(A) the actual knowledge that the manufacturer or distributor had; or

(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(e) Consultation

In carrying out this section, the Secretary shall consult with the Attorney General of the United States and the Secretary of the Treasury, as appropriate.

(June 25, 1938, ch. 675, § 920, as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.)

Editorial Notes

REFERENCES IN TEXT

Section 201 of the Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (a)(1), is section 201 of div. A of Pub. L. 111–31.

§ 387u. Studies of progress and effectiveness

(a) FDA report

Not later than 3 years after June 22, 2009, and not less than every 2 years thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 387j of this title and modified risk product applications received under section 387k of this title, and the number of applications acted on under each category; and

(4) data on the number of full time equivalents engaged in implementing this division.

(b) GAO report

Not later than 5 years after June 22, 2009, the Comptroller General of the United States shall conduct a study of, and submit to the Committees described in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided to the Secretary of Health and Human Services for this division to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

(c) Public availability

The Secretary of Health and Human Services and the Comptroller General of the United States, respectively, shall make the reports required under subsection [1] (a) and (b) available to the public, including by posting such reports on the respective Internet websites of the Food and Drug Administration and the Government Accountability Office.

(Pub. L. 111–31, div. A, title I, § 106, June 22, 2009, 123 Stat. 1841.)

Editorial Notes

REFERENCES IN TEXT

This division, referred to in subsecs. (a)(1), (2), (4) and (b)(1), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776, known as Family Smoking Prevention and Tobacco Control Act. For complete classification of division A to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Family Smoking Prevention and Tobacco Control Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in 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.

§ 387v. Reporting on tobacco regulation activities

(a) In general

For fiscal year 2022 and each subsequent fiscal year for which fees are collected under section 387s of this title, the Secretary of Health and Human Services shall, not later than 180 days after the end of the fiscal year, prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, an annual report that contains the information required under subsection (b).

(b) Required information

Each report submitted under subsection (a) shall contain the following information for the previous fiscal year:

(1) Total annual user fee collections.

(2) Total amount of fees obligated.

(3) The amount of unobligated carryover balance from fees collected.

(4) The amount obligated by the Center for Tobacco Products for each of the following activities:

(A) Compliance and enforcement.

(B) Public education campaigns.

(C) Scientific research and research infrastructure.

[1] So in original. Probably should be plural.