Amendment #2 to RFP-NIH-NIAID-DMID-03-29
"Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine"

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-29
Amendment No.:	2
Issue Date:	June 11, 2003
Effective Date:	June 11, 2003
Proposal Due Date:	July 1, 2003, at 4:00 P.M. local time
Issued By:	Elizabeth Osinski Contracting Officer NIH/NIAID Contract Management Branch 6700 B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Elizabeth Osinski, Contracting Officer Eo43m@nih.gov
Name and Address of Offeror:	To All Potential Offerors

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this amendment. Failure to receive your acknowledgement of this amendment may result in the rejection of your offer. This amendment shall be acknowledged in the following manner:

- By acknowledging receipt of this amendment on each copy of the offer submitted.

RFP No. NIH-NIAID-DMID-03-29 is amended as follows:

The following item, Number 18. is added to page 8, Statement of Work of the RFP:

18. **Center for Disease Control (CDC) Interaction – Serological Assays -** The Center for Disease Control (CDC) will interact with all successful offerors ON AN EQUAL AND IMPARTIAL BASIS in providing assistance with the CDC serological assays and technology transfer. The extent to which CDC will assist successful offerors will be determined BASED ON THE NATURE OF THE REQUEST, AVAILABLE RESOURCES AND by agreement of all Government parties prior to the time the assistance is provided.

The following fourth and fifth paragraphs are added to page 3 of the RFP under Background:

Development of protective and safe vaccines against pathogens that do not allow for efficacy testing in humans has required implementation of new federal regulations to demonstrate efficacy in appropriate animal models referred to as the "Animal Rule." Information describing the animal rule and associated requirements may be found at the following web site:

http://www.fda.gov/cber/rules/humeffic.htm

The following information on Current Issues Related to Specific NIAID Biodefense Product Development Topics is scheduled to be posted on the following website on Friday, June 13, 2003, or as soon thereafter as it becomes available:

http://www.niaid.nih.gov/biodefense/ under Biodefense Research Funding in the article entitled, "Current Issues Related to Specific NIAID Biodefense Product Development Topics."

The websites referenced above are provided as background information only.