

**(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 non-governmental 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.