is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

The Public Health Service Act, referred to in subsec. (f), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

2021—Subsec. (a)(4)(D). Pub. L. 117–9 amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: ''is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act.''

§ 360bbb–4b. Medical countermeasure master files

(a) Applicability of reference

(1) In general

A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or by a person authorized by the master file holder, in accordance with applicable privacy and confidentiality protocols and regulations.

(2) Reference of certain master files

In the case that data or information within a medical countermeasure master file is used only to support the conditional approval of an application filed under section 360ccc of this title, such master file may be relied upon to support the effectiveness of a product that is the subject of a subsequent medical countermeasure submission only if such application is supplemented by additional data or information to support review and approval in a manner consistent with the standards applicable to such review and approval for such countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(b) Medical countermeasure master file content

(1) In general

A master file under this section may include data or information to support—

(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

(2) Required updates

The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are updated during the time such master file is referenced for a medical countermeasure submission.

(c) Sponsor reference

(1) In general

Each incorporation of data or information within a medical countermeasure master file shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such information within such master file without necessitating resubmission of such data or information. Master files shall be submitted in an electronic format in accordance with sections 360b(b)(4), 360ccc(a)(4), and 379k–1 of this title, as applicable, and as specified in applicable guidance.

(2) Reference by a master file holder

A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

(3) Reference by an authorized person

A person submitting an application for review may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a medical countermeasure master file, if the master file holder authorizes the incorporation in writing.

(d) Acknowledgment of and reliance upon a master file by the Secretary

(1) In general

The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified data or information within a master file and the purposes for which such data or information was incorporated by reference if the Secretary has reviewed and relied upon such specified data or information to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

(2) Certain applications

If the Secretary has reviewed and relied upon specified data or information within a medical countermeasure master file to support the conditional approval of an application under section 360ccc of this title to subsequently support the approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, the Secretary shall provide a brief written description to the master file holder regarding the elements of the application fulfilled by the data or information within the master file and how

such data or information contained in such application meets the standards of evidence under subsection (c) or (d) of section 355 of this title, subsection (d) of section 360b of this title, or section 351 of the Public Health Service Act [42 U.S.C. 262] (as applicable), which shall not include any trade secret or confidential commercial information.

(e) Rules of construction

Nothing in this section shall be construed to—

(1) limit the authority of the Secretary to approve, license, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to, as applicable, this Act [this chapter] or section 351 of the Public Health Service Act [42 U.S.C. 262] (as such applicable Act is in effect on the day before June 24, 2019), including the standards of evidence, and applicable conditions, for approval under the applicable Act;

(2) alter the standards of evidence with respect to approval, licensure, or clearance, as applicable, of drugs, biological products, or devices under this Act [this chapter] or section 351 of the Public Health Service Act [42 U.S.C. 262], including, as applicable, the substantial evidence standards under sections 355(d) and 360b(d) of this title and section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]; or

(3) alter the authority of the Secretary under this Act [this chapter] or the Public Health Service Act [42 U.S.C. 201 et seq.] to determine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under sections 355(i), 355(b), 355(j), 360b(b)(1), 360b(b)(2), 360b(j), 360bbb–3, 360ccc, 360j(g), 360e(c), 360c(f)(2), or 360(k) of this title, or subsection (a) or (k) of section 351 of the Public Health Service Act [42 U.S.C. 262], including a supplement or amendment to any such submission, and the requirements associated with such reference.

(f) Definitions

In this section:

(1) The term ''master file holder'' means a person who submits data and information to the Secretary with the intent to reference or authorize another person to reference such data or information to support a medical countermeasure submission, as described in subsection (a).

(2) The term ''medical countermeasure submission'' means an investigational new drug application under section 355(i) of this title, a new drug application under section 355(b) of this title, or an abbreviated new drug application under section 355(j) of this title, a biological product license application under section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] or a biosimilar biological product license application under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)], a new animal drug application under section 360b(b)(1) of this title or abbreviated new animal drug application under section 360b(b)(2) of this title, an application for conditional approval of a new animal drug under section 360ccc of this title, an investigational device application under section 360j(g) of this title, an application with respect to a device under section 360e(c) of this title, a request for classification of a device under section 360c(f)(2) of this title, a notification with respect to a device under section 360(k) of this title, or a request for an emergency use authorization under section 360bbb–3 of this title to support—

(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(3) The terms ''qualified countermeasure'', ''security countermeasure'', and ''qualified pandemic or epidemic product'' have the meanings given such terms in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act [42 U.S.C. 247d–6a, 247d–6b, 247d–6d].

(June 25, 1938, ch. 675, § 565B, as added Pub. L. 116–22, title VI, § 603(b), June 24, 2019, 133 Stat. 953.)

Editorial Notes

REFERENCES IN TEXT

This Act, referred to in subsec. (e), is the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter (§ 301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

The Public Health Service Act, referred to in subsec. (e)(3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Statutory Notes and Related Subsidiaries

MEDICAL COUNTERMEASURE MASTER FILES

Pub. L. 116–22, title VI, § 603, June 24, 2019, 133 Stat. 953, provided that:

''(a) IN GENERAL.—The purpose of this section (including section 565B of the Federal Food, Drug, and Cosmetic Act [this section], as added by subsection (b)) is to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facilitating and encouraging submission of data and information to support the development of such products, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), including data and information submitted to medical countermeasure master files or other master files.

''(b) MEDICAL COUNTERMEASURE MASTER FILES.—[Enacted this section.]

''(c) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act [June 24, 2019], the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products,

and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

''(d) GUIDANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish draft guidance about how reliance on cross-referenced data and information contained within master files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b) or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.''

§ 360bbb–5. Critical Path Public-Private Partnerships

(a) Establishment

The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) Eligible entity

In this section, the term ''eligible entity'' means an entity that meets each of the following:

(1) The entity is—

(A) an institution of higher education (as such term is defined in section 1001 of title 20) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 and exempt from tax under section 501(a) of such title.

(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

(A) developing and critically evaluating tools, methods, and processes—

(i) to increase efficiency, predictability, and productivity of medical product development; and

(ii) to more accurately identify the benefits and risks of new and existing medical products;

(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) Funding

The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) Annual report

Not later than 18 months after September 27, 2007, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) reviewing the operations and activities of the Partnerships in the previous year; and

(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) Definition

In this section, the term ''medical product'' includes a drug, a biological product as defined in section 262 of title 42, a device, and any combination of such products.

(f) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022.[1]

(June 25, 1938, ch. 675, § 566, as added Pub. L. 110–85, title VI, § 603, Sept. 27, 2007, 121 Stat. 898; amended Pub. L. 112–144, title XI, § 1102, July 9, 2012, 126 Stat. 1108; Pub. L. 115–52, title VI, § 602, Aug. 18, 2017, 131 Stat. 1048; Pub. L. 117–180, div. F, title V, § 5005, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, § 301, Dec. 16, 2022, 136 Stat. 2311; Pub. L. 117–328, div. FF, title III, § 3101, Dec. 29, 2022, 136 Stat. 5807.)

[1] See 2022 Amendment notes below.