AMENDMENT TO NIAID SOLICITATION
"DEVELOPMENT OF A THIRD GENERATION ANTHRAX VACCINE"

Solicitation Number:	RFP NIH-NIAID-DMID-07-05
Amendment Number:	5
Amendment Issue Date:	September 6, 2006
Proposal Intent Response Sheet Due Date: **Proposal Due Date:**	July 19, 2006 UNCHANGED September 18, 2006, 4:00PM, Local Time UNCHANGED
Issued By:	Ross Kelley Contracting Officer NIAID, NIH, DHHS Office of Acquisitions, DEA 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20892-7612
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This amendment is issued 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 by identifying this amendment number and date on each copy of the offer submitted. Failure to receive your acknowledgement may result in the rejection of your offer.

If by virtue of this amendment you desire to change an offer already submitted, such change may be made by fax, letter or e-mail, provided each fax, letter or e-mail makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

Except as provided herein, all terms and conditions of the RFP remain unchanged and in full force and effect.

PURPOSE OF AMENDMENT:

1) **TO CHANGE THE MANDATORY QUALIFICATION CRITERIA IN SECTION M - EVALUATION FACTORS FOR AWARD, AND**

2) **TO CHANGE THE OBJECTIVE IN THE STATEMENT OF WORK. LANUAGE THAT HAS BEEN CHANGED BY THIS AMENDMENT IS HIGHLIGHTED.**

1) SECTION M - EVALUATION FACTORS FOR AWARD - PARAGRAPH (3), MANDATORY QUALIFICATION CRITERIA, IS DELETED IN ITS ENTIRETY AND REPLACED WITH THE FOLLOWING:

(3) MANDATORY QUALIFICATION CRITERIA

The mandatory qualification criteria establishes conditions that must be met **at the time of receipt of the Original Proposal submission** in the Office of Acquisitions, NIAID, in order for your proposal to be considered any further for award.

Listed below are the Mandatory Qualification Criteria. **The offeror must include all information that documents and/or supports the Mandatory Qualification Criteria in one clearly marked section at the front of the Technical Proposal.** Technical Proposals that are determined by the Project Officer and Contracting Officer not to meet the Mandatory Qualification Criteria will not be submitted for peer review and will not be considered any further for award.

Mandatory Qualification Criteria:

Documentation must be provided to verify that the proposed anthrax vaccine candidate meets the following minimum development status criteria:

a. As purified Protective antigen (PA) has been shown to be efficacious against B. anthracis spore challenge in animal models, the proposed vaccine must contain a PA component. The PA component may be proteinaceous or nucleotide-encoded.

   Required documentation: The offeror must provide, in this section of the Technical Proposal, a letter on official letterhead certifying that the proposed vaccine contains a PA component. In addition, the letter must be signed by an official legally authorized to bind the organization.

b. Offerors planning to use novel devices/technologies to facilitate the anthrax candidate vaccine dosing, must demonstrate that they have either of the following:

   1) a pre-Investigational Device Exemption (pre-IDE) with the candidate anthrax vaccine or a pre-IDE with another investigational biological product must be filed for the device with the U.S. Food and Drug Administration (FDA) to demonstrate the device is at a clinical-use development stage.

   OR

   2) an Investigational New Drug Application (IND) must be filed at the FDA with another investigational biological product using the proposed device, to demonstrate the device is at a clinical-use development stage.

   Required documentation: A copy of the documentation showing the filing with FDA must be provided in this section of the Technical Proposal.

   OR

   3) an Investigational Review Board (IRB) has determined that the device has been defined as a Non-significant Risk according to 21 CFR 812.2(b), *and* that the device has been previously used in the clinic with another product.

Required documentation: A copy of the documentation indicating that the Offeror's IRB classified the device as a Nonsignificant Risk and approved use of the device in a previous clinical trial; *and* documentation that the Offeror notified the IRB that the clinical trial was completed and that includes a summary of any device-related adverse events.

c. Data and results from a proof-of-concept study of the vaccine candidate in an anthrax spore challenge animal model which has demonstrated vaccine efficacy.

Required documentation: This may be in the form of a final study report or a peer-reviewed publication and must be provided in this section of the Technical Proposal.

JUSTIFICATION: By placing these Mandatory Qualification Criteria in this solicitation, the initial risk of selecting a product with unknown potential is reduced and ensures that the Government secures the best value for its limited product development funding and meets the urgent public health needs for this vaccine development effort.

2) **THE STATEMENT OF WORK - OBJECTIVE (PAGE 1 OF ATTACHMENT 4) IS DELETED IN ENTIRETY AND REPLACED WITH THE FOLLOWING:**

OBJECTIVE

The objective of this contract is to advance the development and testing of an anthrax vaccine candidate that possesses characteristics that shall improve upon the second generation anthrax vaccines. Such characteristics include the following:

1. Long-term stability of final product: Final product shall be suitable for storage in the Strategic National Stockpile (SNS). The vaccine shall be stable for extended periods of storage (i.e., 3 years or longer) at ambient/room temperature.

2. Rapid immune response: Final product shall need no more than two doses to elicit a protective response.

3. Ease of vaccine inoculation: Final product shall possess properties to enable rapid administration to large numbers of people following a bioterror incident and, therefore, shall utilize a platform that shall allow non-technical persons to perform inoculations or self-administration.

The contract shall support the development and testing of anthrax vaccine candidates possessing any one or all of the characteristics listed above, while maintaining a safety profile superior to the currently licensed anthrax vaccine. The Contractor shall advance anthrax vaccine development and methods for novel formulations/final vaccine presentation, new delivery platforms, adjuvants other than aluminum, and inclusion of additional antigens.

For the purposes of this contract, the anthrax vaccine must contain, in part, a Protective antigen (PA) component, as PA has been shown to be efficacious against *B. anthracis* spore challenge in animal models and has progressed through a proof-of-concept efficacy study in a relevant spore challenge animal model. Additionally, if the Contractor plans to use novel devices/technologies to facilitate the anthrax candidate vaccine dosing, they must have one of the following:

1. a pre-Investigational Device Exemption (pre-IDE) with the candidate anthrax vaccine or a pre-IDE with another investigational biological product must be filed for the device with the U.S. Food and Drug Administration (FDA) to demonstrate the device is at a clinical-use development stage.

OR

2. an Investigational New Drug Application (IND) must be filed at the FDA with another investigational biological product using the proposed device, to demonstrate the device is at a clinical-use development stage.

OR

3. an Investigational Review Board (IRB) has determined that the device has been defined as a Non-significant Risk according to 21 CFR 812.2(b), *and* that the device has been previously used in the clinic with another product.

***NOTE**: While the contract will provide funds to support the development of a Final Drug Product (FDP) to be adapted to a novel device, the contract will NOT provide funds for the development of a novel device.*

The base contract shall encompass the development, manufacturing, characterization, and non-clinical testing of the vaccine candidate based on defined milestones and timelines. Options for Phase 1 and Phase 2 Clinical Trial(s) may be exercised at the discretion of the Government.

END OF AMENDMENT # 5 TO RFP-NIH-DMID-07-05