

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: 36C770-20-AP-0018 (766-20-1-400-0013)

1. Contracting Activity:

Network Contracting Office 15
3450 S. 4th St. Trafficway
Leavenworth, KS 66048-5581

Requesting Activity:

VA CMOP Charleston
3725 Rivers Ave., Ste. 2
North Charleston, SC 29405-7038

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

This request is a Justification for BRAND NAME supplies as requested by the VA Medical Centers from the VA CMOP CHARLESTON

Drug Name: GLUCOSE SENSOR - GUARDIAN MMT

ACTION REQUESTED: 1 (New Requirement)

PR-IFCAP: 766-20-1-400-0013

ACQUISITION PRIORITY: 2 (Special)

Purchase of: MedSurg Supplies.

PROCUREMENT VEHICLE: Open Market

SOCIOECONOMIC CATEGORY: Not Set-Aside

CLASSIFICATION CODE: 65(MEDICAL EQUIPMENT)

PURCHASING SCOPE: 1 (Single Site)

FAR13.5 Simplified Procedures for Certain Commercial Items:

This procurement is for Medical Surgical items. In accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

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

BRAND NAME supplies as requested by the VA Medical Centers from the VA CMOP CHARLESTON

Drug Name: GLUCOSE SENSOR - GUARDIAN MMT

· MedSurg supplies have been prescribed for patients by VA Physician to meet the specific needs of the Veteran.

PRODUCT/SERVICE CODE: 6515(Medical and Surgical Instruments, Equipment, and Supplies)

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PRINCIPAL NAICS CODE: 325413(In-Vitro Diagnostic Substance Manufacturing)

IGCE Total = [REDACTED]

DESCRIPTION	PKG	QTY	UNIT	NDC/SKU#	LineID	UnitCost	Total Cost
1 ITEM ID NO. 13642 GLUCOSE SENSOR (3) GUARDIAN MMT-7020A (XJ430) PKG: 5 per BX	5	800	BX	MMT-7020		[REDACTED]	[REDACTED]

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;
- () (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):

Products have been prescribed for patients by VA Physicians. Pharmacy employees do not have the training and/or authority to countermand physician orders. “Brand Specific” products are the same thing as “dispense as written” on a physician prescription. No NDC substitutions are permitted. In the VA, Pharmacy Benefits Management (PBM) has determined that CMOP IDs in the National Drug File (NDF) will most always identify “brand specific” products in the VA PRINT NAME. This is not always inclusive where a particular NDC has been determined to be “formulation specific” by clinical evaluation performed by the PBM or in the case where only one product in the marketplace has been identified to contain the specific ingredients to match the product code. The site is not requesting purchase from any certain vendor. Multiple vendors offer these items.

- Nature of Urgency: *SPECIAL*
- Date Needed: 10-18-19

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

This will be posted on FBO (Open Market & Not Set-Aside) with limited competition per Name Brand Only and Grey Market requirements.

SOLICITATION RFQ NUMBER: 36C77020Q0018
 ISSUE DATE: 10-07-19
 NEED DATE: 10-18-19
 RESPONSE DUE DATE: 10-10-19
 PROCUREMENT VEHICLE: Open Market
 SOCIOECONOMIC CATEGORY: Not Set-Aside

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

- The CO will determine the anticipated cost to be considered fair and reasonable based on the following:
- Comparison with the IGCE.
- Historical purchases of this pharmaceutical

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

Because the Government is not allowed to do business using Wholesale Trade or Retail Trade NAICS codes, searches must be conducted using the manufacturer NAICS codes.

Market research was conducted through Vet Biz under NAICS 325413(In-Vitro Diagnostic Substance Manufacturing).

This search resulted in 2 or more SDVOSB companies doing business using this NAICS code.

The Non-manufacturer rule (NMR) applies to acquisitions OVER the simplified acquisition threshold (SAT) per 13 CFR 121.406(d).

There are no known SDVOSB, VOSB, HUBZone, 8(a), or small business organizations that manufacture the items required for this procurement. Estimated Value for this procurement is OVER the SAT

There is no Class Waiver for NAICS Code 325413 (In-Vitro Diagnostic Substance Manufacturing) per <http://www.sba.gov/content/class-waivers>

Therefore, due to the SBA NMR, as defined in FAR Part 19 and 13 Code of Federal Regulations (CFR) 121.406, an SDVOSB/VOSB/SB set aside of any kind is not feasible as there is no waiver of the Non-Manufacturer Rule from the SBA over the SAT for NAICS code 325413.

VA Rule of Two requirements have not been fulfilled based on the NMR and market research.

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

- None

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

- None

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 these MedSurg supplies will continue to be solicited as quantities in available stock stabilize and become available in the open market.

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.

Glenda Dame

DAME, GLENDA

Inventory Specialist/ CMOP

VA CMOP Charleston - 766

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13. Approvals in accordance with the VHAPM Part 806. 3 OFOC SOP:

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

Prepared by:

MICHAEL W
MCALHANEY
592393

Digitally signed by MICHAEL
W MCALHANEY 592393
Date: 2019.10.07 09:10:12
-05'00'

McAlhane, Michael W.

Contract Specialist

Julian S.
Lake 251184

Digitally signed by Julian
S. Lake 251184
Date: 2019.10.07
13:13:30 -05'00'

Lake, Julian

Contracting Officer

b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Ralph R.
Crum 547284

Digitally signed by Ralph
R. Crum 547284
Date: 2019.10.07
13:43:26 -05'00'

Crum, Ralph R.

Supervisory Contract Specialist