

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. Contracting Activity:

Department of Veteran Affairs
Network Contracting Office (NCO) 10
6150 Oak Tree Blvd. Suite 300
Independence, Ohio 44131

Department of Veterans Affairs, VISN 10, Cleveland VAMC, Pharmacy Service Justification for Other Than Full and Open Competition.

Transaction: 757-14-4-065-1359

2. Nature and/or Description of the Action Being Processed:

The Department of Veterans Affairs, VISN 10, Columbus VAMC, Pharmacy Service has a requirement for a firm fixed price contract for a drug: Imbruvica (Ibrutinib). This drug has no generic form and is only available open market from one vendor, Pharmacyclics, Inc. and will be purchased as a sole source under Other Than Full and Open Competition.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

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

The Department of Veterans Affairs, VISN 10, Columbus VAMC, Pharmacy Service has a requirement for a firm fixed price contract for a drug: Imbruvica 2 BT

(b) ESTIMATED DOLLAR VALUE: \$16,286.28

(c) REQUIRED DELIVERY DATE: Emergency

4. Statutory Authority Permitting Other than Full and Open Competition:

- ☒ (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- ☒ (2) Unusual and Compelling Urgency per FAR 6.302-2;
- ☐ (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ☐ (4) International Agreement per FAR 6.302-4
- ☐ (5) Authorized or Required by Statute FAR 6.302-5;
- ☐ (6) National Security per FAR 6.302-6;
- ☐ (7) Public Interest per FAR 6.302-7;

Transaction 757-14-4-065-1161

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

The Department of Veterans Affairs, VISN 10, Columbus VAMC, Pharmacy Service has a requirement for a firm fixed price contract for a drug: Imbruvica 2 BT. IMBRUVICA® is a prescription medicine used to treat people with:

- Chronic lymphocytic leukemia (CLL) who have received at least one prior treatment; and
- Mantle cell lymphoma (MCL) who have received at least one prior treatment.

Due to there not being any generic drugs available, this brand name is only available with one contractor, Pharmacyclics, Inc.

Accordingly, Pharmacyclics, Inc. is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition

- (a) There is currently no generic form of the drug Imbruvica. Per FAR 6.302-1, *Only One Responsible Source*, Pharmacyclics, Inc. is the only contractor that currently can provide this drug.
- (b) This is an emergency for patient care. Per FAR 6.302-2, *Unusual and Compelling urgency*, to preclude adverse impact on Veteran care due to holding up scheduled patient care.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

A written solicitation was not used due to the procurement being completed under FAR 6.302-2(2)(b)(1), *Unusual and Compelling Urgency*, if the Government would be seriously injured unless the agency is permitted to limit the number of sources from which it solicits bids or proposal for an unusual and compelling urgency.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

By comparison to the Government's IGE and past purchases, 757-A40098, the Contracting Officer has determined the anticipated cost to the Government will be fair and reasonable.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

A search was conducted on NAC/GSA and VA Advantage and no vendor was found that could deliver the supplies.

A search on the internet was conducted to see if there were any similar products to no avail.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** N/A

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Pharmacyclics, Inc.
995 East Aques Avenue
Sunnyvale, CA 94085

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

An extensive search was done to see if there were any other companies that can comply with the brand name or equal specifications to no avail.

On-going research of the industry market place will be conducted to determine if there are new entrants into this product arena.

12. **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 and belief.

Michelle Carr
Pharmacy Procurement Specialist
VISN 10/Chalmers P. Wylie VAACC

08-29-14
Date

13. Approvals in accordance with FAR 6.304

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

Thomas P. Moore
Contracting Officer
NCO 10

Date _____

- b. NCM/PCM (Required \$3K and above): I certify the justification meets requirements for other than full and open competition.

Terry Spitzmiller
Director of Contracting
NCO 10

Date _____