



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On August 18, 2025, the Secretary determined, pursuant to his authority under the FD&C Act, that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World Screwworm (*Cochliomyia hominivorax*) (NWS).

DATES: The determination and declaration were effective August 18, 2025.

FOR FURTHER INFORMATION CONTACT: Tristan Colonius, Chief Veterinary Officer, U.S. Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, Tristan.colonius@fda.hhs.gov, 301-796-2624.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the Federal Food, Drug, and Cosmetic Act (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 sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States 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 United States 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 United States 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 Emergency Use Authorization (EUA), at which point the Commissioner of Food and Drugs of the U.S. Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product, if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The Commissioner of Food and Drugs requested that the Secretary issue the declaration to allow FDA to take measures based on information currently available about NWS. The determination that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*), and the declaration that circumstances exist justifying the authorization of emergency use of animal drugs to treat or

prevent NWS myiasis in animals by the Secretary, enable the Commissioner of Food and Drugs to issue EUAs for animal drugs for prevention or treatment of New World Screwworm myiasis.

II. Determination by the Secretary of Health and Human Services

On August 18, 2025, I determined, pursuant to my authority under section 564(b)(1)(C) of the FD&C Act, that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World Screwworm (*Cochliomyia hominivorax*).

III. Declaration of the Secretary of Health and Human Services

On August 18, 2025, pursuant to section 564(b)(1) of the FD&C Act and subject to the terms of any authorization issued under that section, I declare that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent New World Screwworm myiasis in animals. This declaration remains in effect until the declaration is terminated in accordance with section 564 of the FD&C Act.

Robert F. Kennedy, Jr.,

Secretary,

U.S. Department of Health and Human Services.

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