

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, under paragraph (1), extended the expiration date and authorized the introduction or delivery for introduction into interstate commerce of such product after the expiration date provided by the manufacturer.

(4) Expiration date

For purposes of this subsection, the term “expiration date” means the date established through appropriate stability testing required by the regulations issued by the Secretary to ensure that the product meets applicable standards of identity, strength, quality, and purity at the time of use.

(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)(i); 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.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subssecs. (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

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 355¹ 360b, or 360j of this title or

¹ So in original. Probably should be followed by a comma.

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.

(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.)

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

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-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.