THE ASSISTANT SECRETARY OF DEFENSE

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HEALTH AFFAIRS

DEC 22 2005

MEMORANDUM FOR SURGEON GENERAL OF THE ARMY (Kevin)
SURGEON GENERAL OF THE NAVY (Don)
SURGEON GENERAL OF THE AIR FORCE (Peach)

SUBJECT: Continuation of the Anthrax Vaccine Immunization Program (AVIP)

On December 15, 2005, the Food & Drug Administration (FDA) issued a Final Rule and Final Order on the license status of anthrax vaccine adsorbed (AVA). After reviewing extensive scientific evidence and carefully considering comments from the public, the FDA again determined that AVA is licensed for the prevention of anthrax, regardless of route of exposure. Because its regulatory action removed the basis and need for an Emergency Use Authorization (EUA), it will not be necessary for DoD to seek renewal of the EUA for use of anthrax vaccine to prevent inhalation anthrax. The current EUA expires January 14, 2006.

In response to FDA's action, policy options for AVIP are now under review. Unless otherwise directed by the Secretary or Deputy Secretary of Defense, the Services are directed to continue implementation of AVIP as authorized in April 2005. This interim approach will protect the same personnel, and will continue to include an option to refuse and weekly reporting requirements.

Military clinics will now use a revised trifold brochure (posted at www.anthrax.mil/education) for education sessions. Brochures will be shipped with vaccine orders and can be ordered by email message at vaccines@amedd.army.mil. Services will transition to the revised educational materials also posted at the Military Vaccine Agency Web site (www.anthrax.mil, www.vaccines.mil/anthrax). Documentation, adverse-event follow-up and reporting, and other indicators of quality care will receive the full attention of clinical personnel. The Clinic Quality Improvement Program (described at www.vaccines.mil/CQIP) offers a tool for immunization clinics to enhance their patient services.

Bill

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