

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:**

Department of Veterans Affairs
VHA, SAO Central, Network 15 Contracting Office (NCO 15)
3450 S. 4th St Trwy
Leavenworth KS 66048

VA Medical Center Pharmacy Department, Marion IL 2237# 657-14-3-2622-0688

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

This is a request to approve the use of other than full an open competition for the procurement of a pharmaceutical drug from Pharnacyclics, Inc., 995 E Arques Ave., Sunnyville CA 94085-4521.

The approval request is being processed in accordance with VHA Procurement Manual Chapter VI: Other Than Full and Open Competition (OFOC) policy.

The contract action is a firm fixed price purchase order in accordance with FAR 13.106 procedures.

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

Marion VA Medical Center requires an emergency delivery of a pharmaceutical drug, Imbruvica™, (Ibrutinab) 140mg., #90 count capsules. NDC # 57962-140-09 [REDACTED] to fill a prescription immediately for a patient for the month of May. Delivery of the May requirement is required no later than 5-9-14. Per the prescription the patient requires an additional (7) seven month supply of this drug. A standing Purchase Order was issued on 5-8-14.

The estimated total dollar amount is [REDACTED].

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

41 USC §253(c)(1), as implemented by FAR 6.302-2.

- (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;

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

Patient has been prescribed other drugs which did not work. IMBRUVICA is a kinase inhibitor indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. The physician prescribed Ibrutinib for this particular patient. Delay in the award would cause patient harm by delaying the medical facilities ability to provide prescribed medications to patients in a manner necessitated by their plan of care. This drug was approved by the FDA recently, November 2013.

Within the Veterans Health Administration, brand name drugs may be prescribed by physicians when in their clinical judgment the brand name drug will provide a better therapeutic outcome for patients. Brand name drugs are requested when there is a clinical requirement for the drug or there is a history of clinical requirements for the drug and inventory must be maintained to meet anticipated requirements.

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

Imbruvica is not available through McKesson Prime Vendor and should be ordered as a direct purchase from Pharmacyclics. Pharmacyclics will charge the Federal Ceiling Price (FCP). The Imbruvica FCPs are currently: 90 capsule count bottle NDC 57962-140-09 - \$6,107.36 and the 120 capsule count bottle NDC 57962-140-12 is \$8,143.14.

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

The Contracting Officer has determined the price to be fair and reasonable based upon comparison to the other distribution sources and the independent government estimate submitted by the requesting Medical Center.

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

A query was conducted on the NAC Contract Catalog Search Tool (CCST) and NAC Specialty Pharmaceutical BPA information SharePoint page with no results. The DailyMed website administered by the National Institutes of Health was reviewed to obtain information about this drug, this drug was approved for use by the FDA in November 2013.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

None.

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

None.

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:

The Medical Center will purchase all pharmaceutical drug requirements competitively and fully utilize the prime vendor, national, and FSS contracts whenever possible. However, there are times that contract sources do not have the required drugs available and/or competition isn't available. The Pharmacy Department will remove or overcome barriers to competition by adequately planning known requirements and pledges to do so before any subsequent acquisitions.

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.

[Redacted Signature]

Pharmacy Chief
Marion VA Medical Center
Marion, IL

5/9/2014

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.

[Redacted Signature]
Contracting Officer
NCO 15

Date

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

[Redacted Signature]
Network Contract Manager
NCO 15

Date