Subsec. (g). Pub. L. 113–5, § 302(a)(6)(A), substituted ''Review and revocation'' for ''Revocation'' in heading.

Subsec. (g)(1). Pub. L. 113–5, § 302(a)(6)(B), inserted at end ''As part of such review, the Secretary shall regularly review the progress made with respect to the approval, licensure, or clearance of—

''(A) an unapproved product for which an authorization was issued under this section; or

''(B) an unapproved use of an approved product for which an authorization was issued under this section.''

Subsec. (g)(2). Pub. L. 113–5, § 302(a)(6)(C), amended par. (2) generally. Prior to amendment, text read as follows: ''The Secretary may revoke an authorization under this section if the criteria under subsection (c) of this section for issuance of such authorization are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.''

Subsec. (h)(1). Pub. L. 113–5, § 302(a)(7), inserted at end ''The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.''

Subsec. (j)(4). Pub. L. 113–5, § 302(a)(8), added par. (4).

Subsec. (m). Pub. L. 113–5, § 302(a)(9), added subsec. (m).

2004—Pub. L. 108–276 amended section generally, substituting provisions of subsecs. (a) to (*l*) for similar former provisions, except for additional provisions in subsec. (b)(1) allowing Secretary to authorize use of medical products in actual or potential domestic and public health emergencies in addition to actual or potential military emergencies.

§ 360bbb–3a. Emergency use of medical products

(a) Definitions

In this section:

(1) Eligible product

The term ''eligible product'' means a product that—

(A) is approved or cleared under this subchapter or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262];

(B)(i) is intended for use to prevent, diagnose, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents; or

(ii) is intended for use to prevent, diagnose, or treat a serious or life-threatening disease or condition caused by a product described in clause (i); and

(C) is intended for use during the circumstances under which—

(i) a determination described in subparagraph (A), (B), or (C) of section 360bbb–3(b)(1) of this title has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(ii) the identification of a material threat described in subparagraph (D) of section 360bbb–3(b)(1) of this title has been made pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b].

(2) Product

The term ''product'' means a drug, device, or biological product.

(b) Expiration dating

(1) In general

The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if—

(A) the expiration date extension is intended to support the United States ability to protect—

(i) the public health; or

(ii) military preparedness and effectiveness; and

(B) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

(2) Requirements and conditions

Any extension of an expiration date under paragraph (1) shall, as part of the extension, identify—

(A) each specific lot, batch, or other unit of the product for which extended expiration is authorized;

(B) the duration of the extension; and

(C) any other requirements or conditions as the Secretary may deem appropriate for the protection of the public health, which may include requirements for, or conditions on, product sampling, storage, packaging or repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing or retesting, or product disposition.

(3) 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, 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 sections 353(b) and 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.)

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.

§ 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), or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262];

(B) is authorized for investigational use under section 355 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.

(June 25, 1938, ch. 675, § 564B, as added Pub. L. 113–5, title III, § 302(d), Mar. 13, 2013, 127 Stat. 185.)

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.

§ 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