(c) Current good manufacturing practice

(1) In general

The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including requirements under section 351 or 360j(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 360j(f)(2) of this title.

(2) Effect

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

(d) Emergency dispensing

The requirements of subsections (b) and (f) of section 353, section 354, and section 360j(e) of this title shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because it is dispensed without an individual prescription, if—

(1) the product is dispensed during the circumstances described in subsection (a)(1)(C); and

(2) such dispensing without an individual prescription occurs—

(A) as permitted under the law of the State in which the product is dispensed; or

(B) in accordance with an order issued by the Secretary, for the purposes and duration of the circumstances described in subsection (a)(1)(C).

(e) Emergency use instructions

(1) In general

The Secretary, acting through an appropriate official within the Department of Health and Human Services, may create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning such product's approved, licensed, or cleared conditions of use.

(2) Effect

Notwithstanding any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], a product shall not be considered an unapproved product and shall not be deemed adulterated or misbranded under this chapter because of the issuance of emergency use instructions under paragraph (1) with respect to such product or the introduction or delivery for introduction of such product into interstate commerce accompanied by such instructions—

(A) during an emergency response to an actual emergency that is the basis for a determination described in subsection (a)(1)(C); or

(B) by a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, in preparation for an emergency response.

(June 25, 1938, ch. 675, §564A, as added Pub. L. 113–5, title III, §302(b), Mar. 13, 2013, 127 Stat. 183; amended Pub. L. 114–255, div. A, title III, §3088(c), Dec. 13, 2016, 130 Stat. 1149; Pub. L. 116–22, title VII, §705(c), June 24, 2019, 133 Stat. 964.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsecs. (b)(3), (c)(2), and (e)(2), 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—Subsec. (e)(2)(A). Pub. L. 116–22 substituted ''subsection (a)(1)(C)'' for ''subsection (a)(1)(C)(i)''.

2016—Subsec. (a)(1)(A). Pub. L. 114–255, §3088(c)(1), inserted '', conditionally approved under section 360ccc of this title,'' after ''subchapter''.

Subsec. (d). Pub. L. 114–255, §3088(c)(2), substituted ''subsections (b) and (f) of section 353, section 354, and section 360j(e) of this title'' for ''sections 353(b) and 360j(e) of this title'' in introductory provisions.

§360bbb–3b. Products held for emergency use

It is not a violation of any section of this chapter or of the Public Health Service Act [42 U.S.C. 201 et seq.] for a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, to introduce into interstate commerce a product (as defined in section 360bbb–3(a)(4) of this title) intended for emergency use, if that product—

(1) is intended to be held and not used; and

(2) is held and not used, unless and until that product—

(A) is approved, cleared, or licensed under section 355, 360(k), 360b, or 360e of this title 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.)

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;