



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Emergency Use Authorization Declaration

AGENCY: U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the *Federal Food, Drug, and Cosmetic (FD&C) Act*. On July 15, 2026, the Secretary of War determined under the FD&C that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with a chemical, biological, radiological, or nuclear agent or agents; or an attack by an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. Injuries arising from these attacks may cause those forces to experience moderate to severe acute pain and place them at risk of developing life-threatening hemodynamic instability, including shock or respiratory distress. On the basis of this determination, the Secretary of HHS declared on August 31, 2026, pursuant to the FD&C Act, that circumstances exist justifying the authorization of emergency use of drugs identified and supported by the Department of War (DOW) as addressing an unmet military operations-related medical need for use to manage moderate to severe acute pain in casualties caused by, or associated with, an emergency involving biological, chemical, radiological, or nuclear agent or agents, or agents of military combat, including firearms, projectiles, and explosive devices, that may cause, or may otherwise be associated with, an imminently life-threatening and specific risk to U.S. military forces, subject to the terms of any authorization issued under that section.

DATES: The determination was effective July 15, 2026, and the declaration was effective August 31, 2026.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, telephone at (202) 260-0365 or via email at paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, HHS has the ability to take certain steps to help facilitate the availability of medical countermeasures based on one of four determinations under section 564(b): (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (“CBRN”) agent or agents; (2) the identification of a material threat by the Secretary of the Homeland Security pursuant to section 319F-2 of the *Public Health Service (PHS) Act*¹ sufficient to affect national security or the health and security of U.S. citizens living abroad; (3) a determination by the Secretary of Defense [War] that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a CBRN agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; or (4) a determination by the Secretary [of HHS] that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may declare that circumstances exist that justify the issuance of emergency use authorizations (EUAs), at which point the Commissioner of the U.S. Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA or EUAs authorizing the emergency use of an unapproved medical product or an unapproved use of an approved medical product in certain emergency circumstances, if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

II. Determination by the Secretary of War

On July 15, 2026 the Secretary of War determined, pursuant to sec. 564(b)(1)(B) of the FD&C Act, that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with a chemical, biological, radiological, or nuclear agent or agents; or an attack by an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces (including agents of military combat such as firearms, projectiles, and explosive devices).

Injuries arising from these attacks may cause U.S. military forces to experience moderate to severe acute pain and place them at risk of developing life-threatening hemodynamic instability, including shock or respiratory distress.

III. Declaration of the Secretary of HHS

On August 31, 2026, on the basis of the Secretary of War's determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of drugs identified and supported by the DOW as addressing an unmet military operations-related medical need for use to manage moderate to severe acute pain in casualties caused by, or associated with, an emergency involving biological, chemical, radiological, or nuclear agent or agents, or agents of military combat, including firearms, projectiles, and explosive devices, that may cause, or may otherwise be associated with, an imminently life-threatening and specific risk to U.S. military forces, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the Federal Register as required under section 564 of the FD&C Act.

Robert F. Kennedy, Jr.,
Secretary,
Health and Human Services.

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¹ 42 U.S.C. 247d-6b, which states: “[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.”