DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

28 March 2005

MEMORANDUM FOR FOOD & DRUG ADMINISTRATION
DIVISION OF DOCKETS MANAGEMENT

SUBJECT: Docket Number 1980N-0208, Final Rule & Final Order Involving Bacterial Vaccines and Toxoids

On behalf of the United States Air Force, we commend the Food & Drug Administration (FDA) for proposing the text for the Final Rule & Final Order Involving Bacterial Vaccines and Toxoids, as published on December 29, 2004 in the Federal Register. The finding of the proposed Final Rule & Final Order that the BioThrax anthrax vaccine is effective in preventing anthrax (regardless of route of exposure) codifies the FDA's long-held position on this topic and is a scientifically justified conclusion based on objective medical evidence.

The anthrax attacks in October 2001 illustrated the risk of an unprotected population in an environment contaminated with a biological warfare agent. The initial outbreaks caused panic, and subsequent scares and hoaxes only increased the alarm. Several thousand people, including congressional staffers, mail handlers and media personnel, needed protection using antibiotics and vaccinations--a process that takes extended periods of time and a substantial logistical organization to administer properly. In an operational environment, this type of post-attack recovery process, combined with the inevitable fear and uneasiness in an unprotected population, can have a detrimental impact on our ability to execute our missions.

Anthrax vaccinations are the best single countermeasure we have against this significant threat. As a pre-exposure form of protection, anthrax vaccinations are a key enabler in our force protection efforts. They allow our Airmen to survive an attack, have confidence they are protected, and continue operations. Additionally, there is an inherent deterrent value with regard to our adversaries when our force is protected against this particular biological warfare threat.

The Department of Defense has compiled clinical experience with more than 5.1 million doses of anthrax vaccine administered to over 1.3 million people since March 1998. During this time, a body of pseudo-scientific writings related to anthrax vaccine has accrued on various Internet sites and in other media. We are grateful for FDA's consistent reliance on objective, verifiable, scientifically valid evidence as its standard for evaluating safety and effectiveness. We appreciate and rely on the FDA's continued scientific excellence for the benefit of our healthcare beneficiaries in the Military Health System.

GEORGE PEACH TAYLOR, JR.
Lieutenant General, USAF, MC, CFS
Surgeon General

RONALD E. KEYS, Lt Gen, USAF
Deputy Chief of Staff
Air & Space Operations