

Justification for an Exception to Fair Opportunity

~~—“Source Selection Information—see FAR 2.101 and 3.104”—~~

- **Identification of the agency and contracting activity.** Department of Health and Human Services (HHS)
 - a. **Federal agency and contracting activity.** Assistant Secretary for Preparedness and Response (ASPR)/Biomedical Advanced Research and Development Authority (BARDA)
 - b. **Sponsoring organization.** Defense Health Agency (DHA)/Department of Defense (DoD)
 - c. **Project Officer information**
 - **Contracting Officer's Representative (COR) name.**
Vittoria Cioce
 - **Mailing address.**
330 Independence Ave, Room G644, Washington, DC 20201
 - **E-mail address.**
[REDACTED]
 - **Telephone number.**
[REDACTED]
- **Nature and/or description of the action being approved.**
 - a. **Acquisition purpose and objectives.**

DHA within DoD has requested through an Interagency Agreement that BARDA conduct this procurement of manufacturing one (1) bulk lot of AS03 adjuvant system as an assisted acquisition under the Economy Act and pursuant to FAR subparts 17.5 and 17.7.

With this Justification for an Exception to Fair Opportunity, BARDA is documenting approval on a sole-source basis to solicit and issue a delivery order to GSK under multiple-award ID/IQ Contract No. HHSO1002016000041 to manufacture one (1) bulk lot of AS03 adjuvant system on behalf of DHA.

b. Project Background

DHA and BARDA continuously monitor pandemic risk and prepare to respond to the threat of novel influenza outbreaks in the United States (US) and have established and maintain National Pre-Pandemic Influenza Vaccine Stockpile (NPIS) comprising pre-pandemic A(H5) and A(H7) bulk antigens and adjuvants. Since 2005, DHA has

- **Identification of exception to fair opportunity and supporting rationale.**

Federal Acquisition Regulation (FAR) 16.505(b)(2)(B): "Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized."

- **Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.**

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

GlaxoSmithKline LLC
5 Moore Drive
Research Triangle Park, NC 27709-0143

DUNS: 167380711

TIN: [REDACTED]

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

DHA has a need to procure adjuvant to stockpile for pre-pandemic influenza preparedness.

Maximizing the shelf-life of adjuvant procured for stockpiling is in DHA's best interest to ensure, among other reasons, that (i) adjuvant is readily available for an emergency, and (ii) DHA obtains the best value for the taxpayer by minimizing future obligations and expenditures to replace adjuvant that may expire while stockpiled.

GSK-offered AS03 adjuvant system has a shelf-life of at least [REDACTED] which shelf-life is the longest offered among the multiple-award ID/IQ Contract holders that manufacture adjuvant.

GSK is the only multiple-award ID/IQ Contractor that is permitted to manufacture and sell AS03 adjuvant system according to GSK's quality systems and established manufacturing processes.

Therefore, only GSK is capable of satisfying DHA's requirements by manufacturing one (1) bulk lot of AS03 adjuvant system.

- **Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.**

The contemplated delivery order will be priced at or below the firm fixed prices set forth in Contract Line Item No. 0501 that was determined to be fair and reasonable at the time of award of the multiple-award ID/IQ Contract No. HHSO1002016000041.

- Any other facts supporting the justification.


None

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

None

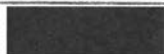
- Program office certification.

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
Contracting Officer's Representative	Vittoria Cioce Stockpile Branch Influenza and Emerging Infectious Diseases Division		9/5/2019


- 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	Kevin Nilles		Sep. 5, 2019

- Competition Advocate signature.

This is to certify that the exception to fair opportunity listed in item 4 above applies to this order.

Official	Name & Title	Signature	Date
Competition Advocate	Schuyler Eldridge Head of the Contracting Activity		9/13/2019