

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA263-16-AP-2985

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Manufacturer/Contractor: Bayer HealthCare Pharmaceuticals

Manufacturer/Contractor POC & phone number: 862-404-5312

Mfgr/Contractor Address: 100 Bayer Blvd, Whippany, NJ 07981-0915

The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Network 23 Contracting Office (NCO23)

4801 Veterans Drive

Saint Cloud, MN 56303

VISN:

23

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

A firm-fixed price delivery order against NAC Contract V797P-2202D.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

Xofigo Injection 6ml/vial (aha: Radium Ra-223 Dichloride Injection 6ml/vial)

22 doses at a cost of \$10,000.00 per dose (\$76.28 per Microcurie)

On Demand Nuclear Medicine will order doses as needed and will receive packages. Special Handling is required.

(b) ESTIMATED DOLLAR VALUE: \$220,000.00

(c) REQUIRED DELIVERY DATE: On Demand Delivery through 9/30/2016

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Bayer HCP is the only vendor currently producing Radium Ra-223 Dichloride injection 6ml/vial (Xofigo).

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.

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.

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

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

Radium Ra-223 Dichloride Injection 6ML/vial are available on FSS Contract V797P-2202D, and in
accordance with FAR 8.404 (d), the price has already been determined fair and reasonable.

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

Bayer HCP is the only vendor currently producing Radium Ra-223 Dichloride injection 6ml/vial (Xofigo),
and the only vendor with an FSS contract for this particular radiopharmaceutical.

(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:

If in the future another vendor of Radium Ra-223 Dichloride injections (6ml/vial) is located, the procurement will be competed amongst the vendors that are able to provide this radiopharmaceutical.

(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.)*

Mary Shaw 1-12-16
SIGNATURE DATE
Mary Shaw Administrative Officer Imaging Services
NAME TITLE SERVICE LINE/SECTION
Minneapolis VA Health Care System
FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:

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

Andrea Harter 1-13-2016
Contracting Officer DATE
NCO 23-St. Cloud

b. Director of Contracting/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Jennifer Myers-King 1-14-2016
Branch Chief-Supply DATE
Network 23 Contracting Office (NCO 23)