

**Justification
for Other than Full and Open Competition**

“Source Selection Information – see FAR 2.101 and 3.104”

1. Identification of the agency and contracting activity.

Agency: United States Department of Health and Human Services (HHS) Office of the Secretary Assistant Secretary for Preparedness and Response (ASPR)

Sponsoring organization: Biomedical Advanced Research and Development Authority (BARDA), Manufacturing, Facilities and Engineering Division (MFE)

Contracting Officer: [REDACTED]

Contracting Officer’s Rep: [REDACTED]

2. Nature and/or description of the action being approved.

In accordance with FAR Subparts 16.505 and 6.302-3 under Industrial Mobilization, this justification seeks authority to approve the utilization of Pfenex Incorporated as a sole source subcontractor. Upon approval of this justification, it is anticipated that a request for task order response (RTOR) will be competitively solicited among all the HHS Centers for Innovation in Advanced Development and Manufacturing (CIADM) to propose on the execution of a technology transfer and the scale-up manufacturing of Pfenex’s unique, experimental *Pseudomonas*-based expression system technology.

3. Description of the supplies or services required to meet the agency’s needs (including the estimated value).

Project title.

A new RTOR for the continued development the Pfenex Expression Technology™ for an anthrax vaccine via the HHS CIADM program.

Project description.

HHS seeks to transfer Pfenex’s experimental *Pseudomonas*-based anthrax vaccine product into a HHS CIADM to enable the manufacture of a recombinant protective antigen (rPA) bulk drug substance (BDS) lot under current good manufacturing practices (cGMP). The objective of the RTOR is to perform the necessary steps to transfer the process into a HHS CIADM and produce a cGMP rPA BDS lot at the 100-200 liter scale. All applicable in-

process release and stability testing will be performed by the HHS CIADM. Certain assays may be performed by Pfenex. Additionally, this RTOR includes the necessary work to formulate and fill a batch of final drug product (FDP) at the discretion of HHS for other assays and/or pre-clinical/clinical testing.

Requirement type.

- Research & development (R&D)
- R & D support services
- Support services (non-R&D)
- Supplies/equipment
- Information technology (IT)
- Construction
- Architect-engineer (A & E) services
- Design-build
- Other (specify): _____

Type of action.

- New requirement
- Follow-on
- Other (specify): _____

Proposed contract/order type.

- Firm-fixed-price
- Other fixed-price (specify, e.g., fixed-price award-fee, fixed-price incentive-fee): _____
- Cost-plus-fixed-fee
- Other cost reimbursement (specify, e.g., cost-plus-award-fee, cost-plus-incentive-fee): _____
- Time and materials
- Indefinite delivery/Indefinite Quantity
- Other (specify): _____
- Completion Form Term form

Acquisition identification number.

Total estimated dollar value and performance/delivery period.

The total estimated dollar value for the task order is [REDACTED] which will fund the technology transfer and BDS process scale-up of Pfenex's anthrax vaccine platform, as well as the manufacture, testing and delivery of one (1) cGMP lot of rPA BDS. Included in the Independent Government Cost Estimate (IGCE) is the storage of bulk and finished vaccine product, the management of necessary stability studies and the funding required to complete the fill/finish manufacturing of one (1) cGMP FDP lot suitable for

clinical testing. The performance period for these activities is estimated to extend up to 30 months, dependent on availability of necessary capacity/ equipment at the HHS CIADM.

4. Identification of the statutory authority permitting an exception to fair opportunity and supporting rationale and the supporting rationale including a demonstration that the proposed contractor's unique qualifications or the nature of the acquisition requires use of the exception cited.

a. Identification of the statutory authority permitting an exception to fair opportunity.

This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 3304(a)(3) as implemented in Federal Acquisition Regulation (FAR) 6.302-3 (a)(2 and FAR 16.505(2)(i)(B).

b. Name and address of the proposed contractor(s).

Pfenex, Inc.
10790 Roselle Street
San Diego, CA 92121

c. Nature of the acquisition and proposed unique qualifications of the contractor(s).

On January 20, 2004, the Secretary of the Department of Homeland Security (DHS) determined that anthrax is a material threat to the U.S. population sufficient to affect national security. Since that determination, the BARDA has set forth to develop safe and efficacious anthrax vaccines to protect the U.S. public from the threat of an anthrax attack/ outbreak.

The U.S. Government (USG) has been instrumental in providing support for the anticipated regulatory licensure of Emergent Biosolutions' Biothrax® anthrax vaccine for post-exposure prophylaxis; currently indicated for the active immunization of adults at high risk of exposure to anthrax (general use prophylaxis). However, the USG has a requirement to develop a next generation anthrax vaccine for use in a public health emergency that has improved qualities. A next generation anthrax vaccine would provide a potentially economical alternative to Biothrax®, which is currently the only approved anthrax vaccine product in the market.

Given the extremely low success rate for vaccine candidates advancing through clinical testing, BARDA has developed a portfolio of recombinant protective antigen (rPA) anthrax vaccines in various stages of research and development. It is vital to the immediate success of the anthrax rPA

vaccine program, and national security, that all viable and reasonable technologies advance in parallel. Therefore, in order to maintain the current portfolio of candidate vaccines, BARDA and key rPA anthrax vaccine developers have agreed to explore the use of core service capabilities offered through the HHS CIADM program. One of the key requirements of the HHS CIADMs is to “*provide core advanced development (“industrialization”) and manufacturing services to other commercial partners under contract to the USG for development of biopharmaceuticals against chemical, biological, radiological and nuclear (CBRN) threats...*”. BARDA’s integration of its anthrax vaccine program(s) into this core service capability will satisfy the mutual requirements of the HHS CIADM program and the anthrax medical countermeasure (MCM) portfolio.

BARDA’s portfolio of next generation anthrax vaccines under development includes Pfenex Inc.’s distinctive capabilities. The additional stability provided by Pfenex’s product could result in a desired extended shelf life and ability to store at less costly conditions. Potentially higher production yields would allow for quicker availability of anthrax vaccine during a public health emergency at a lower cost. Pfenex’s unique technical capabilities include:

- The Pfenex Expression Technology™ offers high-throughput screening of *Pseudomonas fluorescens* strains with high soluble yield and enhanced stability. Pfenex developed a strain to manufacture a mutant recombinant protective antigen (rPA) for use in anthrax vaccine development.
- Pfenex's *Pseudomonas fluorescens*, cell-based system has demonstrated 10 to 100 fold higher antigen production yields than other rPA expression systems currently under development. There is also evidence that Pfenex’s mutant rPA strain might be more stable than other rPA candidates in development. These attributes could lead to a significantly reduced life-cycle cost to the USG.
- Certain mutations at proteolytic sites of the protective antigen, render the mutant rPA resistant to proteases. These mutations have also been reported to render the protective antigen molecule non-toxic in that it can no longer oligomerize to form a channel in the cell membrane to translocate the catalytic moieties of the anthrax toxins, lethal factor and edema factor, into the cell. The combination of this mutant rPA gene and a certain proprietary protease deficient strain derived from the Pfenex platform have contributed to the production of high titers of stable antigen.

To help ensure that this rPA anthrax vaccine candidate has every opportunity to be successful, the USG has determined that the core service capabilities provided by the HHS CIADM are required to further advance Pfenex’s development efforts.

As this RTOR addresses only a small, yet critical, step in developing and licensing a vaccine candidate; many more tasks will need to be completed by Pfenex, potentially with the aid of the BARDA's core service capabilities, to achieve the critical goals of the anthrax MCM program.

5. A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable.

HHS has currently contracted with Pfenex and other anthrax vaccine manufacturers to do similar activities as those contemplated in this justification, HHS has significant historical and current cost data available to determine the cost reasonableness of Pfenex's material cost and the cost for a HHS CIADM to complete a technology transfer and necessary scale-up manufacturing utilizing the Pfenex Expression Technology™ to advance this rPA anthrax vaccine project.

6. Any other facts supporting the justification.

None.

7. A statement of the actions, if any, the agency may take to remove or overcome any barriers that led to the exception to fair opportunity before any subsequent acquisition for the supplies or services is made.

The HHS CIADM Governance process provides an opportunity for programs managed by BARDA, NIH, CDC, FDA, and DoD to be presented for review by the HHS Advanced Development & Manufacturing (ADM) Steering Committee [or HHS-ASC] for potential entrance into a HHS CIADM. Since the HHS-ASC is represented by ranking members from each of these agencies, the group consensus is used to determine the level of support that could be offered by the HHS CIADMs and timing based on emergency medical countermeasure priorities. The assessment by the HHS-ASC takes into consideration the following factors: alignment to the priorities of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) [national security/ public safety]; feasibility of the proposed project based on staffing, equipment, project timing [capability fit]; current status of projects utilizing existing HHS CIADM capacity; and overall estimated project costs versus the programmatic budget.”

8. Program office certification.

This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Official	Name & Title	Signature	Date
Project Officer	[REDACTED]	[REDACTED]	[REDACTED]
Head of the Sponsoring Program Office	[REDACTED]	[REDACTED]	[REDACTED]

9. Contracting Officer Certification.

This is to certify that the justification for the proposed acquisition has been reviewed and that to the best of my knowledge and belief the information and/or data provided to support the rationale and recommendation for approval is accurate and complete.

Official	Name & Title	Signature	Date
Contracting Officer	[REDACTED]	[REDACTED]	[REDACTED]

10. Chief of the Contracting Office and Head of the Contracting Activity signature(s).

Official	Name & Title	Signature	Date
Chief of the Contracting Office (Acting)	[REDACTED]	[REDACTED]	[REDACTED]
Head of the Contracting Activity	[REDACTED]	[REDACTED]	[REDACTED]

11. Competition Advocate signature.

Official	Name & Title	Signature	Date
Competition Advocate	[REDACTED]	[REDACTED]	[REDACTED]