Editorial Notes

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, which directed the substitution of ''$6,000,000 for each of fiscal years 2023 through 2027'' for ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 23, 2022'', could not be executed because ''$1,265,753'' did not appear after the intervening amendment by section 301 of Pub. L. 117–229. See below.

Pub. L. 117–229 substituted ''$1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022'' for ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022''.

Pub. L. 117–180 substituted ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022'' for ''$6,000,000 for each of fiscal years 2018 through 2022''.

2017—Subsec. (f). Pub. L. 115–52 substituted ''2018 through 2022'' for ''2013 through 2017''.

2012—Subsec. (f). Pub. L. 112–144 amended subsec. (f) generally. Prior to amendment, text read as follows: ''To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.''

§ 360bbb–5a. Emerging technology program

(a) Program establishment

(1) In general

The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to drug design and manufacturing.

(2) Actions

In carrying out the program under paragraph (1), the Secretary may—

(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

(B) solicit information regarding, and conduct or support research on, innovative approaches to drug product design and manufacturing;

(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

(D) convene working groups to support drug product design and manufacturing research and development;

(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

(F) advance regulatory science related to the development and review of innovative approaches to drug product design and manufacturing;

(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

(H) award grants or contracts to carry out or support the program under paragraph (1).

(3) Grants and contracts

To seek a grant or contract under this section, an entity shall submit an application—

(A) in such form and manner as the Secretary may require; and

(B) containing such information as the Secretary may require, including a description of—

(i) how the entity will conduct the activities to be supported through the grant or contract; and

(ii) how such activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

(b) Guidance

The Secretary shall—

(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

(2) include in such guidance descriptions of—

(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates and improvements to such technologies after product approval; and

(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

(c) Report to Congress

Not later than 4 years after December 29, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(1) an annual accounting of the allocation of funds made available to carry out this section;

(2) a description of how Food and Drug Administration staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;

(3) the number of public meetings held or participated in by the Food and Drug Administration pursuant to this section, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each such meeting; and

(4) the number of drug products approved or licensed, after December 29, 2022, using an innovative approach to drug product design and manufacturing.

(June 25, 1938, ch. 675, § 566A, as added Pub. L. 117–328, div. FF, title III, § 3203, Dec. 29, 2022, 136 Stat. 5814.)

§ 360bbb–6. Risk communication

(a) Advisory Committee on Risk Communication

(1) In general

The Secretary shall establish an advisory committee to be known as the ''Advisory Committee on Risk Communication'' (referred to in this section as the ''Committee'').

(2) Duties of Committee

The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.