

**BAA NIH-BARDA-NIAID-DMID-AI2007007  
Amendment #2 (Questions & Answers, 1<sup>st</sup> Posting)**

This Amendment provides questions submitted by potential offerors and the responses provided by the NIAID. **The responses are offered for information only and do not modify or become part of this solicitation.** This Amendment will be updated at least weekly to add any further questions and their related responses. **All potential offerors are advised to refer back to this Amendment for additional Q&As.**

**“Biodefense Vaccine Enhancement”**

<b>Amendment No.:</b>	2
<b>Amendment Issue Date:</b>	November 8, 2007 (Questions 1 – 15)
<b>Proposal Due Date/Time:</b>	January 22, 2008, at 3 P.M., EST <b>(UNCHANGED)</b>
<b>Issued By:</b>	Jordan T. Pulaski Contracting Officer OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612
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**Offerors must acknowledge receipt of the final posting of Amendment #2, on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.**

**The hour and date specified for receipt of proposals HAS NOT been extended.**

**A CUTOFF DATE FOR QUESTIONS HAS BEEN SET AT JANUARY 8, 2008.**

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**THE FOLLOWING PAGES PROVIDE ANSWERS CONCERNING A NUMBER OF INQUIRIES WE HAVE RECEIVED FOR THE ABOVE NUMBERED SOLICITATION:**

**Question 1.a.:**

Will this contract include funds for further development and research associated with getting an IND for clinical evaluation of these vaccines?

**Question 1.b.:**

Will it also provide funds for preparation of stable GMP grade material and it's testing in human volunteers?

**Question 1.c.:**

Specifically, will funds be available in a successful application to fund those phase I clinical trials?

**Response to 1.a., 1.b., and 1.c.:**

This issue is addressed in the Part A Option found in PART A – RESEARCH AND TECHNICAL OBJECTIVES, ATTACHMENT 5, on page 3 of 15.

**Question 1.d.:**

Also, what about phase 2 trials?

**Response 1.d.:**

Phase 2 Clinical Trials for anthrax vaccine candidates are addressed in PART B – RESEARCH AND TECHNICAL OBJECTIVES ATTACHMENT 9 on page 3 of 15.

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**Question 2:**

Can you confirm whether the pandemic flu (H5N1 Bird Flu) is covered by this solicitation?

**Response 2:**

Influenza is a NIAID Category C agent and is not eligible for consideration under this solicitation.

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**Question 3:**

Can you confirm that a Calivirus vaccine is an acceptable target for this RFP?

There are no accepted animal models for Caliciviruses infection or disease. Is there a mandatory qualification criterion that requires animal proof of concept data? Will the NIH/BARDA accept human clinical data in lieu of animal model data?

**Response 3:**

Caliciviruses are NIAID Category B agents and as such are eligible to be considered by this solicitation. Please note the statement in page 1, second paragraph of ATTACHMENT 4, “To guide progress toward the goal of public health preparedness, the HHS PHEMCE Implementation Plan provides insight into the current priorities for medical countermeasure development.”

There are no mandatory qualification criteria for this solicitation. If human clinical data exist they will be considered in lieu of animal data.

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**Question 4:**

On page 2 of 3 of Attachment 4, last paragraph, "Part B...", the last two sentences indicate that, "The demonstrated production capability for rPA anthrax vaccine candidates shall be greater than 2000 liter (L) cGMP (current Good Manufacturing Process) scale for Bulk Drug Substance (BDS). The rPA component of the Final Drug Product (FDP) will be from the BDS manufactured at 2000 L scale or greater."

Our question is, if a prospective offeror has a robust manufacturing process that yields a quantity of BDS per manufacturing run that is large enough to produce over 200,000 doses of vaccine per manufacturing run at a scale less than 2000 L, would it be acceptable to NIAID for the offeror to propose to perform the work at a scale less than 2000 L, rather than scaling up to 2000 L, or would NIAID consider this to be a non-responsive/non-compliant proposal?

**Response 4:**

If the rPA anthrax vaccine candidate you would like to propose for consideration has production and performance characteristics that meet or can be shown to be equivalent to the criteria described in the following paragraph, your proposal will be considered. Please refer to the information provided in the last paragraph on page 3 and the first paragraph on page 4 of Attachment 4.

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**Question 5:**

On page 4 there is a brief description of vaccine candidates eligible for support under Part A of the proposal containing certain long term stability characteristic. Specifically, stability of the vaccine for 3 years at 35 degrees Centigrade is mentioned as a minimum. My question is whether **Fahrenheit was actually intended?** Would this stability profile (at 35 degrees Centigrade) be required before one was eligible to apply to this request?

**Response 5:**

As further clarification to the temperature requirement set forth on page 4 (Article B.1.) of this BAA, this solicitation will support a Research and Development Contract that is designed to combine novel materials and/or processes with candidate biodefense vaccines to enhance their thermal stability.

Specifically, the objective established for this solicitation is stability of the vaccine product at temperatures of at least 35°C for 3 years.

The minimum stability temperature of 35°C is based on studies from the CDC and the WHO that document the fact that vaccines with storage requirements of -80°C and 2°C to 8°C, when transported or stored at or above room temperature, quickly lose potency. A vaccine that is stable at temperatures of 35°C and above will enhance vaccine efficacy and eliminate this major component of vaccine wastage. Significant cost savings associated with vaccine storage and distribution will be achieved and the elimination of the need for a "cold chain" will significantly reduce the complexities associated with vaccine storage, transport and administration in a biodefense or public health emergency.

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**Question 6.a.:**

The solicitation contains two parts relating to any CDC category A or B agent and specifically for a next generation anthrax vaccine. Are the described requirements for the vaccine the same for both parts? For example are the stability requirements needed for Part A, or just for Part B?

**Response 6.a.:**

The same stability requirements apply to Part A and Part B. Please review Attachment 4 for the description of the requirements for the vaccines and long term stability requirements.

**Question 6.b.:**

Should we interpret the requirement for existing proof of concept data as relating to solicitation Part A and B or only to Part B?

**Response 6.b.:**

Proof of concept efficacy data are requested for submissions to Part A and B. Please review Attachment 4 for the description of the requirements for the vaccines and long term stability requirements.

**Question 6.c.:**

Should we strictly interpret the requirement for proof of concept data? That is, there are multiple publications showing that adenovirus vectors can be used to generate an effective protective immune response against anthrax. However, we have not participated in these studies. How will this situation be interpreted?

**Response 6.c.:**

Proof of concept data for the vaccine your company is proposing should be the information provided in response to this solicitation.

**Question 6.d.:**

The requirement for stability seems very high for any vectored vaccine. However, it may be possible to achieve long-term stability at 35 degrees C. Could this be an objective of our proposal?

**Response 6.d.:**

Yes. See the objectives of this solicitation, stated in Attachment 4 (Background and Introduction).

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**Question 7:**

Is a LOI requested?

**Response 7:**

An LOI is requested.