or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title;

(B) is authorized for investigational use under section 355, 360b, or 360j of this title or section 351 of the Public Health Service Act [42 U.S.C. 262]; or

(C) is authorized for use under section 360bbb–3 of this title or section 360bbb–3a of this title.

(June 25, 1938, ch. 675, § 564B, as added Pub. L. 113–5, title III, § 302(d), Mar. 13, 2013, 127 Stat. 185; amended Pub. L. 114–255, div. A, title III, § 3088(d), Dec. 13, 2016, 130 Stat. 1149; Pub. L. 116–22, title VII, § 705(d), June 24, 2019, 133 Stat. 964.)

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.)

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.