(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.

(D) Communications.

(E) Leadership, management oversight, and administrative services.

(F) Related overhead activities.

(5) The numbers of applications, categorized by class of tobacco product and review pathway under sections 387e, 387j, and 387k of this title, that were—

(A) submitted;

(B) pending;

(C) accepted;

(D) refused to file;

(E) withdrawn;

(F) denied;

(G) authorized for marketing under an order;

(H) issued a deficiency letter or environmental information request letter; or

(I) referred to the Tobacco Products Scientific Advisory Committee.

(6) The number and titles of draft and final guidance documents and proposed and final regulations issued on topics related to the process for the review of tobacco product applications, whether such regulations and guidance documents were issued as required by statute or by other legal or regulatory requirements, and whether the issuance met the deadlines set forth by the applicable statute or other requirements.

(7) The number and titles of public meetings related to the review of tobacco product applications by the Center for Tobacco Products or other offices or centers within the Food and Drug Administration.

(8) The number of pre-submission meetings relating to applications under section 387j of this title, including the number of meeting requests received, the number of meetings held, and the median amount of time between when such meeting requests were made and when the requests were granted or denied.

(9) The number of full-time equivalent employees funded pursuant to fees collected under section 387s of this title, including identification of the centers and offices within the Food and Drug Administration in which such positions are located.

(10) The number of inspections and investigations conducted at domestic and foreign establishments required to register under section 387e of this title.

(11) The total number of compliance and enforcement actions issued or taken with respect to tobacco products, including warning letters, civil money penalties, no-tobacco-sale orders, and other enforcement actions (including seizures, injunctions, and criminal prosecution).

(c) Public availability

The Secretary of Health and Human Services shall make the reports required under this section available to the public on the website of the Food and Drug Administration.

(d) Limitations

Reporting under this section shall include best estimates for any reporting category for which the Food and Drug Administration does not have precise calculations. Such best estimates shall be accompanied with an explanatory statement for why the Food and Drug Administration does not have access to, or cannot calculate, the exact figure and a date by which the Food and Drug Administration will update its internal accounting procedures to allow for such reporting. If a category is successfully reported by the Food and Drug Administration with regard to another type of user fee but is provided a best estimate by the Center for Tobacco Products, the explanatory statement shall include information regarding how the Food and Drug Administration will align systems and apply learning across the agency to allow for accurate reporting.

(Pub. L. 117–103, div. P, title I, § 112, Mar. 15, 2022, 136 Stat. 790.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Consolidated Appropriations Act, 2022, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER X—MISCELLANEOUS

Editorial Notes

CODIFICATION

Former subchapter IX of this chapter was redesignated as this subchapter.

§ 391. Separability clause

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby.

(June 25, 1938, ch. 675, § 1001, formerly § 901, 52 Stat. 1059; renumbered § 1001, Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 392. Exemption of meats and meat food products

(a) Law determinative of exemption

Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended [21 U.S.C. 601 et seq.].

(b) Laws unaffected

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of Public Health Service Act [42 U.S.C. 262] (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832–833) [21 U.S.C. 151 et seq.]; the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 [21 U.S.C. 61 et seq.]; or the Import Milk Act of February 15, 1927 [21 U.S.C. 141 et seq.].