



DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

DEC 10 2004

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201

Dear Mr. Secretary:

This letter is to request that you declare under section 564(b)(1) of the Federal Food Drug and Cosmetic Act an emergency justifying an Emergency Use Authorization for anthrax vaccine for protection against anthrax disease via inhalation exposure.

As called for in section 564(b)(1)(B) of that Act, I have determined there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. In making this determination, I have considered a classified November 2004 Intelligence Community assessment of the anthrax threat. This heightened risk has been and continues to be the basis for the DoD program of vaccinating personnel serving in the areas of the Central Command and Korea.

We have paused the DoD anthrax vaccination program due to a judicial mandate for additional public comments on an order issued by the Food and Drug Administration (FDA) in December 2003 reaffirming licensure of the vaccine for protection against anthrax via inhalation exposure. While the FDA acts to resolve that procedural issue, I have authorized the Assistant Secretary of Defense for Health Affairs to request from the Commissioner of Food and Drugs an Emergency Use Authorization to allow the timely resumption of the vaccination program.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Wolfowitz", with a long horizontal line extending to the right.

