

DEPARTMENT OF VETERANS AFFAIRS

**FAR 8 – Justification for Limiting Sources (LSJ)
For
Limiting Sources (<\$150K)**

Acquisition Plan Action ID: [REDACTED]

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 15, Colmery-O'Neil VA Medical Center. Network Contracting Office (NCO) 15
- 2. Description of Action:** Firm Fixed Price Delivery Order

Order against: FSS Contract Number: V797P-2202D

Name of Proposed Contractor: Bayer HealthCare Pharmaceuticals
Street Address: 100 Bayer Blvd
City, State, Zip: Whippany, NJ 07981-0915
Phone: 862-404-5196

- 3. Description of Supplies or Services:** Radiopharmaceutical Xofigo NDC: 50419-0208-01

The estimated value of the proposed action is [REDACTED]

Xofigo is an alpha-particle-emitting radioactive therapeutic agent for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease. Xofigo is the only drug that is known to treat the bone pain and reduce bone tumor size. This is the only treatment being prescribed by the VA doctors to treat this type of illness.

Substituting with other brands than that specially prescribed is beyond the role, competency, and professional functions of the Contracting Officer.

4. Authority:

ORDER AGAINST FSS: Authority of the Multiple Award Schedule Program, Title III of the Federal Property and Administrative Services Act of 1949 (41 USC 251, et seq.); Title 40 USC 501, Services for Executive Agencies; and Section 803 of the National Defense Authorization Act of 2002 (PL 107-107) and implemented by [FAR 8.405-6](#). Mark the applicable exception:

An urgent and compelling need exists, and following the procedures would result in unacceptable delays([FAR 8.405-6\(a\)\(1\)\(i\)\(A\)](#));

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; ([FAR 8.405-6\(a\)\(1\)\(i\)\(B\)](#));

In the interest of economy and efficiency, the new work is a **logical follow-on** to an original Federal Supply Schedule order and the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. **The original order was not previously issued under sole-source or limited-sources procedures** ([FAR 8.405-6\(a\)\(1\)\(i\)\(C\)](#)); or

Items peculiar to one manufacturer. An item peculiar to one manufacturer can be a particular brand name, product, or a feature of a product, peculiar to one manufacturer). A brand name item, whether available on one or more schedule contracts, is an item peculiar to one manufacturer ([FAR 8.405-6\(b\)](#)).

5. Rational/explanation to support cited authority:

Bayer Healthcare Pharmaceutical sent a "sole source letter defining Cardinal as the sole distributor". A Google search showed that "Cardinal Health is the sole distributor of Xofigo in the U.S." Xofigo is the only alpha radiation treatment for bone pain.

6. BRAND NAME ONLY: This buy is estimated to exceed \$25,000 and this documentation will be posted along with the RFQ on e-Buy, as required by [FAR 8.405-1\(e\)](#).

7. Note that this determination satisfies the requirements of [FAR 8.405-6](#). The requirement to prepare a written justification [IAW FAR 6.303](#) does not apply to Federal Supply Schedules.

1/9/2018

X Yvonne B. Kittling

Yvonne B. Kittling
Contracting Officer

Signed by: Yvonne B. Kittling