

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO. Amendment # 02	3. EFFECTIVE DATE see block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY HHS/OS/ASPR/BARDA 330 Independence Ave. S.W. Room G640 Washington, D.C. 202021	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) N/A		(X) 9A. AMENDMENT OF SOLICITATION NO. RFP - BARDA - 08 - 15	9B. DATED (SEE ITEM 11) 02/28/2008
CODE		FACILITY CODE	10A. MODIFICATION OF CONTRACT/ORDER NO. 10B. DATED (SEE ITEM 13)

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
 (a) By completing items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
<input type="checkbox"/>	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
<input type="checkbox"/>	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
<input type="checkbox"/>	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The RFP is amended to make changes to Section J. (attachments) #4, #7, & #8, Section M.2 I. (technical merit of the offeror's proposal and time line) b. & c., and provide the minutes (including all questions and answers) of the pre-proposal conference.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Brian K. Goodger
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED
16B. UNITED STATES OF AMERICA Brian K. Goodger (Signature of Contracting Officer)	16C. DATE SIGNED 3/27/08

The RFP is hereby amended as follows:

SECTION J – LIST OF ATTACHMENTS

Replace the title of attachment #4 from "Invoice Instructions for Fixed Price Contracts" to "Invoice Instructions for Fixed Price Contracts with Cost Reimbursement Line Item Numbers (CLINs)"

Replace the title of attachment #7 from "Technical Proposal Cost Information/Summary of Labor and Direct Costs" to "Small Business Subcontracting Plan Template".

Add attachment #8, "Proposal Cover Sheet".

SECTION M – EVALUATION FACTORS FOR AWARD

M.2 Technical Proposal Evaluation (320 points)

I. Technical Merit of the Offeror(s) proposal and time line (30 points)

- b. Proposal does fulfill Statement of Objectives but does not appear to be technically feasible within the base contract period of performance and needs major revision (maximum of 10 points)
- c. Proposal does fulfill Statement of Objectives but does not appear to be technically feasible within the base contract period of performance and needs minor revision (maximum of 30 points)

Pre-Proposal Conference

In accordance with the Amendment #01, please find the attached minutes of the pre-proposal conference and all questions and answers.

Proposal Cover Sheet

In Response to: "RFP-BARDA-08-15"

Title: "recombinant Protective Antigen (rPA) for the SNS"

Offeror (Prime Contractor):

Name: _____

Address: _____

Corporate Official: _____

Principal Investigator/Lead Scientist: _____

Project Manager: _____

Small or Large Business: _____

Cost: \$ _____

Fee: \$ _____

Total Price: \$ _____

Fringe Benefits: _____%

Overhead: _____%

General & Administrative: _____%

Fee for FP CLINs: _____%

Fee for CR CLINs: _____%

First Delivery Date of product: _____

Last Delivery Date of product: _____

Subcontractors:

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Name: _____

Consultants:

Name: _____

Name: _____

Name: _____

Pre-Proposal Conference

“RFP-BARDA-08-15” entitled, “*rPA for the SNS*”

Tuesday March 18, 2008. 9 am – 11 am. Cohen Building, Room #5051

Agenda:

1. 9:05 am Welcome and introductions
2. 9:15 am RFP overview and the RFP process
3. 9:45 am S.O.O. overview and discussion
4. 10:20 am Break (5-10 minutes)
5. 10:30 am Reading of answers to questions submitted by 3/12/08
6. 10:45 am Open discussion
7. 11:00 am Final comments and End

Please note:

The government will do their best to answer all questions today. However, if we are unable to address your question today, we will answer it in one week when we post all questions and answers on www.fedbizopps.gov in an amendment to the RFP.

Anything discussed in today’s pre-proposal conference is not to be interpreted as a change in the solicitation or the statement of objectives (S.O.O.) unless a formal amendment is issued by the Contracting Officer.

- * Tape recorders and videos are prohibited.
- * Attendance is limited to 3 people per company.

HHS/BARDA staff:

1. Lucy MacGabhann, Project Officer
2. Dr. Tom Dreier, Project Manager (BARDA contractor)
3. Jake Lewis, Contract Specialist
4. Brian Goodger, Contracting Officer
5. Alla Bobbitt, Technical Writer (BARDA Contractor)

**Pre-Proposal Conference
MEETING MINUTES**

“RFP-BARDA-08-15” entitled “*rPA for the SNS*”

Tuesday, March 18, 2008; 9 am – 11 am; Cohen Building, Room #5051

1) Welcome and Introductions (*Brian Goodger, Contracting Officer, BARDA*)

Mr. Goodger welcomed the participants, summarized the purpose of the conference, and introduced the BARDA staff supporting the meeting.

2) RFP Overview and the RFP Process (*Brian Goodger*)

Mr. Goodger went over the key parts of the RFP and the RFP submission and evaluation process (including timelines):

- Companies not in attendance today are not required to submit a proposal. Conversely, if a company is not represented today, that does not preclude it from submitting a proposal. This pre-proposal conference is an opportunity for the industry to become more familiar with the requirement by talking to the government, so please seek clarification and ask questions to address any assumptions you might have. The more prepared you are, the better the proposal you will submit, which will directly correlate with the government meeting its timelines.
- Here is a brief review of the RFP process:
 - We posted a synopsis on February 8.
 - The solicitation in the form of an RFP was posted on February 28.
 - Today is March 18, and we are holding the pre-proposal conference.
 - Proposals are still due May 29.
 - Depending on the number of proposals and their quality, the government expects to hold the TEP (Technical Evaluation Panel) the week of June 23. The government evaluators will sequester themselves off-site to review the proposals.
 - You will not hear from us until the second or third week of July.
 - If all the milestones to that point have been met, negotiations will begin the week of July 28.

- Award(s) are scheduled for September 26.
- If no proposal sufficiently addresses our requirements, then the contract may not be awarded.
- All the timelines from this point forward are the responsibility of the government and industry...equally. It is imperative that you put your best proposal forward on May 29. Make sure you read the RFP thoroughly, address all the points the government asks for, and sharpen your pencils from the outset because we expect competition. If you do not provide your best proposal, I can assure you the government will be unlikely to make award(s) on time.
- There are a few points to note in the RFP:
 - Face page, Box 4, Negotiated Full & Open Competition, FAR Part 15: This is a firm fixed price supply contract.
 - Face Page, Box 9: Provide an original and 7 copies.
 - Page 4: Note the fixed price and cost reimbursement clauses.
 - Page 6: 600,000 doses have to be delivered to the stockpile before you can be paid.
 - Page 13: The Project Officer (PO) will inspect and Contracting Officer (CO) will accept all articles, services, and documentation.
 - Page 14: Note that delivery of product shall be FOB Destination.
 - Page 19: Performance will be evaluated annually.
 - Page 24: Your technical proposal will be incorporated into the contract.
 - Page 30: Note the key personnel clause.
 - Page 31. Note the advance payments and milestone payments requirements.
 - Page 32: Note the clauses for both a fixed price and cost reimbursement contract.
 - Page 36: The FAR deviation clause is expected to be incorporated into the contract.
 - Page 37. We will add the proposal cover sheet to the list of attachments.
 - Page 39: Note L.1 and five-year period of performance.

- Page 41: All communication regarding the RFP goes through the CO.
- Page 46: The small business subcontracting goals will change in the amendment to the RFP.
- Page 46: Information other than cost and pricing data might be requested during negotiations.
- Page 48, M.2.: There will be a slight change in wording, which will be noted in the RFP.
- Attachment #06: This attachment does not need to be submitted at the time of proposal.

Q&A:

Q: Is there a designated current thinking document by FDA on rPA or is “current thinking” just a term of art?

A: Yes, there is an FDA current thinking document on the topic.

Q: To be clear on the contract structure, is there a cost associated with each item (CLIN)?

A: Yes, there is a cost associated with each CLIN.

Q: The RFP states that at least 600 K doses have to be delivered to the SNS prior to any payment, and yet it also provides for advance payments and milestone payments, if approved. If such an approval is granted, does the contractor still have to wait for delivery of the 600 K doses to get paid?

A: No, if advance or milestone payments are approved, it is not necessary to wait for the 600 K doses (i.e., payments may be rendered prior to delivery of doses).

3) Statement of Objectives (SOO) Overview and Discussion (*Lucy Mac Gabhann, Project Officer, BARDA*)

Ms. Mac Gabhann provided a brief overview of Section B of the RFP, followed by a detailed overview of Section C.

- Use of “Statement of Objectives” versus “Statement of Work” in Section B:
 - This was a deliberate choice by BARDA.
 - It allows offerors the flexibility and room to innovate to meet key U.S. Government (USG) objectives

- You – the pharmaceutical industry – are the experts. It is up to you to figure out best way to meet USG objectives.
- We need offerors to deliver a comprehensive plan that ties the objectives together and offers the best value.
- Overview of Major Objectives from Section C:
 - The primary objective is 25 M doses of rPA delivered to the Strategic National Stockpile (SNS) within the Period of Performance (PoP) of the contract.
 - We envision a five-year contract, but in accordance with the Project BioShield law, we will evaluate individual plans and requests for an additional three years (as one-year, no-cost extensions).
 - Offerors should propose a delivery schedule that balances delivery of product to the SNS as early as possible with the requirement to maximize the amount of product in the SNS over the PoP.
 - We will evaluate your delivery schedule for feasibility in relation to your overall project plan.
 - We have a firm minimum stability/shelf-life requirement for product delivered under this contract.
 - There is a minimum 24 months stability, with minimum of 20 months remaining at time of delivery to the SNS.
 - We require an extended stability testing program, and have included an option to extend product dating to 36 months.
 - This is not to say that stability testing should end at 36 months.
 - The labeling strategy should be coordinated with the stability program strategy and should promote the logistical ease of relabeling, if necessary. We encourage offerors to consider the recent FDA Interim Final Rule regarding “Exceptions or Alternatives to Labeling Requirements for Products Held by The SNS” in C.2.4.
 - All packaging should be designed with mass vaccination use in mind.
 - The USG does not have a specific requirement for final packaging.
 - We are looking for ease of use in combination with best life-cycle value.
 - We expect to see a thorough rationale of how the proposed packaging will deliver the best value.

- Offerors should also consider the likelihood of long-term temperature-controlled storage and design packaging to promote quality under those conditions.
 - What we would really like is a room-temperature, shelf-stable product with an infinite shelf-life, but we have come to terms with the fact that, at this time, we are probably looking at a refrigerated product.
- We require a maximum of three doses to demonstrate efficacy for a Post-Exposure Prophylaxis(PEP) indication.
 - PEP is our first priority – we want to get product into the SNS as quickly as reasonably possible for use under an Emergency Use Authorization(EUA) in combination with antibiotics.
- Based on our experience with other products, we believe that the easiest path to full PEP licensure is 1) Filing and acceptance by FDA of a package supporting PEP under an EUA; 2) General Use Prophylaxis (GUP) licensure; and 3) Full PEP licensure.
 - We believe FDA is most familiar with licensing vaccines for GUP – thus, presenting GUP as the first indication allows them to review a substantial amount of information under the normal review process.
 - The offerors should propose a development and licensing strategy that aligns with their own discussions with FDA.
- It is the responsibility of the contractor to initiate and maintain a dialogue with FDA about their product.
 - BARDA has no special relationship with or influence over FDA – we want to work with manufacturers, as a team, to succeed in this project.
 - We have experts here who can assist in reviewing draft FDA submissions.
 - The exchange of information between the contractor and FDA is crucial, from our perspective, to the success of the project. Section F.8. outlines standard BARDA procedures for working with contractors in relation to FDA.
 - In summary, it is your responsibility to take the lead for communication, but we want to stay informed.
- Our one mandatory criterion for evaluation involves prior communication with FDA..
 - You must show evidence that you have obtained FDA’s current thinking for rPA vaccine development, including what minimum product information should be submitted for consideration under an EUA.

- If this information is not included, your proposal will not be evaluated further.
- We prefer a copy of FDA's meeting minutes but will accept other documentation, such as minutes taken by your company or written exchanges.

Q&A:

Q: Should extended stability expenses be included in the proposed costs?

A: Yes, this is a firm fixed price (FFP) item in the contract.

Q: Can any direction be provided on developing an FDA labeling strategy?

A: See Section C.2.4.

Q: You have suggested that we need to meet with FDA to be considered, but we have met with FDA already. Do you want the meeting minutes included in the proposal, or do we need to submit them prior to the proposal?

A: No, we do not need the minutes before the proposal – please include them in the proposal, as no materials will be evaluated before that.

Q: We would like to understand the objective of the U.S. government for using the stockpile – is the government more interested in acquiring 25 M doses all at once, or in acquiring the doses gradually so as to have a certain number available for use (unexpired) at any given time?

A: We want you to use your best judgment, since you are the experts – we all know that the delivered doses will only last several years, and that the initially provided doses will have expired by the end of the contract. So we need your best proposal on how to keep the maximum number of viable product in the stockpile at any given time during the contract period. But please do not propose more than one-time-monthly deliveries.

Q: For the relabeling of IND doses to licensed ones, will the doses be shipped from the SNS to the manufacturer? If not, would the relabeling be done while the product is in the SNS, and if so, would we undertake this or would we instruct you to undertake it?

A: Shipping the product back out would be a huge logistical challenge, and we would very much prefer not to do that. Any relabeling would be physically done by the manufacturer at our location.

Q: Once we deliver the first doses of product to the SNS for PEP under an IND (Investigational New Drug application), would it be possible to deliver subsequent

doses without an expiry date (under agreement with FDA) and then institute testing to ensure continued potency and stability?

A: Yes – in fact, FDA’s most recent guidance advocates this approach.

Q: You said that there is at least a reasonable possibility that some of the SNS material will expire before the conclusion of the contract period – do we need to provide a plan for disposal?

A: No, that is SNS’s responsibility.

Q: Can you provide clarity on what mass vaccination would constitute for product presentation purposes? There are different ways to present product for mass vaccination needs, so more clarity would be helpful.

A: The concept of use for the vaccine is in accordance with a publicly available model of post-exposure prophylaxis in case of an anthrax emergency [reference below]. So we are planning to move product from the SNS to the site of use under the assumptions therein, and have prepared push packages accordingly.

Reference: Baccam P, Boechler M. Public Health Response to an Anthrax Attack: An Evaluation of Vaccination Policy Options. *Biosecur Bioterror*, 2007, 5(1): 26-34.

Q (As follow-up): So if we consider this model, and consider mass vaccination under the corresponding model scenarios, can we assume that this is what your model of mass vaccination will be?

A: Yes.

4) Reading of Answers to Questions Submitted by 3/12/08 (*Lucy Mac Gabhann*)

Ms. Mac Gabhann read the answers to the 31 RFP-related questions submitted by March 12 to BARDA by potential offerors.

5) Open Discussion With Meeting Participants (*Brian Goodger, Lucy Mac Gabhann, and Dr. Tom Dreier, Project Manager, BARDA*)

Q&A:

Q: Regarding the prices in the CLIN structure for licensure of the product for GUP and PEP, is it correct that we have an option to either include those as discounts off the base dose price in the proposal, or withhold them from the proposal (i.e., temporarily leave blank) pending negotiation with the government?

A: Yes, that is correct – both choices are acceptable.

Q (As passed on during the break): Is it correct that Attachment #6 does not need to be submitted with the proposal?

A: Yes, there is no need to submit the enrollment form for electronic payment with the proposal – this form does not get filled out prior to negotiations.

Q: Regarding the mandatory eligibility criterion of prior consultation with FDA, as a clarification, is it sufficient to consult FDA only regarding EUA requirements, or does the path to licensure for GUP/PEP need to be discussed as well?

A: EUA needs to be discussed, at a minimum. We perceive these discussions with FDA as part of a sequential series of events on the path to IND approval and eventual licensure. It is your responsibility to communicate with FDA regularly to ensure success – remember that FDA, and not BARDA, has the regulatory decision-making authority.

Q: Is it correct that if your company constitutes a small business, you do not need to submit a small business subcontract plan?

A: Yes, that is correct – in that case, there is no need to submit a small business subcontract plan.

Q: To inform our discussions with FDA about the PEP-plus-antibiotics indication, can you tell us which antibiotics are likely to be deployed in an emergency – is it ones the doctor has on the shelf? Or ones available to the government and/or responders? The availability of certain antibiotics and not others will affect cost.

A: FDA is aware of the antibiotics available for dispensation both on the shelf and in government stockpiles. It is more appropriate to bring up this issue with the agency, which should be able to provide detailed guidance.

6) Final Comments and Conclusion *(Brian Goodger)*

Mr. Goodger thanked everyone for coming, and indicated that the answers to questions posed at the conference, along with the meeting minutes, will be posted on FedBizOpps the week of March 24.

RFP (BARDA-08-15), "rPA for the SNS"

Answers to Questions submitted by 3/12/08

Q.1. Please describe how the Government intends to evaluate efficacy in accordance with RFP Section C.13.

A.1. The Food and Drug Administration (FDA) will determine the vaccine efficacy level sufficient for licensure.

Q.2. What are the relative weights of each of the non-cost-evaluation factors identified in Section M of the RFP?

A.2. First, an offeror must meet the mandatory criterion for eligibility to be considered for further evaluation. Then an offeror will be given a technical score out of 320 points. Next, an offeror will given a past-performance score up to 10 points. Then a general discussion about acceptability or non-acceptability of human subjects, animal welfare, select agents, and small disadvantaged business participation will take place.

Q.3. A. With regard to RFP Section M.2 I, is it possible to be awarded any number of points between 0 and 30, or are points assigned only at the three levels, i.e., 0, 10, and 30? B. Specifically, are interim numbers of points awarded if, for example, a proposal fulfills some portion of the SOO requirements but needs revision? C. Alternatively, if a proposal needs some, but not significant revision, might it be awarded 20 points instead of 10?

A.3. A. Yes, it is possible to be awarded any number of points between 0 and 30.
B. Yes, an offeror will receive some points if their proposal fulfills some portion of the SOO but needs major/significant revision.
C. Yes, if a proposal needs some minor revisions, it might be awarded 20 points instead of 10.

Q.4. With regard to RFP Section M.2 II, isn't the award of the additional 90 points inconsistent with the SOO in that it seems to give an advantage to an entity that has an existing, proven vaccine that is in the licensing process? Because this 90-point advantage is difficult, if not impossible, to overcome, isn't the Government actually limiting competition despite the full and open nature of this procurement?

A.4. In order to successfully fulfill the requirements outlined in the Statement of Objectives (SOO) and meet emergency preparedness goals, the USG believes that it is critical that offerors demonstrate their candidate vaccine is sufficiently mature for Project BioShield procurement. Offerors should provide evidence that their candidate has completed, or made satisfactory progress towards completion of, the milestones outlined in section M.2.II. The USG has set a base Period of Performance of five years on this contract, in accordance with Project BioShield legislation.

Q.5. With regard to RFP Sections M.2 V and VI, does an offeror receive points for the submission alone of a Gantt chart, project plan, etc., or are the Gantt chart, project plan, etc. going to be qualitatively or substantively evaluated? If so, what are the relevant evaluation criteria?

A.5. Please refer to Section L.23-26 for the relevant technical proposal instructions. Materials submitted will be evaluated to determine an offeror's likelihood of successful completion of the SOO requirements. The Gantt chart will be evaluated in Section M.2.V.

Q.6. In evaluating past performance pursuant to RFP Section M.3, is the maximum score an offeror may achieve 10 points, or will the Government award points to each piece/ source of past performance information?

A.6. 10 points is the maximum rating score based on an evaluation of all Past Performance information available.

Q.7. What are the factors for evaluating performance risk pursuant to RFP Section M.3? How does the Government intend to rate performance risk?

A.7. The rating system for performance risk is detailed in Section M.3.

Q.8. When evaluating proposals per RFP Sections C.1.2 and M, will the USG evaluate products more highly if they are amenable to cold-chain-free storage, which would facilitate use in an emergency situation, even if the price per dose is more expensive?

A.8. The USG will evaluate proposals to determine best overall value. As such, the USG will consider trade-offs among cost/price and non-cost factors, in accordance with FAR 15.101-1.

Q.9. With regard to RFP Sections C.1.2, C.1.3 and M, is the USG factoring in feasibility for achieving extended shelf-life (> 3 years) in considering the overall cost of the product? For instance, while a vaccine formulated as a liquid may only be able to achieve a three-year shelf-life, use of more costly technology may facilitate a five-year or longer shelf-life at a lower overall cost for stockpile maintenance.

A.9. Yes. The USG will evaluate life-cycle costs and is seeking products that demonstrate best value.

Q.10. Section A: What is the explanation for item 12 on the Solicitation, Offer, and Award page? What is the significance of provisions at 52.214-16 and minimum bid acceptance period?

A.10. 120 days is recommended for pricing, however it is up to the offeror. The significance is that the prices you submitted in your original business proposal cannot be increased during this period.

Q.11. Section A: Item 13- Please clarify further the “discount for prompt payment.” Does USG have a predetermined schedule for discount at different predetermined calendar days?

A.11. No, the government does not have a predetermined schedule for discount at different predetermined calendar days. A discount for prompt payment is a discount the contractor would offer the government if an invoice were paid very promptly. For example, a contractor might offer a 1% discount on their invoice if the government pays the invoice within 10 days after the CO receives it.

Q. 12 Section B.2. Project Identification and Purpose: Are there a predetermined number of deliveries for 25 million doses over the life (5 year) of the contract? Is there any relationship between number of deliveries and the measure of performance?

A.12. No. Offerors should propose a realistic delivery schedule that meets the USG’s requirements outlined in the SOO. See Section C.5.2.

Q.13. Section B.4. Clin 0006 Security of Contract Operations: Does that refer to the security of manufacturing units and operations?

A.13. See Section H.8. for detailed security requirements. These requirements extend to any facilities involved in manufacturing, testing, or storage of USG product.

Q.14. Section B.4. Clin 0007 Information Technology Security: Do we need to follow Federal Information Security Management Act (FISMA) or any other BARDA guidelines available for this project?

We will be using the globally accepted standard 128-bit encryption for transferring the documents. Is there any other specific transmission and storage guidelines? We would appreciate reference of suggested guidelines.

A.14. Offerors will need to comply with FISMA guidelines.

Q.15. Sections B.5.d. and F.3.n are Reserved. When will they be released?

A.15. There is nothing to be released. This is simply a placeholder for the CO for possible amendments to the RFP or modifications to the contract after award. If something is added to these sections, you will be notified immediately.

Q.16 Section C.1.2. What is the measure for cost effectiveness of the product? Is it by cost of manufacturing/dose or by dose-sparing (amount of antigen/dose) through enhancement of immunogenicity?

A.16 The USG will evaluate the life-cycle costs of a product, including procurement price, transportation and storage costs, deployment and utilization costs, and disposal costs. The USG seeks a product that can deliver the best value with respect to cost and performance.

Q.17. Section C.2.1. Manufacturing Objectives: Does the requirement “maximum of three (3) doses” include both types of immunization, “prime” and “boost”?

A.17. A maximum of three doses in the primary series is required to demonstrate efficacy in the product’s intended use, under Post-Exposure Prophylaxis (PEP) in conjunction with antibiotics. The USG recognizes that PEP and General-Use Prophylaxis (GUP) may require periodic boosters, in addition to the primary series of immunizations.

Q.18. Sections C.2.3. & C.2.4. Clauses state development of plans and strategy in consultation with FDA, CDC, BARDA, e.g. Stability testing plan, labeling strategy, etc. How do you expect to factor in the cost for these heads in our costing, or whether HHS will negotiate cost towards such heads separately?

A.18. USG participation in planning, document review, etc, is at no cost to the contractor, with the exception of FDA, which maintains a fee-based system with manufacturers under the Prescription Drug User Fee Act (PDUFA).

Q.19. Section C.5. 5. Shipment, Storage, and Disposition Objectives: Would USG reimburse the costs of periodic quality testing of vaccine stored in SNS?

A.19. The cost of any periodically required testing should be included in the offerors' proposals for CLIN 0001B.

Q.20. Section C.7.3. Project Management and Risk Mitigation Objectives: Is it mandatory to use USG's Integrated Baseline Review? Can the contractor propose to use their own IBR system?

A.20. Offerors should propose their preferred Earned Value Management System, to include IBR. The USG does not specify a standard for EVMS or IBRs.

Q. 21. Section C.9. When do you expect the first delivery of product? Is there any anticipated timeline or delivery schedule?

A.21. Offerors should propose an optimized, but realistic, delivery schedule that aligns with their product development plan.

Q.22. Section L.11. Alternate Proposals: What would be the process for submission of an alternate proposal? Should that be part of current proposal or a separate proposal?

A.22. Offerors can submit alternative proposals with their proposal under this RFP, but as a separate document. Alternative proposals should not exceed 50 pages.

Q.23. Section L.35. RFP document indicates the anticipated minimum subcontracting goals for this proposal in different percentages, totaling 42% for small business. How will a foreign offeror not subcontracting from small businesses be considered at the time of bid evaluation?

A.23. The 23% has been reduced to 19% in 2008 for HHS. The 19% is inclusive of SDB, WO, HubZone, and SDVB. If you are a foreign company and you plan to have subcontracts with companies in the U.S., you will be required to submit a small business subcontracting plan.

Q.24. Section M.VII. Options Evaluation: It seems there are no points allocated for the option for implementation to plan for Phase-IV PMS?

A.24. The USG will evaluate the merits of the Phase IV post-marketing plan in the technical proposal as described in Section M.2.II.g. It is not appropriate to evaluate the potential future implementation of that plan, under Option 004B, as a part of the technical proposal.

Q.25. Please define the minimum requirement of Section 8(d) of the Small Business Act required by HHS procurement activity.

A.25. The small business subcontracting plan is the minimum requirement to address and report small business subcontracting dollars. A contractor may provide additional information regarding its small business subcontracting plan. The contractor will be expected to make every attempt to ensure the goals of its small business subcontracting plan are met.

Q.26. Please Confirm which antibiotic(s) are required for PEP in adults (section C.1.6) and PEP in pediatrics (section C.8.2).

A.26. Ciprofloxacin, doxycycline, and penicillin are FDA-approved for the treatment of anthrax in adults and children. Levofloxacin has been FDA-approved for use in adults to prevent development of

inhalational anthrax following exposure. Offerors should consult with FDA to discuss the details of their licensing strategy.

Q.27. Does the Government expect the offeror to perform any analytical testing of the product in the SNS in addition to the Quality Assurance Monitoring Plan that determines appropriate storage conditions?

A.27 Offerors should consult with FDA to determine what continued testing is required following delivery to the SNS.

Q.28. Section C.3.2: Offeror plans to place representative lots on stability in accordance with ICH guidelines, as agreed with FDA. For clarity, it is not feasible to test every lot. Please confirm that this approach is acceptable.

A.28. The offerors should work with FDA to define stability testing requirements, including testing sufficient to support the extension of lots delivered to the SNS.

Q.29. Section C.7.1.1: Please provide further information and examples of Work Breakdown Structure levels 5+6.

A.29. For more information on WBSs, consult the Project Management Institute Practice Standard for Work Breakdown Structures, Second Edition (2006). ISBN 1-933890-13-4.

Q.30. Business Proposal Cover Sheet: Section L.32 references the Business Proposal Cover Sheet in Section J. However, it does not appear that the cover sheet is included in Section J. Please provide this form or a reference to find it.

A.30. The cover sheet has been added to section J and will be posted in Amendment #02.

Q.31. Technical Proposal Cost Information: Section J, List of Attachments, states that item 7 should be the Technical Proposal Cost Information/Summary of Labor and Direct Costs. However it appears that the Small Business Subcontracting Plan template has been included instead. Should offerors use the standard NIH Technical Proposal Cost Information form?

A.31. Section J will be amended in amendment #02. The technical proposal cost information/summary of labor & direct costs in attachment #7 will be replaced with the Small Business Subcontracting Plan template; the proposal cover sheet will become attachment #8; and page 2 of attachment 4 will be amended to read "Billing Instructions for Negotiated Cost Type Contract Line Item Numbers (CLINs)."

Questions posed at the Pre-Proposal Conference on 3/18/08

Q1. Is there a designated current thinking document by FDA on rPA or is “current thinking” just a term of art?

A.1. Yes, there is an FDA current thinking document on the topic.

Q.2. To be clear on the contract structure, is there a cost associated with each item (CLIN)?

A.2. Yes, there is a cost associated with each CLIN.

Q.3. The RFP states that at least 600 K doses have to be delivered to the SNS prior to any payment, and yet it also provides for advance payments and milestone payments, if approved. If such an approval is granted, does the contractor still have to wait for delivery of the 600 K doses to get paid?

A.3. No, if advance or milestone payments are approved, it is not necessary to wait for the 600 K doses (i.e., payments may be rendered prior to delivery of doses).

Q.4. Should extended stability expenses be included in the proposed costs?

A.4. Yes, this is a firm-fixed-price (FFP) item in the contract.

Q.5. Can any direction be provided on developing an FDA labeling strategy?

A.5. See Section C.2.4.

Q.6. You have suggested that we need to meet with FDA to be considered, but we have met with FDA already. Do you want the meeting minutes included in the proposal, or do we need to submit them prior to the proposal?

A.6. No, we do not need the minutes before the proposal – please include them in the proposal, as no materials will be evaluated before that.

Q.7. We would like to understand the objective of the U.S. government for using the stockpile – is the government more interested in acquiring 25M doses all at once, or in acquiring the doses gradually so as to have a certain number available for use (unexpired) at any given time?

A.7. We want you to use your best judgment, since you are the experts – we all know that the delivered doses will only last several years, and that the initially provided doses will have expired by the end of the contract. So we need your best proposal on how to keep the maximum number of viable product in the stockpile at any given time during the contract period. But please do not propose more than one-time-monthly deliveries.

Q.8. For the relabeling of IND doses to licensed ones, will the doses be shipped from the SNS to the manufacturer? If not, would the relabeling be done while the product is in the SNS, and if so, would we undertake this or would we instruct you to undertake it?

A.8. Shipping the product back out would be a huge logistical challenge, and we would very much prefer not to do that. Any relabeling would be physically done by the manufacturer at our location.

Q.9. Once we deliver the first doses of product to the SNS for PEP under an IND (Investigational New Drug application), would it be possible to deliver subsequent doses without an expiry date (under agreement with FDA) and then institute testing to ensure continued potency and stability?

A.9. Yes – in fact, FDA’s most recent guidance advocates this approach.

Q.10. You said that there is at least a reasonable possibility that some of the SNS material will expire before the conclusion of the contract period – do we need to provide a plan for disposal?

A.10. No, that is SNS’s responsibility.

Q.11. Can you provide clarity on what mass vaccination would constitute for product presentation purposes? There are different ways to present product for mass vaccination needs, so more clarity would be helpful.

A.11. The concept of use for the vaccine is in accordance with a publicly available model of post-exposure prophylaxis in case of an anthrax emergency [reference below]. So we are planning to move product from the SNS to the site of use under the assumptions therein, and have prepared push packages accordingly.

Reference: Baccam P, Boechler M. Public Health Response to an Anthrax Attack: An Evaluation of Vaccination Policy Options. *Biosecur Bioterror*, 2007, 5(1): 26-34.

Q.12. (As follow-up to Q.11.) So if we consider this model, and consider mass vaccination under the corresponding model scenarios, can we assume that this is what your model of mass vaccination will be?

A.12. Yes.

Q.13. Regarding the prices in the CLIN structure for licensure of the product for GUP and PEP, is it correct that we have an option to either include those as discounts off the base dose price in the proposal, or withhold them from the proposal (i.e., temporarily leave blank) pending negotiation with the government?

A.13. Yes, that is correct – both choices are acceptable.

Q.14. Is it correct that Attachment #6 does not need to be submitted with the proposal?

A.14. Yes, there is no need to submit the enrollment form for electronic payment with the proposal – this form does not get filled out prior to negotiations.

Q.15. Regarding the mandatory eligibility criterion of prior consultation with FDA, as a clarification, is it sufficient to consult FDA only regarding EUA requirements, or does the path to licensure for GUP/PEP need to be discussed as well?

A.15. EUA needs to be discussed, at a minimum. We perceive these discussions with FDA as part of a sequential series of events on the path to IND approval and eventual licensure. It is your responsibility to communicate with FDA regularly to ensure success – remember that FDA, and not BARDA, has the regulatory decision-making authority.

Q.16. Is it correct that if your company constitutes a small business, you do not need to submit a small business subcontract plan?

A.16. Yes, that is correct – in that case, there is no need to submit a small business subcontract plan.

Q.17. To inform our discussions with FDA about the PEP-plus-antibiotics indication, can you tell us which antibiotics are likely to be deployed in an emergency – is it ones the doctor has on the shelf? Or ones available to the government and/or responders? The availability of certain antibiotics and not others will affect cost.

A.17. FDA is aware of the antibiotics available for dispensation both on the shelf and in government stockpiles. It is more appropriate to bring up this issue with the agency, which should be able to provide detailed guidance.