

FAR 8 - JUSTIFICATION FOR LIMITING SOURCES <\$150K

Requirement or RFQ Number: 501-15-2-087-0757 Emergency Privigen

1. Description of Action:

Nature: New Requirement Follow-on Order
 Mod to Existing Order Number Insert task/delivery order no.

Order against: FSS Contract Number: V797P-5045B

Pricing: Firm-Fixed Price Time & Materials Cost Type

Funds: OMA Other Funds: Insert funds type here

Name of Proposed Contractor: CSL Behring LLC
Street Address: 1020 First Avenue
City, State, Zip: King of Prussia, PA 19406-1610
Phone: 610-878-4891

2. Description of Supplies or Services:

The estimated value of the proposed action is \$ 105,655.80

Privigen (immune globulin intravenous (IGIV)) is a sterilized solution made from human plasma. It contains the antibodies to help your body protect itself against infection from various diseases.

Privigen is used as a replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Privigen is a 10% liquid human immunoglobulin for intravenous (IVIg) administration, indicated for PI and Chronic ITP. It is a specialty protein drug product that is required for continuation of patient care. It Is Used In The Oncology Department And Prepared By Pharmacy To Be Infused In Patients.

Items requested are for an estimated 2 month supply of the 20 gram, 10 gram, and 5 gram vials needed urgently by February 28, 2015

3. Authority:

ORDER AGAINST FSS: Authority of the Multiple Award Schedule Program, Title III of the Federal Property and Administrative Services Act of 1949 (41 USC 251, et seq.); Title 40 USC 501, Services for Executive Agencies; and Section 803 of the National Defense Authorization Act of 2002 (PL 107-107) and implemented by FAR 8.405-6. Mark the applicable exception:

An urgent and compelling need exists, and following the procedures would result in unacceptable delays(FAR 8.405-6(a)(1)(i)(A));

Justification for Limiting Sources \$3K up to \$150K
501-15-2-087-0757 Emergency Privigen

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; (FAR 8.405-6(a)(1)(i)(B)) or

In the interest of economy and efficiency, the new work is a logical follow-on to an original Federal Supply Schedule order and the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. **The original order was not previously issued under sole-source or limited-sources procedures.** (FAR 8.405-6(a)(1)(i)(C))

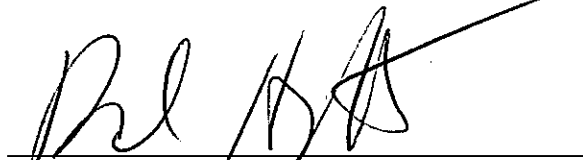
5. **Rational/explanation to support cited authority:** These pharmaceuticals to be procured are peculiar to CSL Behring AG, sole manufacturer and distributor via federal supply schedule contract V797P-5045B effective until 03/31/2015 and verified proprietary via US Food and Drug Administration's National Drug Code Directory at <http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm>

Other than "Name Brand" can't be used for this pharmaceutical procurement as the FDA has not approved any generic brands to Privigen.

6. **BRAND NAME ONLY:** This buy is estimated to exceed \$25,000 and this documentation will be posted along with the RFQ on e-Buy, as required by FAR 8.405-6(b)(3). This documentation will not be posted along with an RFQ on e-Buy, as GSA has determined that SIN 65 I B PHARMACEUTICALS AND DRUGS 42-2A Single source drug, innovator multiple source drug, and any biological product identified under Section 600.3 of Title 21, CFR is not available through eBuy.
7. Note that this determination satisfies the requirements of FAR 8.405-6. The requirement to prepare a written justification IAW FAR 6.303 does not apply to Federal Supply Schedules.

8. APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):


a. **Prepared by:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



David Hetterly
Contract Specialist

2/26/15
Date

b. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Douglas Crowley
Branch Chief – Supply Team 1
Contracting Officer

2/26/2015
Date