

DEPARTMENT OF VETERANS AFFAIRS

**BRAND NAME JUSTIFICATION UNDER SIMPLIFIED PROCEDURES FOR CERTAIN COMMERCIAL
ITEMS IN ACCORDANCE WITH FAR 13.5**

Acquisition Plan Action ID: 36C770-22-AP-0841

1. **Contracting Activity:** Department of Veterans Affairs, NCO 15, National CMOP Contracting Office.
2237 # 760-22-4-050-1314, Leavenworth CMOP, Leavenworth, KS.
2. **Nature and/or Description of the Action Being Processed:** This procurement is for medical surgical supplies (med/surg) 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. The proposed procurement action will be a new firm-fixed-price contract.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This is an individual brand name justification to support the procurement of the medical surgical item listed below in the following table. Items are to be delivered 10 days after receipt of order.

<u>Item Number</u>	<u>File Number</u>	<u>Description</u>	<u>Local Stock Number</u>	<u>Quantity</u>	<u>Unit of Measure</u>	<u>Packaging Multiple</u>	
0001	16366	RESERVOIR, OMNIPOD DASH 5CT, XJ410	08508-2000- 05	2500	PG	5	

4. **Statutory Authority Permitting Restricted Competition:**
FAR 13.5 Simplified Procedures for Certain Commercial Items. The statutory authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. § 1901 and is implemented by FAR 13.106-1(b)(2) for restricting competition on this procurement. **Competition is restricted on this procurement for the reason below:**

- ☒ (X) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements
- ☐ () Unusual and Compelling Urgency
- ☐ () Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services
- ☐ () International Agreement
- ☐ () Authorized or Required by Statute
- ☐ () National Security
- ☐ () Public Interest

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's prescription. No National Drug Code (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.



6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A synopsis of this requirement was posted to SAM.gov and the RFQ will be posted as Other than Full and Open competition. Only qualified vendors will be able to submit quotes due to Gray Market/Name Brand only requirements.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost will be fair and reasonable based off competition or the IGCE.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research, in accordance with FAR Part 10, was conducted. The FSS database was checked for existing contracts and no FSS contracts were found; please refer to Briefcase document P02_FSS search_MR. Reviewed results from similar requirements. Checked VIP and SBA search results. The VIP database search concluded there are 46 SDVOSB or VOSB companies doing business using NAICS code 325413 (In-vitro diagnostic substance manufacturing); however, due to Non-Manufacturer Rule (NMR) requirements, unable to set-aside for SDVOSB/VOSB suppliers without a waiver. VA Rule of Two requirements cannot be met based on this market research and the SBA's NMR as defined in FAR Part 19 and 13 CFR § 121.406. Furthermore, due to the time constraints of this acquisition, there is not sufficient time to request

VHAPG Part 813.5 Simplified Acquisition Procedures for Certain Commercial Items
Attachment 1: Request for Brand Name Justification >SAT-\$7.5M under FAR13.5

an individual waiver to the NMR. Additionally, based on FAR 25.401(a)(5) Buy American Act applies to this procurement due to an exception to Trade Agreements.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This will be an Other than Full and Open competition RFQ due to Gray Market / Brand Name only requirements.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Qualified business vendors tend to vary from procurement to procurement.
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:** No action is being taken at this time due to the fact that no NDC substitutions are permitted based on physician's specific orders.
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.

**RODNEY
YATES**

Digitally signed by
RODNEY YATES
Date: 2022.08.05
13:40:05 -05'00'

Rodney Yates
Inventory Management Specialist
Leavenworth CMOP

Date

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:

Kelley J.
Cunningham
3457862

Digitally signed by Kelley
J. Cunningham 3457862
Date: 2022.08.05
14:01:43 -05'00'

Kelley Cunningham
Contract Specialist
National CMOP Contracting Office (NCO 15)

Date

Approved by:

**LARRY
ZARITZ**

Digitally signed by
LARRY ZARITZ
Date: 2022.08.08
09:50:06 -05'00'

Larry Zaritz
Contracting Officer
National CMOP Contracting Office (NCO 15)

Date

VHAPG Part 813.5 Simplified Acquisition Procedures for Certain Commercial Items
Attachment 1: Request for Brand Name Justification >SAT-\$7.5M under FAR13.5

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$750K):** I certify the justification meets requirements for other than full and open competition

JUSTIN SMITH

Digitally signed by JUSTIN
SMITH
Date: 2022.08.08 14:04:32
-05'00'

J. Braden Smith
Branch Chief
National CMOP Contracting Office (NCO 15)

Date