



THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D C 20301-1200

HEALTH AFFAIRS

JUL 11 2005

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
Rockville, Maryland 20857

Dear Dr. Crawford:

This letter requests an extension of the January 27, 2005 Emergency Use Authorization for the Armed Forces, pending the upcoming FDA re-determination, following an additional opportunity for public comment, on the licensed use of Anthrax Vaccine Adsorbed (AVA) for protection against inhalational anthrax.

My EUA request of December 22, 2004, was for a period of six months based on the anticipated conclusion of the process of evaluating the additional public comments within that timeframe. The request noted the potential need for an extension. Your response of January 27, 2005, authorized the emergency use of AVA for protection against inhalational anthrax for a duration of six months, with a proviso that "this EUA may be extended within the duration of the declaration of emergency if the criteria under section 564(c) of the Act for issuance of such authorization are still met." The declaration of emergency was January 10, 2005, with a duration of one year, unless earlier terminated.

It now appears necessary to obtain an extension of the EUA for such time as necessary pending the upcoming FDA re-determination of the licensed use of AVA for protection against inhalational anthrax. The information presented in my letter of December 22 is still accurate, except to incorporate subsequent actions directed or approved by the FDA (e.g., later approved versions of the tri-fold brochure).

Thank you for your urgent attention to this request, as well as to the resolution of the licensed use of AVA for protection against inhalational anthrax.

Sincerely,

A handwritten signature in black ink that reads "William Winkenwerder, Jr." in a cursive script.

William Winkenwerder, Jr., MD