

Attachment 2: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 11, 610A4-VA Northern Indiana Health Care Systems (Ft Wayne campus), 610-14-4-166-0619
2. **Nature and/or Description of the Action Being Processed:** Imbruvica 140mg, 1 bottle of 120 capsules, NDC# 57962-140-12, \$8,143.14 per bottle and 1 bottle of 90 capsules, NDC# 57962-140-09, \$6,107.36 per bottle. Orders placed:
Pharmacyclics 3PL, RxCrossroads
Phone – 888-345-9915
Fax – 866-230-7960
PCYCCS@rxcrossroads.com (Invoiced by Pharmacyclics)
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Imbruvica, 1 bottle 90 count capsules NDC# 57962-140-09, and 1 bottle of 120 count capsules NDC# 57961-140-12. Total cost \$14,250.50 for delivery NLT 7/25/14.
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;
 - (x) (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):** Imbruvica is not on a Federal Supply Schedule and is not manufactured in a Trade Agreement Act (TAA) designated country. The National Acquisition Center is attempting to get Imbruvica on a contract and currently is unable to give a timeline as to when an award will be made. This order is for refills for two patients. Medication is expensive which prevents the pharmacy from being about to stock it. Provider has just allowed for refill. Patient has enough medication to last until 7/28/14.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Only direct orders placed with Pharmacyclics 3PL, RxCrossroads will be

billed at the Federal ceiling price. McKesson Plasma and Biologics cannot sell Imbruvica at the Federal ceiling price and facilities will incur a substantially higher cost if ordered from McKesson.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** 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. Current Federal ceiling price is: 90 capsules/NDC 57962-140-09 \$6,107.36 and 120 capsules/NDC# 57961-140-12 \$8,143.14.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** No Market Research was performed.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Imbruvica was just approved by the FDA in November of 2013. For the treatment of mantle cell lymphoma and in February of 2014 for the treatment of chronic lymphocytic leukemia. Imbruvica is an anticancer drug targeting B-cell malignancies.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Orders must be placed with Pharmacyclics 3PL, RxCrossroads, phone 888-345-9915, fax 866-230-7960
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 National Acquisition Center is attempting to get Imbruvica on a contract but currently has no timeline for completion.
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.



Name: Diana Chaplin

Title: Inventory Specialist

Facility: VA NIHCS (610A4), Ft Wayne Campus

7/16/2014
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.

Name
Title
Network 11 Contracting Office

Date

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

Name
Director of Contracting/Supervisory Contract Specialist (as appropriate)
Network 11 Contracting Office

Date

- c. **SAO(If over \$650K)**: I certify the justification meets requirements for other than full and open competition.

Ricky L. Lemmon
SAO Director
Central Region

Date

- d. **VHA HCA Review and Approval**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$12.5 million) or approve (\$650K to \$12.5 million) for other than full and open competition.

NORBERT S. DOYLE
Chief of Procurement and Logistics Officer
VHA, Head of Contracting Activity (HCA)

Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$12.5 million but not exceeding \$50 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 other than full and open competition.

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Assistant Secretary for Acquisition and Logistics

Date

Department of Veterans Affairs

- f. **VHA Senior Procurement Executive Approval (over \$50 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 other than full and open competition.

JAN R. FRYE

Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date