

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Exception to Fair Opportunity Memo

Acquisition Plan Action ID: 36C261-19-AP-4732

1. **Contracting Activity:** Department of Veterans Affairs Network Contracting Office (NCO) VISN 21, located at 3801 Miranda Avenue, Palo Alto, CA 94304-1209 proposes to enter into a firm-fixed price contract on the basis of justification for exception to fair opportunity for the VA Northern California Health Care System. The Purchase request number is 612-20-1-116-0009.

2. **Description of Action:** Pet isotope 68 Ga Dotatate

3. **Description of Supplies or Services:**

Purchase request is for Pet isotope 68 Ga Dotatate used in the evaluation and monitoring of malignant neuroendocrine tumor processes, with the use of positron emission tomography. 68Ga Dotatate is now the standard radiotracer used for staging and monitoring cancer patient that have been diagnosed with malignant Neuroendocrine Tumor (NET).

4. **Statutory Authority:** The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c) as implemented by the Federal Acquisition Regulation (FAR) Subpart 16.505 Subpart 16.505(b)(2)(i):

() FAR Subpart 16.505(b)(2)(i)(A): The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.

(x) FAR Subpart 16.505(b)(2)(i)(B): Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.

(x) FAR Subpart 16.505(b)(2)(i)(C): The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.

() FAR Subpart 16.505(b)(2)(i)(D): It is necessary to place an order to satisfy a minimum guarantee.

() FAR Subpart 16.505(b)(2)(i)(E): For orders exceeding the simplified acquisition threshold, a statute expressly authorizes or requires that the purchase be made from a specified source". The statutory authority permitting an exception to fair opportunity for this action is 38 U.S.C. 8127(c), known as the Veterans First Contracting Program which provides the authority to directly contract

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with a Service-Disabled Veteran-Owned Small Business (SDVOSB) or a Veteran-Owned Small Business (VOSB).

() FAR Subpart 16.505(b)(2)(i)(F) In accordance with section 1331 of Public Law 111-240 (15 U.S.C. 644(r)), contracting officers may, at their discretion, set aside orders for any of the small business concerns identified in 19.000(a)(3). When setting aside orders for small business concerns, the specific small business program eligibility requirements identified in part 19 apply.

5. Rationale Supporting Use of Authority Cited Above: *If this is a Brand Name Justification*

This is a brand name justification in support of FAR 11.105, Items Peculiar to One Manufacturer.

Advanced Accelerator Applications is the sole FDA approved source of 68Ga Dotatate, a diagnostic positron emitting radiopharmaceutical.

6. Efforts to Obtain Competition: *A description of efforts made to ensure that offers are solicited from as many potential sources as is practicable.*

Advanced Accelerator Applications is the sole FDA approved source of 68Ga Dotatate, a diagnostic positron emitting radiopharmaceutical. Actions to remove or overcome any barriers to competition for subsequent acquisitions will have to be made at the time when another manufacturer is available and it is FDA approved.

7. Actions to Increase Competition: *Describe actions taken, or that will be taken, to remove or overcome any barriers to competition before initiating any subsequent acquisitions for the supplies, or services required, including challenges to restrictive data markings, data rights, preparation of a performance based work statement, and etc.*

In the future, if another vendor supplies this product we will evaluate their qualifications, in the meantime we have no choice. In order to serve our Veteran with the Best Practice for this diagnostic imaging of NET's we need to purchase this radiopharmaceutical from Advanced Accelerator Applications.

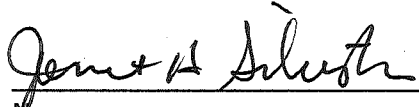
8. Market Research: *Provide a description of the market research conducted among the contract holders and the results. If market research was not conducted, the reasons it was not conducted should be stated. When citing 16.505(b)(2)(i)(b) or 16.505(b)(2)(i)(e), the only possible way to state in paragraph 5 of the J&A that there is only one contractor who can fulfill the agency's needs is to conduct market research, and it should be summarized here.*

Limited market research was conducted as Advanced Accelerator Applications is the sole FDA approved source of 68Ga Dotatate, a diagnostic positron emitting radiopharmaceutical.

9. Other Facts: *None*

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10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.



Name

Title *Chief Technologist, COR*

Facility *VA NCHCS*

9.23.2019

Date

11. Determination that Anticipated Cost is Fair and Reasonable: A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable:

Price is already negotiated and pre-determined under IDIQ Contract 36F79719D0169.

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

Name

Title

Facility

Date