Summary Report on Supplemental Testing of Lot FAV 030 of Anthrax Vaccine Absorbed

1. Lot Identity

Anthrax Vaccine Adsorbed lot number FAV 030 manufactured by Michigan Biologic Products Institute (MBPI), Lansing, Michigan.

2. Testing Dates

Supplemental testing was performed at Michigan Biologic Products Institute (MBPI) beginning on 4 January 1998 and concluding on 13 March 1998. Samples were collected on 4 January 1998. Results were reported by MBPI on 8 May 1998.

3. Standard Operating Procedures (SOPs)

All tests were performed using the most recent version of the applicable MBPI SOPs. Some SOPs were updated after the test plan was written but before the testing began. Changes in the SOPs were technically acceptable, and had no detrimental effect on testing.

4. Testing Summary

The vaccine lot passed all supplemental testing. All testing was performed according to Food and Drug Administration (FDA) guidelines and MBPI SOPs. All results were acceptable, and all associated quality control samples were acceptable. The report issued by MBPI is an accurate reflection of the testing.

Minor deviations from the SOPs occurred during testing. These deviations had no impact on the results.

All steps of the sampling and testing were observed by Mitretek personnel.