SOLICITATION, OFFER AND AWARD	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 51

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	HHS-BARDA-08-25	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)	07/31/2008	

7. ISSUED BY CODE

Department of Health and Human Services
OS/ASPR/BARDA
330 Independence Ave. SW, Room G644
Washington, DC 20201

8. ADDRESS OFFER TO *(If other than Item 7)*

NOTE: In sealed bid solicitations "offer" and "Offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and 5 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8 , or if handcarried, in the depository located in Block 7 until 2:30pm *(Hour)* local time 08/29/2008 *(Date)*

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE NUMBER EXT:	C. E-MAIL ADDRESS
	Mekeba Barrett	(202) 260-1591	Mekeba.Barrett@hhs.gov

11. TABLE OF CONTENTS

(x)	SEC.	DESCRIPTION	PAGE(S)	(x)	SEC.	DESCRIPTION	PAGE(S)
		PART I – THE SCHEDULE				PART II – CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	23-29
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2-8			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	9-13	X	J	LIST OF ATTACHMENTS	30
X	D	PACKAGING AND MARKING	14			PART IV – REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	15	X	K	REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS	31
X	F	DELIVERIES OR PERFORMANCE	16				
X	G	CONTRACT ADMINISTRATION DATA	17-18	X	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	32-47
X	H	SPECIAL CONTRACT REQUIREMENTS	19-22	X	M	EVALUATION FACTORS FOR AWARD	48-51

OFFER *(Must be fully completed by Offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 60 calendar days *(60 calendar days unless a different period is inserted by the Offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS %

14. ACKNOWLEDGMENT OF AMENDMENTS *(The Offeror acknowledges receipt of amendments to the SOLICITATION for Offerors and related documents numbered and dated:*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	DUNS CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER *(Type or Print)*

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )

23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)* ITEM

24. ADMINISTERED BY *(If other than Item 7)* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE
Linda D. Luczak		

IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

SECTION B--SUPPLIES OR SERVICES AND PRICES/COSTS

For the purposes of this solicitation, the U.S. is defined as the fifty states, the District of Columbia and Puerto Rico.

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This project from the Department of Health and Human Services (HHS) through the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) focuses on the acquisition of avian influenza H5N1 vaccine for the US Government Stockpile. A key goal of the US Pandemic Preparedness Plan is to build sufficient stockpiles of pre-pandemic vaccine in order to immunize a 20 million member critical workforce at the onset of an influenza pandemic and to continue the maintenance of an active and evolving U.S. stockpile of H5N1 vaccine for use at the time a pandemic is declared. Therefore, HHS wishes at this time to obtain H5N1 vaccine manufactured during the open window for seasonal influenza vaccine manufacturing using the U.S.-licensed commercial scale manufacturing process and facilities for seasonal trivalent egg-based inactivated influenza vaccines. The H5N1 virus seed stock will be derived from the virus reassortant of avian influenza H5N1 virus strain from the World Health Organization (WHO) list of recommended vaccine strains. HHS shall designate the specific virus strains for production by the Contractors.

B.2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This is an indefinite-delivery, indefinite-quantity (IDIQ) contract for H5N1 vaccine. During the ordering period of the contract, the Government may order supplies and services at the unit price or may request the Contractor to propose a price that will not exceed the unit price.

B.3. CONTRACT LINE ITEM NUMBERS (CLINS)

BASE YEAR: (September 15, 2008 through September 14, 2013)

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0001	**H5N1 Bulk Vaccine-Clade TBD (FFP)**				
0001AA	Bulk Dose	1-250,000	15µg HA/ dose	$	$
0001AB	Bulk Dose	250,001-5,000,000	15µg HA/ dose	$	$
0001AC	Bulk Dose	5,000,001-25,000,000	15µg HA/ dose	$	$
0001AD	Bulk Dose	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per dose/36mo)	Unit Price	Total Extended Estimated Amount
0002	**Storage w/Stability Testing for H5N1 Bulk Vaccine purchased under CLIN 0001 - Storage is for a period of 36 months after acceptance of product by the Contracting Officer(CO) (FFP)**				
0002AA	Bulk Storage	1-250,000	15µg HA/ dose	$	$
0002AB	Bulk Storage	250,001-5,000,000	15µg HA/ dose	$	$
0002AC	Bulk Storage	5,000,001-25,000,000	15µg HA/ dose	$	$
0002AD	Bulk Storage	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per dose/24 Mo)	Unit Price (per (does/mo)	Total Extended Estimated Amount (24 months)
0003	**Extended Storage of CLIN 0001 with Stability Testing for 24 months (Beyond initial 36 month storage w/stability testing)(FFP)**				
0003AA	Bulk Extended Storage	1-250,000	15µg HA/ dose	$	$
0003AB	Bulk Extended Storage	250,001-5,000,000	15µg HA/ dose	$	$
0003AC	Bulk Extended Storage	5,000,001-25,000,000	15µg HA/ dose	$	$
0003AD	Bulk Extended Storage	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0004	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen Only (FFP)**				
0004AA	Final Container	1-250,000	Dose	$	$
0004AB	Final Container	250,001-5,000,000	Dose	$	$
0004AC	Final Container	5,000,001-25,000,000	Dose	$	$
0004AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0005	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen and Adjuvant mixed together (FFP)**				
0005AA	Final Container	1-250,000	Dose	$	$
0005AB	Final Container	250,001-5,000,000	Dose	$	$
0005AC	Final Container	5,000,001-25,000,000	Dose	$	$
0005AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0006	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen and adjuvant vialed separately (FFP)**				
0006AA	Final Container	1-250,000	Dose	$	$
0006AB	Final Container	250,001-5,000,000	Dose	$	$
0006AC	Final Container	5,000,001-25,000,000	Dose	$	$
0006AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per dose/24 mo)	Unit Price	Total Extended Estimated Amount
0007	**Storage of final container for a period of 24 months of Item 0004, 0005, 0006, and 0011 (FFP)**				
0007AA	Storage (Final Cont.)	1-250,000	Dose	$	$
0007AB	Storage (Final Cont.)	250,001-5,000,000	Dose	$	$
0007AC	Storage (Final Cont.)	5,000,001-25,000,000	Dose	$	$
0007AD	Storage (Final Cont.)	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per dose/36 mo)	Unit Price	Total Extended Estimated Amount
0008	**Bulk Adjuvant (FFP)**				
0008AA	Bulk Adjuvant Dose	1-250,000	TBD	$	$
0008AB	Bulk Adjuvant Dose	250,001-5,000,000	TBD	$	$
0008AC	Bulk Adjuvant Dose	5,000,001-25,000,000	TBD	$	$
0008AD	Bulk Adjuvant Dose	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per dose/36 mo)	Unit Price	Total Extended Estimated Amount
0009	**Storage with Stability Testing of Bulk Adjuvant for a period of 36 months (FFP)**				
0009AA	Bulk Adjuvant Storage	1-250,000	TBD	$	$
0009AB	Bulk Adjuvant Storage	250,001-5,000,000	TBD	$	$
0009AC	Bulk Adjuvant Storage	5,000,001-25,000,000	TBD	$	$
0009AD	Bulk Adjuvant Storage	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price	Total Extended Estimated Amount
0010	**Extended Storage with Stability Testing for 24 months for CLIN 0008 (Beyond initial 36 month storage w/stability testing) (FFP)**				
0010AA	Ext. Adj. Storage	1-250,000	TBD	$	$
0010AB	Ext. Adj. Storage	250,001-5,000,000	TBD	$	$
0010AC	Ext. Adj. Storage	5,000,001-25,000,000	TBD	$	$
0010AD	Ext. Adj. Storage	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0011	**Final Container- Adjuvant filled in single dose or multi-dose vial at concentration TBD by HHS (FFP)**				
0011AA	Final Container	1-250,000	TBD	$	$
0011AB	Final Container	250,001-5,000,000	TBD	$	$
0011AC	Final Container	5,000,001-25,000,000	TBD	$	$
0011AD	Final Container	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0012	**Murine Immunogenicity Study (FFP)**	3	study	$	$

CLINS	Description	Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0013	**Clinical Study Immunogenicity (FFP)**	3	study	$	$

CLINS	Description	Qty	U/I	Unit Price	Total Extended Amount
0014	**Reports**				NOT SEPARATELY PRICED

OPTION YEAR I: (September 15, 2009 through September 14, 2014)

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0015	**H5N1 Bulk Vaccine-Clade TBD (FFP)**				
0015AA	Bulk Dose	1-250,000	15µg HA/ dose	$	$
0015AB	Bulk Dose	250,001-5,000,000	15µg HA/ dose	$	$
0015AC	Bulk Dose	5,000,001-25,000,000	15µg HA/ dose	$	$
0015AD	Bulk Dose	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/36 mo)	Unit Price	Total Extended Estimated Amount
0016	**Storage w/Stability Testing for H5N1 Bulk Vaccine purchased under CLIN 0015 a period of 36 months after acceptance of product by the Contracting Officer(CO) (FFP)**				
0016AA	Bulk Dose	1-250,000	15µg HA/ dose	$	$
0016AB	Bulk Dose	250,001-5,000,000	15µg HA/ dose	$	$
0016AC	Bulk Dose	5,000,001-25,000,000	15µg HA/ dose	$	$
0016AD	Bulk Dose	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price (per Dose/mo)	Total Extended Estimated Amount (24 months)
0017	**Extended Storage of CLIN 0015 with Stability Testing for 24 months (Beyond initial 36 month storage w/stability testing) (FFP)**				
0017AA	Bulk Ext. Storage	1-250,000	15µg HA/ dose	$	$
0017AB	Bulk Ext. Storage	250,001-5,000,000	15µg HA/ dose	$	$
0017AC	Bulk Ext. Storage	5,000,001-25,000,000	15µg HA/ dose	$	$
0017AD	Bulk Ext. Storage	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0018	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen Only (FFP)**				
0018AA	Final Container	1-250,000	Dose	$	$
0018AB	Final Container	250,001-5,000,000	Dose	$	$
0018AC	Final Container	5,000,001-25,000,000	Dose	$	$
0018AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0019	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen and Adjuvant mixed together (FFP)**				
0019AA	Final Container	1-250,000	Dose	$	$
0019AB	Final Container	250,001-5,000,000	Dose	$	$
0019AC	Final Container	5,000,001-25,000,000	Dose	$	$
0019AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0020	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen and adjuvant vialed separately (FFP)**				
0020AA	Final Container	1-250,000	Dose	$	$
0020AB	Final Container	250,001-5,000,000	Dose	$	$
0020AC	Final Container	5,000,001-25,000,000	Dose	$	$
0020AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price	Total Extended Estimated Amount
0021	**Storage of final container for a period 24 months of Item 0018, 0019, 0020 and 0025 (FFP)**				
0021AA	Storage (Final Cont.)	1-250,000	Dose	$	$
0021AB	Storage (Final Cont.)	250,001-5,000,000	Dose	$	$
0021AC	Storage (Final Cont.)	5,000,001-25,000,000	Dose	$	$
0021AD	Storage (Final Cont.)	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0022	**Bulk Adjuvant (FFP)**				
0022AA	Bulk Adjuvant Dose	1-250,000	TBD	$	$
0022AB	Bulk Adjuvant Dose	250,001-5,000,000	TBD	$	$
0022AC	Bulk Adjuvant Dose	5,000,001-25,000,000	TBD	$	$
0022AD	Bulk Adjuvant Dose	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per dose/36 mo)	Unit Price	Total Extended Estimated Amount
0023	**Storage with Stability Testing of Bulk Adjuvant purchase under CLIN 0022 for a period of 36 months (FFP)**				
0023AA	Bulk Adjuvant Storage	1-250,000	TBD	$	$
0023AB	Bulk Adjuvant Storage	250,001-5,000,000	TBD	$	$
0023AC	Bulk Adjuvant Storage	5,000,001-25,000,000	TBD	$	$
0023AD	Bulk Adjuvant Storage	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price	Total Extended Estimated Amount
0024	**Extended Storage with Stability Testing for a period of 24 months for product purchased under CLIN 0022 (Beyond initial 36 month storage w/stability testing) (FFP)**				
0024A	Ext. Adj. Storage	1-250,000	TBD	$	$
0024B	Ext. Adj. Storage	250,001-5,000,000	TBD	$	$
0024C	Ext. Adj. Storage	5,000,001-25,000,000	TBD	$	$
0024D	Ext. Adj. Storage	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0025	**Final Container- Adjuvant filled in single dose or multi-dose vial at concentration TBD by HHS (FFP)**				
0025A	Final Container	1-250,000	TBD	$	$
0025B	Final Container	250,001-5,000,000	TBD	$	$
0025C	Final Container	5,000,001-25,000,000	TBD	$	$
0025D	Final Container	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0026	**Murine Immunogenicity Study (FFP)**	3	study	$	$

CLINS	Description	Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0027	**Clinical Study Immunogenicity (FFP)**	3	study	$	$

CLINS	Description	Qty	U/I	Unit Price	Total Extended Amount
0028	**Reports**				NOT SEPARATELY PRICED

OPTION YEAR II: (September 15, 2010 through September 14, 2015)

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0029	**H5N1 Bulk Vaccine-Clade TBD (FFP)**				
0029AA	Bulk Dose	1-250,000	15µg HA/ dose	$	$
0029AB	Bulk Dose	250,001-5,000,000	15µg HA/ dose	$	$
0029AC	Bulk Dose	5,000,001-25,000,000	15µg HA/ dose	$	$
0029AD	Bulk Dose	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/36 mo)	Unit Price	Total Extended Estimated Amount
0030	**Storage w/Stability Testing of H5N1 Bulk Vaccine purchased under CLIN 0029, for a period of 36 months after acceptance of product by the Contracting Officer(CO) (FFP)**				
0030AA	Bulk Dose	1-250,000	15µg HA/ dose	$	$
0030AB	Bulk Dose	250,001-5,000,000	15µg HA/ dose	$	$
0030AC	Bulk Dose	5,000,001-25,000,000	15µg HA/ dose	$	$
0030AD	Bulk Dose	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price	Total Extended Estimated Amount
0031	**Extended Storage of product purchased under CLIN 0029 with stability testing for a period of 24 months (beyond initial 36 month storage with Stability testing) (FFP)**				
0031AA	Bulk Ext. Storage	1-250,000	15µg HA/ dose	$	$
0031AB	Bulk Ext. Storage	250,001-5,000,000	15µg HA/ dose	$	$
0031AC	Bulk Ext. Storage	5,000,001-25,000,000	15µg HA/ dose	$	$
0031AD	Bulk Ext. Storage	25,000,001-50,000,000	15µg HA/ dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0032	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen Only(FFP)**				
0032AA	Final Container	1-250,000	Dose	$	$
0032AB	Final Container	250,001-5,000,000	Dose	$	$
0032AC	Final Container	5,000,001-25,000,000	Dose	$	$
0032AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0033	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen and Adjuvant mixed together (FFP)**				
0033AA	Final Container	1-250,000	Dose	$	$
0033AB	Final Container	250,001-5,000,000	Dose	$	$
0033AC	Final Container	5,000,001-25,000,000	Dose	$	$
0033AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0034	**Final Container Vaccine formulated and filled into multi-dose vials (dosage TBD by HHS) Antigen and adjuvant vialed separately (FFP)**				
0034AA	Final Container	1-250,000	Dose	$	$
0034AB	Final Container	250,001-5,000,000	Dose	$	$
0034AC	Final Container	5,000,001-25,000,000	Dose	$	$
0034AD	Final Container	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price	Total Extended Estimated Amount
0035	**Storage of final container for a period of 24 months for CLINS 0032, 0033, 0034 and 0039 (FFP)**				
0035AA	Storage (Final Cont.)	1-250,000	Dose	$	$
0035AB	Storage (Final Cont.)	250,001-5,000,000	Dose	$	$
0035AC	Storage (Final Cont.)	5,000,001-25,000,000	Dose	$	$
0035AD	Storage (Final Cont.)	25,000,001-50,000,000	Dose	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0036	**Bulk Adjuvant (FFP)**				
0036AA	Bulk Adjuvant Dose	1-250,000	TBD	$	$
0036AB	Bulk Adjuvant Dose	250,001-5,000,000	TBD	$	$
0036AC	Bulk Adjuvant Dose	5,000,001-25,000,000	TBD	$	$
0036AD	Bulk Adjuvant Dose	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/36 mo)	Unit Price	Total Extended Estimated Amount
0037	**Storage with Stability Testing for Bulk Adjuvant purchased under CLIN 0036 for a period of 36 months (FFP)**				
0037AA	Bulk Adjuvant Storage	1-250,000	TBD	$	$
0037AB	Bulk Adjuvant Storage	250,001-5,000,000	TBD	$	$
0037AC	Bulk Adjuvant Storage	5,000,001-25,000,000	TBD	$	$
0037AD	Bulk Adjuvant Storage	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I (per Dose/24 mo)	Unit Price	Total Extended Estimated Amount
0038	**Extended Storage of CLIN 0036 with Stability Testing for 24 months (Beyond initial 36 month storage w/stability testing) (FFP)**				
0038AA	Ext. Adj. Storage	1-250,000	TBD	$	$
0038AB	Ext. Adj. Storage	250,001-5,000,000	TBD	$	$
0038AC	Ext. Adj. Storage	5,000,001-25,000,000	TBD	$	$
0038AD	Ext. Adj. Storage	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Maximum Estimated Qty	U/I	Unit Price	Total Extended Estimated Amount
0039	**Final Container- Adjuvant filled in single dose or multi-dose vial at concentration TBD by HHS (FFP)**				
0039AA	Final Container	1-250,000	TBD	$	$
0039AB	Final Container	250,001-5,000,000	TBD	$	$
0039AC	Final Container	5,000,001-25,000,000	TBD	$	$
0039AD	Final Container	25,000,001-50,000,000	TBD	$	$

CLINS	Description	Estimated Qty	U/I	Unit Price	Total Extended Amount
0040	**Murine Immunogenicity Study (FFP)**	3	study	$	$

CLINS	Description	Estimated Qty	U/I	Unit Price	Total Extended Amount
0041	**Clinical Study Immunogenicity (FFP)**	3	study	$	$

CLINS	Description	Qty	U/I	Unit Price	Total Extended Amount
0042	**Reports**				NOT SEPARATELY PRICED

B.4 MINIMUM AND MAXIMUM ORDER LIMITATIONS

B.4.1. The Government shall guarantee a minimum of only 250,000 bulk vaccine antigen doses at 15 μg HA/dose under CLIN 0001 (CLIN 0015 for Option Year I and CLIN 0029 for Option Year II).

B.4.2. The maximum ordering limitation for CLINS 0001 through 0011, CLINS 0015 through 0025 and CLINS 0029 through 0039 is 50,000,000 vaccine doses.

B.5. ADVANCE UNDERSTANDINGS:

B.5.1. The offeror may invoice for CLINS 0001, 0004, 0005. 0006, 0008, and 0026 (Base Year); CLINS 0015, 0018, 0019, 0020, 0022 and 0025 (Option Year I; and CLINS 0029, 0032, 0033, 0034, 0036 and 0039 (Option Year II) after acceptance of product by the Contracting Officer.

B.5.1. The offeror may invoice for CLINS 0002, 0003, 0007, 0009 and 0010 (Base Year); CLINS 0016, 0017, 0021, 0023 and 0024 (Option Year I); and CLINS 0030, 0031, 0035, 0037 and 0038 (Option Year II), once the bulk or final product is accepted by the Contracting Officer, storage shall begin immediately. The offeror will be responsible for maintain the Government Furnished Property in accordance with FAR 52.245-1. Invoicing for these CLINS shall be done at a minimum on a quarterly, semi-annually or annual basis.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

C.1.2 Background

C.1.2.1 Independently and not as an agent of the U.S. Government (USG), the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to perform the work described below:

C.1.2.1.1 The Contractor shall provide an egg-based inactivated monovalent H5N1 bulk vaccine product based on a dosage of 15μg per dose and suitable for formulation and filling. The Contractor shall demonstrate a successful experience in the bulk manufacturing of H5N1 vaccine at commercial scale using a U.S licensed manufacturing and release process. Bulk manufacturing facilities shall be in compliance with current WHO biosafety guidelines for avian influenza vaccine manufacturing including BSL2+ enhanced biocontainment facilities and procedures .

C.1.2.1.2. It is a preference of the USG that the Contractor manufactures bulk vaccines and bulk adjuvants in the U.S. However, when a Contractor is using a manufacturing facility outside the U.S. the bulk vaccine and adjuvant shall be shipped to the US as soon as the bulks are lot released and accepted by the USG. Bulk vaccine and adjuvant shall be stored in a US facility approved by the USG. The contractor using a FDA-cGMP approved storage site shall specify the location and terms of the storage contract and receive approval by the USG. If the bulk vaccine and adjuvant requires any testing for importation into the U.S the testing should be perform according to USDA requirements and the Contractor will bear all costs for shipping and testing. Shipment of the vaccine or adjuvant to the U.S. shall be coordinate with HHS and other offices/agencies involved in importation of vaccines.

C.1.2.1.3 Formulation/fill/finish activities of vaccine and adjuvant shall be carried out in the U.S at facilities in compliance with FDA cGMP guidelines and in accordance with the formulation and filling requirements that apply to FDA-licensed seasonal trivalent influenza vaccine product unless otherwise requested and specified by the USG.

C.1.3. Description:

C.1.3.1 Under CLINS 0001, 0015 and 0029 the Contractor shall provide an egg-based inactivated monovalent H5N1 bulk vaccine product based on a dosage of 15μg per dose and suitable for formulation and filling multi-dose vials. The H5N1 vaccine product shall be manufactured using the same facilities, systems, equipment, processes, and testing as those used for the FDA-licensed seasonal egg-based inactivated trivalent influenza vaccine. The H5N1 vaccine shall be produced using a qualified virus reference strain comprised of the reassortant avian influenza virus, as designated by HHS.

C.1.3.1.1 The Contractor shall:

- Manufacture the bulk vaccine product at commercial scale in FDA-licensed commercial manufacturing facilities, during the off-season time for inter-pandemic seasonal trivalent influenza vaccine manufacturing, according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing and prior to formulation.
- Use a validated and licensed commercial-scale production process for seasonal influenza vaccine to manufacture an egg-based inactivated monovalent H5N1 bulk vaccine concentrate.
- Provide lot release product testing of the H5N1 bulk vaccine concentrates including potency using lot release specifications similar to those of the FDA-licensed seasonal influenza vaccine product and provide, if requested, samples of the bulk product to the FDA (or other designated laboratory) for hemagglutinin (HA) antigen calibration as performed for seasonal influenza vaccine
- Provide batch records for the manufactured lots at HHS request.
- Provide viral reference antigen and sera for calibration of HA antigen in the H5N1 bulk vaccine appropriate for this strain of H5N1 virus when requested.

C.1.3.2. Under CLIN 0002, 0016 and 0030, the contractor shall store H5N1 bulk vaccine concentrates up to thirty six (36) months at the Contractor site or at a designated facility approved by HHS and perform stability studies up to thirty six (36) months past release of the bulk final product applying FDA cGMP guidelines and in accordance with the storage and stability requirements that apply to FDA-licensed seasonal trivalent influenza vaccine product.

C.1.3.3. Under CLINS 0003, 0017 and 0031, the Contractor shall extend the storage of H5N1 bulk vaccine concentrates for twenty four (24) months at the Contractor site or at a designated facility approved by the Contrating Officer and perform stability studies for this additional twenty four (24) months upon execution of this option by the Contracting Officer.

C.1.3.4. Under CLINS 0004, 0018 and 0032, the Contractor shall perform the following activities upon execution of this option in the contract by the U.S. Government:

- Formulation of commercial scale lots of H5N1 bulk vaccine concentrates at the approved concentration and at a dosage to be determined by the U.S. Government based on clinical experience with these vaccines.
- Dispense formulated H5N1 vaccine product into multi-dose vials (10doses/vial) at a volume of 0.1-1.0 ml per dose.
- Affix labels onto filled vials with FDA-approved text for a similar product such as seasonal flu vaccine product.
- Package filled and labeled vials into suitable containers used similarly for the FDA-licensed seasonal influenza vaccine product and store at appropriate conditions during lot release product testing.
- Provide lot release product testing of the H5N1 final container vaccine using lot release specifications similar to those of the FDA-license seasonal influenza vaccine product.

C.1.3.5. Under CLINS 0005, 0019 and 0033, the Contractor shall perform the following activities upon execution of this option in the contract by the U.S. Government:

- Formulation of commercial scale lots of H5N1 bulk vaccine concentrates with adjuvant at the approved concentration and at a dosage to be determined by the U.S. Government based on clinical experience with these vaccines.
- Dispense formulated H5N1 vaccine product into multi-dose vials (10doses/vial) at a volume of 0.1-1.0 ml per dose.
- Affix labels onto filled vials with FDA-approved text for a similar product such as seasonal flu vaccine product.
- Package filled and labeled vials into suitable containers used similarly for the FDA-licensed seasonal influenza vaccine product and store at appropriate conditions during lot release product testing.
- Provide lot release product testing of the H5N1 final container vaccine using lot release specifications similar to those of the FDA-license seasonal influenza vaccine product.

C.1.3.6. Under CLINS 0006, 0020 and 0034, the Contractor shall perform the following activities upon execution of this option in the contract by the U.S. Government:

- Formulation of commercial scale lots of H5N1 bulk vaccine concentrates and adjuvant separately. Antigen and adjuvant will be formulated at the approved concentration and at a dosage to be determined by the U.S. Government based on clinical experience with these vaccines.
- Dispense formulated H5N1 vaccine product into multi-dose vials (10doses/vial) at a volume of 0.1-1 ml per dose.
- Dispense formulated adjuvant into separate multi-dose vials (10doses/vial) at a volume of 0.1-0.5 ml per dose.
- Affix labels onto filled vials with vaccine and adjuvant with FDA-approved text for a similar product such as seasonal flu vaccine product.
- Package filled and labeled vials into suitable containers used similarly for the FDA-licensed seasonal influenza vaccine product and store at appropriate conditions during lot release product testing.
- Provide lot release product testing of the H5N1 final container vaccine using lot release specifications similar to those of the FDA-license seasonal influenza vaccine product.

C.1.3.7. Under CLINS 0007, 0021 and 0035, the Contractor shall store the final container product at the Contractor site or at a designated facility approved by HHS.

- Perform stability studies up to twenty four (24) months past release of final container product upon execution of this option by the Contracting Officer and in compliance with FDA cGMP guidelines and in accordance with the storage and stability requirements that apply to FDA-licensed seasonal trivalent influenza vaccine product.
- Manage and account for intellectual property rights that pre-exist or may develop through the activities of the Contractor, including maintenance of security of confidential and/or proprietary data.

C.1.3.8. Under CLINS 0008, 0022 and 0036, the Contractor shall provide an adjuvant bulk product based on a dosage to be determined by HHS. The Contractor shall:

- Manufacture the bulk adjuvant product at commercial scale according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing.
- Provide lot release product testing of the adjuvant.

C.1.3.9. Under CLINS 0009, 0023, and 0037, the contractor shall store adjuvant bulk vaccine concentrates up to thirty six (36) months at the Contractor site or at a designated facility approved by the Contracting Officer and perform stability studies up to thirty six (36) months past release of the product upon execution of this option by the Contracting Officer, in compliance with FDA cGMP

guidelines and in accordance with the storage and stability requirements that apply to FDA-licensed seasonal trivalent influenza vaccine product.

C.1.3.10. Under CLINS 0010, 0024 and 0038, the Contractor shall extend the storage of the adjuvant bulk for twenty four (24) months at the Contractor site or at a designated facility approved by HHS and perform stability studies for additional twenty four (24) months upon execution of this option by the Contracting Officer.

C.1.3.11. Under CLINS 0011, 0025 and 0039, the Contractor shall perform the following activities upon execution of this option in the contract by the U.S. Government:

- Formulation of commercial scale lots of adjuvant bulk at a dosage to be determined by the U.S. Government based on clinical experience with these adjuvants.
- Dispense formulated adjuvant product into single dose or multi-dose vials (10doses/vial) at a volume of 0.1-0.5 ml per dose.
- Affix labels onto filled vials with adjuvant with FDA-approved text for a product such as seasonal flu vaccine product..
- Package filled and labeled vials into suitable containers used similarly for the FDA-licensed seasonal influenza vaccine product and store at appropriate conditions during lot release product testing.
- Provide lot release product testing of adjuvant final container.

C.1.3.12. Under CLINS 0012, 0026 and 0040, the Contractor shall perform murine immunogenicity studies using the stored vaccine upon execution of this option in the contract by the U.S. Government:

- Bulk vaccine or filled vaccine stored can be used for animal studies to monitor vaccine safety and stability. A baseline study shall be conducted as soon as the bulk vaccine or filled vaccine is released.
- Protocol will be provided by HHS and the study to be conducted by the Contractor or Subcontractor will involve the use of 80 mice, divided in 4 groups. Each group will receive vaccine at different dosage.

C.1.3.13. Under CLINS 0013, 0027 and 0041, the Contractor shall perform clinical studies to assess and monitor immunogenicity of the stored vaccine upon execution of this option in the contract by the U.S. Government:

- Bulk vaccine or filled vaccine stored can be used for clinical studies. A baseline study shall be conducted as soon as the bulk vaccine or filled vaccine is released.
- Protocol will be provided by HHS and the study to be conducted by the Contractor or subcontractor will involve the use of 50-500 subjects, receiving two doses of vaccine at concentration to be determined by HHS or placebo.

C.1.3.14. Under CLINS 0014, 0028 and 0042, the Contractor shall submit inventory reports, monthly progress reports, executive summaries, and a final report as described in detail in the Reporting requirements and Deliverables. Release protocols and reports shall be also provided to HHS after each manufacturing campaign.

C.1.4 Resources:

C.1.4.1. The Contractor shall provide the following items for the manufacturing, testing, and storage of the H5N1 vaccine products:

- Validated facilities, systems, equipment, and manufactured processes for cGMP manufacturing of licensed bulk and final container egg-based inactivated influenza vaccine product.
- Validated and approved assays and equipment for lot release of licensed bulk and final container influenza vaccine products and in stability studies.
- Validated facilities, systems, and equipment suitable for cGMP storage of bulk and final container influenza vaccine products.
- Approved facilities, equipment, and policies to receive, store, utilize, and dispose of biohazardous materials (Biosafety Level 2 +) in appropriate conditions
- Approved biosafety measures compliant with WHO biosafety guidelines for avian influenza vaccine including protective garments, equipment, sufficient monitoring to assure safe handling of potentially hazardous materials for the safety and protection of workers. Conduct work under the contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions.
- Stability testing of the bulk monovalent and final container vaccines in a manner consistent with the stability program in place for commercial, licensed inactivated influenza virus vaccines.
- System to retain all records, samples, etc. as indicated under GLP and cGMP guidelines for U.S. Government inspection during site visits of the manufacturing facilities
- Notification to the Contracting Officer prior to any disposal of material, records, documentation, and/or reports for consultation and disposition

C.1.5 Meetings and Conferences:

The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Contracting Officer's Representative. Such meetings may include, but are not limited to, meetings of all Contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, clinical study designs and regulatory issues, meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the Contractor. Monthly teleconferences with the Contractor and subcontractors with HHS officials will be held at times and dates to be determined to review technical and product development progress, except during clinical lot manufacturing when meetings shall be held on a weekly basis. In addition, the Contracting Officer's Representative may schedule progress reviews, including quarterly progress reviews, on-site at the Contractor's facilities and other locations.

C.2. REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the Contracting Officer and the Contracting Officer's Representative technical progress reports covering the work accomplished during each reporting period on a periodic basis as established by the Contracting Officer's Representative. These reports are subject to the technical inspection and requests for clarification by the Contracting Officer's Representative. These reports shall be brief and factual and prepared in accordance with the following format:

C.2.1. **Technical Progress Reports**: On the fifteenth (15^{th}) of each month for the previous calendar month or within fifteen days past the achievement of prescribed project milestones, the Contractor shall submit a report to the Contracting Officer's Representative and the Contracting Officer. The frequency of Technical Progress Reporting will be determined by the Contracting Officer and Contracting Officer's Representative during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the Contracting Officer's Representative. Technical Progress Reports will include baseline and updated project timelines, milestones and summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period when the Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail to the Contracting Officer's Representative, Contract Officer and any others they designate. Any attachments to the e-mail report shall be submitted in Microsoft Word or Word Perfect, Microsoft Excel, Microsoft Project Manger, and/or Adobe Acrobat PDF files. Such reports shall include the following specific information:

C.2.1.a Title page- containing Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

C.2.1.b Introduction/Background - An introduction covering the purpose and scope of the contract effort

C.2.1.c Progress - The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also, to be included is a summary of work planned for the next reporting period.

C.2.1.d Issues - Issues resolved, new issues and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines are provided

C.2.1.e Invoices – Summary of any invoices submitted during the reporting period

C.2.1.f Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom.

C.2.1.g Distribution List – A list of persons receiving the Technical Progress report

C.2.1.h Attachments – Results on the project are provided as attachments

C.2.2. **Executive Summary**- The executive summary shall accompany each Technical Progress Report, will be formatted in Microsoft Power Point presentations and include the following:

C.2.2.a. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission

C.2.2.b. Project Progress presented as milestone events, test results, tasks, and other activities achieved during the reporting period as talking point bullets

C.2.2.c. Project Issues presented headings and each item as a talking point bullet.

C.2.3. **Final Reports** - By the expiration date of the contract, the Contractor shall submit a comprehensive Final Report that shall detail, document, and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved. A draft Final Report will be submitted to the Contracting Officer's Representative for review and revision, then the original, four copies, and an electronic file containing the Final Report with revisions shall be submitted to the Contracting Officer's Representative for distribution to the Contracting Officer and the Program office.

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. SHIPPING

D.1.1.. Method of Delivery

Unless otherwise specified by the Contracting Officer, delivery of items, to be furnished to the government under this contract (including invoices), shall be made by United States Postal Service mail delivery, overnight mail delivery or courier service.

D.1.2. Addressees – For all contract deliverables.

Contracting Officer's Representative (COR)
HHS/OS/ASPR/BARDA
330 Independence Avenue, SW
Room G640
Washington, D.C. 20201

Contracting Officer
HHS/OS/ASPR/BARDA
330 Independence Avenue, SW
Room G644
Washington, D.C. 20201

D.2. PREPARATION OF VACCINES FOR TRANSPORT

All vaccines shall be labeled, packaged and marked in standard commercial manner. Products shall be packed to ensure maintenance of FDA recommended temperature during transit and safe arrival at destination. Freeze Watch Indicators (FWI) or equivalent temperature indicating devices shall be packed in each container containing influenza vaccine. The Contractor is required to maintain records that document the date of delivery receipt, and that the vaccine was properly maintained within the recommended cold chain temperatures during transit and receipt.

SECTION E – INSPECTION AND ACCEPTANCE

E.1 The Contracting Officer or the duly authorized representative (who for purposes of this contract will be the COR) will perform inspection and acceptance of materials and services to be delivered under the contract. Any product produced or stored under this contract shall be subject to inspection by the Contracting Officer and Contracting Officer's Representative. Upon receipt and inspection of final lot release data, the Contracting Officer will notify the Contractor and if applicable, storage of product shall begin.

E.2 Announced or unannounced inspections of stockpile quantities may be made at storage facilities by a duly authorized US Government representative, not to exceed two per year and with reasonable notice (i.e. not less than 24 hours). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this contract and all records related to the manufacture, testing and storage of the product.

E.3 FAR 52,252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://www.acquisition.gov
http://www.hhs.gov/oamp/policies/
http://www.gpoaccess.gov/cfr/index/html

FAR REFERENCE	TITLE	DATE
FAR 52.246-1	Contractor Inspection Requirements	Apr 1984
FAR 52.246-2	Inspection of Supplies – Fixed Price	Aug 1986
FAR 52.246-16	Responsibility for Supplies	Apr 1984

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ORDERING PERIODS

The ordering period for each contract period shall be as follows:

- Base Year: CLIN 0001 and 0008 may be ordered between September 15, 2008 through September 14, 2009. CLINS 0002 through 0007 and 0009 through 0014 may be ordered between December 1, 2008 through September 14, 2013.

- Option Year I: CLIN 0015 and 0022 may be ordered between September 15, 2009 through September 14, 2010. CLINS 0016 through 0021 and 0023 through 0028 may be ordered between December 1, 2009 through September 14, 2014.

- Option Year II: CLINS 0029 and 0036 may be ordered between September 15, 2010 through September 14, 2011. CLINS 0030 through 0035 and 0037 through 0042 may be ordered between December 1, 2010 through September 14, 2015.

F.2 INVENTORY REPORTS

The Contractor shall provide the Contracting Officer's Representative with monthly inventory summaries of all H5N1 influenza vaccines in storage. Inventories reported shall be current as of the last working day of the month, and submitted within 15 days following the end of the month, unless otherwise directed. The report shall provide the following information for each vaccine lot:

Lot Number
Expiration Date
Number of Doses

(End of Clause)

F.3 DATES FOR DELIVERY OR PERFORMANCE

The Contractor shall accomplish delivery or performance no later than 12 months after the date of each order unless the period of performance as referenced in the Schedule B references a longer period of performance or an earlier date for the order is mutually agreed between the Government and the Contractor.

F.4 CLAUSES

FAR 52.252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://www.acquisition.gov
http://www.hhs.gov/oamp/policies/
http://www.gpoaccess.gov/cfr/index/html

FAR REFERENCE	TITLE	DATE
FAR 52.242-15	Stop-Work Order	AUG 1989
FAR 52.242-17	Government Delay of Work	APR 1984
FAR 52.247-34	F.O.B. – Destination	NOV 1991

SECTION G – CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

G.1.1. The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

G.1.2. The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

G.1.3. No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from this contract.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The USG Contracting Officer's Representative(s) will be identified in the final contract.

The Contracting Officer's Representative is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

G.3. HHSAR 352.270-5 KEY PERSONNEL (JANUARY 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individual(s) are considered essential to the work being performed hereunder:

NAME	TITLE
[To Be Specified Prior To Award]	

G.4. PAYMENT BY ELECTRONIC FUNDS TRANSFER

G.4.1. The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer – Central Contractor Registration, in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.4.2. The contractor shall make the designation by submitting the form entitled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. The form either is attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer.

G.4.3. In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required.

G.4.4. The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted to the Contracting Officer.

G.5 INVOICE SUBMISSIONS

G.5.1. The Contractor shall submit invoices to the Contracting Officer.

G.5.2. The Contractor agrees to include (as a minimum) the following information on each invoice:

G.5.2.1. Contractors's Name & Address
G.5.2.2. Contractor's Tax Identification Number (TIN)
G.5.2.3. Contract Number
G.5.2.4. Invoice Number
G.5.2.5. Invoice Date
G.5.2.6. Contract Line Item Number
G.5.2.7. Quantity
G.5.2.8. Unit Price & Extended Amount for each line item
G.5.2.9. Total Amount of Invoice
G.5.2.10. Name, title and telephone number of person to be notified in the event of a defective invoice.
G.5.2.11. Payment Address, if different from the information in G.6.2.1.

G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the pre-award negotiation process, the acquisition of property (other than real property), this paragraph will include applicable provisions and incorporate the HHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990), which can be found at:

http://www.knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

G.7. POST AWARD EVALUATION OF PAST PERFORMANCE

Interim and final evaluations of contractor performance shall be conducted on this contract in accordance with FAR 42.15. The final performance evaluation shall be completed at the time of completion of work. Interim and final evaluations will be submitted to the Contractor as soon as practicable. The Contractor will be permitted thirty (30) days to review the document and to submit additional information or a rebutting statement.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities see FAR Subpart 3.8, FAR Clause 52.203-12 and HHSAR 352.270-10.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or and State or Local legislature.

H.2. SUBCONTRACTING PROVISIONS

H.2.1 Small Business Subcontracting Plan

H.2.1.1 The Small Business Subcontracting Plan, dated (to be completed at contract award) is attached hereto and made a part of this contract.

H.2.1.2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

H.2.2. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

H.2.2.1. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

H.2.2.2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following email address:

[Email address to be included at award]

H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.4. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.5. NOTICE PRIOR TO PUBLICATION

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.270-6.

H.6. ACKNOWLEDGEMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 104-208 mandates that contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, request for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. *[insert #]*"

C. Press Releases

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H.7. PRODUCT LICENSURE

H.7.1. The influenza vaccines purchased, stored and distributed under this contract shall be manufactured under a current establishment and product licensure issued by the Food and Drug Administration. Offeror shall indicate number below:

Name of Vaccine (as applicable): _____

License Number (s) (as applicable: _____

H.7.2. The Contractor agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological and reagents.

H.7.3. The Contractor agrees to advise the Contracting Officer and Contracting Officer's Representative immediately of any relocation of their prime manufacturing facility or the relocation of any subcontractor's facility. Contractor also agrees to advise the Contracting Officer and Contracting Officer's Representative immediately if at any time during the life of the contract, the items listed under this contract fail to comply cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

H.8. FINAL DISTRIBUTION

Prior to expiration or termination of this contract, the Government may effect final distribution of any vaccines remaining in storage by any one or combination of the following methods:

H.8.1. The Government may elect to require shipment of the vaccine to US Government facilities or to state and local health agencies and/or other providers.

H.8.2. The Government may direct the Contractor to destroy all quantities remaining in storage at a charge to be negotiated between the parties. Such charges shall not exceed the actual costs incurred by the Contractor, and agreed to by the Government in advance of the destruction and/or disposal.

H.8.3. The Contractor cannot reclaim title to product upon acceptance.

H.9. HUMAN SUBJECTS (IF NECESSARY, APPLICABLE TO CLINS 0012, 0013, 0026, 0027, 0040 AND 0041)

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

H.10. HUMAN MATERIALS (IF NECESSARY, APPLICABLE TO CLINS 0012, 0013, 0026, 0027, 0040 AND 0041)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

H.11. ANIMAL WELFARE (IF NECESSARY, APPLICABLE TO CLINS 0012, 0013, 0026, 0027, 0040 AND 0041)

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:
http://grants1.nih.gov/grants/olaw/references/phspol.htm.

H.12. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of the contract, the Offeror fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Offeror shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Offeror fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H.13. PUBLICATIONS AND PUBLICITY (January 2006)

(a) Unless otherwise specified in this contract and the Confidentiality of Information clause is included, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

> "The views expressed in written conference materials or publications and by speakers and moderators at HHS-sponsored conferences, do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

(c) Unless authorized by the Project Officer, the contractor shall not display the HHS logo on any conference materials or publications.

(End of clause)

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

THE FOLLOWING GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO THE CONTRACT RESULTING FROM THIS RFP. OFFERORS ARE ENCOURAGED TO REVIEW THESE CLAUSES AND TO DISCUSS ANY QUESTIONS THEY MAY HAVE ABOUT THEM PRIOR TO THE CLOSING DATE OF THE RFP.

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also the full text of a clause may be accessed electronically at this/these address(es):

http://www.acquisition.gov/comp/far/index.html.
http://www.hhs.gov/oamp/policies/hssar.doc

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE .	DATE	TITLE
52.202-1	Jul 2004	Definitions (Over $100,000)
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sep 2007	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Apr 2008	Central Contractor Registration
52.209-6	Sep 2006	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data (Over $650,000)
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $650,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions

52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.216-18	Oct 1995	Ordering (In paragraph (a), insert "the date of contract award" and "contract completion date."
52.216.19	Oct 1995	Order Limitations (In paragraph (a), insert "250,000 bulk doses under CLIN 0001, 0015 and 0029 only. In paragraph (b), insert in subparagraphs (1) and (2) "50 million doses" and in subparagraph (3) "30". In paragraph (d), insert "30".)
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Apr 2008	Small Business Subcontracting Plan (Over $550,000, $1,000,000 for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $550,000, $1,000,000 for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sep 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over $100,000)
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Sep 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over $100,000)
52.222-50	Aug 2007	Combating Trafficking in Persons
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act – Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-12	Jan 1997	Patent Rights - Retention by the Contractor (Long Form).
52.227-14	Dec 2007	Rights in Data - General

52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-1	Aug 1987	Changes – Fixed Price
52.244-2	Jun 2007	Subcontracts
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Mar 2007	Subcontracts for Commercial Items
52.245-1	Jun 2007	Government Property
52.245-9	Jun 2007	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-2	May 2004	Termination for Convenience of the Government (Fixed-Price)
52.249-8	Apr 1984	Defaut (Fixed-Price Supply and Service)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2006)
352.216-72	Jan 2006	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Jan 2006	Withholding of Contract Payments
352.233-70	Jan 2006	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-6	Jan 2006	Publications and Publicity
352.270-10	Jan 2006	Anti-Lobbying

I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/ Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

FAR 52.219-9, Small Business Subcontracting Plan (April 2008), **Alternate II** (October 2001) is added.

I.3. ADDITIONAL CONTRACT CLAUSES INCORPORATED BY REFERENCE

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

I.3.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (July 2005).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

FAR 52.217-9, Option to Extend the Term of the Contract (March 2000)

(Insert under Paragraph (a) "30 days" under both references; and insert under Paragraph (c) " ... nine years.")

I.3.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) **HHSAR 352.223-70, Safety and Health (January 2006).**

(2) **HHSAR 352.224-70, Confidentiality of Information (January 2006).**

(3) **HHSAR 352.249-14 Excusable delays (January 2006)**

I.4. ADDITIONAL FAR CLAUSES INCORPORATED IN FULL TEXT

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

I.4.1. **FAR 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees (December 2004)**

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National

Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov .

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;
(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or
(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

I.4.2. FAR 52.227-14, Rights in Data-General (December 2007), Alternate II (December 2007)

(g)(2) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (December 2007)

(a) These data are submitted with limited rights under Government Contract No. (TBD at award) and subcontracts. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

(i) Use (except for manufacture) by support service contractors.

(b) This Notice shall be marked on any reproduction of these data, in whole or in part.

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

I.4.3. HHSAR 352.270-8 PROTECTION OF HUMAN SUBJECTS (Jan 2006) ***(IF NECESSARY, APPLICABLE TO CLINS 0012, 0013, 0026, 0027, 0040 AND 0041)***

Protection of Human Subjects (January 2006)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.
(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The

parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting Officer determines, in consultation with the OHRP, OPHS, ASH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OHRP, OPHS, ASH, terminate this contract in a whole or in part, and the Contractor's name may be removed form the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of clause)

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

All attachments are located at the end of Section M and are incorporated into this RFP:

J.1 SOLICITATION ATTACHMENTS:

Attachment No.	Title	Number of Pages
Attachment 1:	Packaging and Delivery of Proposal	2
Attachment 2:	Proposal Intent Response Sheet	1
Attachment 3:	Past Performance Questionnaire	4
Attachment 4:	Government Notice for Handling Proposals	1
Attachment 5:	Offeror's Points of Contact	1
Attachment 6:	Disclosure of Lobbying Activities, OMB Form SF-LLL	3 (including instructions)
Attachment 7:	ACH Vendor/Miscellaneous Payment Enrollment Form (w/instructions)	2

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and

   (Offerors shall indicate in their business proposal that the Online Representations and Certifications have been completed.)

To Be Completed by the Offeror: The following must be completed and included as part of your Business Proposal. By submission of its signed offer, the Offeror makes the following Representations and Certifications:

K.1. FAR 52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2006)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is 325414.

(2) The small business size standard is 500 employees.

(3) The small business size standard for a concern, which submits, and offer in its own name, other than on a construction or service contract but which proposes to furnish a product, which it did not itself manufacture, is 500 employees.

(b) (1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (c) of this provision applies.

(2) If the clause at 52.204-7 is not included in this solicitation and the Offeror is currently registered in CCR and has completed the ORCA electronically, the Offeror may choose to use paragraph (c) of this provision instead of competing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

[ ] (i) Paragraph (c) applies

[ ] (ii) Paragraph (c) does not apply and the Offeror has completed the individual representations and certifications in the solicitation.

(c) The Offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at http://orca.bpn.gov. After reviewing the ORCA database information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (se FAR 4.1201); except for the changes identified below [*Offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate and complete as of the date of this offer.

FAR Clause #	Title	Date	Change

Any changes provided by the Offeror are applicable to this solicitation only and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1. BACKGROUND

L.1.1. INTRODUCTION AND RATIONALE

The Department of Health and Human Services has a requirement for the acquisition of avian influenza H5N1 vaccine for the US Government Stockpile. A key goal of the US Pandemic Preparedness Plan is to build sufficient stockpiles of pre-pandemic vaccine in order to immunize a 20 million member critical workforce prior to and at the onset of an influenza pandemic.

As part of a pandemic vaccine stockpile preparedness measure, the objective of this solicitation is to continue establishment and maintenance of an active and evolving U.S. stockpile of H5N1 vaccine for usage at the time a pandemic is declared. Therefore, HHS wishes at this time to obtain H5N1 vaccine manufactured during the open window for seasonal influenza vaccine manufacturing using the U.S.-licensed commercial scale manufacturing process and facilities for seasonal trivalent egg-based inactivated influenza vaccines. The H5N1 virus seed stock will be derived from the virus reassortant of avian influenza H5N1 virus strain from the WHO list of recommended vaccine strains. HHS shall designate the specific virus strains for production by the Contractors.

This requirement is for the initial acquisition of 1 to 20 million doses of bulk vaccine product (assuming 15 micrograms per dose) to be formulated and filled into multi-dose vials, based on the availability of funds. Potential offerors must be able to manufacture an egg-based inactivated monovalent H5N1 vaccine at commercial scale using the same facilities, systems, equipment, and processes employed for their FDA-licensed seasonal trivalent influenza vaccine and using H5N1 virus reference strains prescribed by HHS.

Potential offerors must be able to manufacture an egg-based inactivated monovalent H5N1 vaccine at commercial scale using the same facilities, systems, equipment, and processes employed for their FDA-licensed seasonal trivalent influenza vaccine and using H5N1 virus reference strains prescribed by HHS. Released bulk vaccines and bulk adjuvants shall be stored in the U.S. When an Offeror is going to use a manufacturing facility outside the U.S the bulk vaccine and adjuvant shall be shipped to the US as soon as the bulks are lot released. Formulation/fill/finish activities of vaccine and adjuvant shall be carried out in the U.S.

L.1.2. PURPOSE

The threat of an avian influenza H5N1 virus emerging as a potential pandemic virus strain continues to be real, as outbreaks of H5N1 virus infection in poultry and man have continued since late 2003 especially in China, Vietnam and Indonesia. Since 2003 the number of confirmed cases (updated June 19, 2008) of influenza A/H5N1 (385 total cases/243 total deaths) have increased in part because of the spread of clade 2.2 viruses across Eurasia and to Africa That the global population including the U.S. has little or no immunity to H5N1 viruses and that H5N1 viruses are highly pathogenic in animals and man (mortality rate ~ 63% in man) are two of three requirements established by the World Health Organization (WHO) for emergence of an influenza pandemic. There is uncertainty regarding which virus would be the cause of a pandemic. Even when a pandemic emergency is announced it would take at least 3-4 months before the first batch of a strain matched pandemic vaccine will be available for use.

These observations create an urgent need to establish a stockpile of H5N1 vaccine against the currently circulating clades of H5N1 for pandemic preparedness. Further, these efforts will prepare influenza vaccine manufacturers with the necessary surge capacity to meet a domestic pandemic response. The continued spread and genetic diversification of H5N1 virus into clades and sub-clades indicated there was and there is a continued need to add additional vaccines of different clade/subclade to the HHS stockpile. HHS in 2004-2005-2006-2007 has awarded six contracts to manufacturers to produce H5N1 vaccine. The manufacturers produced several million doses (at 15μg HA/dose) of H5N1 bulk vaccine of different clades and sub-clades as listed below:

A/ Vietnam/1203/2004 (clade 1)
A/ Indonesia/05/2005 (clade 2.1)
A/ Bar-headed Goose/QuinghaiLake/1A/05 (clade 2.2)
A/Anhui/01/2005 (clade 2.3)

In April 2007, the US FDA approved the first "Influenza Virus Vaccine, H5N1". The vaccine, manufactured by Sanofi Pasteur, was approved for use in case of pandemic declaration and administered in two 90μg HA doses 28 days apart. Consequently, the total number of doses of H5N1 pre-pandemic vaccine needed to immunize 20 million people as established in the US Pandemic Preparedness Plan has been adjusted to two doses/ person at 90μg HA/dose. Of the 40 million doses needed in the stockpile at the present time, the US Government has on hand 22.94 million doses (90μg HA/dose) of vaccine.

Recently, independent clinical studies performed by NIH and the vaccine manufacturers have indicated that when H5N1 vaccines are used in combination with adjuvants, a substantial decrease of antigen is needed to induce a good immune response. The decrease in the amount of viral antigen needed for influenza vaccination in a pandemic event is a key element in managing vaccination of as many people as possible.

The purpose of this acquisition plan is to purchase 1 to 20 million doses of bulk vaccine product (assuming 15 micrograms per dose) to be formulated and filled into multi-dose vials, based on the availability of funds.

L.2. FAR PROVISIONS

L.2.1. FAR PROVISIONS INCORPORATED IN FULL TEXT

L.2.1.1. FAR 52.215-1 INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION (Jan 2004) (Paragraph (e) has been replaced with HHSAR 315.215-1, paragraph (e))

(a) *Definitions.* As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the Offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the Offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the Offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the Offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 3:00 PM EST, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an Offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the Offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the Offeror).

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The

use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted: ''Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes. The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act. If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act. The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).''

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement: ''Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.''

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with nonconforming statement(s).

(f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible Offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with Offerors (except clarifications as described in FAR 15.306(a)). Therefore, the Offeror's initial proposal should contain the Offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the Offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so. In the event that more than one award is made, the U.S. Government reserves the right to use contract clauses, including 52.249-6, Termination (Cost-Reimbursement) to down-select at any time.

(7) Exchanges with Offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful Offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting Offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed Offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed Offeror and past performance information on the debriefed Offeror.
(iii) The overall ranking of all Offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful Offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed Offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

L.2.1.2. FAR 52.216-1 TYPE OF CONTRACT (Apr 1984)

The Government contemplates award of a multi-year, firm-fixed price indefinite delivery/indefinite quantity type contract resulting from this solicitation with three option periods.

L.2.1.3. FAR 52.216-17 SINGLE OR MULTIPLE AWARDS (Oct 1995)

The Government may elect to award a single delivery order contract or task order contract or to award multiple delivery order contracts or task order contracts for the same or similar supplies or services to two or more sources under this solicitation.

L.2.1.4. FAR 52,233-2 SERVICE OF PROTEST (Sep 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Department of Health & Human Services
Assistant Secretary for Preparedness & Response
Biomedical Advanced Research Development Authority
330 Independence Avenue, S.W.
Room G644
Washington, DC 20201

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

L.2.1.5 FAR 52.232-28 Submission of Electronic Funds Transfer Information with Offer (MAY 1999)

The Offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The Offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the Offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the Offeror's financial agent.
(5) The Offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the Offeror's financial agent.

(7) If applicable, the Offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the Offeror's financial agent is not directly on-line to the Fedwire and therefore, not the receiver of the wire transfer payment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) PROVISIONS:

L.2.1.6. HHSAR 352.215-70 LATE PROPOSALS AND REVISIONS (Jan 2006)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it appears to offer the best value to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

L.2.1.7. HHSAR 352.270-8 PROTECTION OF HUMAN SUBJECTS (Jan 2006) ***(IF NECESSARY, APPLICABLE TO CLINS 0012, 0013, 0026, 0027, 0040 AND 0041)***

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (January 2006)

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS.
(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.
The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.
(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OPDIV will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301–496–7014), is recommended.
(e) In accordance with 45 CFR Part 46 prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site: *http://www.hhs.gov/ohrp/.*
(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

L.2.1.8. HHSAR 352.270-9 CARE OF LABORATORY ANIMALS (Jan 2006) ***(IF NECESSARY, APPLICABLE TO CLINS 0012, 0013, 0026, 0027, 0040 AND 0041)***

Notice to Offerors of Requirement for Compliance With the Public Health Service Policy on Humane Care and Use of Laboratory Animals (January 2006)

The PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane

Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, contact OLAW at NIH, Bethesda, Maryland 20892 (301–496–7163).

(End of provision)

L.2.2. FAR 52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (Feb 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The Offeror is cautioned that the listed provisions may include blocks that must be completed by the Offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the Offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address:

http://www.acquisition.gov/far/index.html .

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

FAR 52.204-6 Data Universal Numbering System (DUNS) Number (October 2003)

FAR 52.222-24 Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), (February 1999)

L.3. GENERAL INFORMATION

L.3.1. PRE-PROPOSAL CONFERENCE

A pre-proposal conference will not be held with prospective Offerors for this solicitation. However, if an offeror has any questions or needs clarification they encouraged to contact the Contracting Officer.

L.3.2. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. **Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.**

L.3.3. .RELEASE OF INFORMATION

Contract selection and award information will be disclosed to Offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful Offerors as they are eliminated from the competition, and to all Offerors following award.

L.3.4.. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

L.4. INSTRUCTIONS TO OFFERORS

L.4.1. General Instructions

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

L.4.1.1. General

Offerors are requested to submit proposals, to the maximum extent possible, on white paper which can be recycled.

L.4.1.2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. However, the technical proposal should **not** include pricing data. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page*, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal (written proposal and slides for oral presentation) consist of a cover page*, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

*Cover pages shall include at a minimum: RFP title, number, name of organization, DUNS No., identification of the proposal part and indicate whether the proposal is an original or copy

L.4.1.3 Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals, which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

L.4.1.4. Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

L.4.1.5. Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The Offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

L.4.1.6. Privacy Act – Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The HHS is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract. Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of HHS contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

L.4.1.7. Selection of Offerors

L.4.1.7.1 The acceptability of the technical portion of each contract proposal will be evaluated by using a combination of written technical proposal and oral presentation. The entire technical proposal (written and oral) shall be reviewed by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. During the oral presentation the technical review panel may request clarifying information from an Offeror.

L.4.1.7.2 The business portion of each contract proposal will be subjected to a cost/price analysis, management analysis, etc.

L.4.1.7.3. If awards are made without conducting discussions, Offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an Offeror's past performance information and adverse past performance information to which the Offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

L.4.1.7.4. If the Government intends to conduct discussions prior to awarding a contract-

L.4.1.7.4.1. Communications will be held with Offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an Offeror has not had a prior opportunity to respond. Also, communications may be held with any other Offerors whose exclusion from, or inclusion in, the competitive range is uncertain. Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

L.4.1.7.4.2. The Contracting Officer will determine which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all Offerors in the competitive range. HHS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient

competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each Offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

L.4.1.7.5. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price Offeror or other than the highest technically rated Offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable), the cost analysis and other evaluation factors listed in Section M.

L.4.1.7.6. The HHS reserves the right to make a single award, multiple awards or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet HHS requirements. Synopses of awards exceeding $25,000 will be published in FedBizOps.

L.4.1.8. Pre-Award Site Visits

Possible pre-award site visits will be conducted with Offerors in the competitive range in conjunction with discussions/negotiations, if timing permits. The site visits will be required to inspect Offerors manufacturing facilities.

L.4.1.9. Facsimile Proposals: Facsimile proposals are not authorized unless this solicitation incorporates FAR. 52.215-5, Facsimile Proposals.

L.5. TECHNICAL PROPOSAL INSTRUCTIONS

The offeror shall submit a detailed technical proposal and presentation demonstrating how your company intends to respond to the solicitation and meet the technical evaluation criteria. your technical approach. should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

L.5.1. THE TECHNICAL PROPOSAL SHALL BE DIVIDED AS FOLLOWS AND SHALL NOT EXCEED THE FOLLOWING PAGE LIMITS OR TIME ALLOTMENTS:

- Technical Written Proposal: 10 pages in length, not including one page resumes of key personnel.
- Technical Oral Presentation: There is no limit on the number of slides that may be presented. However, the offeror will only be allotted 1 ½ hours to present their oral presentation. NOTE: Any slides not presented (Example: offeror runs out of time) will not be evaluated. Offeror's presentations will be stopped after 1 ½ hours. The time will be as monitored by the Contracting Officer.

L.5.2. Breakdown of Technical Proposal: The offeror shall include in their entire technical proposal all information necessary to respond to the RFP and all technical evaluation factors including mandatory criteria.

L.5.2.1. Technical Written Proposal: The technical written proposal shall include, at a minimum, the following documents:

- Resumes of Key Personnel Resumes of all key personnel are required. Each resume must indicate educational background, recent experience, specific or technical accomplishments and a listing of relevant publications. (resumes shall not exceed one page)
- Response to Mandatory Criteria (insure that the Mandatory criteria are addressed in written and clearly identified in the written proposal)
- Any other information that the offeror feels is necessary or cannot be properly defined in an oral presentation

L.5.2.2 Oral Presentations: The offeror will be required to submit a copy of their slides for the oral presentation with their technical proposal. Once the offeror's proposal is submitted no revisions may be made to the slides. The technical oral presentation shall define the offeror's approach and capabilities in enough detail to permit evaluation under each of the technical evaluation criteria referenced in Section M (not including Mandatory Evaluation Criteria). Some of the areas that the presentation should address are as follows:

- Description of the facility(ies) that will be used during the project and the physical security of the facility(ies).
- Procedures for protection, controlling, handling or accessing US Government data and property
- Subcontracting relationships
- Manufacturing and storage facilities
- Identify performance risks
- Shipment methods and requirements

L.5.3. Procedures for Oral Presentations:

The Contracting Officer will notify the offerors of the date and time they are scheduled to give the oral presentation. It is anticipated that the oral presentations will begin on **September 2, 2008**. Depending on the number of offerors, additional presentation may be scheduled for September 3, 2008. Offerors are encouraged to submit their Letters of Intent (Attachment 2) as soon as possible so that presentation times may be assigned. It is anticipated that these times will be assigned prior to the closing of the RFP based on the letter of intent. The Contracting Officer will determine the order in which offerors are scheduled. Requests to reschedule may not be honored due to the short acquisition period and will be at the sole discretion of the Contracting Officer. Each oral presentation will be videotaped and a copy of their presentation will be made available to the offeror.

The proceedings will be formal and structured, consisting of a timed presentation (1 ½ hours) by the offeror followed by a question and answer session (approximately 30 minutes). The offerors must conform to the technical written and oral presentation proposal requirements as well as the business proposal. All offerors will be asked a few common questions. Other questions may be asked at each oral presentation.

L.5.4. Technical Evaluation

Proposals will be technically evaluated in accordance with the factors and weights as described in SECTION M Evaluation Factors for Award of this solicitation.

L.6 BUSINESS PROPOSAL INSTRUCTIONS

L.6.1 Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee and profit. The costs for each milestone item (i.e., direct labor) shall be provided in the business proposal.

L.6.2. Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. Date of submission; and
8. Name, title and signature of authorized representative.

This cover sheet information is for use by Offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism as necessary. Such information is not considered cost or pricing data and shall not be certified in accordance with FAR 15.406-2.

L.6.3. Business Proposal Submission:

The business proposal shall include:

- Cover Sheet (See paragraph L.6.2)
- Offeror's DUNs number
- Completed and signed Standard Form 33
- Completed Pricing Schedule (Schedule B)
- Product Licensure in Section H
- Completed Section K (Representations and Certifications)
- Back up documentation

L.6.4. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the Offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation,

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The Offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the Offeror, the Offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the Offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the Offeror for award of the contract.

(5) It is the Offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the Offeror's plan will be judged independent of the other.

(6) The Offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the Offeror who will administer the Offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the Offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the Offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the Offeror.

(10) Assurances that the Offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the Offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the Offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

23 % for Small Business; **5 %** for Small Disadvantaged Business; **5 %** for Women-Owned Small Business; **3 %** for HUBZone Small Business; **3 %** for Veteran-Owned Small Business and **3 %** for Service-Disabled Veteran-Owned Small Business.

L.6.5 HUBZone Small Business Concerns

Small Business Offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

L.6.6. Extent of Small Disadvantaged Business Participation

(Note. This paragraph on small disadvantaged business participation applies to all Offerors, including Offerors who are small business concerns even though they are exempt from the requirement for a Subcontracting Plan under FAR 52.219.)

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.
The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is:
http://www.arnet.gov/References/sdbadjustments.htm

**Note: Public Law 103-355, which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, Offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

L.6.7. Other Administrative Data

L.6.7.1. Financial Capacity

The Offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

L.6.7.2. Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the Offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

L.6.7.3. Offeror's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

L.6.7.4. Past Performance Information

L.6.7.4.1. Offerors shall submit the following information as part of their **business** proposal.

The offeror shall provide a list of the last five (5) 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 and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The Offeror may provide information on problems encountered on the identified contracts and the Offeror's corrective actions.

L.6.7.4.2. Each offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which the offerors relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. The government is not required to contact all references provided by the offeror, and references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offerors past performance.

L.6.7.4.3 Each offeror shall provide copies of inspection reports from the last three years provided by regulatory authorities following GMP inspections of the facility they are proposing to use. These reports will be part of the Technical Appendices and will not count as part of the technical evaluation proposal page limit.

L.6.7.5. Past Performance Questionaire: A Past Performance Questionnaire must be sent by the Offeror to the references for their response. It is the Offeror''s responsibility to ensure that the questionnaires are completed and returned to the Government by their references in accordance with the instructions provided in **Article M.6.** of this RFP.

SECTION M – EVALUATION FACTORS FOR AWARD

M.1. BASIS OF AWARD

Selection of an Offeror for contract award will be based on an evaluation of proposals against four Evaluation Factors, in order of importance: technical, price, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance, SDB participation, and, if applicable, FAR 52.219-9 Subcontracting Plan is also important to the overall contract award decision. For an Offeror (other than a small business concern) to be selected for award the Subcontracting Plan required by FAR 52.219-9 must be acceptable.

All evaluation factors other than cost or price, when combined, are approximately equal to cost or price. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among price and non-price factors and allows the USG to consider award(s) to other than the lowest priced or highest technically rated offeror. In any case, the Government reserves the right to make an award(s) to the Offeror whose proposal provides the best overall value to the Government.

The Contracting Officer intends to evaluate proposals and make an award without discussions. However, the Government reserves the right to conduct discussions if it is determined to be in the best interest of the Government. Therefore, offerors are encouraged to ensure that initial proposals contain the offeror's most favorable terms and reflect its best possible performance potential.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

As a threshold matter, Offerors will be evaluated as either "acceptable" or "unacceptable" based upon three (3) Mandatory Criteria as described under M.2. In order to be considered further, offers must be evaluated as "acceptable" under all three criteria. If determined to be "acceptable" under all three criteria, further proposal evaluation will be conducted.

M.2. MANDATORY CRITERIA FOR ELIGIBILITY

The Offeror shall include all information, which documents and/or supports the mandatory criteria for eligibility in one clearly marked section of their written technical proposal. The mandatory criteria for eligibility establish conditions that **must** be met at time of proposal submission in order for your proposal to be considered any further for award.

To be eligible for award, the Contractor must hold a US license to produce inactivated influenza virus vaccine. Vaccine manufacturers of the H5N1 vaccine must meet the following set of requirements:

- Approved and active U.S. license for seasonal inter-pandemic egg-based inactivated trivalent influenza vaccine at the time of H5N1 vaccine bulk manufacturing
- Successful experience in the bulk manufacturing of H5N1 vaccine at commercial scale using the licensed manufacturing process
- Bulk manufacturing facilities in compliance with current WHO biosafety guidelines for avian influenza vaccine manufacturing including BSL2+ enhanced biocontainment facilities and procedures

These requirements are based in part on guidance from the FDA stating that manufacturing and release of H5N1 vaccine should be treated as a normal influenza virus strain change for the licensed influenza vaccine.

Failure to adequately document compliance for any of the above mandatory requirements will result in the elimination of the Offeror's proposal from further consideration. The proposal will be considered to be non-responsive and the Offeror's proposal will not be further evaluated. No further discussions will be held.

M.3. TECHNICAL EVALUATION CRITERIA

Each proposal shall be evaluated according to the criteria and points as set forth below:

Evaluation Criteria (Technical Factors)	Points
1. Technical Methodology and Approach	30
2. Facilities	30
3. Organizational Experience	20
4. Personnel	20
TOTAL	100

Technical Factor 1. Technical Methodology and Approach

The proposal should provide a Contractor's Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget specifying activities to be supported by the government. The level of detail contained in the CWP and the corresponding Gantt chart should be sufficient to facilitate management and execution of the contract by the successful Offeror(s).

The proposal should describe, in detail, your plan of work to complete all activities identified in the statement of work. Indicate your level of experience with each area, anticipated difficulties and potential approaches to overcome them.

Technical Factor 2. Facilities

The proposal should describe facilities to be used for development and manufacture of commercial scale lots of vaccine and adjuvant suitable as specified in the proposal, including documentation of compliance with cGMP. The proposal should also describe storage facilities to be used to store bulk vaccine, bulk adjuvant and vaccine final container

Technical Factor 3. Organizational Experience

The proposal should describe previous programs for vaccine production to document organizational capabilities to complete proposed activities and successfully produce vaccine.

Technical Factor 4. Personnel

The proposal should provide the name of the Principal Investigator (PI)/Project Director responsible for the overall implementation of the contract and Co-investigators and key contacts for technical aspects of the project. Describe the qualifications, experience, and accomplishments of the PI and Co-investigators of the Offeror and Subcontractors. Include, in an attachment, curricula vitae of supervisors and key technical personnel, and the approximate percentage of time each will be available for this program.

The proposal should describe the experience and qualifications of other personnel who will be assigned to work on this program. Using organizational charts show the composition of task or work groups by project area. Document the general qualifications of work groups and recent experience with similar programs. A clear description and schematic of the Offeror's project organization including subcontractors.

The proposal should list names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment or on a subcontract or consultant basis. Indicate the technical areas, character, and extent of subcontract or consultant activities and anticipated sources. For all proposed personnel who are not currently members of Offeror's staff, provide a letter of commitment or other evidence of availability. The letter of commitment must at a minimum include (1) the specific items or expertise they will provide; (2) their availability to the project and the amount of time anticipated; (3) their willingness to act as a consultant and (4) how rights to publication and patents will be handled.

M.4. COST/PRICE EVALUATION CRITERIA:

The proposed prices will be evaluated to determine reasonableness. The basis of evaluation may include the use of various cost/price realism analysis techniques to ensure a fair and reasonable price such as;

M.4.1. Comparison of proposed prices received in response to the solicitation.
M.4.2. Comparison of proposed prices with resources proposed.
M.4.3. Obtaining information/reports from DCAA or other outside agencies, and the independent Government Estimate.
M.4.4. Review and analysis of other than cost and pricing data. (If cost and pricing data is later obtained, the data will be used in the evaluation.)

M.5. RELATIVE IMPORTANCE OF PRICE AND OTHER EVALUATION FACTORS

Technical evaluation factors 1 and 2 are of equal importance. Factors 3 and 4 are of equal importance. Factors 1 and 2 together are slightly more important than Factor 3 and 4 together. All evaluation factors other than price, when combined, are approximately equal to cost or price.

M.6 EVALUATION OF PAST PERFORMANCE

An evaluation of Offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

Each Offeror will be evaluated on their performance under five (5) existing and/or prior contracts for similar services. Contracts/awards may include those entered with the Federal Government, state and local governments and commercial concerns. Past performance will be evaluated using a set of questions that address the quality of service, cost control, timelines of performance, business relations and the overall customer satisfaction for projects of similar nature. The questionnaires must be sent by the Offeror to previous or existing customers, who in turn shall complete and submit the surveys to the contracts office as instructed on the questionnaire provided in this RFP, SEE SECTION J LIST OF ATTACHMENTS.

Each past performance question shall be worth a maximum of 5 points. Questions seeking a "yes" or "no" answer will be scored as follows: "yes" = 5 and "no" = 0. The total score of each questionnaire received will be determined by calculating the average of the ratings provided in the questionnaire. Therefore, the maximum number of points for each questionnaire is 5. If specific questions are not answered or are answered with "N/A", then the question will not be included in the calculation of the average. The overall total score for the past performance rating for an Offeror will be determined by calculating the average of the total scores of the questionnaires received for that Offeror. The overall total score will be rounded to the nearest whole number.

The Government will consider the currency and relevance of the information, source of the information, context of the data and general trends in the Offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will be used to neither the advantage nor disadvantage of the Offeror.

The Government reserves the right to consider past performance information from any source.

It is the responsibility of the Offerors to ensure submission of these questionnaires to be *delivered directly from their references to the Government.* All questionnaires should be submitted to:

Mekeba Barrett
Contract Specialist
HHS/ASPR/BARDA
330 Independence Ave. SW Rm G640
Washington, D.C. 20201
Fax: 202-260-1591
Email: mekeba.barrett@hhs.gov

All questionnaires must be submitted via facsimile, no later than **8/20/2008, 3:00 P.M. E.S.T.** and reference this solicitation. The Government reserves the right not to consider any past performance questionnaires that are received after the due date or by means other than facsimile.

M.7. EVALUATION TO THE EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be used in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of Offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

M.8 FAR 52.217-5 EVALUATION OF OPTIONS (July 1990)

Except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. Evaluation of options will not obligate the Government to exercise the option(s).

Attachment 1

PACKAGING AND DELIVERY OF PROPOSAL

Read all instructions on this page and in the RFP before mailing or submitting forms, proposals or CDs.

Your proposal will have **two separate parts**.

Volume I - Business proposal

Volume II - Technical proposal

In addition, several other forms are required -- see the RFP and the table below for details.

You will submit your proposal in **two formats**:

- Official paper (Original and 2 copies)
- CDs or USB Drives (4 electronic copies) Please ensure that you do not include any .exe files.

- **The original paper proposal with original signatures is the official, legally binding copy. There are no acceptable substitutes.**
- The CD or USB memory stick versions of the proposal are for the benefit of BARDA. Electronic versions may be used for review, at the discretion of BARDA.

As a potential Offeror, you must routinely check the FedBizOps for amendments because we do not notify you directly of changes.

Send your proposal to BARDA at the address below. If you have any questions, ask Contract Specialist or Contracting Officer specified in the RFP.

Hand written proposals will not be accepted.

PAPER SUBMISSION: The original paper copy is the official record copy for timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal. Proposals will not be returned to the offeror.

NUMBER OF COPIES:

Document	Number of Copies	Page Limits	File Size
Technical Written Proposal	One (1) bound SIGNED ORIGINAL. Two (2) copies bound in three ring binders Four (4) CDs or USB Drives*	Written Proposal Limited to not-to-exceed **10** Pages	Unlimited
Technical Oral Presentation	One (1) bound SIGNED ORIGINAL. Two (2) copies bound in three ring binders Four (4) CDs or USB Drives*	No page limit on submission of slides. Time limit for oral presentation is 1 ½ hours.	Unlimited
Business Proposal	One (1) bound SIGNED ORIGINAL. Two (2) bound copies in three ring binders Four (4) CDs or USB Drives	N/A	Unlimited
Representations and Certifications	Provide representations and certifications electronically via the BPN website (www.bpn.gov/orca)	N/A	N/A

*** All technical documents (written and oral presentation) may be included in the same binder and on the same electronic media.**

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.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

COURIER DELIVERIES WILL BE TO THE FOLLOWING ADDRESS:

Attn:
Mekeba Barrett
Contract Specialist
HHS/ASPR/BARDA
330 Independence Ave. SW Rm G640
Washington, D.C. 20201
Phone: 202-260-1591
Email: mekeba.barrett@hhs.gov

Attachment 2

PROPOSAL INTENT RESPONSE SHEET

RFP No.: HHS-BARDA-08-25
RFP Title: **"Acquisition of Avian Influenza H5N1 Vaccine for Strategic National Stockpile (SNS)"**

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **08/13/2008**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (please print clearly): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (please print clearly):
_____
_____

Names of Subcontractors (including Consultants) (please print clearly):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
HHS/OS/ASPR/BARDA
330 Independence Avenue
Room G640
Washington, D.C. 20201
Attn: Mekeba Barrett
RFP-HHS-BARDA-08-25
FAX# 202-260-1591
Email: mekeba.barrett@hhs.gov

Attachment 3

PAST PERFORMANCE QUESTIONNAIRE

Please complete the following questionnaire and return via regular fax to the attention of:

_____ by _____
(Name) *(Title)* *(Date)*

_____
(Address)

_____
(Fax Number)

This survey pertains to: _____**(VENDOR NAME)**_____

Department/Component: _____

Contract Number: _____

Date of Survey: _____

Name of Person Completing Survey: _____

Signature of Person Completing Survey: _____

Your Company/Agency: _____

Your Role in this Contract *(circle one)*:

Contracting Officer Contract Specialist Project Officer Other _____

Contract Value *(including options)*: $_____

Performance Period: _____
(including option periods)

Type of Contract: _____

Approximate percentage of work being performed (or completed) by subcontractor(s): _____%

Information on subcontractor(s) *(where more than ____% of work was completed by the subcontractor)*:

_____	_____	_____
Subcontractor	Program Manager	Phone
_____	_____	_____
Subcontractor	Program Manager	Phone

General description of products/services required under the contract: _____

RATINGS

Please answer each of the following questions with a rating that is based on objective measurable performance indicators to the maximum extent possible. Commentary to support rating may be noted at the end of the questionnaire under 'additional comments'.

Assign each area a rating of 0 (Unsatisfactory), 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent) or 5 (Outstanding). Use the attached Rating Guidelines as guidance in making these evaluations. Circle the appropriate rating. If you do not have enough personal knowledge or feedback from internal customers who directly received products and services from the contractor to make a determination on any of the performance criteria below, please circle "N/A" (not applicable /no opinion).

QUALITY OF SERVICE

1. Compliance with contract requirements
   0 1 2 3 4 5 N/A

2. Accuracy of reports
   0 1 2 3 4 5 N/A

3. Effectiveness of personnel
   0 1 2 3 4 5 N/A

4. Technical excellence
   0 1 2 3 4 5 N/A

COST CONTROL

1. Record of forecasting and controlling target costs
   0 1 2 3 4 5 N/A

2. Current, accurate and complete billings
   0 1 2 3 4 5 N/A

3. Relationship of negotiated costs to actuals
   0 1 2 3 4 5 N/A

4. Cost efficiencies
   0 1 2 3 4 5 N/A

TIMELINESS OF PERFORMANCE

1. Met interim milestones
   0 1 2 3 4 5 N/A

2. Reliability
   0 1 2 3 4 5 N/A

3. Responsive to technical direction
   0 1 2 3 4 5 N/A

4. Completed on time including wrap-up and contract administration
   0 1 2 3 4 5 N/A

5. Met delivery schedules

0 1 2 3 4 5 N/A

6. Liquidated damages assessed: Yes No *(circle one)*

BUSINESS RELATIONS

1. Effective management, including subcontracts
   0 1 2 3 4 5 N/A

2. Reasonable/cooperative behavior
   0 1 2 3 4 5 N/A

3. Responsive to contract requirements
   0 1 2 3 4 5 N/A

4. Notification of problems
   0 1 2 3 4 5 N/A

5. Flexibility
   0 1 2 3 4 5 N/A

6. Pro-active vs. reactive
   0 1 2 3 4 5 N/A

7. Effective small/small disadvantaged business subcontracting program
   0 1 2 3 4 5 N/A

CUSTOMER SATISFACTION

1. The contractor is committed to customer satisfaction.
   Yes No *(circle one)*

2. Would you recommend selection of this firm again?
   Yes No *(circle one)*

ADDITIONAL COMMENTS

RATING GUIDELINES

	QUALITY OF PRODUCT OR SERVICE	COST CONTROL	TIMELINESS OF PERFORMANCE	BUSINESS RELATIONS
0 – Unsatisfactory	Contractor is not in compliance and is jeopardizing achievement of contract objectives	Contractor is unable to manage costs effectively	Contractor delays are jeopardizing performance of contract objectives	Response to inquiries, technical/service/administrative issues is not effective
1 – Poor	Major problems have been encountered	Contractor is having major difficulty in managing costs effectively	Contractor is having major difficulty meeting milestones and delivery schedules	Response to inquiries, technical/service/administrative issues is marginally effective
2 – Fair	Some problems have been encountered	Contractor is having some problems in managing costs effectively	Contractor is having some problems meeting milestones and delivery schedules	Response to inquiries, technical/service/administrative issues is somewhat effective
3 – Good	Minor inefficiencies/errors have been identified	Contractor is usually effective in managing costs	Contractor is usually effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/administrative issues is usually effective
4 – Excellent	Contractor is in compliance with contract requirements and/or delivers quality products/services	Contractor is effective in managing costs and submits current, accurate and complete billings	Contractor is effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/administrative issues is effective
5 – Outstanding: The contractor has demonstrated an outstanding performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent".				

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR 352.215-1.

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or [[Page 4256]] statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

Attachment 5

OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Name, Institutional Title and Address of Proposed Principal Investigator

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Subcontractor(s): Name, Institutional Title and Address of Proposed Principal Investigator

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

*Please use actual street address, not P.O. Box.

Attachment 6

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

1. Type of Federal Action:	2. Status of Federal Action:	3. Report Type:
a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	a. bid/offer/application b. Initial award c. post-award	a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report_____

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime
☐ Prime ☐ Subawardee Tier_____, if known: Congressional District, if known:	Congressional District, if known:
6. Federal Department/Agency:	7. Federal Program Name/Description CFDA Number, if applicable: _____
8. Federal Action Number, if known:	9. Award Amount, if known: $
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s)	b. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI) SF-LLL-A, if necessary)
11. Amount of Payment (check all that apply): $_____ ☐ actual ☐ planned	13. Type of Payment (check all that apply): ☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment (check all that apply): ☐ a. cash ☐ b. in-kind; specify: nature_____ value_____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: Yes No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each failure.	Signature:_____ Print Name:_____ Title:_____ Telephone No.:_____Date:_____
Federal Use Only	Authorized for Local Reproduction Standard Form—LLL

DISCLOSURE OF LOBBYING ACTIVITIES

Reporting Entity:_____ Page _____ of _____

CONTINUATION SHEET
Approved by OMB

0348-0046

Authorized for Local Reproduction
Standard Form--LLL-A

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing of attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

ACH Vendor/Miscellaneous Payment Enrollment Form

Instructions for Completing SF 3881 Form

1. Agency Information Section - Federal agency prints or types the name and address of the Federal program agency originating the vendor/miscellaneous payment, agency identifier, agency location code, contact person name, and telephone number of the agency. Payee prints or types the Grant Number.

2. Payee/Company Information Section - Payee prints or types the name of the payee/company and address that will receive ACH vendor/miscellaneous payments, social security or taxpayer ID number, contact person name, and telephone number of the payee/company. Payee also verifies depositor account number, account title, and type of account entered by your financial institution in the Financial Institution Information Section.

3. Financial Institution Information Section - Financial institution prints or types the name and address of the payee/company's financial institution who will receive the ACH payment, ACH coordinator name and telephone number, nine-digit routing transit number, depositor (payee/company) account title and account number. Also, the box for type of account is checked, and the **signature, title, and telephone number of the appropriate financial institution official are included.**

Burden Estimate Statement

The estimated average burden associated with this collection of information is 15 minutes per respondent or record keeper, depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Financial Management Service, Facilities Management Division, Property and Supply Branch, Room B-101, 3700 East West Highway, Hyattsville, MD 20782 and the Office of Management and Budget, Paperwork Reduction Project (1510-0056), Washington, DC 20503.

ACH VENDOR/MISCELLANEOUS PAYMENT ENROLLMENT FORM

OMB No. 1510-0056

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program. Recipients of these payments should bring this information to the attention of their financial institution when presenting this form for completion.

PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

AGENCY INFORMATION		
FEDERAL PROGRAM AGENCY		
AGENCY IDENTIFIER:	AGENCY LOCATION CODE (ALC):	ACH FORMAT: ☐ CCD+ ☐ CTX ☐ CTP
ADDRESS:		

CONTRACT PERSON NAME:	TELEPHONE NUMBER
ADDITIONAL INFORMATION	

PAYEE/COMPANY INFORMATION	
NAME	SSN NO. OR TAXPAYER ID NO.
ADDRESS	
CONTACT PERSON NAME:	TELEPHONE NUMBER: ( )

FINANCIAL INSTITUTION INFORMATION
NAME:
ADDRESS:

ACH COORDINATOR NAME:	TELEPHONE NUMBER: ( )
NINE-DIGIT ROUTING TRANSIT NUMBER:	
DEPOSITOR ACCOUNT TITLE:	
DEPOSITOR ACCOUNT NUMBER:	LOCKBOX NUMBER:
TYPE OF ACCOUNT: ☐CHECKING ☐ SAVINGS ☐ LOCKBOX	

SIGNATURE AND TITLE OF AUTHORIZED OFFICIAL:
(Could be the same as ACH Coordinator)

TELEPHONE NUMBER:
( )

SF 3881 (Rev. 12/90)
NSN 7540-01-274-9925

3881-102

Prescribed by Department of Treasury