DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For Other Than Full and Open Competition

1. Contracting Activity:

Department of Veterans Affairs SAO Central, NCO 15 3450 S. 4th Street Trafficway Leavenworth, KS 66048

Justification for Other than Full and Open Competition. The purchase request number is **766-14-3-400-0951**. Items are to be delivered to the Charleston CMOP.

- Nature and/or Description of the Action Being Processed: The Charleston-CMOP, 3725 Rivers Ave, Suite 2, North Charleston, SC 29405 Consolidated Mail Outpatient Pharmacy is requesting approval to purchase BRAND NAME specific NDC drug items. This is a new procurement and will be a firm fixed price contract. The total estimated value for this request is \$243,957.16
- 3. <u>Description of Supplies/Services Required to Meet the Agency's Needs:</u>

ALENDRONATE 40MG TAB A0609

- NDC-00093-5142-56(NOSUBSTITUTES)
- Quantity and Description of request: ALENDRONATE 40MG TAB, 30-COUNT
- Supplier: TEVA PHARMA

AMIODARONE 200MG TAB A1246

- NDC-00185-0144-05(NOSUBSTITUTES)
- Quantity and Description of request: AMIODARONE 200MG TAB, 500-COUNT
- Supplier: SANDOZ

AVIANE TAB A1304

- NDC-00555-9045-58(NOSUBSTITUTES)
- Quantity and Description of request: AVIANE TAB, PACK OF 28, BOX OF 6
- Supplier: TEVA/BARR

CASTELLANI COLORLESS TOPICAL PAINT C0125

- NDC-00884-2993-01(NOSUBSTITUTES)
- Quantity and Description of request: CASTELLANI PAINT MODIFIED, 1 OZ
- Supplier: VALEANT PHARMA

766-14-3-400-0951

CHLORHEXIDINE GLUCONATE 0.12% ALCOHOL-FREE MOUTHWASH C1287

- NDC-52376-0021-02(NOSUBSTITUTES)
- Quantity and Description of request: GUM PEROEX DAILY PREVENTION RINSE, 16 OZ
- Supplier: GUM/SUNSTAR AMERICAS

CHOLECALCIFEROL 50,000 UNITS CAP C1356

- NDC-53191-0362-01(NOSUBSTITUTES)
- Quantity and Description of request: VIT D-350 CAP 50,000 IU, 100 COUNT
- Supplier: BIO TECH PHARMACAL

DAPSONE 100MG TAB D0010

- NDC-49938-0101-30 (NOSUBSTITUTES)
- Quantity and Description of request: DAPSONE 100MG TAB, 30 COUNT
- Supplier: JACOBUS PHARMACEUTICAL

DAPSONE 25MG TAB D0011

- NDC-49938-0102-30(NOSUBSTITUTES)
- Quantity and Description of request: DAPSONE 25MG, 30 COUNT
- Supplier: JACOBUS PHARMACEUTICAL

DEXTRAN 70/HYPROMELLOSE 0.3% PRESERVATIVE-FREE UNIT DOSE D0649

- NDC-00065-0416-25(NOSUBSTITUTES)
- Quantity and Description of request: TEARS NATURALE FREE PRESERVATIVE FREE, 36 SINGLE-USE VIALS
- Supplier: ALCON LABS

EFLORNITHINE HCL 13.9% CREAM E0307

- NDC-00023-4857-45(NOSUBSTITUTES)
- Quantity and Description of request: VANIQA CREAM 13.9%, 45GM
- Supplier: ALLERGAN PHARMACEUTICAL

GENTIAN VIOLET 1% TOPICAL SOLUTION G0011

- NDC-00395-1003-92(NOSUBSTITUTES)
- Quantity and Description of request: GENTIAN VIOLET 1% SOLUTION, 10Z
- Supplier: HUMCO HOLDING GROUP

HYDROXYZINE PAMOATE 100MG CAP H0086

- NDC-00555-0324-02 (NOSUBSTITUTES)
- Quantity and Description of request: HYDROXYZINE PAMOATE 100MG CAPSULE, 100-COUNT
- Supplier: TEVA PHARMA

HYPROMELLOSE 0.5% OPTHALMIC SOLUTION H0433

766-14-3-400-0951

- NDC-00998-0408-15 (NOSUBSTITUTES)
- Quantity and Description of request: ISOPTO TEARS 0.5% EYE DROPS, 15ML
- Supplier: ALCON LABS

HYPROMELLOSE 0.3% OPTHALMIC GEL H0442

- NDC-00078-0429-47(NOSUBSTITUTES)
- Quantity and Description of request: GENTEAL EYE GEL, 10ML
- Supplier: ALCON LABS

LACTASE 250MG CAP L0302

- NDC-00091-3505-01(NOSUBSTITUTES)
- Quantity and Description of request: LACTRASE 250MG CAPSULES, 100-COUNT
- Supplier: SCHWARTZ PHARMAC

NITROGLYCERIN 2% OINTMENT N0066

- NDC-00281-0326-60(NOSUBSTITUTES)
- Quantity and Description of request: NITRO-BID 2% OINTMENT, 60GM
- Supplier: SANDOZ

NEFAZODONE 100MG TAB N0243

- NDC-00093-1024-06(NOSUBSTITUTES)
- Quantity and Description of request: NEFAZODONE 100MG TABLETS, 60-COUNT
- Supplier: TEVA PHARMA

NEFAZODONE 150MG TAB N0244

- NDC-00093-7113-06(NOSUBSTITUTES)
- Quantity and Description of request: NEFAZODONE 150MG TABLETS, 60-COUNT
- Supplier: TEVA PHARMA

NEFAZODONE 200MG TAB N0245

- NDC-00093-1025-06(NOSUBSTITUTES)
- Quantity and Description of request: NEFAZODONE 200MG TABLETS, 60-COUNT
- Supplier: TEVA PHARMA

PROPYLENE GLYCOL 0.6% OPTHALMIC SOLUTION P1000

- NDC-00065-1433-02(NOSUBSTITUTES)
- Quantity and Description of request: SYSTANE BALANCE RESTORATIVE EYE DROPS, 10ML
- Supplier: ALCON LABS

ARTIFICIAL SALIVA S0002

- NDC-50930-0098-08 (NO SUBSTITUTES)
- Quantity and Description of request: MOUTHKOTE DRY MOUTH SPRAY, 80Z

Supplier: PARNELL PHARMACEUTICALS

SODIUM CHLORIDE 2% OPTHALMIC SOLUTION S0167

- NDC-24208-0276-15(NOSUBSTITUTES)
- Quantity and Description of request: MURO-128 2% EYE DROPS, 15ML
- Supplier: VALEANT PHARMACEUTICALS

SINUS RINSE NEILMED PACKET S0573

- NDC-00592-8002-00(NOSUBSTITUTES)
- Quantity and Description of request: NEILMED SINUS RINSE PREMIXED PACKETS, 100-COUNT
- Supplier: NEILMED PRODUCT

SINUS RINSE NEILMED REGULAR KIT S0574

- NDC-00592-8001-00(NOSUBSTITUTES)
- Quantity and Description of request: NEILMED SINUS RINSE KIT WITH 50 PREMIXED PACKETS
- Supplier: NEILMED PRODUCTS

ARTIFICIAL SALIVA ORAL BALANCE GEL S0666

- NDC-04858-2512-01(NOSUBSTITUTES)
- Quantity and Description of request: BIOTENE ORAL BALANCE MOISTURIZING GEL, 1.50Z
- Supplier: GLAXOSMITHKLINE

TICLOPIDINE 250MG TAB T0054

- NDC-57664-0327-86(NOSUBSTITUTES)
- Quantity and Description of request: TICLOPIDINE 250MG TABLET, 60-COUNT
- Supplier: CARAC PHARMA

This is a one-time buy estimated at \$243,957.16 and expected to be delivered by 08/01/2014.

- Statutory Authority Permitting Other than Full and Open Competition: 41 USC §253(g), as implemented by FAR 6.302.
 - (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1 (c) *Application for brand name description*: Brand Name description application applies.
- 5. <u>Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires</u>
 the Use of the Authority Cited Above (applicability of authority): Within the VHA, physicians may prescribe brand name drugs when in their clinical judgment the brand name drug will provide a better therapeutic outcome for patients. Brand name drugs are requested when there is a clinical requirement for the drug. In this case, the brand specific drug name is requested on the list above.
- 6. <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable</u>: The requesting pharmacy indicated this medication could be obtained from these small businesses:

DMS PHARMACEUTICAL GROUP INC- SWOB 810 BUSSE HWY PARK RIDGE, ILLINOIS 60068-2302 PH: 847-518-1100

CAPITAL WHOLESALE DRUG CO-SB 873 WILLIAMS AVENUE COLUMBUS, OH 43212-3850 PH: 614-297-8225 X 2128

3 VETS INC-SDVOSB 1907 E. HILLSBOROUGH AVE TAMPA, FL 33610 PH: 813-837-8387

MILLANN LLC - SDVOSB 5116 ROUNDTREE ST SHAWNEE, KS 66226-3877 PH: 913 378-7284

EMED MEDICAL COMPANY - SB 12163 BRIDGETON SQUARE DRIVE BRIDGETON, MO 63044 PH: 314 291-3633

UNITED DRUG SUPLY INC - SWOB 620 VALLEY FORGE RD HILLSBOURGH, NC 27278 PH: 877-400-0214 X 301

QUANTUM PHARM RX - SB 745 ATLANTA HWY STE CUMMING, GEORGIA 30040 PH: 678-648-1369

7. <u>Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable</u>: The Charleston-CMOP anticipates the cost to the Government will be fair and reasonable based on competition and comparison to recent prices paid by CMOP.

- 8. <u>Description of the Market Research Conducted and the Results, or a Statement of the Reasons</u> Market Research Was Not Conducted: After a search of the NAC & GSA websites, there are no available contracts for any of the items requested. Products to be acquired 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. A search of the Center for Veteran Enterprise Vendor Information Pages indicates there are no SDVOSB or VOSB vendors, which are engaged in the manufacture of pharmaceuticals. A query at the SBA Dynamic Search portal returned 71 possible small business vendors. However, these vendors are not engaged in manufacture, but are distributors for large business wholesalers. Because the Government is not allowed to do business using Wholesale Trade or Retail Trade NAICS codes, searches must be conducted using the manufacture NAICS code of 325412 Pharmaceutical Preparation Manufacturing.
- 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: At this time, the physician has stated the above mentioned name brand drugs are the only brands that will meet the specific needs of the patients; however, we are still competing this amongst distributors
- 12. <u>Requirements Certification</u>: 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.

Rachel MacCumbee 541722

Digitally signed by Rachel MacCumbee 541722

DN: dc=gov, dc=va, o=Internal, ou=people,

0.9.2342.19200300.100.1.1=rachel.maccumbee@va.gov,
ch=Rachel MacCumbee 541722

Date: 2014.07.02 11.17.06 -04'00'

Rachel MacCumbee Inventory Manager Charleston-CMOP

Date

13. Approvals in accordance with FAR 6.304

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 Contracting Officer

Network Contracting Office 15

b.) NCM/PCM: I certify the justification meets requirements for other than full and open competition.

christine.scena@va.g Digitally signed by christine.scena@va.gov

OV

DN: cn=christine.scena@va.gov Date: 2014.07.02 17:21:37 -05'00'

Christine L. Scena

Date

Director of Contracting Network Contracting Office 15

QA Review Lori Kopacz 7/2/14