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

Solicitation Number:	RFP NIH-NIAID-DMID-07-05
Amendment Number:	3
Amendment Issue Date:	August 15, 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:

TO DELETE AMENDMENT 2 IN ENTIRETY AND REPLACE IT WITH THE FOLLOWING:

1) **TO CHANGE THE STATEMENT OF WORK (ATTACHMENT 4) MILESTONES 6, 7 AND 9. LANUAGE THAT HAS BEEN CHANGED BY THIS AMENDMENT IS HIGHLIGHTED.**

1) PRODUCTION DEVELOPMENT MILESTONES, MILESTONES 6, 7 AND 9 ARE DELETED IN ENTIRETY AND REPLACED WITH THE FOLLOWING:

Milestone 6. Non-clinical General-Use Prophylaxis (GUP) Study(ies) in the Rabbit Model.

a. Aerosol Anthrax Spore-challenge Study(ies) -- *Within twelve (12) months of contract award*, initiate one or more aerosol anthrax spore-challenge study(ies) in the rabbit model using a GUP regimen to determine the efficacy and immunogenicity of the vaccine candidate in order to define immune correlates of protection in support of the CBER/FDA "Animal Rule" as outlined in 21 CFR 601.91(a)(1-4)..

1) Draft Non-clinical Rabbit GUP Protocol(s) -- *Within 10 months of contract award*, develop and submit a Draft Non-clinical Rabbit GUP Protocol(s) and provide the rationale for proposed study design(s) to the Project Officer.

2) Final Non-clinical Rabbit GUP Protocol -- *Within 30 calendar days of receipt of Project Officer comments*, revise the Draft Non-clinical Rabbit GUP Protocol as necessary and submit the Final Protocol for Project Officer approval. The Contractor must be in receipt of the Project Officer's written approval of the Final Protocol prior to study initiation.

3) Conduct the Non-clinical GUP studies in accordance with the approved Final Protocol.

4) Summary Interim Non-clinical Rabbit GUP Report -- *Within 14 weeks of study initiation*, prepare and submit a Summary Interim Non-clinical Rabbit GUP Report, for Project Officer review and approval, containing at a minimum, post-challenge survival data, and all raw and analyzed data available up to the post-challenge survival time point.

5) Final Rabbit GUP Report(s) -- *Within 30 calendar days after completion of the approved Non-clinical Rabbit GUP study(ies)*, prepare and submit a Final Rabbit GUP Report(s) to the Project Officer. Completion of Milestone 6 shall be based on delivery of the Non-clinical Rabbit GUP Study Report(s) and Project Officer determination of the acceptability of the Final Report(s).

Milestone 7. Non-clinical Post-Exposure Prophylaxis (PEP) Study in the Rabbit Model.

a. Aerosol Anthrax Spore-challenge PEP Study -- *Within 14 months of contract award*, initiate an aerosol anthrax spore-challenge PEP study in the rabbit model to determine if the candidate vaccine provides added value over antibiotic use alone in this animal model when used in conjunction with antibiotic therapy using a post-exposure regimen. Study design should define immune correlates of protection in support of the CBER/FDA "Animal Rule" as outlined in 21 CFR 601.91(a)(1-4).

1) Draft Non-clinical Rabbit PEP Protocol -- *Within 12 months of contract award*, develop and submit, for Project Officer review, a Draft Non-clinical Rabbit PEP Protocol and provide the rationale for the proposed study design(s).

2) Final Non-clinical Rabbit PEP Protocol -- *Within 30 calendar days of Project Officer review*, revise the Draft Protocol as necessary, and submit the Final Non-clinical Rabbit PEP Protocol for Project Officer approval. Project Officer written approval of the Final Protocol shall be required prior to study initiation.

3) Conduct the Non-clinical PEP study in accordance with the approved Final Protocol.

4) Summary Interim Non-clinical Rabbit PEP Report -- *Within 8 weeks of study initiation*, prepare and submit, for Project Officer review and approval, a Summary Interim Non-clinical Rabbit PEP Report containing, at a minimum, post-challenge survival data, and all raw and analyzed data available up to the post-challenge survival time point.

5) Final Non-clinical Rabbit PEP Study Report(s) -- *Within 30 calendar days after completion of the approved study,* prepare and submit a Final Non-clinical Rabbit PEP Study Report(s). Completion of Milestone 7 shall be based on delivery of the Non-clinical Rabbit PEP Study Report(s) and Project Officer determination of the acceptability of the Final Study Report(s).

Milestone 9. Non-clinical Post-Exposure Prophylaxis (PEP) Study in a Non-Human Primate (NHP) Model.

a. Aerosol Anthrax Spore-challenge PEP Study -- *Within 18 months of contract award*, initiate an aerosol anthrax spore-challenge PEP study in a NHP model to determine if the candidate vaccine provides added value when used in conjunction with antibiotic therapy over antibiotic use alone in this animal model. Study design should define immune correlates of protection in support of the CBER/FDA "Animal Rule" as outlined in 21 CFR 601.91(a)(1-4).

1) Draft Non-Clinical NHP PEP Protocol -- *Within 16 months of contract award*, develop and submit, for Project Officer review, a Draft Non-clinical NHP PEP Protocol and provide the rationale for the proposed study design.

2) Final Non-clinical NHP PEP Protocol -- *Within 30 calendar days of Project Officer review*, revise the Draft Protocol as necessary, and submit the Final Non-clinical NHP PEP Protocol for Project Officer approval. Project Officer approval of the Final Protocol shall be required prior to study initiation.

3) Conduct the Non-clinical NHP PEP study in accordance with the approved Final Protocol.

4) Summary Interim Non-clinical NHP PEP Report -- *Within 8 weeks of study initiation*, prepare and submit, for Project Officer review and approval, a Summary Interim Non-clinical NHP PEP Report containing at a minimum, post-challenge survival data, and all raw and analyzed data available up to the post-challenge survival time point.

5) Final Non-clinical NHP PEP Study Report(s) -- *Within 30 calendar days after completion of the approved study*, prepare and submit a Final Non-clinical NHP PEP Study Report. Completion of Milestone 9 shall be based on delivery of the Non-clinical NHP PEP Study Report and Project Officer determination of the acceptability of the Final Study Report.

END OF AMENDMENT # 3 TO RFP-NIH-DMID-07-05