

LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 36C261-19-AP-4208

- 1. Contracting Activity:** Department of Veterans Affairs Network Contracting Office (NCO)
VISN 21, located at 3801 Miranda Avenue, Palo Alto, CA 94304-1209
- 2. Description of Action:** This acquisition is conducted under the authority of the Multiple-Award
Schedule Program ([41 U.S.C. 251](#) and [40 U.S.C. 501](#)).

The proposed purchase is to enter into a firm-fixed price contract on the basis of justification for
other than full and open competition for the VA Northern California Healthcare System.

The sole source for Radium – 223 is Bayer Healthcare Inc distributed by Cardinal Health.
This purchase is available under FSS contract V797-2202D.

Manufacturer/Contractor: Bayer Healthcare Pharmaceuticals Inc
Manufacturer/Contractor POC & phone number: Lauree Casey 425-275-8849
Mfgr/Contractor Address: 100 Bayer Blvd, Whippany, NJ 079811544

Dealer/Rep address/phone number: Cardinal Health
201 Lathrop Way Suite D
Sacramento, CA 95815
916-648-2181

3. Description of Supplies or Services:

The estimated value of the proposed action is \$334,000.00 for 12 months

Purchase request is for Radium – 223 Therapy protocol to be purchased on as needed basis up
to 24 doses. Each dose is based on average patient of 220 pounds. Dose is 1.49 uCi per
kilogram.

(4) IDENTIFY THE AUTHORITY AND SUPPORTING RATIONALE (see 8.405-6(a)(1)(i)(A), (B), and (C) or 8.405-6(b)), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

x Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized;

☐ In the interest of economy and efficiency, the new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☐ Items peculiar to one manufacturer:

☐ A patent, copyright or proprietary data limits competition. The proprietary data is: (If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

☐ These are "direct replacements" parts/components for existing equipment.

☐ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

As referenced in FAR 8.404(d):

(d) Pricing. Supplies offered on the schedule are listed at fixed prices. Services offered on the schedule are priced either at hourly rates, or at a fixed price for performance of a specific task (e.g., installation, maintenance, and repair). GSA has already determined the prices of supplies and fixed-price services, and rates for services offered at hourly rates, under schedule contracts to be fair and reasonable. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing, except for a price evaluation as required by 8.405-2(d). By placing an order against a schedule contract using the procedures in 8.405, the

ordering activity has concluded that the order represents the best value (as defined in FAR 2.101) and results in the lowest overall cost alternative (considering price, special features, administrative costs, etc.) to meet the Government's needs.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

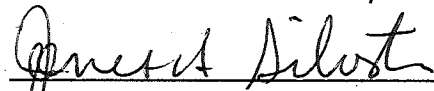
Limited market research was conducted as this is sole source to Cardinal Health. Cardinal Health is the only authorized distributor of Radium -223 for Bayer Healthcare Pharmaceuticals Inc.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: None

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

The prescribed item will be purchased from the Vendor identified because they are able to meet the Veteran's medical need. Actions to remove or overcome any barriers to competition for subsequent acquisitions will have to be made at the medical center level.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

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|---|---------------------------|-------------------------|--|
|  | | <u>9.18.2019</u> | |
| SIGNATURE | | DATE | |
| <u>Janet H Silvestri</u> | <u>Chief Technologist</u> | <u>Nuclear Medicine</u> | |
| NAME | TITLE | SERVICE LINE/SECTION | |
| <u>VA - NCITCS</u> | | | |
| FACILITY | | | |

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM Part 806.3 OFOC SOP: *This part is filled out by Contracting Staff as part of the Justification*

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

VHAPM Part 808.405-6 Limiting Sources
Attachment 2: Request for Limited Sources Justification Format >SAT

Carol Lam
Contracting Officer

Date

b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):**

I certify the justification meets requirements for other than full and open competition.

Don Neal
Supply Branch Supervisor

Date