AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE 1 OF 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00002	See 16C		

6. ISSUED BY CODE 2538

Centers for Disease Control and Prevention (CDC)
Procurement and Grants Office/BTSPO
2920 Brandywine Road, Room 3000
Atlanta, GA 30341-5539

Contract Specialist: Pete Penny

7. ADMINISTERED BY *(If other than Item 6)* CODE 2538

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

CODE FACILITY CODE

(√)	
	9A. AMENDMENT OF SOLICITATION NO. 2004-N-01102
X	9B. DATED *(See Item 11)* 02/18/2004
	10A. MODIFICATION OF CONTRACT/ORDER NO.
	10B. DATED *(See Item 13)*

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] 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 0 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 ACKNOWLEGMENT 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.)*

See Page 2

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 OF CONTRACTING OFFICER Lorenzo J. Falgiano	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY Lorenzo J. Falgiano *(Signature of Contracting Officer)*	16C. DATE SIGNED 04/01/2004

Delete Section B.2 Schedule and replace with:

B.2 Schedule

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	Phase I: Development, Testing and Manufacturing Plan	1 Each		
0002	Phase II: Completed Protocol	1 Each		
0003	Phase III: Production Facility Plan	1 Each		
0004	Phase IV: Feasibility Plan	1 Each		
0005	Phase V: Contractor Defined Milestones	1 Each		
0006	Monthly Technical Progress Reports	12 Each		
0007	Final Report	1 Each		

Delete Section F.4 Deliverable(s) Schedule (Jul 1999) and replace with:

F.4 Deliverable(s) Schedule (Jul 1999)

The Contractor shall deliver, within the time frames specified, Item(s) No. 1 through 5 to the Project Officer, Carole Andres, at Carole.Andres@HHS.GOV, and Item(s) No. 1 through 5 to the Contract Sepcialist, Pete Penny at pmp7@cdc.gov.

Description	No. of Copies	Delivery Date
1. Phase I: Development, Testing and Manufacturing Plan	3	Three(3) months after contract award
2. Phase II: Completed Protocol	3	Four (4) months after contract award
3. Phase III: Production Facility Plan	3	Nine (9) months after contract award
4. Phase IV: Feasibility Plan	3	Twelve (12) months after contract award
5. Phase V: Contractor Defined Milestones	3	Twelve (12) months after contract award
6. Monthly Technical Progress Reports	3	30 days after contract award and monthly thereafter, due on the 15th of each month
7. Final Report	3	30 days before contract expiration

(End of Clause)

Delete Section C.3 and replace with:

C.3 Contract Tasks

1. **Phase I**: Within three (3) months of contract award, the Contractor shall provide to the USG a development, testing, and manufacturing plan for a trivalent inactivated influenza vaccine produced in cultured cells at a U.S.-manufacturing facility, using intellectual property to which the company has unencumbered access and a cell culture technology known to be suitable for the production of vaccines licensed for use in the U.S. or internationally. The development, testing, and manufacturing plan shall, at a minimum, include the following items:

A. A pre-clinical testing plan that is integrated with the clinical testing and manufacturing plans using the most current and available information including consultation with FDA.

B. A clinical testing plan that is integrated with the pre-clinical testing and manufacturing plans using the most current and available information including consultation with FDA. Clinical trials performed as a result of this solicitation shall include any of Phase 1, Phase 2, and Phase 3 trials, as needed to achieve U.S. licensure. Trials should include children, adults, and the elderly, as needed, to support licensure for both low and high-risk populations. Given the duration, cost, and importance of clinical trials, the schedule for each clinical trial should clearly indicate key events.

C. A regulatory development and support plan that is integrated with all testing and manufacturing activities using the most current and available information including consultation with FDA.

2. **Phase II**: Within four (4) months of contract award, the Contractor shall submit for review and approval a completed protocol and initiate vaccine development, pre-clinical studies, or clinical studies, as appropriate based on the current stage of development and as outlined in the development, testing, and manufacturing plan.

3. **Phase III:** Within nine (9) months of contract award, the Contractor shall provide the USG with a plan to establish a U.S- based production facility suitable for manufacture of a licensable trivalent inactivated influenza vaccine produced in cell culture. The manufacturing facility and production processes shall be maintained at current Good Manufacturing Practices (cGMP) standards throughout all manufacturing operations. The Contractors ability to meet standards for Biosafety Level (BSL) 3 is considered advantageous.

4. **Phase IV**: Within twelve (12) months of contract award, the Contractor shall provide a feasibility plan to manufacture, formulate, fill, and finish up to 300 million doses of monovalent inactivated influenza vaccine (assuming that a dose includes 15 mcg antigen) on an annualized basis when operating at full capacity. The routine level of operation and production of trivalent inactivated influenza vaccine for annual influenza outbreaks may be less. If the facility is designed as a multi-use facility, describe in detail, plans and timelines to switch-over to production of influenza vaccine at full capacity on an emergency basis at any time of year.

5. Phase V: Contactor defined Milestones
The Contractor shall provide a work breakdown structure including timelines and major Milestones to complete the remaining scope of work as relevant given the stage of vaccine development and evaluation. The Contractor shall propose Milestones at which time data will be presented summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Potential Milestones may include FDA acceptance of an Investigational New Drug (IND) application, production of an investigational lot of vaccine, completion of a clinical trial and progress to a new phase of vaccine evaluation, submission of a BLA, etc.