

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

The agency responsible for this acquisition is: The Department of Veterans Affairs (DVA), Consolidated Mail Order Pharmacy (CMOP). The Contracting Officer for this procurement is Kristine Hostetler. The DVA proposes to solicit quotes on the basis of other than full and open competition for the Chelmsford CMOP (CMOP NE 761) located in Chelmsford, MA. The Purchase Request Number is 761-13-1-015-0024.

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

This is a requirement for the purchase of a brand name pharmaceutical which is manufactured in a non-Trade Agreements Act (TAA) country. The resulting purchase order(s) will be firm fixed price.

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

This procurement is to provide Lamictal in the following strengths and quantities:

Lamictal 25 MG TAB 100CT	NDC 00173-0633-02
Lamictal 150 MG TAB 60CT	NDC 00173-0643-60
Lamictal 200 MG TAB 60CT	NDC 00173-0644-60

for the Chelmsford CMOP. The contractor is required to deliver the pharmaceuticals 7 days after award or not later than 23 November 2012.

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;

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

Lamictal is a brand name medication indicated for both adjunctive and monotherapy of partial seizures, primary generalized tonic-clonic seizures and for generalized seizures of Lennox-Gastaut syndrome. This medication cannot be therapeutically substituted with other antiepileptic products including the generic

Lamotrigine due to the risk of breakthrough seizures. Lamictal is available in four strengths (25mg, 100mg, 150mg, and 200mg) and is manufactured by GlaxoSmithKline.

All strengths of Lamictal were removed from GlaxoSmithKline's FSS contract because the items are now being manufactured exclusively outside the U.S. in a non-TAA country. As a result, all strengths of this patented drug are no longer available to the VA from a U.S. or TAA-designated country.

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

This is a brand name drug manufactured exclusively by GlaxoSmithKline and available from distributors using an open market purchase order

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

Price fair and reasonableness will be determined by comparing quotes received from offerors (distributors) against the IGCE and previous purchases.

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

Since this is a brand name product that cannot be substituted due to the risk of breakthrough seizures, market research was not warranted. The manufacturer, GlaxoSmithKline, has notified the Government that all manufacturing of this product in all strengths has been moved to a non-TAA compliant country.

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

Lamictal is used to treat seizures and any interruption in therapy puts the Veteran at risk for seizure activity. Chelmsford CMOP is currently canceling prescriptions for this product back to the medical centers because of our inability to procure a TAA Brand Specific product.

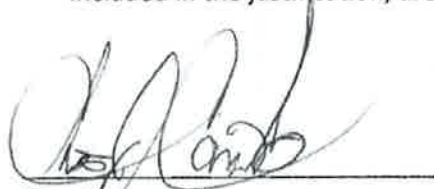
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

See Section 6. above.

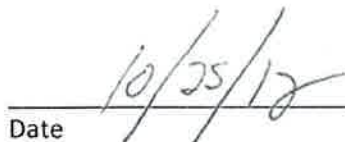
11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

There are no intentions of taking other actions for this medication. It is considered brand specific and cannot be substituted due to the risk of breakthrough seizures. Lamictal is only required by a small number of Veterans.

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
Title
Facility



Date

13. Approvals in accordance with FAR 6.304

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



Kristine S. Hostetler
Contracting Officer



Date