(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(E) withdrawn;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.].