



U.S. Department of Veterans Affairs (VA)
Service Area Organization (SAO) West,
Network Contracting Office (NCO) 19
Rocky Mountain Acquisition Center (RMAC)
4100 East Mississippi Avenue, Suite 900
Glendale, CO 80246

Justification and Approval (J&A)
For
Other Than Full and Open Competition (OTFOC)

1. Contracting Activity:

- 1.1. Department of Veterans Affairs, VISN 19/ NCO 19, VA Salt Lake City Health Care System (VASLCHCS).
- 1.2. Justification for Other than Full and Open Competition (Sole Source).
- 1.3. Transaction Purchase Request Number (2237) TBD; received a Certificate of Availability Funds.

2. Nature and/or Description of the Action Being Processed: The VASLCHCS currently utilizes the LC Bead Particle Embolization (LCBPE) product that delivers chemo-therapy treatment through the blood vessels to variety of hyper vascularized tumors and arteriovenous while creating an embolism effect which occludes blood flow to those abnormalities in a specified timely manner. This LCBPE product procurement is recurring, and this proposed contract will be firm fixed-priced sole source procurement.

3. Description of Supplies/Services Required to Meet the Agency's Needs: The LCBPE product is Food and Drug Administration (FDA) approved, and is a controlled embolization system that the VASLCHCS utilizes in their chemotherapy treatment to their Veteran patients for the purpose of embolizing the blood vessels to efficiently deliver chemotherapy directly to hyper-vascularized tumors and arteriovenous malformation within a specific time period of these treatment procedures. The VASLCHCS has requested a base and four option years (5 years) period of performance (POP) for this proposed required LCBPE product contract. The independent government cost estimate (IGCE) amount for the Base year is estimated \$319,200.00 (not to exceed (NTE)), and the IGCE amount for the total proposed contract POP is estimated at \$1,596,000.00.

4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §253(c)(1), as implemented by FAR 6.302-1

- (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): In detail, the VASLCHCS

currently uses the LCBPE Stock Number # VEE220GS for the embolization of hyper vascularized tumors and arteriovenous malformations (AVMs). The LCBPE product consists of Particle Embolization Polyvinyl Alcohol Based Hydrogel, 100-300 Microns Yellow 2 ML Microsphere Sterile in Buffered Saline. The 100-300 micro bead size is optimum for treatment of cancer in the liver. It is the size of the vessels that are being administered with the chemotherapy. These LCBPE product beads will bind to doxorubicin (chemo-therapy) and then once the bead is in place, up stream of the tumor, the bead releases the doxorubicin directly to the cancer. The bead then occludes the vessel, stopping the blood flow to the tumor. In the past, other beads in clinical trials have shown they do not administer the same amounts of chemo and occlude the vessel too quickly to deliver the chemotherapy treatment.

The treatment consistency of this specific LCBPE product is vital to VASLCHCS Facility's patients that are receiving these treatments and / or care. The VASLCHCS have attempted to use other products in the past, but the clinical results with the LCBPE product were superior to the others. With the other products like HepaSphere from Merit Medical, the Medical staff discovered that the hemostasis rate was too early and was unable to deliver ample amounts of chemotherapy to treat the patient effectively. This was demonstrated through follow up Computer Tomography (CT) exams that demonstrated a greater enhancement of the treatment area. The other bead particles were also larger and harder to deploy through the specific blood vessels.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Within the collective market research conducted by the Contracting Specialists/ Officers (CS/CO) and the NCO 19 Small Business Specialist (SBS), there were no small or large vendors that responded to the Sources Sought Notice that were capable of satisfying and/or meet the requiring activity's (VASLCHCS) distinctive medical requirements. Presently, Biocompatibles, Inc. is the only vendor that offers this unique item, in which, they are the only vendor that can provide these LCBPE products that are consistence with the procedural processes required for the desired patient care outcome that are undergoing these particular chemo-therapy treatments.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Historical and present data cost to include related type industry products was compared and with the unique characteristics and complex purpose pricing was determined to be fair and reasonable. Contracting Officer will continue to determine that the costs/prices are the best value to the government through the procurement process and before award of this proposed contract action.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: The initial Market Research was conducted by the Contracting Officer, starting off with a Sources Sought Notice posted on FBO.gov from 10-27-2015 through 11-05-2015. Upon the suspense of this notice there were no interested and/or capable vendors responses received. Also, this research was done by utilizing the phrase "companies that provide LCBPE products intended for the purpose delivering of the chemotherapy treatment while embolizing the blood vessels within the desired timed stage of the process". The market research results found there were not any matches for these specific or similar products on the GSA Website; and according to searches by the CO and the SBS, there were no small businesses to include other socioeconomics concerns cable of meeting the unique characteristics required of this LCBPE product.

The large company Eisai has bought Morphotek and H3 Biomedicine is an affiliate. Eisai is a Japan based company which works with Biocompatible International to develop their E7040 embolic bead within the European market. The brand name is called DC beads and in the US, the brand name is called LC beads. The Eisai Company has acquired the exclusive rights to develop and market the product in Japan in a licensing agreement it concluded with Biocompatibles in July 2009. Biocompatible Inc. is a

large business and the contracting officer found no small businesses capable of providing the item needed to meet the Medical Center's need. There is no other vendor that can supply this particular item except Biocompatibles.

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

There are no other factors supporting the use of other than full and open competition.

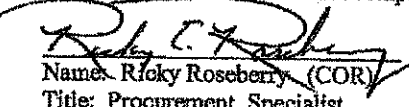
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Biocompatibles, Inc.

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:

Biocompatibles Inc. is presently the sole provider of this LCBPE product. The Contracting Officer will continue to conduct due diligence to evaluate competitors, their capabilities, cost efficacy, and the VASLHCS's specific need and adaptability to innovative similar chemotherapeutic qualities in the future.

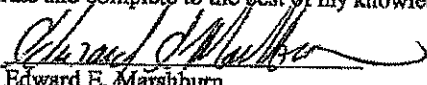
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Name: Ricky Roseberry (COR)
Title: Procurement Specialist
Facility: VASLCHCS

05/18/2016
Date


13. Approvals in accordance with FAR 6.304

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


Edward E. Marshburn
Contracting Officer
NCO 19

05-18-2016
Date

- b. **NCM/PCM (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.


Curtis Jordan
Director of Contracting
NCO 19

5-20-2016
Date

- c. **SAO (If over 650K):** I certify the justification meets requirements for other than full and open competition.

05-26-16
Date
Delia A. Adams, MBA, CPCM
Director, SAO West
SAO-W Head of Contracting Activity (HCA)

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