

Attachment 1: Request for SDVOSB/VOSB 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: 36C245-19-AP-2270

1. **Contracting Activity:** The U.S. Department of Veterans Affairs (VA), Regional Procurement Office East (RPOE), VA Capitol Healthcare Network (VISN 5), Beckley Veterans Affairs Medical Center (VAMC), is responsible for the proposed Justification for Full and Open Competition for the purchase of Axumin Fluciclovine Tracer Injections under purchase request number 517-19-3-147-0050.
2. **Nature and/or Description of the Action Being Approved:** The action being processed as a new contract for Axumin Fluciclovine Tracer injections and will be a base year with four one-year options firm-fixed price contract. The new contract is expected to cost approximately \$82,832.22 for 18 doses per year. The Delivery Order/Task Order (DO-TO) in the Base year will be funded by the purchase request number 517-19-3-147-0050. Total estimated value: \$414,161.10.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Axumin Fluciclovine Tracer injections 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 purpose of these simplified procedures is to vest contracting officers with additional procedural discretion and flexibility, so that commercial item acquisitions in this dollar range may be solicited, offered, evaluated, and awarded in a simplified manner that maximizes efficiency and economy and minimizes burden and administrative costs for both the Government and industry (10 U.S.C. 2304(g) and 2305 and 41 U.S.C. 3305, 3306, and chapter 37, Awarding of Contracts).

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** In late Spring 2016, the United States Food and Drug Administration approved Fluciclovine F18, branded as Axumin. This injectable drug is a molecular imaging agent used in positron emission tomography imaging to identify suspected sites of prostate cancer recurrence in men who have elevated blood levels of prostate-specific antigen following prior treatment. Currently, to image patients meeting the requirements for the use of Fluciclovine F18, Beckley VAMC sends patients into the community. The use of Fluciclovine F18 will allow the VA to image patients in-house, ensuring a continuity of care and reducing the cost of imaging for patients with suspected prostate cancer. The cost of this tracer from the manufacturer's (Blue Earth Diagnostics, Ltd.) sole distributor, PETNET Solutions, Inc., is approximately \$4,602 per patient. The new contract is expected to cost approximately \$82,832.22, per year, for 18 doses. The total value of the acquisition, including the base year and four one-year options is \$414,161.10.

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4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(5), 38 U.S. Code § 8127(c), as implemented by FAR 6.302-5 (Authorized or Required by Statute). COs may use the non-competitive (sole source) procedures authorized in VAAR 819.7007 or 819.7008 up to \$5,000,000. Check the specific VAAR clause used below:

(X) 819.7007 Sole source awards to a verified service-disabled veteran-owned small business; or
() 819.7008 Sole source awards to a verified veteran-owned small business

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

This contract is to procure an Axumin injection which is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment. Currently, to image patients meeting the requirements for the use of Fluciclovine F18, Beckley VAMC sends patients into the community. The use of Fluciclovine F18 will allow the VA to image patients in-house, ensuring a continuity of care and reducing the cost of imaging for patients with suspected prostate cancer.

Blue Earth Diagnostics, Ltd. licensed the product from GE Healthcare, Inc. who have patented the preparation methods for Fluciclovine F18 through patent # W02014023775 A1. PETNET Solutions, Inc. is the only source of Fluciclovine F18 as they are the United States' sole distributor and manufacturer for Blue Earth Diagnostics, Ltd., an England-based pharmaceutical company. TrillaMed, LLC is PETNET Solutions' authorized reseller for the federal government.

The authority allows sole source awards to SDVOSB/VOSB based on 38 U.S.C. 8127(c) and TrillaMed, LLC. has been determined to be a responsible source with respect to performance. Additionally, TrillaMed, LLC. meets the eligibility requirements in 819.7003.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable, including whether a notice was or will be publicized as required by subpart 5.2 and, if not, which exception under 5.202 applies:**

The Contract Specialist conducted Market Research by querying VIP, reviewing of GSA platforms, reviewing of NAC MedSurg Catalog, reviewing IFCAP procurement history, and the great use of online search engines via the Internet. A search of VIP using NAICS 325412 yielded only 76 results, however, due to the patent and licensing agreements of the manufacturer, only TrillaMed, LLC. (Service-Disabled Veteran Owned Small Business) can provide Axumin Fluciclovine Tracer injections.

A Sources Sought notice, 36C24519Q0486, was issued on FedBizOpps (FBO) on July 25, 2019 and closed on August 5th, 2019. No responses were received.
An Authorized Distributor notice for TrillaMed, LLC. from PETNET Solutions was provided.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Pricing was compared to historical purchases of Axumin Fluciclovine Tracer injections by the VA. The quotation offered by TrillaMed, LLC. in their Quotation #

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TM5302019KM2, is equal to prices paid in previous procurements. Based on this market research, the pricing can be determined as fair and reasonable.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research for this procurement was conducted in a collaborative effort between the requiring activity and Contract Specialist in accordance with (IAW) FAR part 10, which describes the policies and procedures that govern the market research process. FAR part 10 assists requesting stations, program offices, and acquisition professionals in determining the most suitable approach for acquiring, distributing, and supporting supplies and services. FAR part 10 implements the requirements of 41 U.S.C. 3306(a)(1), 41 U.S.C 3307, 10 U.S.C. 2377, and 6 U.S.C. 796. The Beckley VAMC has a need for the purchase of Axumin Fluciclovine Tracer injections. A NAICS code search of Axumin Fluciclovine Tracer injections was utilized and yielded a NAICS code of 325412, which includes corresponding index entries such as Pharmaceutical Preparation Manufacturing. The NAICS code size standard for 325412 is 1,250 employees to be considered a small business.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There are no other facts supporting the use of other than full and open competition.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** There were no responses to RFI #36C24519Q0486, posted on FBO on July 25, 2019, closed on August 5, 2019.
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:** Due to the sole proprietary nature of the product, no further actions are planned.
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.
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

Kathleen C. Maynor
Kathleen Maynor
Administrative Officer
Radiology/Dental – Beckley VAMC

08/12/2019
Date

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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.

David J. Valenciabonilla
Contracting Officer, NCO 5

Date

Anna J Fitzgerald

Anna J Fitzgerald
Contract Specialist NCO 5

8/12/2019

Date