

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE 1	Of 3
2. AMENDMENT/MODIFICATION NO. Three (3)	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.**

- 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.
- 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).
- C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
- 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.

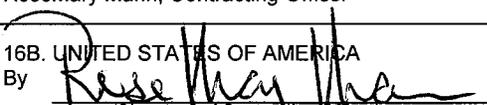
**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

The following changes are made to this solicitation:

- Revise the following to change the mandatory criteria for eligibility for FDA-licensed biological products and the timeline to licensure as detailed on pages 2 and 3 of this Amendment: Section B.1 paragraph 2; Section C.1 "Mandatory Criteria for Eligibility" paragraph; M.1 paragraph 1b and 2(b); and Section M.2 paragraph 1b and 5

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)	
		RoseMary Mann, Contracting Officer	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By 	16C. DATE SIGNED 8/15/06
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

**1. To revise paragraph 2, number (2) of B.1 to read as follows:**

Eligibility requirements for these contracts include the following: (1) The facility is located in the U.S.; (2) For proposed bulk and/or fill finish manufacturing, the facilities must be used currently to manufacture FDA licensed biological products and/or select pharmaceutical products (i.e. antibodies and biological enzymes); (3) Pilot facilities, as well as commercial scale facilities shall be in compliance with FDA, USDA and CDC regulatory and biosafety guidelines for pandemic influenza vaccine manufacturing, as applicable; (4) Commitment to share at least 25% of the overall adaptation capital cost; (5) Commitment to maintain the retrofitted manufacturing facility to support rapid stockpile production commensurate with U.S. pre-pandemic and pandemic influenza vaccine needs.

**2. To revise the first sentence and bullet number 2 of the below paragraph of section C.1 (Statement of Work), to read as follows:**

**Mandatory Criteria for Eligibility**

This solicitation is broad in scope to encourage proposal submissions from potential Offerors who manufacture FDA-licensed biological products and/or select pharmaceutical products (i.e. antibodies and biological enzymes). Because the timing of the next pandemic is uncertain and avian H5N1 influenza in Eurasia poses a substantial pandemic threat, short timelines to product licensure and availability are critical. Therefore, only Offerors that can fulfill the following pre-requisites will be eligible for funding under this solicitation:

- The facility is located in the U.S.
- For proposed bulk and/or fill finish manufacturing, the facilities must currently be used to manufacture FDA licensed biological products and/or select pharmaceutical products (i.e. antibodies and biological enzymes). Pilot facilities, as well as commercial scale facilities shall be in compliance with FDA, USDA and CDC regulatory and biosafety guidelines for pandemic influenza vaccine manufacturing, as applicable
- Commitment to share at least 25% of the adaptation or renovation costs.
- Commitment to maintain the retrofitted manufacturing facility to support rapid stockpile production commensurate with U.S. pre-pandemic and pandemic influenza vaccine needs.

**2. To revise paragraph 1b and paragraph 2(b) of M.1 (Mandatory Criteria for Eligibility)**

**1b. Manufacturer of FDA licensed biological product and/or select pharmaceutical products**

- For bulk manufacturing and/or fill finish, the facility is currently used to manufacture FDA-licensed biological product and/or select pharmaceutical products (i.e. antibodies and biological enzymes).

**2. Timeline and Intent for U.S. Product Licensure**

Given the ongoing threat of an influenza pandemic, it is essential that efforts funded as a result of this requirement lead to FDA approval of a facility that can be used to produce pandemic vaccines

to protect the U.S. population in the event of an influenza pandemic. Therefore, Offerors must commit to the following to be considered for award:

- (a) Provision of a clear and comprehensive plan and timeline for FDA licensure of the facility presented in the proposal.
  - (1) Including a description of key scientific, technical and managerial risks posed by the project, and plans to mitigate such risks
  - (2) Go/No Go decision tree with quantitative and qualitative criteria for evaluating the scientific and engineering merit of progressing to the next stage of the project.
- (b) Submission of a BLA supplement for the licensed influenza vaccine product manufactured in the proposed commercial scale manufacturing facility based on a contractor-defined timeline, that is subject to review and approval by the USG. (For bulk manufacturing and/or fill/finish facility proposals only)

**4. To revise paragraph 1 (b) (Methodology and Approach) and paragraph 5 of M.2 (Technical Evaluation Criteria) to read as follows:**

(b) The technical proposal must list products currently and previously manufactured at the proposed facilities. For proposed bulk and/or fill finish manufacturing, the Offeror must identify FDA licensed biological products and/or select pharmaceutical products (i.e. antibodies and biological enzymes) which are currently manufactured at the proposed facilities. The proposal shall provide a brief description of the manufacturing process. The proposal shall describe location and the biosafety containment of the facilities.

**5. Timeline to licensure**

The proposal shall provide a timeline for seeking FDA licensure of using the facility to manufacture influenza vaccine. Timelines for expedited facility reconstruction supporting licensure will be evaluated more favorably.