

**LIMITED SOURCES JUSTIFICATION**  
**ORDER >\$150,000**  
**FAR PART 8.405-6**

Acquisition Plan Action ID: VA248-16-AP-0415

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

**Restricted to the following source:** Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: CSL Behring LLC

Manufacturer/Contractor POC & phone number: Ron Ritter / (610) 878-4891

Mfgr/Contractor Address: 1020 First Ave / King of Prussia, PA

Dealer/Rep address/phone number: Robert Cuvala (NAC CO) / (708) 786-5132

The requested material or service represents the minimum requirements of the Government.

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs

James A. Haley Medical Center

Network Contracting Office (NCO) 8

8875 Hidden River Pkwy

Tampa (673), FL 33637-1035

VISN:

8

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**

A Blanket Purchase Agreement for the streamlined procurement of the pharmaceutical Privigen for the James A. Haley Medical Center shall be established against a mandatory NAC schedule in accordance with VAAR 808.002 (a)(3). The BPA will establish an indefinite delivery contract vehicle that will readily meet the unpredictable, recurring requirement for Privigen. CSL Behring has a mandatory NAC FSS Schedule with Privigen. CSL Behring current NAC contract expires March 2020. The BPA will be available for use for up to four years (base plus three options).

**(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**

Privigen provides the immune system with antibodies that the patient's body is not making at appropriate levels in order to avoid leading to life threatening infections. Globulin Immune is a sterilized solution made from human plasma. It contains the antibodies to help the body protect itself against infection. The FSS pricing for each unit of Globulin Immune Privigen INJ 5GM is \$261.90. The James A. Haley Medical Center requires this product at undetermined times and undetermined quantities between 5 October 2015 through 30 September 2019.

**(b) ESTIMATED DOLLAR VALUE:** \$314,280 per year for a total of \$1,257,120 (base + 3 options)

**(c) REQUIRED DELIVERY DATE:** 1 November 2015 until 30 September 2019

**(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)**

Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.  
Privigen is the only FDA approved immune globulin formulated with an amino acid called proline. This is crucial to maintaining the stability of the product. The use of proline as a stabilizer has less risk of causing acute kidney failure compared to use of a product with different type of stabilizer such as sucrose. Privigen is the only pharmaceutical of its type that meets these government needs.

A patent, copyright or proprietary data limits competition. The proprietary data is:  
Food and Drug Administration (FDA) issued approval letter on July 26, 2007, for proprietary labeling of "Privigen" to CSL Behring .

These are "direct replacements" parts/components for existing equipment.

The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

The new work is a logical follow-on 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 order must not have been previously issued under sole source or limited source procedures.

An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

Due to the unanticipated need for Privigen, a firm fixed price contract was not feasible. The customer could not provide an accurate estimated quantity. Award of an NAC (FSS) BPA represents the best value because subsequent orders against the BPA shall be based on terms and pricing from the NAC contract. CSL Behring's NAC contract (V797D-50358) expires 31 March 2020. The BPA against this NAC shall be reviewed annually to assess the continued need.

**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:**

A review of FSS under SIN 651B (Pharmaceuticals and Drugs), Category 42-2A was conducted. There were several NAC vendors that fell in this category. However, CSL Behring purchased the exclusive rights for Privigen, the pharmaceutical that meets the Government requirement.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

The BPA would provide an expedited method to procure emergent pharmaceuticals and reduce administrative effort put into individual orders.

**(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:**

The Contracting Officer shall publicize the BPA supported by this justification within fourteen days of establishing the BPA for thirty days in accordance with FAR 8.405-6. The post shall include an invitation for prospective vendors to submit their capabilities for future consideration.

**(9) REQUIREMENTS CERTIFICATION:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
NAME

\_\_\_\_\_  
TITLE

\_\_\_\_\_  
Pharmacy

\_\_\_\_\_  
SERVICE LINE/SECTION

\_\_\_\_\_  
Tampa (673)

\_\_\_\_\_  
FACILITY

**(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:** *This part is filled out by Contracting Staff as part of the Justification*

**a. CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

|  |             |
|--|-------------|
| _____  | 10/27/2015  |
| CONTRACTING OFFICER'S SIGNATURE              | DATE        |
| Marvin B. Butler / Branch Chief, Commodities | Tampa (673) |
| NAME AND TITLE                               | FACILITY    |

**b. Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

|   |       |             |
|---|-------|-------------|
|   | 477   |             |
| /   | fre@  | 28 OCT 2015 |
| _____                                       | _____ | _____       |
| SIGNATURE                                   |       | DATE        |
| Kawan Afre                                  |       |             |
| Division Chief, Commodities and Prosthetics |       |             |

**c. VHA HCA REVIEW AND APPROVAL (over \$650,000 to \$12.5 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

|  |       |
|--|-------|
| _____  | _____ |
| Terry Spitzmiller  | DATE  |
| SAO East Director/VHA Head of Contracting Activity (HCA) |       |