

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A) for
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: 36C249-19-1930

1. **Contracting Activity:** Department of Veterans Affairs, VISN 09, 603 Louisville VA Medical Center
PR# 603-20-1-1070-0004

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

This is a Justification and Approval for a Sole Source contract to Advanced Accelerator Applications (AAA) IAW all applicable FAR and VAAR regulations. This will be a new contract for Ga-68 Dotatate for the requisite Veterans Affairs Medical Center (VAMC). This will be a firm fixed price contract for the medical supplies described herein.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for AAA Ga-68 Dotatate IAW FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures (SAP) are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2. Estimated Value: \$700,000.00

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

The Louisville VAMC has a new requirement for Gallium (Ga-68) Dotatate for diagnosing and treating patients with Endocrine cancer. This is a radioactive product that binds to SSTRs, thereby highlighting neuroendocrine tumor(s) on positron emission tomography (PET) scan images to help your doctors assess this disease and plan the most effective treatment. This treatment has only become available for use in 2017 and is only available through Advanced Accelerator Applications (AAA). This requirement is for a base year (12-months) plus four (4) option years. Each period of performance will cost an estimated \$140,000, with a total overall estimated cost of \$700,000.

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):**

Advanced Accelerator Applications Corp is the sole manufacturer and distributor of Ga-68 Dotatate. As the sole source, Advanced Accelerator Applications (AAA) is the only vendor that can provide the Ga-68 Dotatate. AAA has provided a sole source letter documenting their proprietorship of Ga-68 Dotatate.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted to determine potential vendors that can fulfill this requirement. Through searches of FBO,FDA,FPDS,NAC, and VIP no other vendors were discovered that can potentially fulfill this requirement. A sole source letter has been provided from the vendor and is included in the contract file.

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

The CO has determined that the anticipated cost is fair and reasonable based on the ICGE and comparisons with acquisitions from other Veterans Affairs located through a search of FPDS for Dotatate. Costs listed for those requirement were consistent with pricing provided for this requirement.

TABLE 7.1

CONTRACT No.	VENDOR	POP	TOTAL VALUE	DESCRIPTION
36C24819P0413	ADVANCED ACCELERATOR APPLICATIONS USA, INC.	03/07/2019-09/30/2019	\$171,900.00	GA-68 DOTATATE
36C24119P0020	ADVANCED ACCELERATOR APPLICATIONS USA, INC.	10/01/2018-09/30/2019	\$139,000.00	GA-68 DOTATATE
36C25719P0407	ADVANCED ACCELERATOR APPLICATIONS USA, INC.	02/01/2019-01/30/2020	\$73,500.00	GA-68 DOTATATE

The prices found on these contracts are comparable to the price proposed for the requirement under consideration by this J&A. The above prices were found to be fair and reasonable by a duly appointed and warranted contracting officer. As such the CO has basis to believe and expect AAA will offer fair and reasonable pricing for this requirement as well.

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

Market Research was conducted IAW FAR Part 10. Databases were queried to include VIP, GSA, FPDS, but due to the sole source nature of this procurement no other vendors were found. The VA's Rule of Two in association with Veteran's First Contracting initiative could not be satisfied in conjunction with this requirement. An open market procurement utilizing the authority of FAR 13.5 is being contemplated. Full analysis of Market Research is available in the Market Research Report located in the eCMS Briefcase and is a part of the contract file.

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

Advanced Accelerator Applications has provided a sole source letter explaining that Ga-68 Dotatate is proprietary to AAA and there are no authorized vendors or distributors.

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

Advanced Accelerator Applications, 57 E. Willow St., Milburn, NJ 07041

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:**

Market research will be conducted on future acquisitions to obtain other potential vendors to solicit in order to obtain maximum competition and resultant pricing that represents a best value to the government.

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.

TRINA HOPSEGER
Louisville VAMC

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.

MONICA THOMPSON
Supply West Branch Chief
NCO 9

Date

b. **Division Chief's Concurrence:** Concur Non-concur

ROBERT (BOBBY) KELLNER
NCO 9, Division Chief (Supplies, Services, &
Prosthetics)
VISN 9

Date

c. **Director of Contracting Recommendation:** Approve Disapprove

LINDA S. GREAVES
NCO 9, Director of Contracting
VISN 9

Date

d. **VHA RPO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

RANDY L. HAYS
Acting Executive Director
VHA Regional Procurement Office Central

Date