

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Termination, By Expiration, of Declaration of Emergency Justifying Emergency Use Authorization of Anthrax Vaccine Adsorbed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice, under the Federal Food, Drug, and Cosmetic Act (the act), of the termination, by expiration, of the declaration of emergency justifying emergency use authorization of Anthrax Vaccine Adsorbed (AVA) that was issued by the former Secretary of Health and Human Services Secretary Tommy G. Thompson (the former HHS Secretary) on January 14, 2005. The declaration of emergency terminated by expiration on January 14, 2006, which is the end of the 1-year period that began on the date that the declaration was made. Under the act, advance notice of the termination of the declaration was provided to the Department of Defense.

DATES: The Notice is effective as of [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism Policy and Planning (HF-29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4067.

SUPPLEMENTARY INFORMATION:

I. Background

On December 10, 2004, the Deputy Secretary of Defense determined, under section 564(b)(1)(B) of the act (21 U.S.C. 360bbb-3(b)(1)(B)), that there was a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On the basis of such determination and under section 564(b)(1) of the act, the former HHS Secretary declared an emergency justifying the authorization of the emergency use of Anthrax Vaccine Adsorbed. A notice of the determination of the Deputy Secretary of Defense and the declaration of the former HHS Secretary was published in the **Federal Register** of February 2, 2005 (70 FR 5452).

II. Advance Notice of Termination

Under section 564(b)(3) of the act, the FDA Commissioner provided advance notice of the termination of the former HHS Secretary's declaration of emergency to the Department of Defense.

The January 2006 letter notifying the Department of Defense of the termination of the declaration of emergency follows:

William Winkenwerder, Jr., M.D.,
Assistant Secretary of Defense for Health Affairs,
The Pentagon,
Washington, D.C. 20301-1200

Dear Dr. Winkenwerder:

This letter is to provide advance notice of the termination of the above-referenced declaration of emergency that was issued by Secretary of Health and Human Services Tommy G. Thompson on January 14, 2005, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3.

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In accordance with section 564(b)(2)(A)(ii) of the Act, the declaration of emergency will terminate by expiration on January 14, 2006, which is the end of the one year period that began on the date that the declaration was made. This advance notice of termination will be published in the **Federal Register**, pursuant to section 564(b)(4) of the Act.

Sincerely,

Andrew C. von Eschenbach, M.D.

Acting Commissioner of Food and Drugs

Dated: January 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S