

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA260-16-AP-3122

1. **Contracting Activity:** Department of Veterans Affairs, VISN 20, NCO20, Seattle VA Medical Center Puget Sound Health Care System. Purchase Request 663-16-3-022-1522
2. **Nature and/or Description of the Action Being Processed:** Puget Sound VAMC Inpatient Pharmacy requires THIOTEPA 15 MG Vial for Injection, NDC# 00143-9565-01. This will be a one-time firm fixed price Purchase order.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This was an urgent, life-saving requirement for a total of 108 vials at an estimated \$1400 each for \$151,200.00 total over the next 3-day period. 6 vials will be delivered 04/05, 23 vials on 04/06, and 79 vials on 04/07.
4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (X) (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;

The Authority permitting Other than Full and Open Competition is 41 USC §3304(a), as implemented by FAR 6.302.

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

a. **Only One Responsible Source (FAR 6.302-1)** – West-Ward is the manufacturer of Thiotepa, and their Prime Vendor and sole source distributor is McKesson Corporation. This is a pharmaceutical which has no generic and no known equivalent currently on the market. Accordingly, McKesson Corporation is the only firm capable of providing the supplies described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

b. **Unusual and Compelling Urgency (FAR 6.302-2, 6.303-2(a)(9)(ii))** – This is an urgent, life-saving effort. A patient needs this medication, requiring a total delivery of 108 vials over the next 3-day period. The Thiotepa is essential for immediate delivery for a patient care emergency. The delivery

will preclude impairment of healthcare delivery capabilities and mission performance. It is urgent and compelling to preclude adverse impact to Veteran care.

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

Market research was conducted, and McKesson was found to be the one and only Prime Vendor for West-Ward, the manufacturer of Thiotepa. Additional market research was conducted, which indicated that the product was not available from any additional known sources of supply. The research included all Orders of Priority, and a copy of this documentation is in the file. Furthermore, a copy of this justification will be posted to Federal Business Opportunities.

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

The anticipated cost will be fair and reasonable. IAW FAR 13.106-3(a)(2)(iv), Market research was performed and the product was compared to similar items. Market research on Thiotepa revealed it is an Alkylating Agent used in cancer treatments. The US National Library of Medical Science maintains LiverTox, which is a government database of clinical research and information on drug-induced liver injury. LiverTox gives an overview of the six anticancer drug classes, and categorizes Thiotepa as one of the Ethylenamine and methylanamine derivatives. The only other drug in its class is altretamine (or its generic hexalen). Therefore, the price of thiotepa was compared to the price of altretamine/hexalen. Pricing found for 50mg capsules of altretamine/hexalen was \$1,955.00. Pricing per vial on Thiotepa was \$1,400.00, which is a more concentrated dose. Also, Thiotepa is a new product and has no generic version. Therefore, the price is considered fair and reasonable in comparison to similar items in a related industry.

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

Market research was conducted, and McKesson was found to be the one and only Prime Vendor for West-Ward, the manufacturer of Thiotepa. Additional market research was conducted, which indicated that the product was not available from any additional known sources of supply. The research included all Orders of Priority, and a copy of this documentation is in the file. Furthermore, a copy of this justification will be posted to Federal Business Opportunities.

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: N/A

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: Future acquisitions for Thiotepa will continue to be available only through McKesson, unless and until a generic version is commercially available.

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

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.



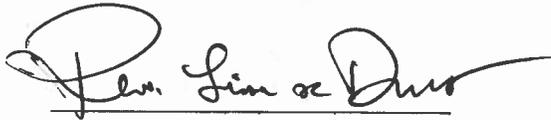
04/06/2016

Name Michael Haaseth
Title Procurement Technician
Facility VA Puget Sound HCS

Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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



04/06/2016

Name Lisa Spiral Ducret
Title Contracting Officer, Supply Branch 2
Facility NCO20

Date

- b. **Director of Contracting / Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

April 7, 2016

Name Stacia Nunn
NCO20 Contracting Office Division Chief
Facility NCO20

Date