(iii) 1 individual as a representative of the general public;

(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

(vi) 1 individual as a representative of the interests of the tobacco growers.

(B) Nonvoting members

The members of the committee appointed under clauses (iv), (v), and (vi) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

(C) Conflicts of interest

No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.

(2) Limitation

The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this chapter. The Secretary may appoint Federal officials as ex officio members.

(3) Chairperson

The Secretary shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(c) Duties

The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

(1) as provided in this subchapter;

(2) on the effects of the alteration of the nicotine yields from tobacco products;

(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

(d) Compensation; support; FACA

(1) Compensation and travel

Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently.

(2) Administrative support

The Secretary shall furnish the Advisory Committee clerical and other assistance.

(3) Nonapplication of FACA

Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

(e) Proceedings of advisory panels and committees

The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5.

(June 25, 1938, ch. 675, §917, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1824.)

REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (d)(3), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

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.

§387r. Drug products used to treat tobacco dependence

(a) In general

The Secretary shall—

(1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products as fast track research and approval products within the meaning of section 356 of this title;

(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

(b) Report on innovative products

(1) In general

Not later than 3 years after June 22, 2009, the Secretary, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to regulate, promote, and encourage the development of innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use.

(2) Recommendations

The report under paragraph (1) shall include the recommendations of the Secretary on how the Food and Drug Administration should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Administration and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant agencies.

(June 25, 1938, ch. 675, § 918, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1825.)

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.

§ 387s. User fees

(a) Establishment of quarterly fee

Beginning on June 22, 2009, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this subchapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

(b) Assessment of user fee

(1) Amount of assessment

The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

(A) For fiscal year 2009, $85,000,000 (subject to subsection (e)).

(B) For fiscal year 2010, $235,000,000.

(C) For fiscal year 2011, $450,000,000.

(D) For fiscal year 2012, $477,000,000.

(E) For fiscal year 2013, $505,000,000.

(F) For fiscal year 2014, $534,000,000.

(G) For fiscal year 2015, $566,000,000.

(H) For fiscal year 2016, $599,000,000.

(I) For fiscal year 2017, $635,000,000.

(J) For fiscal year 2018, $672,000,000.

(K) For fiscal year 2019 and each subsequent fiscal year, $712,000,000.

(2) Allocations of assessment by class of tobacco products

(A) In general

The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

(B) Applicable percentage

(i) In general

For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

(I) Cigarettes.

(II) Cigars, including small cigars and cigars other than small cigars.

(III) Snuff.

(IV) Chewing tobacco.

(V) Pipe tobacco.

(VI) Roll-your-own tobacco.

(ii) Allocations

The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 518d(c) of title 7 for each such class of product for such fiscal year.

(iii) Requirement of regulations

Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 387a(b) of this title or is deemed by the Secretary in a regulation under section 387a(b) of this title to be subject to this subchapter.

(iv) Reallocations

In the case of a class of tobacco products that is not listed in section 387a(b) of this title or deemed by the Secretary in a regulation under section 387a(b) of this title to be subject to this subchapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this subchapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).