Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in text, 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

2019—Par. (2)(B). Pub. L. 116–22, § 705(d)(1), inserted comma after ''355''.

Par. (2)(C). Pub. L. 116–22, § 705(d)(2), inserted ''or section 360bbb–3a of this title'' before period at end.

2016—Par. (2)(A). Pub. L. 114–255, § 3088(d)(1), substituted ''360b, or 360e of this title'' for ''or 360e of this title'' and inserted ''or conditionally approved under section 360ccc of this title'' after ''Public Health Service Act''.

Par. (2)(B). Pub. L. 114–255, § 3088(d)(2), substituted ''360b, or 360j of this title'' for ''or 360j of this title''.

§ 360bbb–3c. Expedited development and review of medical products for emergency uses

(1) In general

The Secretary of Defense may request that the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, take actions to expedite the development of a medical product, review of investigational new drug applications under section 355(i) of this title, review of investigational device exemptions under section 360j(g) of this title, and review of applications for approval and clearance of medical products under sections 355, 360(k), and 360e of this title and section 262 of title 42, including applications for licensing of vaccines or blood as biological products under such section 262 of title 42, or applications for review of regenerative medicine advanced therapy products under section 356(g) of this title, if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk.

(2) Actions

Upon a request by the Secretary of Defense under paragraph (1), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall take action to expedite the development and review of an applicable application or notification with respect to a medical product described in paragraph (1), which may include, as appropriate—

(A) holding meetings with the sponsor and the review team throughout the development of the medical product;

(B) providing timely advice to, and interactive communication with, the sponsor regarding the development of the medical product to ensure that the development program to gather the nonclinical and clinical data necessary for approval or clearance is as efficient as practicable;

(C) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(D) assigning a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor;

(E) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment;

(F) applying any applicable Food and Drug Administration program intended to expedite the development and review of a medical product; and

(G) in appropriate circumstances, permitting expanded access to the medical product during the investigational phase, in accordance with applicable requirements of the Food and Drug Administration.

(3) Enhanced collaboration and communication

In order to facilitate enhanced collaboration and communication with respect to the most current priorities of the Department of Defense—

(A) the Food and Drug Administration shall meet with the Department of Defense and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority, on a semi-annual basis for the purposes of conducting a full review of the relevant products in the Department of Defense portfolio; and

(B) the Director of the Center for Biologics Evaluation and Research shall meet quarterly with the Department of Defense to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the Department of Defense (which may include freeze dried plasma products and platelet alternatives),

unless the Secretary of Defense determines that any such meetings are not necessary.

(4) Medical product

In this subsection, the term ''medical product'' means a drug (as defined in section 321 of this title), a device (as defined in such section 321 of this title), or a biological product (as defined in section 262 of title 42).

(Pub. L. 115–92, § 1(b), Dec. 12, 2017, 131 Stat. 2023.)

Editorial Notes

CODIFICATION

Section was enacted as part of Pub. L. 115–92, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 360bbb–4. Countermeasure development, review, and technical assistance

(a) Definitions

In this section—

(1) the term ''countermeasure'' means a qualified countermeasure, a security countermeasure, and a qualified pandemic or epidemic product;

(2) the term ''qualified countermeasure'' has the meaning given such term in section 247d–6a of title 42;

(3) the term ''security countermeasure'' has the meaning given such term in section 247d–6b of title 42; and

(4) the term ''qualified pandemic or epidemic product'' means a product that meets the definition given such term in section 247d–6d of title 42 and—

(A) that has been identified by the Department of Health and Human Services or the Department of Defense as receiving funding directly related to addressing chemical, biological, radiological, or nuclear threats, including pandemic influenza; or

(B) is included under this paragraph pursuant to a determination by the Secretary.

(b) General duties

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—

(1) ensure the appropriate involvement of Food and Drug Administration personnel in interagency activities related to countermeasure advanced research and development, consistent with sections 247d–6, 247d–6a, 247d–6b, 247d–6d, 247d–7e, and 300hh–10 of title 42;

(2) ensure the appropriate involvement and consultation of Food and Drug Administration personnel in any flexible manufacturing activities carried out under section 247d–7e of title 42, including with respect to meeting regulatory requirements set forth in this chapter;

(3) promote countermeasure expertise within the Food and Drug Administration by—

(A) ensuring that Food and Drug Administration personnel involved in reviewing countermeasures for approval, licensure, or clearance are informed by the Assistant Secretary for Preparedness and Response on the material threat assessment conducted under section 247d–6b of title 42 for the agent or agents for which the countermeasure under review is intended;

(B) training Food and Drug Administration personnel regarding review of countermeasures for approval, licensure, or clearance;

(C) holding public meetings at least twice annually to encourage the exchange of scientific ideas; and

(D) establishing protocols to ensure that countermeasure reviewers have sufficient training or experience with countermeasures;

(4) maintain teams, composed of Food and Drug Administration personnel with expertise on countermeasures, including specific countermeasures, populations with special clinical needs (including children and pregnant women that may use countermeasures, as applicable and appropriate), classes or groups of countermeasures, or other countermeasure-related technologies and capabilities, that shall—

(A) consult with countermeasure experts, including countermeasure sponsors and applicants, to identify and help resolve scientific issues related to the approval, licensure, or clearance of countermeasures, through workshops or public meetings; and

(B) improve and advance the science relating to the development of new tools, standards, and approaches to assessing and evaluating countermeasures—

(i) in order to inform the process for countermeasure approval, clearance, and licensure; and

(ii) with respect to the development of countermeasures for populations with special clinical needs, including children and pregnant women, in order to meet the needs of such populations, as necessary and appropriate; and

(5) establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 247d–6a of title 42), security countermeasures (as defined in section 247d–6b of title 42), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.

(c) Final guidance on development of animal models

(1) In general

Not later than 1 year after March 13, 2013, the Secretary shall provide final guidance to industry regarding the development of animal models to support approval, clearance, or licensure of countermeasures referred to in subsection (a) when human efficacy studies are not ethical or feasible.

(2) Authority to extend deadline

The Secretary may extend the deadline for providing final guidance under paragraph (1) by not more than 6 months upon submission by the Secretary of a report on the status of such guidance to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(d) Development and animal modeling procedures

(1) Availability of animal model meetings

To facilitate the timely development of animal models and support the development, stockpiling, licensure, approval, and clearance of countermeasures, the Secretary shall, not later than 180 days after March 13, 2013, establish a procedure by which a sponsor or applicant that is developing a countermeasure for which human efficacy studies are not ethical or practicable, and that has an approved investigational new drug application or investigational device exemption, may request and receive—

(A) a meeting to discuss proposed animal model development activities; and

(B) a meeting prior to initiating pivotal animal studies.

(2) Pediatric models

To facilitate the development and selection of animal models that could translate to pediatric studies, any meeting conducted under paragraph (1) shall include discussion of animal models for pediatric populations, as appropriate.

(e) Review and approval of countermeasures

(1) Material threat

When evaluating an application or submission for approval, licensure, or clearance of a countermeasure, the Secretary shall take into account the material threat posed by the chemical, biological, radiological, or nuclear agent or agents identified under section 247d–6b of title 42 for which the countermeasure under review is intended.

(2) Review expertise

When practicable and appropriate, teams of Food and Drug Administration personnel reviewing applications or submissions described under paragraph (1) shall include a reviewer with sufficient training or experience with countermeasures pursuant to the protocols established under subsection (b)(3)(D).

(f) Regulatory management plan

(1) Definition

In this subsection, the term ''eligible countermeasure'' means—

(A) a security countermeasure with respect to which the Secretary has entered into a procurement contract under section 247d–6b(c) of title 42; or

(B) a countermeasure with respect to which the Biomedical Advanced Research and Development Authority has provided funding under section 247d–7e of title 42 for advanced research and development.

(2) Regulatory management plan process

The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority, shall establish a formal process for obtaining scientific feedback and interactions regarding the development and regulatory review of eligible countermeasures by facilitating the development of written regulatory management plans in accordance with this subsection.

(3) Publication

The Secretary shall make available on the internet website of the Food and Drug Administration information regarding regulatory management plans, including—

(A) the process by which an applicant may submit a request for a regulatory management plan;

(B) the timeframe by which the Secretary is required to respond to such request;

(C) the information required for the submission of such request;

(D) a description of the types of development milestones and performance targets that could be discussed and included in such plans; and

(E) contact information for beginning the regulatory management plan process.

(4) Submission of request and proposed plan by sponsor or applicant

(A) In general

A sponsor or applicant of an eligible countermeasure may initiate the process described under paragraph (2) upon submission of a written request to the Secretary. Such request shall include a proposed regulatory management plan.

(B) Timing of submission

A sponsor or applicant may submit a written request under subparagraph (A) after the eligible countermeasure has an investigational new drug or investigational device exemption in effect.

(C) Response by Secretary

The Secretary shall direct the Food and Drug Administration, upon submission of a written request by a sponsor or applicant under subparagraph (A), to work with the sponsor or applicant to agree on a regulatory management plan within a reasonable time not to exceed 90 days. If the Secretary determines that no plan can be agreed upon, the Secretary shall provide to the sponsor or applicant, in writing, the scientific or regulatory rationale why such agreement cannot be reached.

(5) Plan

The content of a regulatory management plan agreed to by the Secretary and a sponsor or applicant shall include—

(A) an agreement between the Secretary and the sponsor or applicant regarding developmental milestones that will trigger responses by the Secretary as described in subparagraph (B);

(B) performance targets and goals for timely and appropriate responses by the Secretary to the triggers described under subparagraph (A), including meetings between the Secretary and the sponsor or applicant, written feedback, decisions by the Secretary, and other activities carried out as part of the development and review process; and

(C) an agreement on how the plan shall be modified, if needed.

(6) Milestones and performance targets

The developmental milestones described in paragraph (5)(A) and the performance targets and goals described in paragraph (5)(B) shall include—

(A) feedback from the Secretary regarding the data required to support the approval, clearance, or licensure of the eligible countermeasure involved;

(B) feedback from the Secretary regarding the data necessary to inform any authorization under section 360bbb–3 of this title;

(C) feedback from the Secretary regarding the data necessary to support the positioning and delivery of the eligible countermeasure, including to the Strategic National Stockpile;

(D) feedback from the Secretary regarding the data necessary to support the submission of protocols for review under section 355(b)(5)(B) of this title;

(E) feedback from the Secretary regarding any gaps in scientific knowledge that will need resolution prior to approval, licensure, or clearance of the eligible countermeasure and plans for conducting the necessary scientific research;

(F) identification of the population for which the countermeasure sponsor or applicant seeks approval, licensure, or clearance and the population for which desired labeling would not be appropriate, if known; and

(G) as necessary and appropriate, and to the extent practicable, a plan for demonstrating safety and effectiveness in pediatric populations, and for developing pediatric dosing, formulation, and administration with respect to the eligible countermeasure, provided that such plan would not delay authorization under section 360bbb–3 of this title, approval, licensure, or clearance for adults.

(7) Prioritization

(A) Plans for security countermeasures

The Secretary shall establish regulatory management plans for all security countermeasures for which a request is submitted under paragraph (4)(A).

(B) Plans for other eligible countermeasures

The Secretary shall determine whether resources are available to establish regulatory management plans for eligible countermeasures that are not security countermeasures. If resources are available to establish regulatory management plans for eligible countermeasures that are not security countermeasures, and if resources are not available to establish regulatory management plans for all eligible countermeasures for which requests have been submitted, the Director of the Biomedical Advanced Research and Development Authority, in consultation with the Commissioner, shall prioritize which eligible countermeasures may receive regulatory management plans.

(g) Annual report

Not later than 180 days after March 13, 2013, and annually thereafter, the Secretary shall make publicly available on the Web site of the Food and Drug Administration a report that details the countermeasure development and review activities of the Food and Drug Administration, including—

(1) with respect to the development of new tools, standards, and approaches to assess and evaluate countermeasures—

(A) the identification of the priorities of the Food and Drug Administration and the progress made on such priorities; and

(B) the identification of scientific gaps that impede the development, approval, licensure, or clearance of countermeasures for populations with special clinical needs, including children and pregnant women, and the progress made on resolving these challenges;

(2) with respect to countermeasures for which a regulatory management plan has been agreed upon under subsection (f), the extent to which the performance targets and goals set forth in subsection (f)(4)(B) and the regulatory management plan have been met, including, for each such countermeasure—

(A) whether the regulatory management plan was completed within the required timeframe, and the length of time taken to complete such plan;

(B) whether the Secretary adhered to the timely and appropriate response times set forth in such plan; and

(C) explanations for any failure to meet such performance targets and goals;

(3) the number of regulatory teams established pursuant to subsection (b)(4), the number of products, classes of products, or technologies assigned to each such team, and the number of, type of, and any progress made as a result of consultations carried out under subsection (b)(4)(A);

(4) an estimate of resources obligated to countermeasure development and regulatory assessment, including—

(A) Center-specific objectives and accomplishments; and

(B) the number of full-time equivalent employees of the Food and Drug Administration who directly support the review of countermeasures;

(5) the number of countermeasure applications and submissions submitted, the number of countermeasures approved, licensed, or cleared, the status of remaining submitted applications and submissions, and the number of each type of authorization issued pursuant to section 360bbb–3 of this title;

(6) the number of written requests for a regulatory management plan submitted under subsection (f)(3)(A), the number of regulatory management plans developed, and the number of such plans developed for security countermeasures; and

(7) the number, type, and frequency of meetings between the Food and Drug Administration and—

(A) sponsors of a countermeasure as defined in subsection (a); or

(B) another agency engaged in development or management of portfolios for such countermeasures, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense.

(h) Accelerating countermeasure development and review during an emergency

(1) Acceleration of countermeasure development and review

The Secretary may, at the request of the sponsor of a countermeasure, during a domestic, military, or public health emergency or material threat described in section 360bbb–3a(a)(1)(C) of this title, expedite the development and review of countermeasures that are intended to address such domestic, mili-

tary, or public health emergency or material threat for approval, licensure, clearance, or authorization under this title or section 262 of title 42.

(2) Actions

The actions to expedite the development and review of a countermeasure under paragraph (1) may include the following:

(A) Expedited review of submissions made by sponsors of countermeasures to the Food and Drug Administration, including rolling submissions of countermeasure applications and other submissions.

(B) Expedited and increased engagement with sponsors regarding countermeasure development and manufacturing, including—

(i) holding meetings with the sponsor and the review team and providing timely advice to, and interactive communication with, the sponsor regarding the development of the countermeasure to ensure that the development program to gather the nonclinical and clinical data necessary for approval, licensure, clearance, or authorization is as efficient as practicable;

(ii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iii) assigning a cross-disciplinary project lead for the review team to facilitate;

(iv) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; and

(v) streamlining the review of approved, licensed, cleared, or authorized countermeasures to treat or prevent new or emerging threats, including the review of any changes to such countermeasures.

(C) Expedited issuance of guidance documents and publication of other regulatory information regarding countermeasure development and manufacturing.

(D) Other steps to expedite the development and review of a countermeasure application submitted for approval, licensure, clearance, or authorization, as the Secretary determines appropriate.

(3) Limitation of effect

Nothing in this subsection shall be construed to require the Secretary to grant, or take any other action related to, a request of a sponsor to expedite the development and review of a countermeasure for approval, licensure, clearance, or authorization under paragraph (1).

(i) Third party evaluation of tests used during an emergency

(1) In general

For purposes of conducting evaluations regarding whether an in vitro diagnostic product (as defined in section 809.3 of title 21, Code of Federal Regulations (or any successor regulations)) for which a request for emergency use authorization is submitted under section 360bbb–3 of this title meets the criteria for issuance of such authorization, the Secretary may, as appropriate, consult with persons with appropriate expertise with respect to such evaluations or enter into cooperative agreements or contracts with such persons under which such persons conduct such evaluations and make such recommendations, including, as appropriate, evaluations and recommendations regarding the scope of authorization and conditions of authorization.

(2) Requirements regarding evaluations and recommendations

(A) In general

In evaluating and making recommendations to the Secretary regarding the validity, accuracy, and reliability of in vitro diagnostic products, as described in paragraph (1), a person shall consider and document whether the relevant criteria under subsection (c)(2) of section 360bbb–3 of this title for issuance of authorization under such section are met with respect to the in vitro diagnostic product.

(B) Written recommendations

Recommendations made by a person under this subsection shall be submitted to the Secretary in writing, and shall include the reasons for such recommendation and other information that may be requested by the Secretary.

(3) Rule of construction

Nothing in this subsection shall be construed to require the Secretary to consult with, or enter into cooperative agreements or contracts with, persons as described in paragraph (1) for purposes of authorizing an in vitro diagnostic product or otherwise affecting the emergency use authorization authorities under this section or section 360bbb–3 of this title.

(June 25, 1938, ch. 675, § 565, as added Pub. L. 109–417, title IV, § 404, Dec. 19, 2006, 120 Stat. 2875; amended Pub. L. 113–5, title III, §§ 303–306, Mar. 13, 2013, 127 Stat. 185–190; Pub. L. 116–22, title V, § 503, June 24, 2019, 133 Stat. 951; Pub. L. 117–328, div. FF, title II, §§ 2501, 2502(a), Dec. 29, 2022, 136 Stat. 5796, 5797.)

Editorial Notes

AMENDMENTS

2022—Subsec. (h). Pub. L. 117–328, § 2501, added subsec. (h).

Subsec. (i). Pub. L. 117–328, § 2502(a), added subsec. (i).

2019—Subsec. (f)(3) to (5). Pub. L. 116–22, § 503(1), (2), added par. (3) and redesignated former pars. (3) and (4) as (4) and (5), respectively. Former par. (5) redesignated (6).

Subsec. (f)(6). Pub. L. 116–22, § 503(1), (3), redesignated par. (5) as (6) and, in introductory provisions, substituted ''paragraph (5)(A)'' for ''paragraph (4)(A)'' and ''paragraph (5)(B)'' for ''paragraph (4)(B)''. Former par. (6) redesignated (7).

Subsec. (f)(7). Pub. L. 116–22, § 503(1), redesignated par. (6) as (7).

Subsec. (f)(7)(A). Pub. L. 116–22, § 503(4), substituted ''paragraph (4)(A)'' for ''paragraph (3)(A)''.

2013—Pub. L. 113–5, § 304(1), substituted ''Countermeasure development, review, and technical assistance'' for ''Technical assistance'' in section catchline.

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