

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 15, *Department of Veterans Affairs CMOP Program, NCO 15 Contracting.*

Planning Module UID: VA255-15-AP-0858

Contracting Module UID:

2237 – 766-15-1-400-0164

2. **Nature and/or Description of the Action Being Processed:** This emergency request is for 2,155,000 capsules of Tamsulosin HCL 0.4mg. This drug will be used to treat eligible veterans. The CMOP currently dispenses approximately 9.3 million capsules of this drug monthly. Currently the CMOP is out of inventory of this item. Shipments for a large quantity are expected but the amounts due in are not adequate to satisfy the demand for the rest of the month of December. Even with the receipt of the expected quantities at current usage rates the CMOP will run out around December 24th and therefore cannot wait for the traditional solicitation process and posting on FedBiz to be completed. The drug is currently being allocated by the two major manufacturers: Actavis and Mylan, and is not available through the Pharmaceutical Prime Vendor. One of the two major suppliers, Actavis, has also removed this item from FSS further complicating the procurement process.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Tamsulosin HCL 0.4MG capsules from various manufacturers. This may include Non TAA sources although as required by FAR TAA compliant sources will be considered first. Currently Real Value Products Corporation DBA Hospital Pharmaceutical Consulting has [REDACTED] 4310 bottles of 500) available for purchase. The estimated value [REDACTED] is \$499,960.00. The estimated delivery date is December 9, 2014.

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):** Currently this drug is on manufacturer's allocation from all sources. The CMOP needs 9.3 million capsules/ month to satisfy demand. Current inventories were depleted today. Shipments for a large quantity are expected but the amounts due in are not adequate to satisfy the demand for the rest of the month of December. Even with the receipt of the expected quantities at current usage rates the CMOP will run out around December 24th and therefore cannot wait for the traditional solicitation process and posting on FedBiz to be completed. A quantity of tamsulosin has been identified as being currently available and therefore acquiring this and other quantities that become available is imperative to ensure that there is no interruption in care to veterans. TAA sources have been canvassed and found to have no inventory available at this time.
6. Tamsulosin (Flomax) belongs to a group of drugs called alpha-adrenergic (AL-fa ad-ren-ER-jik) blockers. It relaxes the muscles in the prostate and bladder neck, making it easier to urinate. Tamsulosin is used to improve urination in men with benign prostatic hyperplasia (enlarged prostate).
7. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Teva discontinued tamsulosin 0.4 mg capsules in April 2014. PAR also recently discontinued tamsulosin 0.4 mg capsules. These two actions have increased the demands on other manufacturers and may be contributing to the shortages being experienced currently. In an effort to secure the required quantities (9.3 Million capsules/ month) CMOP personnel have contacted all the manufacturers/repackagers listed in Daily med to ascertain if product was available. No available product has been found from these sources. At least one recent solicitation for this product has received no offers.
8. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Currently there is a worldwide shortage of Tamsulosin HCL. Recent market pricing was in the range of \$0.50/ capsule. A review of commercial pricing on the internet reveals that [REDACTED] is currently charging \$1.34/ capsule and [REDACTED] is charging \$1.68/ capsule. Limited quantities have been acquired at pricing as low as \$0.29/ capsule but the quantities have not been sufficient to satisfy the demand and therefore additional product must be acquired at current market prices. The current government pricing in the

range of \$0.29 to \$0.50 is considered fair and reasonable due to the shortages and the difficulty in acquiring the large quantities required by the CMOP program.

9. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** . In an effort to secure the required quantities (9.3 Million capsules/ month) CMOP personnel have contacted all the manufacturers/repackagers listed in DailyMed to ascertain if product was available. No available product has been found from these sources. At least one recent solicitation for this product has received no offers.
10. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** *The current shortage is expected to continue until late January 2015. The CMOP demand will remain constant as this is a maintenance type drug and cannot be readily changed or discontinued without the potential for adverse patient events.*
11. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Due to the worldwide shortage of this drug no sources have expressed an interest in writing. Due to the shortage CMOP personnel have contacted the manufacturers and repackagers listed on DailyMed to determine if any inventory is available. No other source has been identified for the quantities required by the CMOP program.
12. **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 agency has attempted to competitively solicit for the pharmaceutical with no offers and has canvased potential sources with no inventory being found. Industry is aware of the demand and production is being increased but increased inventories will not reach the market until approximately late January 2015.
13. **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.

PETER J CARBREY 168392

Peter J. Carbrey
Chief Logistics Office
Consolidated Mail Outpatient Pharmacy

Digitally signed by PETER J CARBREY 168392
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=peter.carbrey@va.gov, cn=PETER J CARBREY
168392
Reason: I agree to specified portions of this document.
Date: 2014.12.05 09:50:31 -06'00'

Date

14. **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.

Donald J.

Denno 927072

Digitally signed by Donald J. Denno 927072
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=donald.denno@
va.gov, cn=Donald J. Denno 927072
Date: 2014.12.05 14:28:51 -06'00'

Linda Bayer
Contracting Officer
NCO-15, CMOP Division

Date

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

Donald J.

Denno 927072

Digitally signed by Donald J. Denno 927072
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=donald.denno@
va.gov, cn=Donald J. Denno 927072
Date: 2014.12.05 14:29:18 -06'00'

for: Christine L. Scena
Director of Contracting
NCO-15

Date

QA Review
Lori Kopacz
12/5/14