LII > U.S. Code > Title 21. FOOD AND DRUGS

- > Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT
- > Subchapter V. DRUGS AND DEVICES
- > Part E. General Provisions Relating to Drugs and Devices
- > Section 360bbb-3b. Products held for emergency use

21 U.S. Code § 360bbb-3b. Products held for emergency use

U.S. Code Notes

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

1 of 3 4/13/20, 2:17 PM

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.)

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2 of 3 4/13/20, 2:17 PM

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[LII]

3 of 3 4/13/20, 2:17 PM