Amendment #1 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.:	1
Issue Date:	June 9, 2003
Effective Date:	June 9, 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:

- **SECTION M - EVALUATION FACTORS FOR AWARD, item 2. - COMPARATIVE IMPORTANCE OF PROPOSALS is deleted in its entirety and replaced with the following:**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, and SDB participation are also important to the overall contract award decision. Technical evaluation factors however are significantly more important than cost or price and SDB participation factors. In any case, the Government reserves the right to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government based on the evaluation factors set forth in this Section.

The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

- **SECTION I - CONTRACT CLAUSES, is modified to add the following**:

FAR 52.227-16, Additional Data Requirements (JUNE 1987)

FAR 52.219-25 - Small Disadvantaged Business Participation Program - Disadvantaged Status and Reporting

- **NOTE 16 to Offerors is added as follows:**

Offerors are reminded that initial proposals must contain a draft agreement signed by all parties involved outlining:
(1) procedures to be used for obtaining patent coverage and licensing of the resulting vaccine, and (2) procedures to be followed for the resolution of potential legal issues that may arise. Initial proposals that do not include this agreement will be returned to the offeror without further review and will not be scored. (Refer to Mandatory Criterion 4(a) on page 58)

- **The following are a list of questions and answers for this solicitation**:

1. Will a recombinant Protective Antigen (rPA) DNA-based vaccine product be immediately rejected solely based on the fact that it is a DNA-based product rather than a preformed protein-based product?

   No, a DNA-based product will not be rejected solely because it is a DNA-based product rather than a pre-formed protein-based product; however, this does not eliminate the requirement for the proposal to meet Mandatory requirement, 4(c) , among other mandatory criteria, in the RFP which states:

   4 (c). Given the timeline requirements for this vaccine development effort, it is also essential that efforts funded as a result of this RFP build on the most advanced vaccine candidates(s). Therefore, offerors that have generated the following will be eligible to apply for this award(s): 1) well characterized vialed rPA vaccine using a process amenable to intermediate scale manufacturing, 2) a developed plan for intermediate scale manufacturing and processing of rPA vaccine, and 3) pre-clinical rabbit toxicology and immunogenicity data.

2. Milestone plans are required for Milestones 1, 2, 3 and 7. Are milestone plans required for the other milestones?

   No, just the milestones listed above because the revised plans are deliverables for those milestones. For clarification, Milestones 1, 2, 3 and 7 also include initiation and implementation of associated activities. Therefore, budgets for these activities shall be linked to these milestones, as appropriate.