



ACQUISITION,  
TECHNOLOGY  
AND LOGISTICS

OFFICE OF THE UNDER SECRETARY OF DEFENSE

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FEB 19 2003

The Honorable Bob Stump  
Chairman  
Committee on Armed Services  
U.S. House of Representatives  
Washington, DC 20515-6035

Dear Mr. Chairman:

The conference report accompanying the Department of Defense Appropriations Act 2003, (H.R. Report No.107-732, page 315), requests the enclosed report be submitted to the congressional defense committees on the Department of Defense's Anthrax Vaccine Supply Preparedness. A similar letter has been provided to the other congressional defense committees.

Sincerely,



E. C. Aldridge, Jr.

Enclosures:  
As Stated

cc: The Honorable Ike Skelton  
Ranking Member



## **Report on Preparedness of the Anthrax Vaccine Supply**

This report is in response to a requirement from the House of Representatives October 9, 2002, Conference Report 107-732 for the FY03 Department of Defense (DoD) Appropriations Act.

“The conferees are concerned about the adequacy of the supply and production capacity for the only FDA-licensed anthrax vaccine currently available in the U.S. to protect our military and civilian defense personnel from the demonstrated and potential future threat of anthrax. The Secretary of Defense is directed to provide a report which assesses the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, the potential need for expanded production capacity to meet that need, and the need for a separate production capacity to mitigate risks of an event which could result in a halt to current vaccine production. The Secretary shall submit this report to the congressional defense committees within 90 days after enactment of this act.”

### **Assessment of the immediate and short-term preparedness and potential future total biowarfare defense need for the FDA-licensed anthrax vaccine, and the potential need for expanded production capacity to meet that need:**

The DoD has conducted an evaluation of projected Anthrax Vaccine Adsorbed (AVA) requirements and the industrial base. It concludes that the capacity at the BioPort facility in Lansing, Michigan, given present capabilities and absent major manufacturing interruptions, is adequate to meet currently projected DoD immunization requirements and other validated federal agency requirements through September 2006. However, the Department has received additional requests for AVA from other domestic and foreign sources that are not addressed in this analysis because they have not yet been validated as requirements. If these additional requests increase the requirement the current capacity at the Lansing facility would not be sufficient.

### **Assessment of the need for a separate production capacity to mitigate risks of an event that could result in a halt to current vaccine production:**

The DoD is reviewing all options associated with this issue. Efforts are currently underway to establish redundancy that will mitigate risks to a halt in vaccine production. An alternative site for potency testing is in the final stages of qualification for submission to the FDA. A secondary vaccine filling facility is currently being sought. New vaccine storage and animal testing facilities are under construction. Critical utilities for production are being expanded. A fourth production train is being validated and is expected to come on line during FY03. By employing these risk mitigation strategies, and in the absence of any unforeseen surge requirement for AVA, BioPort Corporation will meet DoD and other federal agency needs for AVA for the foreseeable future.