks to commercially market under this section.

**(m) Distributors**

Except as provided in this section, no distributor may take any action, after June 22, 2009, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(June 25, 1938, ch. 675, §911, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1812.)

**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.

**§ 387I. Judicial review**

**(a) Right to review**

**(1) In general**

Not later than 30 days after—

(A) the promulgation of a regulation under section 387g of this title establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 387j(c) of this title,

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

**(2) Requirements**

**(A) Copy of petition**

A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

**(B) Record of proceedings**

On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

- (i) the record of the proceedings on which the regulation or order was based; and
- (ii) a statement of the reasons for the issuance of such a regulation or order.

**(C) Definition of record**

In this section, the term “record” means—

- (i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;
- (ii) all information submitted to the Secretary with respect to such regulation or order;
- (iii) proceedings of any panel or advisory committee with respect to such regulation or order;
- (iv) any hearing held with respect to such regulation or order; and
- (v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

**(b) Standard of review**

Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5.

**(c) Finality of judgment**

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

**(d) Other remedies**

The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

**(e) Regulations and orders must recite basis in record**

To facilitate judicial review, a regulation or order issued under section 387f, 387g, 387h, 387i,

387j, or 387p of this title shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

(June 25, 1938, ch. 675, §912, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1819.)

**§ 387m. Equal treatment of retail outlets**

The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

(June 25, 1938, ch. 675, §913, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1820.)

**§ 387n. Jurisdiction of and coordination with the Federal Trade Commission**

**(a) Jurisdiction**

**(1) In general**

Except where expressly provided in this subchapter, nothing in this subchapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

**(2) Enforcement**

Any advertising that violates this subchapter or a provision of the regulations referred to in section 387a-1 of this title, is an unfair or deceptive act or practice under section 45(a) of title 15 and shall be considered a violation of a rule promulgated under section 57a of title 15.

**(b) Coordination**

With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act [15 U.S.C. 1333] and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 [15 U.S.C. 4402]—

(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

(June 25, 1938, ch. 675, §914, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1820.)

REFERENCES IN TEXT

The Federal Cigarette Labeling and Advertising Act, referred to in subsec. (b), is Pub. L. 89-92, July 27, 1965, 79 Stat. 282, which is classified generally to chapter 36 (§1331 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1331 of Title 15 and Tables.

The Comprehensive Smokeless Tobacco Health Education Act of 1986, referred to in subsec. (b), is Pub. L.