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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declaration Regarding Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services is issuing this notice pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act to justify the emergency use of Anthrax Vaccine Adsorbed (AVA) for prevention of inhalation anthrax. The Secretary provides notice of the determination of the Department of Defense that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. The Secretary also provides notice that, on the basis of such determination, he has declared an emergency justifying the authorization of the emergency use of AVA.

DATES: This Notice and the referenced declaration are effective as of January 14, 2005. The determination of the Department of Defense is effective as of December 10, 2004.

FOR FURTHER INFORMATION CONTACT: Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness, (202) 205-2882.

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SUPPLEMENTARY INFORMATION:

I. Background

AVA was first licensed by the National Institutes of Health in November 1970. Upon the delegation of vaccine regulation to FDA in 1972, FDA undertook a comprehensive review of the safety, effectiveness, and labeling of all vaccines. See 21 CFR 601.25. Under this review, independent advisory panels evaluated the safety and effectiveness data of vaccines to assure that they met appropriate standards. The advisory panel that reviewed AVA concluded that it is safe, effective, and not misbranded, and FDA issued a proposal to adopt the panel's recommendation (the Bacterial Vaccines and Toxoids Efficacy Review). 50 FR 51002 (Dec. 13, 1985).

In March 2003, six plaintiffs, known as John and Jane Doe 1 through 6, filed suit in the United States District Court for the District of Columbia (the Court) seeking the Court to enjoin the Anthrax Vaccine Immunization Program (AVIP) of the Department of Defense, and to declare AVA an investigational drug when used for protection against inhalation anthrax. On December 22, 2003, the Court issued a preliminary injunction barring inoculations under

the AVIP in the absence of informed consent or a Presidential waiver of the informed consent requirement.

In the Federal Register of January 5, 2004 (69 FR 255), FDA published a final rule and final order in response to the report and recommendations of the independent advisory panel that reviewed the safety and effectiveness data pertaining to AVA. Following FDA's issuance of the final rule and final order, the Court lifted the preliminary injunction on January 7, 2004, except as it applied to the six Doe plaintiffs.

On October 27, 2004, the Court issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. The Court also enjoined operation of the AVIP for inoculation using AVA to prevent inhalation anthrax. On December 29, 2004, FDA reopened the comment period on the Bacterial Vaccine and Toxoids Efficacy Review for 90 days. As a result of the Court's October 27, 2004, order, the use of AVA for the prevention of inhalation anthrax under the AVIP is deemed an unapproved use of an approved product.

II. Determination of the Department of Defense

On December 10, 2004, pursuant to section 564(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1)(B), the Deputy Secretary of Defense determined that there

is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax.

By letter dated December 22, 2004, the Assistant Secretary of Defense for Health Affairs (Assistant Secretary) requested that the Food and Drug Administration issue an Emergency Use Authorization for the use of AVA for protection against inhalation anthrax. The letter of the Assistant Secretary states that the Deputy Secretary of Defense has assigned authority from the Secretary of Defense to make the statutory determination under section 564(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act.

III. Declaration of the Secretary of Health and Human Services

On December 10, 2004, the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. Pursuant to 21 U.S.C. § 360bbb-3(b) and on the basis of such determination, I hereby declare an emergency justifying the authorization of the emergency use of Anthrax Vaccine Adsorbed subject to the conditions described in the authorization issued under 21 U.S.C. § 360bbb(a).

Notice of the authorization issued under 21 U.S.C. § 360bbb(a) is provided elsewhere in this issue of the Federal Register.

Dated: January 14, 2005

Tommy G. Thompson

Secretary