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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUSTIFICATION FOR SOLE SOURCE PROCUREMENT (OPEN MARKET OR GSA) UNDER $150,000

Sole source acquisitions may be used on a limited basis and only when the Contracting Officer's Representative (COR)/Program Official has provided sufficient justification and the Contracting Officer has determined that the circumstances warrant such action. The content for a justification must contain detailed facts and rationale to justify the sole source acquisition. Soliciting from a single source must be done in accordance with FAR 13.106-1(b) or 8.405-6. At a minimum, the following information must be included:

Identification of Program Office, Contracting Activity, and Proposed Requirement, Justification and Program Office Certification:

A. Program Office:

Office of Public Health Preparedness & Response
Division of Strategic National Stockpile
Logistics Branch
Centers for Disease Control and Prevention
Atlanta, GA 30333

B. Contracting Activity:

Centers for Disease Control and Prevention
Office of Financial Resources
Acquisition Branch
2920 Brandywine Road Atlanta, GA 30341

C. Identification of Requirement:

1. Nature of Action to be Approved by Contracting Officer:

   a. Sole source acquisition of: Perform a plaque titration to quantify the titer of Wetvax for the CDC Wetvax smallpox stability program

   b. Procurement Request (PR) Number (if available): **20876**

2. Proposed Vendor and Estimated Procurement Amount (if available):

   a. Proposed Vendor: Emergent Biosolutions Inc., 50 Shawmut Road, Canton, MA 02021

   b. Estimated Procurement Amount $127,526.00

3. Is the requirement on GSA Schedule? ☐ Yes ☒ No

   If yes, provide schedule number: Click here to enter text.

D. Justification:

1. The justification for this non-competitive action is:

☒ In accordance with FAR 13.106-1(b)(1), "only one source [is] reasonably available" which states that, "For purchases not exceeding the simplified acquisition threshold. (i) Contracting officers may solicit from one source if the contracting officer determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). (ii) Where a single source is identified to provide a portion of a purchase because that portion of the purchase specifies a particular brand-name item, the documentation in paragraph (b)(1)(i) of this section only applies to the portion of the purchase requiring brand-name item. The documentation should state it is covering only the portion of the acquisition which is brand- name."

☐ Urgency

☒ Exclusive licensing agreements/Proprietary data

☐ Brand name required

☐ Industrial mobilization

☐ Other (e.g., compatibility, space issues, continuity, compatibility, etc.)

☐ In accordance with FAR 8.405-6 "Limiting Sources" which states that, "the only circumstances that may justify the action are – (A) An urgent and compelling need exists, and following the procedures would result in unacceptable delays; (B) Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized; or (C) In the interest of economy and efficiency, the new work is a logical follow-up to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original BPA must not have been previously issued under sole-source or limited-sources procedures."

☐ Urgency

☐ Only One Source

☐ Logical Follow Up

2. Other facts supporting sole source procurement:

a. What can this product/service do that other products/services cannot do?
The service is unique to Emergent Biosolutions due to its ownership of the only approved process and proprietary process. The current approved potency testing of the Aventis Pasteur Smallpox Vaccine (APSV, or "Wetvax") was made through the CDC current Wetvax smallpox vaccine investigational new drug (IND) 10812 Serial #008 June 7, 2004 submission and acceptance by the Food and Drug Administration (FDA) of the Baseline Plaque Forming Unit Titer Determination of IND-Labeled Live Aventis Pasteur Smallpox Vaccine (Lots D02242-D02255, Inclusive). The test and data submitted to the FDA had been developed by Acambis, which created the smallpox vaccine ACAM2000. The assay was developed by Acambis as a release assay for ACAM2000. The validated procedure for VERO cell plaque forming unit assay entitled, "Potency testing for Vaccinia Samples", document #US02-QCP-069, is the only accepted potency test that can be used under the current smallpox release protocol. This assay will be used to generate data for the FDA to monitor the potency of Wetvax/APSV. The assay needs to be validated in order to provide data of sufficient quality for regulatory evaluation. The only present source using a validated version of

this assay is Emergent. Acambis was bought by Sanofi Pasteur, whose United States smallpox ACAM2000 division, including potency testing for APSV, was bought by Emergent Biosolutions. Since Emergent Biosolutions now owns the proprietary ACAM2000 data, a sole source is being issued with Emergent BioSolutions.

b. What other products/services were considered and why did they not meet the need?
The government reached out to Sanofi Pasteur to enquire if it could perform this service and it affirmed it could not. Because of the unique, proprietary nature of the testing and the WetVax/APSV vaccine being tested, no alternative vendors could be found. Wetvax is a decade old legacy vaccine and not sold or licensed any more. The stock the government is testing is preserved older stock, periodically tested to verify potency. Since there is no market for this, there is also no market for testing its potency.

3. Program Office efforts to seek potential offerors:
This assay was developed by Acambis and is an FDA reviewed and concurred stability protocol for APSV. Using this assay allows CDC/SNS to have a standard potency for all vaccinia smallpox vaccines currently being stockpiled in the SNS. Acambis initially owned ACAM2000 and the ACAM2000 validated assay is used to determine the potency titers of APSV . Acambis was bought by Sanofi Pasteur. Sanofi's ACAM2000 division and research center was bought by Emergent Biosolutions. Sanofi Pasteur is the inheritor company of the APSV vaccine invented by Aventis Pasteur. The government reached out to Sanofi Pasteur to see if they retained capacity to test APSV small pox potency. They confirmed they do not and directed the government to Emergent Biosolutions. A notice of intent to sole source was also posted on the FedBizOps's website to allow potential vendors to submit an offer.

E. Program Office Certification:

I have reviewed this sole source justification and certify the justification is true and accurate to the best of my knowledge and adequate to support other than full and open competition.

Center/Institute/Office COR/Program Official Name/Title: Bruce Lee, OPHPR/DSNS/Logistics certification date

Bruce Lee -S Digitally signed by Bruce Lee -S
Date: 2018.05.31 16:00:29 -04'00'
_____ Center/Institute/Office COR/Program Official Signature:

Certification Date: June 1, 2018

F. Contracting Office Certification:

I have fully relied on the information provided herein and hereby certify that this justification is accurate and complete to the best of my knowledge and belief:

Contracting Officer Name: *Click here to enter text.*

David A. Smythe -S Digitally signed by David A. Smythe -S
Date: 2018.08.17 17:49:28 -04'00'
_____ Contracting Officer Signature:

Certification Date: