

REQUEST FOR QUOTATION (THIS IS NOT AN ORDER)			This RFQ ☐ is ☒ is not a small Business set-aside			Page 1 of 26			
1.REQUEST NO FDA-SOL-08-Medical Uptake_HealthcareDatabases		2.DATE ISSUED Aug 11, 2008		3.REQUISITION/PURCHASE REQ NO. 1047148		4. CERT FOR NAT. DEF. UNDER BDSA REG 2 AND/OR DMS REQ. 1		RATING	
5a. ISSUED BY U.S. Food and Drug Administration (FDA) Office of Acquisitions and Grants Services (OAGS) 5630 Fishers Lane, HFA-500, Room 2137 Rockville, Maryland 20857						6. DELIVERY BY (Date) All Deliverables due 6 Months from date of Award			
5b. FOR MORE INFORMATION EMAIL: NAME Terry Frederick, Terry.Frederick@fda.hhs.gov Area Code Telephone						7. DELIVERY ☒ FOB Destination ☐ Other (See Schedule)			
						9. DESTINATION			
8. TO a. NAME						a. NAME OF CONSIGNEE			
b. COMPANY						b. STREET ADDRESS			
c. STREET ADDRESS						c. CITY			
d. CITY				e. STATE	f. ZIP CODE	d. STATE	e. ZIP CODE		
10. Quotations (Original & 3 Copies & 1 CD-ROM) Shall Be Received at the Address Provided In Block 5 No Later Than 10:00 AM, ET on: SEPTEMBER 2, 2008						IMPORTANT: This is a Request for Quotations (RFQ). This request does not commit the Government to pay any costs incurred in the the submission of this quotation or to contract for supplies or services. Any representations and/or certifications to this RFQ must be completed by the quoter. All quotations received by the deadline in accordance with Block 10. will receive a <u>confirmation email</u> in response from the Government POC. If you submit a quotation but do not receive a confirmation email by 11:00 AM on September 2, 2008, call 301.827.7043.			
11. SCHEDULE (Indicate applicable Federal, State and local taxes)									
ITEM NO. (a)	SUPPLIES/SERVICES (b)				QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	
0001	IN ORDER TO COMPLY WITH THE DEBT COLLECTION IMPROVEMENT ACT OF 1966, ALL CONTRACTORS MUST BE REGISTERED IN THE CENTRAL CONTRACTOR REGISTRATION (CCR) TO BE CONSIDERED FOR AN AWARD OF A FEDERAL CONTRACT. FOR INFORMATION REGARDING REGISTRATION IN CCR CONTACT THE CCR WEBSITE AT WWW.CCR.GOV/INDES.CFM DUNS NO.: _____ TIN: _____ Complete all work in accordance with the attached Statement Of Work (SOW).				1	Lot	FFP (Including Travel)	\$ _____	
12. DISCOUNT FOR PROMPT PAYMENT		a. 10 Calendar Days (%)		b. 20 Calendar Days (%)		c.30 Calendar Days (%)		D. CALENDAR DAYS	
								NUMBER	PERCENTAGE
NOTE: Additional provisions and representations ☒ are				are not attached.					
13. NAME AND ADDRESS OF QUOTER				14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION			15. DATE OF QUOTATION		
a. NAME OF QUOTER									
b. STREET ADDRESS				16. SIGNER					
c. COUNTY				a. NAME (Type or print)			b. TELEPHONE		
							AREA CODE		
d. CITY		e. STATE	f. ZIP CODE	c. TITLE (Type or print)			NUMBER		
AUTHORIZED FOR LOCAL REPRODUCTION				STANDARD FORM 18 (Rev. 6/95)					

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1. PRICE/COST SCHEDULE

Evaluation of Timeliness of Medical Product Uptake for Surveillance in Health Care Databases for the Sentinel Initiative

(Period of Performance: 6 Months from Date of Award)

Cost Category	Description / Breakdown	Sub-Totals
Fully Loaded Labor Hours/Rates		\$ _____
Other Direct Costs		\$ _____
Indirect Costs		\$ _____
Travel		\$ _____
CLIN 0001 Total Firm-Fixed-Price (FFP) [Including All Costs & Travel]		\$ _____
<u>NOTE:</u> The budget for this requirement has been allocated in accordance with the Independent Government Cost Estimate (IGCE) of \$98,000. Any quotation submitted that is above the IGCE will not receive any consideration for award.		

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2. STATEMENT OF WORK

Evaluation of Timeliness of Medical Product Uptake for Surveillance in Health Care Databases for the Sentinel Initiative

BACKGROUND

In September 2005, the HHS Secretary asked FDA to expand its current system for monitoring medical product performance. The Secretary asked FDA to explore the possibility of working in collaboration with **multiple healthcare data systems** to augment the Agency's capability of identifying and evaluating product safety information beyond its existing voluntary reporting systems. Such a step would strengthen FDA's ability, ultimately, to monitor the performance of a product throughout its entire life cycle. The Secretary recommended that FDA explore:

- Creating a public-private collaboration as a framework for such an effort
- Leveraging increasingly available large, electronic healthcare databases
- Taking advantage of emerging technologies and building on existing systems and efforts, rather than creating new systems

In 2006, the IOM issued a report, entitled *The Future of Drug Safety—Promoting and Protecting the Health of the Public*.¹ Among other suggestions, this IOM report recommended FDA identify ways to access other health-related databases and create a public-private partnership to support safety and efficacy studies.

In early 2007, as a direct response to the Secretary's request, FDA held a two-day, workshop with representatives from the federal government, the pharmaceutical industry, the medical device industry, academia, public and private healthcare facilities, healthcare providers, bioinformatics institutions, and the public to explore the feasibility of creating a *national electronic system for monitoring medical product safety*, based on multiple, broad-based partnerships, including public-private partnerships. The discussion indicated broad support of the concept of developing such a process, which was referred to as "The Sentinel Initiative". There is a need to supplement the Agency's existing systems for monitoring post-market adverse events² with an active surveillance component that enables linking to electronic data that can be queried and analyzed in accordance with strong security and privacy safeguards.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007³ (FDAAA). Section 905 of this statute calls for the HHS Secretary to develop methods to obtain access to disparate data sources and to establish an active post-market risk identification and analysis system that links and analyzes healthcare data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires FDA to work closely with partners from public, academic, and private entities. FDA views its Sentinel Initiative as a mechanism through which this mandate can be carried out.

The Sentinel Initiative is a long-term effort that will proceed in stages. FDA has already created a broad public forum to begin discussing the scientific and policy issues that must be addressed as the

¹ Institute of Medicine, *The Future of Drug Safety —Promoting and Protecting the Health of the Public*, September 22, 2006, <http://www.iom.edu/>.

² Any untoward medical event associated with the use of a drug, device, or biologic in humans, whether or not considered product related. When known to be caused by a medical product, these events are called *adverse reactions*.

³ Food and Drug Administration Amendments Act of 2007, Public Law 110-85, was signed into law in September 2007. See Title IX, Section 905.

partnership is established. In the meantime, in collaboration with the public and private sectors, FDA is continuing to evaluate how to capitalize on and integrate existing pilot projects, many of which directly support the ultimate formation of this new distributed data system.

PROJECT OBJECTIVES

Consistent with FDA's mission to protect and promote the public health, the Agency is embarking on the Sentinel Initiative to create a national, electronic distributed network, strengthening FDA's ability to monitor the post-market performance of a product. As currently envisioned, the Sentinel Initiative will enable FDA to utilize the capabilities of multiple, existing data systems (e.g. electronic health record systems, Medicare data, other medical claims databases) to augment the Agency's current surveillance capabilities. The System will enable surveillance or queries of distributed data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Operations will adhere to strict privacy and security safeguards.

The success of this Initiative will depend largely on the time it takes for medical products under surveillance to be used by sufficient numbers of patients in participating health care databases. It is essential that FDA understand the timeliness of the surveillance possible in the Sentinel Initiative.

SCOPE OF WORK

The Sentinel Initiative is intended to be created through a public-private partnership involving a broad spectrum of stakeholders, including government agencies, data holders, academia, patients, consumers, and healthcare professionals. The scope of work of this specific project is to examine two recent medical product launches each in at least two different types of health care databases that could participate in the Sentinel Initiative in order to assess the timeliness of uptake of these products by patients in each database.

This project will require a thorough analysis of two medical products launched within the past several years in at least two different health care databases for: (1) the number of patients identified as using each medical product each month in each health care database throughout the first year after launch; (2) a description of the patients using the product, and characteristics of that use (e.g., product strength, days supply and overall duration of use); (3) the time elapsed before 1 patient, 100 patients, 1000 patients, 10,000 patients and 100,000 patients could be identified in each database using these products; (4) identification of factors that influence the uptake of new medical products in each of the databases examined. These analyses will be interpreted in the context of the population included and represented by the health care database to determine the generalizability of the findings to the nation as a whole.

These analyses should lead to specific recommendations for important characteristics or minimum criteria relating to medical product uptake that could be considered when evaluating health care data systems for inclusion as the Sentinel Initiative moves forward.

DETAILED REQUIREMENTS

1. Identify at least two potential data sources and/or data environments that could support the Sentinel Initiative, in consultation with FDA. For each, evaluate capture of the utilization of FDA-regulated drugs (including new molecular entities), biologics (including blood and tissue products), and devices.

2. For each potential data source and/or data environment, describe the types of electronic healthcare data (e.g., claims/transactional, laboratory, pharmacy, medical records, other) that could be used for post-market product safety surveillance. Description of each data type should include (but not be limited to):
 - (a) Size of population, degree of capture and duration of longitudinal follow-up across different patient care settings, and payment systems;
 - (b) structure and coding, including consistency with widely recognized standards;
 - (c) completeness, timeliness, and accessibility of data, including estimated times from service delivery to accessibility of data via queries;
 - (d) level of detail that would be available to examine temporal relationships between product administration and associated adverse events/outcomes;
 - (e) potential limitations if used for post-market product safety surveillance.

Description of pharmacy data should include (but not be limited to) availability of data for: prescribing-only vs. transactional/claims vs. documentation of actual product use/administration, new molecular entities, brand-name vs. generic products, dosing, and route of administration. Description of medical data on diagnoses, procedures and laboratory values should include a description of the coding systems used.

3. For each potential data source/and or environment, describe the patient population, participating institutions, and patient care settings.
 - (a) Description of patient populations should include (but not be limited to): payer status (if applicable), criteria for inclusion/exclusion, average length of follow-up, and participation in other healthcare systems. Description of the patient populations' representativeness should include (but not be limited to) comparisons of its size and patient characteristics to the respective catchment area(s) and national-level data.
 - (b) Description of patient care settings should include (but not be limited to): number, types, and catchment areas of participating institutions; estimated annual number of patients and/or visits in each setting; ability to longitudinally track patients through different settings, including content and quality of data available in each setting.
4. In consultation with FDA staff, select two medical products that have been launched within the past several years for evaluation of uptake in this pilot. For each product and each database, evaluate the following:
 - (a) the number of patients identified as using each medical product each month in each health care database throughout the first two years after launch;
 - (b) a description of the patients using the product, and characteristics of that use (e.g., product strength, days supply and overall duration of use);
 - (c) the time elapsed before 1 patient, 100 patients, 1000 patients, 10,000 patients and 100,000 patients could be identified in each database using these products;
 - (d) provide graphical displays of product uptake over the first two years after launch;
 - (e) identify factors that influence the uptake of new medical products in each of the databases examined.
5. Provide specific recommendations for important characteristics or minimum criteria relating to medical product uptake that could be considered when evaluating health care data systems for inclusion in the Sentinel Initiative, including identification of potential liabilities that should be addressed prior to and/or during participation.

REPORTING REQUIREMENTS AND SCHEDULE

- (XII) Submit three bi-monthly progress reports addressing the detailed requirements, culminating in a final report to be submitted within 6 months of the date the contract is awarded. Draft final reports should be provided to the Agency for review and comment within 4.5 months of the date the contract is awarded. All Agency comments should be addressed in the final report. Multiple specific requirements may be combined in one or more reports, pending agreement of FDA and the awardee within 2 months of the contract being awarded.
- 2. Schedule monthly progress teleconference meetings throughout this 6-month period with the Office of Critical Path Programs to report on progress to date, ability to meet stated deadlines, and any problems encountered. Refinements of contract requirements will be discussed and agreed upon, as necessary.

TRAVEL

Two contractor key personnel will be required to travel to Montgomery County, Maryland, in order to attend an in-person meeting at the FDA. All other meetings will be made via teleconference.

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3. HHS & FDA Agency-Specific Clauses

3.1. Electronic And Information Technology Standards (FDA)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the “Electronic and Information Technology Accessibility Standards” set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the “Access Board”) in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at <http://www.access-board.gov/>

The standards applicable to this requirement are listed below:

- § 1194.21 Software applications and operating systems
- § 1194.22 Web-based intranet and internet information and applications
- § 1194.31 Functional performance criteria
- § 1194.41 Information, documentation, and support.

3.2. Reporting Matters Involving Fraud, Waste And Abuse (FDA)

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in FDA 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

3.3. Restrictions Against Disclosure (FDA)

(a) The Contractor agrees, in the performance of this contract, to keep the information furnished by the Government and designated by the Contracting Officer or Contracting Officer’s Technical Representative in the strictest confidence. The Contractor also agrees not to publish or otherwise divulge such information in whole or in part, in any manner or form, nor to authorize or permit others to do so, taking such reasonable measures as are necessary to restrict access to such information while in the Contractor’s possession, to those employees needing such information to perform the work provided herein, i.e., on a “need to know” basis. The Contractor agrees to immediately notify the Contracting Officer in writing in the event that the Contractor determines or has reason to suspect a breach of this requirement.

(b) The Contractor agrees that it will not disclose any information described in Subsection A to any persons or individual unless prior written approval is obtained from the Contracting Officer. The Contractor agrees to insert the substance of this clause in any consultant agreement or subcontract hereunder.

3.4. Organizational Conflict Of Interest (MARCH 2000)

(a) The Contractor warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, or that the Contractor has disclosed all such relevant information.

(b) The Contractor agrees that if an actual or potential organizational conflict of interest is discovered after award, the Contractor will make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict.

I Remedies – The Contracting Officer may terminate this contract for convenience, in whole or in part, if it deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

(d) The Contractor further agrees to insert provisions which shall conform substantially to the language of this clause, including this paragraph (d), in any subcontract or consultant agreement hereunder.

3.5. Compliance With The Laws (MARCH 2000)

The Contractor shall comply with all applicable laws and rules and regulations having the force of law which deal with or relate to performance hereunder or the employment by the Contractor of the employees.

3.6. 352.270-8 Protection Of Human Subjects (Jan 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.

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 from the list of those contractors with approved Health and Human Services Human Subject Assurances.

3.7. Protection Of Human Subjects (FDA)

For any clinical studies involving human subjects and/or the use of patient records, necessary reviews and approvals shall be obtained from Institutional Review Boards (IRBs) and compliance with the Health Insurance Portability and Accountability (HIPAA) Act. Additionally, studies involving research on human subjects and/or the use of patient records will require review and prior approval by FDA's Research in Human Subjects Committee (RIHSC) before proceeding.

3.8. 352.270-9 Care Of Laboratory Animals (Jan 2006)

(a) Before undertaking performance of any contract involving animal related activities the Contractor shall register with the Secretary of Agriculture of the United States in accordance with [7 U.S.C. 2136](#) and [9 CFR sections 2.25 through 2.28](#). The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under [7 U.S.C. 2133](#) and [9 CFR Sections 2.1-2.11](#), or from a source that is exempt from licensing under those sections.

I The Contractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the [PHS Policy on Humane Care of Use of Laboratory Animals](#), the current Animal Welfare Assurance, the [Guide for the Care and Use of Laboratory Animals](#) prepared by the [Institute of Laboratory Animal Resources](#) and the pertinent laws and regulations of the United States Department of Agriculture (see [7 U.S.C. 2131](#) et seq. and [9 CFR Subchapter A, Parts 1-4](#)). In case of conflict between standards, the more stringent standard shall be used.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) 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 OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PHS Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

3.9. Care Of Laboratory Animals (FDA)

For any animal studies conducted, appropriate and necessary Institutional Animal Care and Use Committee (IUCAC) reviews and approvals shall be obtained and presented to the FDA.

3.10. 352.270–14 Restriction On Use Of Human Subjects (January 2006)

Pursuant to [45 CFR part 46, Protection of Human Research Subjects](#), the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the receipt by the Contracting Officer of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) designated under the Contractor's Federal-wide assurance of compliance. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

3.11. Federal Health Architecture (FHA) Health Information Technology Requirements: Interoperability

Executive Order 13410:

Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs promotes efficient delivery of quality health care through the use of health information technology, transparency regarding health care quality and price, and incentives to promote the widespread adoption of health information technology and quality of care. To support this mission, the awardee shall, at a minimum, implement the following clause(s)/condition(s) and, in doing so, the actions and steps taken to implement the clause(s)/condition(s) shall not impose additional costs onto the Federal Government.

In Response to Executive Order 13410, the following clauses shall apply:

Use recognized health information interoperability standards at the time of the system update, acquisition, or implementation, in all relevant information technology systems supported, in whole or in part, through this agreement/contract.

NOTE: If interoperability of health IT systems is applicable to the contract/agreement, the aforementioned clause/condition is mandatory.

Where offerors/awardees support or participate in health information [or data] exchange with disparate entities, offerors/awardees must be compatible with the following, where applicable architectures and data-exchange standards already exist:

HHS Nationwide Health Information Network (NHIN)

(www.hhs.gov/healthit/healthnetwork/background).

FDA Data Standards Council: Data Exchange Standards (<http://www.fda.gov/oc/datacouncil/>)

HHS Data & Technical Standards: Health Information Technology Standards Panel (HITSP) (<http://www.hhs.gov/healthit/standards/activities/>)

3.12. RECEIPT AND ACCEPTANCE OF SUPPLIES/SERVICES (FDA)

THE SUPPLIES AND/OR SERVICES DELIVERED HEREUNDER SHALL BE INSPECTED AND ACCEPTED AT DESTINATION BY THE CONTRACTING OFFICER'S REPRESENTATIVE (COR) SPECIFIED BELOW. IF THE SUPPLIES OR SERVICES ARE ACCEPTABLE, THE COR SHALL PROMPTLY FORWARD A REPORT OF INSPECTION AND ACCEPTANCE TO THE PAYING OFFICE. IF THE SUPPLIES OR SERVICES ARE NOT

ACCEPTABLE, THE COR SHALL DOCUMENT THE NONCONFORMING ITEMS/SERVICES AND IMMEDIATELY NOTIFY THE CONTRACTING OFFICER.

3.12.1. POINTS OF CONTACT

THE COR FOR THIS ORDER IS:

MELISSA ROBB, Melissa.Robb@fda.hhs.gov, Telephone: 301.827.1516

QUESTIONS CONCERNING THE PRICING OR TERMS OF THIS ORDER SHOULD BE DIRECTED TO CONTRACT SPECIALIST:

TERRY FREDERICK, Terry.Frederick@fda.hhs.gov, Telephone: 301.827.7043

3.12.2. FDA INVOICE REQUIREMENTS

THE CONTRACTOR SHALL SUBMIT INVOICES TO THE ADDRESS DESIGNATED IN THE PURCHASE ORDER (SEE BLOCK 21) TO RECEIVE INVOICES. TO CONSTITUTE A PROPER INVOICE, THE INVOICE MUST BE SUBMITTED ON COMPANY LETTERHEAD AND INCLUDE-

- (I) NAME AND ADDRESS OF THE CONTRACTOR;
- (II) INVOICE DATE AND INVOICE NUMBER;
- (III) PURCHASE ORDER NUMBER;
- (IV) DESCRIPTION, QUANTITY, UNIT OF MEASURE, UNIT PRICE AND EXTENDED PRICE SUPPLIES DELIVERED OR SERVICES PERFORMED;
- (V) SHIPPING NUMBER AND DATE OF SHIPMENT, INCLUDING THE BILL OF LADING NUMBER AND WEIGHT OF SHIPMENT IF SHIPPED ON GOVERNMENT BILL OF LADING;
- (VI) TERMS OF ANY DISCOUNT FOR PROMPT PAYMENT OFFERED;
- (VII) NAME AND ADDRESS OF OFFICIAL TO WHOM PAYMENT IS TO BE SENT (MUST BE THE SAME AS THAT IN THE PURCHASE ORDER OR IN A PROPER NOTICE OF ASSIGNMENT);
- (VIII) NAME, TITLE, AND PHONE NUMBER OF PERSON TO NOTIFY IN EVENT OF DEFECTIVE INVOICE;
- (IX) TAXPAYER IDENTIFICATION NUMBER (TIN).
- (X) ELECTRONIC FUNDS TRANSFER (EFT) BANKING INFORMATION.
- (XI) NAME AND TELEPHONE NUMBER OF THE FDA PROJECT OFFICER REFERENCED ON THE PURCHASE ORDER; AND
- (XII) ANY OTHER INFORMATION OR DOCUMENTATION REQUIRED BY THE PURCHASE ORDER.

AN ELECTRONIC INVOICE IS ACCEPTABLE IF SUBMITTED IN ADOBE ACROBAT (PDF) FORMAT. ALL ITEMS LISTED IN (I) THROUGH (XII) OF THIS CLAUSE MUST BE INCLUDED IN THE ELECTRONIC INVOICE. ELECTRONIC INVOICES MUST BE ON COMPANY LETTERHEAD AND MUST CONTAIN NO INK CHANGES AND BE LEGIBLE FOR PRINTING.

QUESTIONS RELATING TO WHEN PAYMENT WILL BE RECEIVED SHOULD BE DIRECTED TO THE FDA PAYMENT OFFICE AT (301) 827-3742.

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4. Federal Acquisition Regulation (FAR) Clauses

4.1 52.252-2 Clauses Incorporated by Reference (Feb 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 address:

<http://acquisition.gov/far/index.html>.

- | | |
|--------------------------|--|
| 4.1.1. 52.204-7 | Central Contractor Registration (Apr 2008) |
| 4.1.2. 52.213-4 | Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (Feb 2008) |
| 4.1.3. 52.224-1 | Privacy Act Notification (Apr 1984) |
| 4.1.4. 52.224-2 | Privacy Act (Apr 1984) |
| 4.1.5. 52.227-14 | Rights in Data—General (Dec 2007) |
| 4.1.6. 52.227-16 | Additional Data Requirements (June 1987) |
| 4.1.7. 52.227-17 | Rights in Data—Special Works (Dec 2007) |
| 4.1.8. 52.227-18 | Rights in Data—Existing Works (Dec 2007) |
| 4.1.9. 52.227-23 | Rights to Proposal Data (Technical) (June 1987) |
| 4.1.10. 52.232-25 | Prompt Payment (Oct 2003) |
| 4.1.11. 52.232-33 | Payment by Electronic Funds Transfer—Central Contractor Registration (Oct 2003) |
| 4.1.12. 52.233-4 | Applicable Law for Breach of Contract Claim (Oct 2004) |
| 4.1.13. 52.239-1 | Privacy or Security Safeguards (Aug 1996) |
| 4.1.14. 52.243-1 | Changes—Fixed-Price (Aug 1987) <i>Alternate III (Apr 1984)</i> |
| 4.1.15. 52.249-2 | Termination for Convenience of the Government (Fixed-Price) (May 2004) |
| 4.1.16. 52.249-8 | Default (Fixed-Price Supply and Service) (Apr 1984) |

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5. Federal Acquisition Regulation (FAR) Solicitation Provisions

5.1. 52.204-8 Annual Representations and Certifications (Jan 2006)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 541690.

(2) The small business size standard is \$6.5 Million.

(3) The small business size standard for a concern which submits an 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 completing 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 (see 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
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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.

5.2. 52.215-1 Instructions to Offerors—Competitive Acquisition (Jan 2004)

(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 quotation.

“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.

“Quotation modification” is a change made to a quotation 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.

“Quotation revision” is a change to a quotation 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 quotations.

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, quotations and modifications to quotations 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 quotation 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 quotation 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, and 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 quotation. Quotations 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 quotations.

(i) Offerors are responsible for submitting quotations, 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 4:30 p.m., local time, for the designated Government office on the date that quotation or revision is due.

(ii)(A) Any quotation, 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 quotations; 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 quotation received.

(B) However, a late modification of an otherwise successful quotation 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 quotation 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 quotations cannot be received at the office designated for receipt of quotations by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of quotations 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) Quotations may be withdrawn by written notice received at any time before award. Oral quotations in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile quotations, quotations may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at [52.215-5](#), Facsimile Quotations. Quotations 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 quotation 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 quotations 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 quotations 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 quotations only if requested or allowed by the Contracting Officer.
- (8) Quotations may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) Offer expiration date. Quotations 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) See HHSAR Addendum.
- (f) Contract award.
- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose quotation(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 quotations if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in quotations received.
- (4) The Government intends to evaluate quotations and award a contract without discussions with offerors (except clarifications as described in FAR [15.306\(a\)](#)). Therefore, the offeror's initial quotation 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 quotations 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 quotations in the competitive range to the greatest number that will permit an efficient competition among the most highly rated quotations.
- (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 quotation.
- (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.
- (7) Exchanges with offerors after receipt of a quotation do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a quotation 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 quotation 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 quotation mailed or otherwise furnished to the successful offeror within the time specified in the quotation 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 the 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.

- HHSAR Addendum -

352.215-1 Instructions to offerors--Competitive acquisition

Insert the following paragraph (e) in place of paragraph (e) of the provision at FAR 52.215-1:

(e) Restriction on disclosure and use of data.

(1) The quotation 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 quotation. 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 quotation with the following statements, specifying the particular portions of the quotation 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 quotation 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 quotation, the Government shall have the right to use or disclose the data to the extent provided in the contract. Quotations 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 quotation or quotation.”

(3) Offerors are cautioned that quotations 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 quotation submitted with nonconforming statement(s).

6. Solicitation Disclosures and Instructions

6.1. Commitment of Public Funds

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

6.2 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 RFQ. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

6.3 Inquiries

Quoters shall submit all questions concerning this solicitation in writing to the FDA electronically by email at Terry.Frederick@fda.hhs.gov. **All contractor-submitted questions** shall be received no later than **August 15, 2008, at 10:00 AM, Eastern Time**. All responses to the questions will be made in writing and included in an amendment to the solicitation.

6.4 Comparative Importance of Quotation Volumes

You are advised that paramount consideration shall be given to the evaluation of technical quotations. Subject to the predetermined ceiling on cost or price, all evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in Section 8 of this solicitation. The Government reserves the right to make an award without discussions to the deserving contractor who submits a quotation that represents the best value to the Government, cost and other factors considered.

6.5 Preparation Costs

This RFQ does not commit the Government to pay for the preparation and submission of a quotation.

7. Quotation Instructions

Quotations will consist of two independent volumes, technical and price.

7.1 Technical Volume

The technical volumes shall be submitted in an original, three (3) paper copies, and one electronic copy (on CD-ROM) in MS Word and/or Excel.

The cover page of the technical volumes shall include the following:

1. RFQ title
2. RFQ number
3. Responding organization's name
4. Responding organization's authorized signatory and signatory contact email/telephone
5. Responding Organization's DUNS number
6. Responding Organization's socio-economic business program status for the applicable NAICS code of 541690 - \$6.5 Million (i.e., Small Business, 8(a), Small Disadvantaged

- Business, Service-Disabled Veteran-Owned Small Business, HUBZone Small Business, Women-Owned Small Business, or Large Business)
7. Identification of quotation volume, marked either original or copy (numbered 1-3).

The Government will evaluate technical volumes in accordance with the evaluation criteria set forth in Section 8 of this solicitation.

The technical volumes shall be presented on 8 ½ x 11 inch paper, 12-point pitch or larger, with 1 inch margins on all four sides.

Technical volumes shall not exceed **15 pages**, excluding (1) curriculum vitae for key personnel, (2) past performance information [Attachment 1], and (3) Non-Public Information (NPI) Agreements for Contractor Key Personnel [Attachment 2]. Any and all pages, including cover sheets, table of contents, charts, exhibits, tab dividers, unmarked pages, and any other narrative and attachments to the quotation, shall be included in the page calculation. Any technical volume pages submitted beyond the page limit will not be considered.

7.2 Price Volume

The technical volumes shall be submitted in an original, three (3) paper copies, and one electronic copy (on CD-ROM) in MS Word and/or Excel.

The cover page of the technical volumes shall include the following:

1. RFQ title
2. RFQ number
3. Responding organization's name
4. Responding organization's authorized signatory and signatory contact email/telephone
5. Responding Organization's DUNS number
6. Responding Organization's socio-economic business program status for the applicable NAICS code of 541690 - \$6.5 Million (i.e., Small Business, 8(a), Small Disadvantaged Business, Service-Disabled Veteran-Owned Small Business, HUBZONE Small Business, Women-Owned Small Business, or Large Business)
7. Identification of quotation volume, marked either original or copy (numbered 1-3).

The price volumes shall be presented on 8 ½ x 11 inch paper, 12-point pitch or larger, with 1 inch margins on all four sides.

There is **no page limit for price volumes**. Price volumes shall include a completed copy of the Cost/Price Schedule provided in Section 1. Quoters may choose to provide addenda, if necessary and/or appropriate.

In addition, the quoter shall complete all applicable blocks of the enclosed Standard Form 18, including requisite signatures and dates.

[This Space Intentionally Left Blank]

8. Evaluation Criteria

8.1. Background

The Government will award a simplified purchase order to the responsive contractor who offers the “best value” to the Government in accordance with the requirements of the Statement of Work (SOW). The anticipated procurement procedures are those prescribed by FAR Part 13 for Simplified Acquisition Procedures. Written quotations will be evaluated against the following evaluation factors listed in descending order of importance: Technical Approach/Management Plan, Experience, Socio-Economic Status, Past Performance, and Price.

8.2. Best Value

The Government plans to award a purchase order to the Quoter whose quote represents the best value solution. The Contracting Officer may reasonably determine that the superior solution/approach merits a higher price, and therefore represents the best value to the Government.

8.3. Evaluation Factors

Factor 1: Technical Approach/Management Plan

Factor 2: Experience

Factor 3: Socio-Economic Status

Factor 4: Past Performance

*****Price*****

8.3.1. Factor 1: Technical Approach & Management Plan

The technical approach will be evaluated for its quality and evidence of the extent to which the submitted quotation will achieve FDA’s objectives as expressed in the SOW.

The evaluation will include but will not be limited to an assessment that the quotation:

- Reflects a significant understanding of the program’s objectives, operating environment and constraints, and demonstrates contributions to the development and execution of best practices in task areas
- Reflects a sound approach for staffing and completing task activities with appropriately qualified personnel and in an efficient manner
- The management plan will be evaluated for content, clarity, quality, accuracy, and completeness

8.3.2. Factor 2: Experience

Experience will be evaluated on the extent to which contractors demonstrate organizational experience within the last three years completing projects that are similar in subject matter, scope, and complexity to the requirements of the SOW.

The quoter shall explain (1) how the stated experience is relevant to the present requirement and (2) how it will help prepare the quoter to meet the demands of the present requirement.

The quoter shall identify the customer, performance period, and value of each project.

8.3.3. Factor 3: Socio-Economic Status

Socio-Economic Status of the quoter shall be considered as an evaluation factor for award with the goal of achieving one of the FDA's socio-economic goals. FDA's socio-economic goals are provided as follows:

Awards to:	FDA Goal
Small Business	40%
8(a)	5%
Small Disadvantaged Business	5%
Service-Disabled Veteran-Owned Small Business	3%
HUBZone Small Business	3%
Women-Owned Small Business	5%

8.3.4. Factor 4: Past Performance

The quoter shall identify up to three projects similar in subject matter, scope, and complexity that it has performed within the last three years or is presently performing.

The quoter shall submit completed, dated, and signed copies of the provided past performance questionnaire as part of its technical volume submittal for each of its past performance references. *See Attachment 1.*

The quoter shall identify the customer, performance period, and value of each project, as well as the name and telephone number of the customer's contractual and technical points of contact (POCs).

The Government may contact some or all of the POCs identified by the quoter to verify and obtain past performance information. In addition, the Government reserves the right to consider past performance information obtained from all other available sources.

8.3.5. Price

The budget for this requirement has been allocated in accordance with the Independent Government Cost Estimate (IGCE) of: \$ 98,000. Any quotation submitted that is above the IGCE will not receive any consideration for award.

Subject to the limitations provided above, price will not be a primary factor for award. However, price will become increasingly important as quotation evaluation ratings for the non-price determinants approach equality between responsive quotations.

PAST PERFORMANCE QUESTIONNAIRE

(To be Completed by the Customer/Reference, but Submitted to FDA Before Quotation Deadline)

Offerors may use this form to obtain past performance information from their clients and customers, in addition to providing list of references. Clients/customers should submit completed form directly to the Contracting Officer at email: XXX or fax: XXX, NLT the due date and time for offers submitted in response to the RFQ.

CONTRACTOR:

CONTRACT NUMBER:

CONTRACT/PURCHASE ORDER/DELIVERY/TASK ORDER #:

CONTRACT TYPE:

ORIGINAL CONTRACT VALUE:

CURRENT CONTRACT VALUE:

DESCRIPTION OF EFFORT:

PERIOD OF PERFORMANCE:

PLACE OF PERFORMANCE:

Please complete the questionnaire as a coordinated effort for the Contracting Officer. Narrative comments supporting the rating are highly desirable to accurately assess the performance of the contractor. Choose the number on the scale of 1 to 5 that most accurately describes the Contractor's performance on the contract listed above. The following definitions apply:

1). Excellent Performance - Objectives/requirements essentially always achieved or exceeded, with inconsequential exceptions.

2). Good Performance - Objectives/requirements achieved with only rare exceptions, and the exceptions had minor consequences.

3). Adequate Performance - Objectives/requirements generally achieved with occasional exceptions and, in almost all cases, exceptions had minor consequences.

4). Marginal Performance - Objectives/requirements were frequently not fully achieved, often with significant consequences.

5). Poor Performance - Objectives/requirements were not achieved, with significant consequences.

Technical/Quality

1. Did the contractor meet the technical or mission objectives set out in the contract or task order?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

2. Where the objectives proved more difficult than originally predicted, how did the contractor respond to these technical challenges?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

Workforce Qualifications and Stability

3. Evaluate the Contractors work force in terms of overall qualifications to perform the work required.

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

4. Evaluate the Contractors performance in terms of the stability of its workforce and continuity of performance of the Contract/Task Order.

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS

Subcontractor Management

5. For work with substantial subcontractor involvement, evaluate the overall effectiveness of the Contractors subcontractor management.

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

Conformance to Schedule

6. Did the contractor meet the schedule requirements set out in the contract or task order?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

7. When schedule requirements proved more difficult than originally predicted, how did the contractor respond to these schedule challenges?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

Cost Estimating

8. Did the contractor estimates accurately reflect what the work actually cost?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

9. If the actual project costs exceeded the contractor's original estimate, evaluate the quality of the contractor's corrective action.

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

Business Relations/Customer Satisfaction

10. Was the contractor responsive to customer requests?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

11. Evaluate the contractor's commitment to total customer satisfaction.

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

12. How responsive and reasonable was the Contractor with regard to negotiating changes and modifications?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ N/A ☐

COMMENTS:

13. Have there been any terminations of tasks due to inability to meet technical requirements, delivery schedules, or cost predictions? If so, how many?

YES ☐ NO ☐

COMMENTS:

14. Would you award similar contracts to the Contractor in the future?

YES ☐ NO ☐

COMMENTS:

15. What role did you play (e.g., COR, Contract Specialist, ACO)?
How long?

NAME (Printed)/Phone:

SIGNATURE: _____

DATE: _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

**CONTRACTOR'S COMMITMENT TO PROTECT
NON-PUBLIC INFORMATION (NPI) AGREEMENT**

Whereas access to non-public information (NPI) from the files of the Food and Drug Administration (FDA) is required in the performance of my official duties, under Contract Number _____, and between FDA and my employer, _____,

I, _____, hereby agree that I shall not further release, publish or disclose such information and I shall protect such information entrusted to me in accordance with the provisions of 21 U.S.C. § 331(j), 21 U.S.C. § 360(j), 18 U.S.C. § 1905, as well as other applicable statutory and regulatory provisions.

Further, I agree to:

1. Store NPI in the secured offices of the FDA or in FDA approved contractor facility containers if work is performed off an FDA site.
2. Grant access to NPI only to known employees of the FDA or to other persons designated in writing by the FDA.
3. Return all NPI and any pertinent notes to the FDA Project Officer I am assigned to upon completion of the contract, or at any time upon the FDA's request.
4. Report in writing to the FDA Project Officer I am assigned to, all incidents in which unauthorized persons may have gained access to any NPI entrusted to me.

I understand the provisions of 21 U.S.C. § 331(j), 21 U.S.C. § 360(j), 18 U.S.C. § 1905 and that I am subject to criminal penalties prescribed by law for any violation thereof.

Signature: _____ Date: _____

Type or Print Name: _____

Witnessed by: _____ Date: _____

Type or Print Name: _____