**(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