

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE 1	Of 7
2. AMENDMENT/MODIFICATION NO. Two (2)	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE NO.	5. PROJECT NO. (If applicable)	
6. ISSUED BY CODE	7. ADMINISTERED BY (If other than Item 6) CODE			
Department of Health and Human Services Office of Public Health Emergency Preparedness Office of Public Health Emergency Medical Countermeasures 330 Independence Avenue SW, Room G640 Washington DC 20201				
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, county, State and ZIP Code)		(x)	9A. AMENDMENT OF SOLICITATION NO. DHHS-ORDC-VB-0607	
		X	9B. DATED (SEE ITEM 11) July 24, 2006	
			10A. MODIFICATION OF CONTRACT/ORDER NO.	
			10B. DATED (SEE ITEM 13)	
CODE	FACILITY CODE			

**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 1 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 you 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 APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

<input type="checkbox"/>	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 following changes are made to this solicitation:

- Revise the following clauses as detailed on page 2 of this Amendment: Section L ITEM 17, Section M.2 paragraph 3 and Section M.3 paragraph 1; and
- Provide answers to technical and business questions.

Proposal due date and time remain unchanged – August 23, 2006 at 3:00 PM (Local Time).

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)	
		David K. Beck, Chief Contracting Officer	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By 	16C. DATE SIGNED 8/10/2006
<i>(Signature of person authorized to sign)</i>		<i>(Signature of Contracting Officer)</i>	

1. To change ITEM 17 of Section L to read as follows:

**ITEM 17: Past Performance Information** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as a separate section within the **Business** proposal.

1. Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors.
2. The Offeror shall provide a list of the last three (3) contracts completed during the past three years and all contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts as required above for all key personnel:
  - a. Name of Contracting Organization
  - b. Contract Number
  - c. Total Contract Value
  - d. Description of Requirement
  - e. Contract Officer's name and telephone number

2. To revise paragraph 3 of M.2 to read as follows:

### **3. Organizational Experience**

The proposal should describe current and recent programs for vaccine or other biological product, evaluation, licensure, and production to document organizational capabilities to complete proposed activities, achieve regulatory approvals, and successfully produce biological products. The proposal shall describe how the Offeror will interact with A&ME firm, construction and other contractors.

3. To revise paragraph 1 of M.3 to read as follows:

### **M.3. Past Performance Information**

1. Offerors shall submit the following information as a separate section of their business proposal for both the Offeror and proposed major subcontractors:

4. To provide answers to technical and business questions as follows:

**Question 1:** In the RFP we understand that there is no particular technology required with respect to the pandemic influenza vaccine to be produced at the renovated or expanded facility. We would like confirmation of this understanding, i.e. that funding is available for renovation or expansion of a facility using cell culture technology, not just for renovation or expansion of facilities using egg based technology.

**Answer 1: Funding is available for either cell-based or egg-based facilities.**

**Question 2:** We understand that with respect to a pilot plant, there are two core requirements: the site must be located in the US and must be in compliance with FDA, CDC and USDA regulatory and biosafety guidelines. Is the renovation or expansion of a pilot lot facility located in the US satisfying these RFP conditions eligible for funding, if there is currently no FDA approved vaccine manufactured at the site and there is no intent to also request funding for renovation of a bulk manufacturing/fill finish facility producing a US licensed product?

**Answer 2:** **Pilot plants do not have to be co-located at an FDA-approved vaccine-manufacturing site. The FDA approval issue only pertains to commercial manufacturing. However, the pilot plant must be in compliance with CGMP guidelines from the FDA and biosafety guidelines from CDC and USDA.**

**Question 3:** C.1. Statement of Work – Milestones, on pg 7 of 61 list milestone due dates: What will be the government's timeframe for approval of milestone deliverables? A long approval process for the Conceptual Facility A&ME Plan (Milestone 1) could impact subsequent Milestone 2, Detailed Facility A&ME Plan, due three (3) months later.

**Answer 3:** **We believe the time is sufficient. Remember, the government will be cognizant of the applicant's concepts and ideas prior to submission of Milestone 1; details included in the application and monthly technical progress reports.**

**Question 4:** Section H, paragraph H.16, pg. 20 It is our understanding that the security controls noted in Section H, paragraph H.16, pg. 20, of the RFP relate to inventory control, access, and accountability as described in the regulations cited, and not in physical security controls for the sites that are under the contract. Is this an accurate interpretation?

**Answer 4:** **The requirements of 42 CFR Part 73 and other cited documents require that the offeror have a complete biosecurity system in place before possession or use of select biological agents and/or toxins. Site physical security controls are a component of that system. Further information may be obtained National Select Agent Registry website, <http://www.selectagents.gov/index.html>**

**Question 5:** Please clarify the biosecurity requirement as it relates to physical security controls, inventory control, access, and accountability in facilities that handle Select Agents.

**Answer 5:** **See answer 4, above.**

**Question 6:** Section C, paragraph C.1, Statement of Work, Milestones, IV Milestone 4: Within nine (9) months of the contract award, the Contractor shall submit to HHS for review and acceptance of a Facility Operation Plan ... The plan shall describe warm base operation with one commercial lot production each year. Would product from a pilot plant qualify as a commercial lot to satisfy the requirement of Milestone 4? If not, would the cost of licensing the pilot plant for commercial product be eligible for consideration under this solicitation?

**Answer 6:** **A pilot lot is 4,000 doses under the terms of the contract. The cost of licensing a pilot plant expansion for production at commercial scale is not included within the scope of this RFP.**

**Question 7:** 1) Page 55 M.1 (b) (and elsewhere). The Mandatory Criteria in the Solicitation refers to submission of a BLA supplement for the licensed influenza vaccine product manufactured in the proposed commercial scale facility within thirty months of a contract award. From other information in the Solicitation, this would result in a date of approximately May, 2009. It is possible that we may not be in a position to begin demolition and renovation of our existing facility to meet

this proposed timeline. Are you prepared to consider proposals that, while not meeting the 30 month time schedule set forth in the RFP, are otherwise responsive to the stated objectives of the US Government to increase the supply of influenza vaccine? In the interest of maintaining current manufacturing capacity, what would be the latest acceptable date (month/year) for submission of the facility BLA?

**Answer 7: No, the 30-month requirement remains.**

**Question 8:** Milestone 6. Can we assume that one lot corresponds to operation of the facility at full capacity? Can we assume this lot will be of a pre-pandemic strain, rather than a seasonal strain?

**Answer 8: The requirement for commercial manufacturing is for 50,000,000 doses per year. A "lot" is the size you propose to meet the 50,000,000-dose requirement. For example, if you propose 50 lots per year in your campaign, then a "lot" would be 1,000,000 doses.**

**Question 9:** Page 6. Objectives. Can we assume that the "influenza vaccine manufacturing campaign" to produce at least 50 M doses will occur over 12 months? Do you have a specific yield for a pandemic strain that we should use for our calculations?

**Answer 9: We cannot predict what the yield will be for each process and/or strain. We shall evaluate the feasibility of your facility, and its history, to produce sufficient antigen for 50,000,000 15 µg doses.**

**Question 10:** Page 11. Is the Contractor to supply bulk or formulated and filled vaccine?

**Answer 10: Either or both.**

**Question 11:** Section J, paragraph at bottom of page, page 29 **TECHNICAL PROPOSAL PAGE LIMITS INCLUDE:** The technical approach to be used by the Offeror(s) in order to implement the requirements stated in the Statement of Work. **TOTAL PAGE COUNT DOES NOT INCLUDE:** 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section. We would request that the Technical Proposal Cover Sheet and the Government Notice for Handling Proposals also be excluded from the technical proposal page count.

**Answer 11: The Technical Proposal Cover Sheet and Government Notice for Handling Proposals will not be included in the technical proposal page count.**

**Question 12:** Page 3, B.4 (b), What is the cancellation ceiling?

**Answer 12: The cancellation ceiling will be negotiated with each offeror at the same time period of other negotiations.**

**Question 13:** Page 16 (Section G.6) - When will the Ceiling rates be determined?

**Answer 13: Indirect ceiling rates will be negotiated with each offeror at the same time period of other negotiations.**

**Question 14:** Pages 28 and 53. Can we assume that a Cover Page is required for the Business Volume - and that we should use the same format as for the Technical Volume?

**Answer 14: Yes. Please note the cover page will not count towards the page limit for business proposals.**

**Question 15:** The Solicitation appears to suggest the summary of Past Performance should be part of both the Technical Proposal (page 53) and the Business Proposal (Item 17, page 51). Please clarify.

**Answer 15:** See response to question 18.

**Question 16:** Are we correct in understanding that successful Offerors will own full and unencumbered title to the resulting facility which is expanded or renovated with government funding?

**Answer 16:** Yes, the successful Offeror(s) will retain title to all property purchased, with Government funds, under the resulting contract(s). Please see Section I clause 52.245-5.

**Question 17:** Will pre-award costs be eligible for reimbursement? If so, will there be a limitation on the time period during which pre-award costs will be reimbursed? In other words, if an Offeror began renovation or expansion at risk during the RFP evaluation and award period, would those costs be eligible for funding?

**Answer 17:** All direct costs charged to a resultant contract must occur either during the contract period of performance or in accordance with the cost principle in FAR 31.205-32 Pre-contract costs. If an offeror anticipates pre-award costs, they should be included in their business proposal. Based on the business proposal, negotiations (if warranted) will determine the time period and the allowability and allocability of pre-award costs.

**Question 18:** Three questions follow these five RFP references Section L, Item 17, pg. 51, Section M, para. M.3 pages 56-57, Section L, Item 21, paragraph (a) (9) pg. 53(technical proposal instructions), Section L, Item 21, final paragraph pg. 53 and Section M, paragraph M.2 part 3 pg. 56 (technical evaluation criteria):

**Question a:** Per the first two references, the Past Performance information requested will be submitted and evaluated as part of the business proposal. In the fourth reference, the technical proposal requirement for both a section on organizational experience and one on past performance seems redundant. Additionally, there is no paragraph in Section M that states how the Past Performance section in the technical proposal will be evaluated. Would you remove the requirement for a separate Past Performance section in the technical proposal, or if it is required but not scored against the technical proposal, remove it from the page count?

**Question b:** From the fifth reference, only current programs will be evaluate as part of the organizational experience score for the technical proposal. Is it your intent that the organizational experience part of the proposal be restricted to current activities? If not, we recommend the evaluation criteria change read something like this: "**3. Organizational Experience** The offeror's organizational capability to complete proposed activities, achieve regulatory approvals, and successfully produce biological products is documented in descriptions of current and recent programs for vaccine or other biological product, evaluation, licensure, and production."

**Question c:** The requirement in the third reference for contract name, number, value, and contact information seems redundant with the requests in the business proposal Past Performance. If it is not redundant, please explain how you expect this information to differ in content from that in the business proposal. If it is redundant, please consider eliminating the requirement.

**Answer 18: a: Past Performance information will be included as a separate section of the offeror's business proposal. Please see Amendment Two (2) for revised language to appropriate sections of the RFP. Section M.3 discusses how past performance will be evaluated.**

**Answer 18: b: No, language will be changed to include current and recent programs. See above for revised language.**

**Answer 18: c: This information relates to organizational experience.**

**Question 19:** Section M, Para M.1.1a pg. 54: Is the phrase "the contractor will be required to fund twenty-five (25%)" meant to indicate that the prime contractor alone, not the contractor plus subcontractors, is required to fund this amount?

**Answer 19: The reference to contractor as stated in Section M.1.1a includes the prime contractor plus any subcontractors.**

**Question 20:** Section G, paragraph G.6. Indirect Cost Rates, page 16 of 61: Does the rate ceiling allow for annual rate escalation?

**Answer 20: No. The ceiling indirect rates do not allow for annual rate escalations. These are the maximum indirect rates that the Government will pay over the life of the contract. Indirect rates may be adjusted (up or down) annually but can not exceed the ceiling indirect rates that will be negotiated prior to contract award.**

**Question 21:** Section J, Form Breakdown of Proposed Estimated Cost (Plus Fee) and Labor Hours, para. 5, p 39 It is requested that you use the ELECTRONIC SPREADSHEET that is provided below to prepare your business proposal in lieu of the hardcopy contained in this Attachment. It is in EXCEL format and has instructions for use and submission. If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation. In our electronic document, the table did not come through as a spreadsheet. Would you post the spreadsheet document on the website?

**Answer 21: The electronic spreadsheets were posted on the Federal Business Opportunities Website on August 3, 2006 as part of Amendment One (1) to the RFP.**

**Question 22:** Will HHS consider expanding the mandatory criteria from FDA licensed biological products to include companies which currently manufacture FDA licensed pharmaceutical products?

**Answer 22: The government will not change the criterion from FDA-licensed biological products.**

**Question 23:** We have a pilot plant on-site only and the seasonal influenza vaccine made with our technology (cell culture based) we anticipate receiving approval for next year. Can we apply to upgrade our pilot facility - we will be able to produce the doses outlined in the RFP? Secondly, how does HHS envision a pilot facility maintain its approval (I would propose that we would make at least one lot of either our seasonal product, or a different vaccine product that gets approved in the future)?

**Answer 23: Pilot facilities are for manufacturing of clinical investigational lots of pandemic influenza vaccines for the United State Government's usage. The intent of this RFP is not to renovate pilot facilities into commercial licensed product facilities.**

**Question 24:** We are working with a commercial group to make commercial scale bulk product, however, their facility is not yet FDA approved. Can we jointly submit a proposal that will be responsive to the RFP?

**Answer 24: A commercial facility that does not produce an FDA-licensed biological product is not eligible.**

**Question 25:** One company (Alfa Laval Biokinetics) has requested that their contact information be posted with the Questions and Answers so that prospective bidders may have contact information for their company.

**Answer 25:** Alfa Laval Biokinetics stands ready to assist any company with their plans to produce pandemic flu vaccine in their US plant site(s). We are an Architectural Design/ Engineer ( A&E ) capable of providing facility and process design , process simulation and optimization , engineering , design/build, procurement, commissioning and validation services to satisfy your requirements for these services in keeping with the proposed project. Contact information is as follows:

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