

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Veteran Health Administration (VHA), Service Area Office (SAO) – East, 323 North Shore, Suite 500, Pittsburgh, PA 15212. Obligation # 648-11-4-372-0505
2. **Nature and/or Description of the Action Being Processed:** The VHA/SAO-East office, on behalf of the VA Cooperative Studies Program (VACSP) in Albuquerque, NM requests the sole source procurement of an Uhlmann B1240 automated thermal forming blister system that will be used to support clinical trials conducted for the VASCP. This thermal forming blister system is used to package active and placebo tablets/capsules into unit dose blister packs. These packs are formed, sealed, labeled, and perforated in preparation for distribution to patients participating in multimillion dollar VA funded trials. This requirement is commercially available and will be procured as a Firm-Fixed Price purchase order under FAR Part 12, Commercial Items and FAR Part 13, Simplified Acquisition Procedures.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The VACSP needs a machine that utilizes technology to meet the current requirements of the Food and Drug Administration (FDA) and Consumer Safety Product Commission (CSPC) for child resistant/senior friendly blister card packaging. In order for the VACSP to meet their minimum operating needs they requires a blister packing machine that has integrated thermal forming machine, a printer with a UV dryer and a chilling unit. Additionally, VACSP requires the following salient characteristics:
 - Platen sealing plate system
 - Servo-driven index motors for high precision operation (less product and material loss)
 - Self adjusting drives
 - Capable of utilizing PVC, PVC/PVDC, PVC/Aclar laminates
 - Automated vision system (integrated camera). This will not allow blister cards to be sealed without a tablet or capsule in the blister cell and is considered an **essential** quality validation.
 - Machine "footprint" must not be larger than 140"L x 40"W x 60"H due to the size of the current production room
 - Safety mechanism need to have:
 - Access control for printing (password protected)
 - Power overload safety mechanism
 - Safety guards in sealing areas
 - Audible safety alarms
 - Color indicators for operational status
 - Electro-magnetically closing doors
 - Must be capable of utilizing a flood filling system
 - Plug assist for pre-forming
 - Perforation station for blister packs
 - Pneumatic blow off at perforation station
 - Chiller system for continuous cooling
 - In-line printing system- printer must be fully integrated with thermal forming machine

The estimated total value of this procurement is \$434,400.00. Delivery is requested within 180 days after receipt of order.

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

- (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):** VACSP has approximately \$300,000.00 in existing Uhlmann tooling, which includes nine sets of tooling listed below. Each tooling range in value from \$33,000 - \$54,000 each. Seven (7) of these toolings, worth approximately \$240,000, can be utilized on the new B1240 Thermal forming machine without modification. The Government would *achieve a substantial savings of approximately \$240,000.00* by acquiring a new Uhlmann blistering machine versus acquiring a non-Uhlmann blistering machine. Purchasing the B1240 would allow VACSP to support ongoing trials with our existing tooling. *The following equipment, aggregately valued at \$240,000.00 would need to be purchased in order to sustain current capabilities with a non-Uhlmann blistering machine:*
- Size 1capsule
 - Size 0 capsule
 - Football shaped
 - Two-up round tablet
 - Small round tablet
 - Oval tablet
 - Medium round tablet
 - CSP 563 custom blister
 - Round tablet (cold forming)
6. **Description of efforts made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research was conducted in accordance with FAR Part 10 by both the end user and the contract specialist. A Request For Information (RFI) was sent out to all veteran owned businesses registered under NAICS 334510 (Electromedical and Electrotherapeutic Apparatus Manufacturing) on VetBiz.gov and no interest was received. *A special notice was published on FedBizOpps publicizing the intent to award solely to Uhlmann and no responses have been received.* Additionally market research was performed on the internet.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The contracting officer has evaluated the market in accordance with FAR Parts 12.209 and 13.106-3 to ensure price fair and reasonableness.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted in accordance with FAR Part 10 by both the end user and the contract specialist. A Request For Information (RFI) was sent out to all veteran owned businesses registered under NAICS 334510 (Electromedical and Electrotherapeutic Apparatus Manufacturing) on VetBiz.gov and no interest was received. *A special notice was published on FedBizOpps publicizing the intent to award solely to Uhlmann and no responses have been received.* Additionally market research was performed on the internet.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The VACSP conducts "blind studies" utilizing placebos blistered from their current Uhlmann machine. Because current tooling can be used on a new Uhlmann machine these blind studies will not be compromised. The purchase of a non-Uhlmann machine would compromise study blinding and negatively affect timelines of current studies. Lastly, an email from Markus Haid, Managing Director of Uhlmann USA confirming no authorized resellers or distributors in the North America.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None
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:** An Intent to Sole Source has been posted on FBO. Additionally, this J&A will be posted post-award to FBO for 30 days in accordance with FAR 6.305(d).

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.

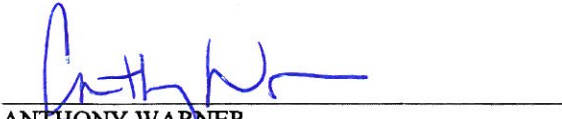

FRANK LUEDDEKE

CONTRACTING OFFICER'S REPRESENTATIVE
VA COOPERATIVE STUDIES PROGRAM, CLINICAL RESEARCH PHARMACY

09/19/2011
Date

13. **Approvals in accordance with FAR 6.304 & VHA SOP Other Than Full and Open Competition**

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


ANTHONY WARNER
CONTRACTING OFFICER
SERVICE AREA OFFICE (SAO) - EAST

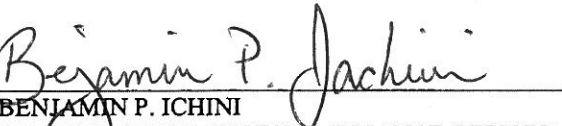
9/19/11
Date

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


TREVOR MARTIN
SUPERVISORY CONTRACTING OFFICER
SERVICE AREA OFFICE (SAO) - EAST

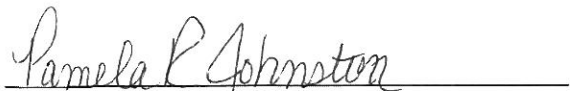
9/19/11
Date

- c. **SAO East Quality Assurance (Required \$3K and above):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


BENJAMIN P. ICHINI
QUALITY ASSURANCE/COMPLIANCE OFFICER
SERVICE AREA OFFICE (SAO) - EAST

9/21/11
Date

- d. **NCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.


PAMELA R. JOHNSTON
DEPUTY DIRECTOR
SERVICE AREA OFFICE (SAO) - EAST

9/22/11
Date