

Justification Tracking Number: [REDACTED]

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: [REDACTED]

1. **Contracting Activity:** Department of Veterans Affairs, Veterans Health Administration (VHA)
Regional Procurement Office West, Network Contracting Office 19, 6162 South Willow Drive, Suite
300, Greenwood Village, CO 80111

Organizational Activity: Oklahoma City VA Health Care System, 921 NE 13th St., Oklahoma City, OK
73104

2237#: [REDACTED]

2. **Nature and/or Description of the Action Being Processed:** The action being reviewed and approved is an Emergency Sole Source Justification for a GermFree Mobile Cleanroom Rental for Oklahoma City VA Health Care System (OKCVAHCS). This emergency was approved on July 25, 2019 and the 2237 funding document was received on August 01, 2019. Subsequently, a Firm-Fixed-Price Purchase Order was awarded on August 06, 2019 to Stripes Global Inc, a responsible Service Disabled Veteran Owned Small Business (SDVOSB) with the capability to fulfill the emergency requirement for the OKCVAHCS.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for a GermFree Mobile Cleanroom Rental in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The mobile cleanroom rental will maintain pharmacy sterile compounding services for hazardous and non-hazardous medications to support patient care for the OKC VA Health Care System during a period of renovation/construction. This requirement include field installation of the mobile unit, certifications of all areas to meet current USP <797>, <800>, NIOSH, and FDA anteroom and cleanroom regulations. This rental is needed for a Base Year plus One (1) Option Year, for a total of at least 24 months. The estimated total is approximately [REDACTED]. Delivery, install, and room certifications are required to be completed on or before November 01, 2019. A later date of completion would have a tremendous negative impact on veteran care at the facility. The following is encompassed in this mobile cleanroom rental:

Item #	Description	QTY
1	Field Installation Assistance for Germfree's Mobile Pharmacy Cleanroom Trailer	1

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	<p>INCLUDES:</p> <ul style="list-style-type: none"> - Dedicated trailer transit from Germfree to client's destination site - Costs for one (1) Germfree Technician to meet the Rx Trailer upon arrival and remain on site for up to 3 days - While on site GF technician will unpack the trailer, set and level, install stairs and awning, start-up the trailer, provide an initial cleaning service and operator training in the start-up and daily operations of the trailer (not SOPs for Rx work). -Third Party Certification of Pharmacy Cleanroom - Certification of Pharmacy Equipment - Certification or approvals from state boards of pharmacy - Any seismic strapping or bracing required by federal code - Hook-up of main power supply, connection to client's network, fire/burglar systems (dry connection), hook up of grey water waste (if required) and hook up fresh water. All utilities must be run to the trailer, running of other support utility services is not included. 	
2	Base Year- Monthly Rental of Mobile Pharmacy Cleanroom Trailer: 12 Month minimum, Per Month	12
3	Option Year 1- Monthly Rental of Mobile Pharmacy Cleanroom Trailer: 12 Month minimum, Per Month	12
4	Decommissioning of Rental Mobile Pharmacy Cleanroom Trailer. Includes travel to and from jobsite located central US eastward for 1 person / 2 days to pack up and prepare trailer for return to factory.	1

4. Statutory Authority Permitting Other than Full and Open Competition

- () (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (X) (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;

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- () (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;

FAR 13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

- 5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The OKCVAHCS is requiring an emergency mobile compounding pharmacy rental to be able to continue to provide sterile hazardous and non-hazardous medications while renovation/construction takes place due to the compliance timeline for USP <797> and <800> standards implementation. Due to the need to be in compliance with the standards implementation the renovation/construction will begin a little after November 01, 2019 for a period of 18-24 months. Therefore OKCVAHCS is emergently needing to acquire a mobile compounding pharmacy cleanroom rental to maintain pharmacy services and provide optimal patient care needs. The delivery, installation, and all certifications for these specialize rooms are needed on or before November 01, 2019. In reaching out to the commercial market for Mobile Cleanroom Trailers' availability are backlogged to calendar year 2020 due to high demand. The lowest lead time for delivery, install, and certifications to be complete by November 01, 2019 was around 90 days from time of award by Stripes Global Inc. Stripes Global is the only vendor capable of providing the requested rental in the timeframe required to allow for continued patient care during the renovation/construction time. Not completing the procurement now will result in unacceptable delays in the renovation/construction to meet the compliance timeline and not having the required trailers in place for use and critically degrade the facility's ability to provide the necessary care to the Veterans during the renovation/construction timeframe.
- 6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Due to the emergent need, a quick market research was conducted to identify sources who can fulfill this requirement. Refer to paragraph 8 for market research details..
- 7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Based on the comparison to the prices found reasonable on similar contract 36C24219P1222 (a three-year lease for the same Mobile Cleanroom Compounding Pharmacy Trailer), our Order 36C25919P0947 ([REDACTED]) is within 15% of the Base plus 1 OY total for 36C24219P1222 ([REDACTED]). The 15% difference ([REDACTED]) is due to additional utility hookups requested by OKC, the increase in building material (ie. steel), and a discount given on the comparison contract due to having a longer lease term (3 years instead of 2 years). It is hereby determined that pricing is both fair and reasonable and in the best interest of the government.
- 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, which included a quick search on VIP, FPDS, and in eCMS to identify sources for this emergent need. The VIP search resulted in only 1 SDVOSB (Stripes Global), FPDS resulted in only the

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Large Business Manufacturer (Germfree Laboratories), and eCMS resulted in 1 possible small business source (Modular Devices) identified with the capability of providing the requested items. Attempts to contact the possible vendor were made, resulting in only 1 vendor (Stripes Global) able to meet this emergent need in the timeframe required due to the high demand of the requested item. No phone contact or email response was ever received by Germfree Laboratories and Modular Devices indicated the earliest they could deliver is January 2020 (not to include the install and certification required).

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: Mobile Cleanroom is required to be onsite and certified for use by November 1, 2019.

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

Modular Devices, Inc
6678 Guion Rd
Indianapolis, Indiana 46268

Stripes Global Inc
245 4th St Ste 204
Bremerton, Washinton 98337

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: The Government will continue to conduct market research to ascertain if there are changes in the market place at the time a new Mobile Cleanroom Rental is required. Future actions for this type of requirement will be competed, depending on the market conditions, in compliance with small business regulations.

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.

[REDACTED]

Pharmacy Facility Program Manager
OKC VA Health Care System

[REDACTED]

Date _____

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13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

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

[Redacted Signature]

[Redacted Date]

Date

Branch Chief, Supply 1
VHA Regional Procurement Office West
Network Contracting Office (NCO) 19

- 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.

[Redacted Signature]

[Redacted Date]

Date

Director of Contracting
VHA Regional Procurement Office West
Network Contracting Office (NCO) 19

- c. **VHA RPO HCA Review and Approval**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve (\$700K to \$68 million) for other than full and open competition.

[Redacted Signature]

[Redacted Date]

Date

Executive Director, Regional Procurement Office West
Head of Contracting Activity (HCA)