

Pub. L. 113-5, §303, designated existing provisions as subsec. (b) and inserted heading.

Subsec. (a). Pub. L. 113-5, §303, added subsec. (a).

Subsec. (b). Pub. L. 113-5, §304(2), reenacted heading without change, substituted “In order to accelerate the development, stockpiling, approval, licensure, and clearance of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products, the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, shall—” for “The Secretary, in consultation with the Commissioner of Food and Drugs, shall”, added pars. (1) to (4), and designated remainder of existing provisions as par. (5).

Subsecs. (c) to (e). Pub. L. 113-5, §304(3), added subsecs. (c) to (e).

Subsec. (f). Pub. L. 113-5, §305, added subsec. (f).

Subsec. (g). Pub. L. 113-5, §306, added subsec. (g).

Statutory Notes and Related Subsidiaries

GUIDANCE

Pub. L. 117-328, div. FF, title II, §2502(b), Dec. 29, 2022, 136 Stat. 5798, provided that: “Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this subsection as the ‘Secretary’) shall issue draft guidance on consultations with persons under subsection (i) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-4), as added by subsection (a), including considerations concerning conflicts of interest, compensation arrangements, and information sharing. Not later than 1 year after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.”

PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Pub. L. 114-255, div. A, title III, §3091, Dec. 13, 2016, 130 Stat. 1149, provided that:

“(a) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the ‘Advisory Committee’) shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

“(b) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee’s first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of such committee’s review.

“(c) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

“(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

“(2) could be used in a public health emergency.

“(d) DEFINITION.—In this section, the terms ‘Advisory Committee on Immunization Practices’ and ‘Advisory Committee’ mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.”

§ 360bbb-4a. Priority review to encourage treatments for agents that present national security threats

(a) Definitions

In this section:

(1) Human drug application

The term “human drug application” has the meaning given such term in section 379g(1) of this title.

(2) Priority review

The term “priority review”, with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

(3) Priority review voucher

The term “priority review voucher” means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] after the date of approval of the material threat medical countermeasure application.

(4) Material threat medical countermeasure application

The term “material threat medical countermeasure application” means an application that—

(A) is a human drug application for a drug intended for use—

(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F-2(c)(2)(A)(ii) of the Public Health Service Act [42 U.S.C. 247d-6b(c)(2)(A)(ii)]; or

(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

(B) the Secretary determines eligible for priority review;

(C) is approved after December 13, 2016; and

(D) is for—

(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 355(b)(1) of this title; or

(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act [42 U.S.C. 262].

(b) Priority review voucher

(1) In general

The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

(2) Transferability

The sponsor of a material threat medical countermeasure application that receives a

priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(3) Notification

(A) In general

The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) Transfer after notice

The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

(c) Priority review user fee

(1) In general

The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under subchapter VII.

(2) Fee amount

The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) Annual fee setting

The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

(4) Payment

(A) In general

The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the priority review voucher is used.

(B) Complete application

An application described under subparagraph (A) for which the sponsor requests the

use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) No waivers, exemptions, reductions, or refunds

The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) Offsetting collections

Fees collected pursuant to this subsection for any fiscal year—

(A)¹ shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(6)² shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(d) Notice of issuance of voucher and approval of products under voucher

The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

(1) The Secretary issues a priority review voucher under this section.

(2) The Secretary approves a drug pursuant to an application submitted under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the sponsor of the application used a priority review voucher issued under this section.

(e) Eligibility for other programs

Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this chapter, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this chapter with respect to such drug.

(f) Relation to other provisions

The provisions of this section shall supplement, not supplant, any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] that encourage the development of medical countermeasures.

(g) Sunset

The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.

(June 25, 1938, ch. 675, §565A, as added Pub. L. 114-255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144; Pub. L. 117-9, §1(a)(5), Apr. 23, 2021, 135 Stat. 258.)

Editorial Notes

REFERENCES IN TEXT

Section 101(b) of the Food and Drug Administration Safety and Innovation Act, referred to in subsec. (a)(2),

¹ So in original. No subpar. (B) has been enacted.

² So in original. Probably should be designated as subpar. (B).

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