

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

1. Contracting Activity:

Department of Veterans Affairs
Network 15 Contracting Office
3450 S. 4th Street Trafficway
Leavenworth, KS 66048

The purchase request number is: 770-16-3-801-0148

Items are to be delivered to six (6) VA CMOP's since this is a National CMOP Requirement. The VA CMOP's that stock these items are: Leavenworth, Chelmsford, Tucson, Dallas, Murfreesboro, and Hines.

Estimated Dollar Value: \$494,383.68

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

The National CMOP, 5049 S. 13th Street Leavenworth, KS 66048, Consolidated Mail Outpatient Pharmacy is requesting approval to purchase the BRAND NAME only per physicians determination of need for the following item: Accu-Chek Aviva Plus Glucose Test Strips, 50CT. This is a firm fixed price contract to replenish inventories. The test strips are used by patients with diabetes in conjunction with other diabetic devices to control their blood sugar and keep their diabetes under control.

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

- Accu-Chek Aviva Plus Glucose Test Strips, 50CT
 - Item #: 12011
 - Estimated Quantity: 90,216 boxes to be divided up between the 6 VA CMOP's.

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; Brand name description application applies.

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

The Department of Veterans Affairs has standardized on the Accu-Check Aviva and Aviva Plus blood Glucose meters for everyday testing of blood glucose levels. This standardization requires the Department of Veterans Affairs to use the Accu-Chek Aviva (and Aviva Plus) test strips. The use of these specific test strips is required as the manufacturer will NOT guarantee test accuracy using any other manufactured products. There are several products on the market that are of a similar form and function as we are requiring. However, the use of other products that are not approved, tested, or standardized in this meter will create a patient care issue. In addition, the use and dispensing of these foreign items creates a liability for the Department of Veterans Affairs and the physicians that prescribed the treatment path to control glucose levels in a patient. Most importantly, the use of

non-standardized, non-approved, items in this meter can cause the patient to treat their diabetes improperly. If treated improperly, a diabetic patient can develop long term complications. These complications include blindness, kidney failure, and infections that can lead to amputation (gangrene). All these complications can be controlled with accurate test meter readings and continued care. Using other than these products is not ideal as it is our responsibility to properly treat our nation's veterans.

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

Thorough market research has been conducted and it has been found that Accu-Chek Aviva Plus Glucose Test Strips (50CT) are not found to be on VA NAC or GSA contract. While Roche is the manufacturer of Accu-Chek Aviva Plus (Glucose) test strips, it is not a sole source of this product. The test strips are a commercial/retail item available through other suppliers. The solicitation for bids will be synopsized as a Brand Name only on FedBidOpps to allow prospective vendors the opportunity for full and open competition.

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

- The National CMOP anticipates the cost to the Government will be fair and reasonable based on recent prices paid by CMOP.
- There will be competition between wholesalers/distributors for the requested items.

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

- After searching NAC & GSA, there are no available contracts for the item being requested. Because the Government is not authorized to do business using Wholesale Trade or Retail Trade NAICS codes, searches must be conducted using the manufacture NAICS code of 325413 In-Vitro Diagnostic Substance Manufacturing. A search of the Center for Veteran Enterprise Vendor Information Pages indicates there are 5 SDVOSB or VOSB vendors listed under NAICS code 325413. A query at the SBA Dynamic Search portal returned 407 possible small business vendors under NAICS code 325413. However, these vendors are not engaged in manufacture, but are distributors for large business wholesalers.
- Acquisition History:
 - Award #: VA770-16-P-0927
 - Vendor: Roche Diabetes Care, Inc.
 - Award date: April 20, 2016
 - Award amount:\$494,383.68
 - Socio-economic size: Large Business
 - NAICS code: 325413
 - Period of Performance: one time buy

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Not applicable as the information is included in Item 5.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
Vendors have responded to previous acquisitions, therefore, it is probable that there will be ample response for this acquisition as well.
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:**
At this time, the physician has stated the above mentioned name brand item is the only brand that will meet the specific needs of the patients; however, we are still competing this amongst distributors.
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.

Pete Barrett Digitally signed by Pete Barrett
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ou=Supply
Date: 2016.04.29 10:10:19 -05'00'

Peter Barrett
Supply System Specialist
National CMOP- 770

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.

John C. Fisher 629338 Digitally signed by John C. Fisher 629338
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=john.fisher4@va.gov, cn=John C. Fisher 629338
Date: 2016.04.29 10:38:18 -05'00'

John C. Fisher
Contracting Officer
CMOP Acquisitions, NCO 15

Date

- b. **Director, CMOP Acquisitions (Required \$150K and above)** I certify the justification meets requirements for other than full and open competition.

Christine L
SCENA 346512

Digitally signed by Christine L SCENA 346512
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0.9.2342.19200300.100.1.1=christine.scena@
va.gov, cn=Christine L SCENA 346512
Date: 2016.04.29 15:46:32 -05'00'

Christine L. Scena
Director, CMOP Acquisitions Team
Network Contracting Office (NCO) 15

29 April 2016

Date