(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(E) withdrawn;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.].

(June 25, 1938, ch. 675, § 1002(b), (c), formerly § 902(b), (c), 52 Stat. 1059; Pub. L. 90–399, § 107, July 13, 1968, 82 Stat. 353; renumbered § 1002(b), (c), Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.)

Editorial Notes

REFERENCES IN TEXT

The Meat Inspection Act, approved March 4, 1907, as amended, referred to in subsec. (a), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90–201, 81 Stat. 584, which are classified generally to subchapters I to IV (§ 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

Act of March 4, 1913, referred to in subsec. (b), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act referred to relating to viruses, etc., applicable to domestic animals, are contained in the eighth paragraph under the heading ''Bureau of Animal Industry'', 37 Stat. 832, as amended, popularly known as the Virus-Serum-Toxin Act, which is classified generally to chapter 5 (§ 151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

The Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), referred to in subsec. (b), is act June 6, 1896, ch. 337, 29 Stat. 253, which had been classified to chapter 10 (§ 1000 et seq.) of Title 26, Internal Revenue, and included as chapter 17 (§ 2350 et seq.) of Title 26, Internal Revenue Code of 1939. Such chapter 17 was covered by section 4831 et seq. of Title 26, Internal Revenue Code, prior to the repeal of section 4831 et seq. of Title 26 by Pub. L. 93–490, § 3(a)(1), Oct. 26, 1974, 88 Stat. 1466.

The Filled Milk Act of March 4, 1923, referred to in subsec. (b), is act Mar. 4, 1923, ch. 262, 42 Stat. 1486, which is classified generally to chapter 3 (§ 61 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 61 of this title and Tables.

The Import Milk Act of February 15, 1927, referred to in subsec. (b), is act Feb. 15, 1927, ch. 155, 44 Stat. 1101, which is classified generally to subchapter IV (§ 141 et seq.) of chapter 4 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 141 of this title and Tables.

CODIFICATION

Subsecs. (a) and (b) of this section comprise respectively subsecs. (b) and (c) of section 1002 of act June 25, 1938. Subsecs. (a) and (d) of section 1002 of act June 25, 1938, which prescribed the effective date of this chapter and made appropriations available, are set out as notes under section 301 of this title and this section, respectively.

AMENDMENTS

1968—Subsec. (b). Pub. L. 90–399 substituted ''section 351 of Public Health Service Act (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);'' for ''the virus, serum, and toxin Act of July 1, 1902 (U.S.C., 1934 ed., title 42, chap. 4);''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

AVAILABILITY OF APPROPRIATIONS

Act June 25, 1938, ch. 675, § 1002(d), formerly § 902(d), 52 Stat. 1059; renumbered § 1002(d), Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784, provided that: ''In order to carry out the provisions of this Act which take effect [see section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title] prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended [former sections 1 to 5 and 7 to 15 of this title], appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.''

§ 393. Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the ''Administration'').

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(c) Interagency collaboration

The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

(d) Commissioner

(1) Appointment

There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the ''Commissioner'') who shall be appointed by the President by and with the advice and consent of the Senate.