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21 U.S. Code § 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, conditionally approved under section 360ccc of this title, 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.