

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Limited Sources Justification Format >\$150K

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: _VA770-17-AP-0656__

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.

Restricted to the following source: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Kaleo, Inc.

Manufacturer/Contractor POC & phone number: Boldi Kocsor 858-405-2315

Mfgr/Contractor Address: 111 Virginia Street, Suite 300 Richmond, VA 23219

Dealer/Rep address/phone number: Same as above

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Hines CMOP

5th & Roosevelt Road

Hines, IL 60141

VISN:

NCO 15

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

NALOXONE 2MG AUTOINJECTOR KIT (EVZIO 2MG) NDC-60842-0051-01 VA CLASS;OPIOD

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

NALOXONE 2MG AUTOINJECTOR KIT (EVZIO 2MG) NDC-60842-0051-01 VA CLASS;OPIOD

(b) ESTIMATED DOLLAR VALUE: \$198,000.00

(c) REQUIRED DELIVERY DATE: 09/18/2017

(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.

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There is only one company that manufactures the requested product – Kaleo, Inc. There are no known acceptable generic substitutions and they do not distribute this item to any other vendor.

☐ 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:

Within the VHA brand name drugs may be prescribed by physicians when in their clinical judgment the brand name drug will provide a better therapeutic outcome for patients. Brand name drugs are requested when there is a clinical requirement for the drug. In this case, the brand specific drug name is requested on the list above.

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

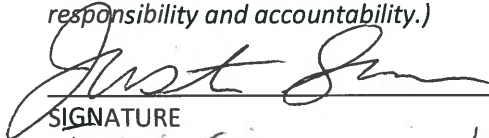
This item is found on Kaleo Inc FSS contract V797D-60717. A delivery order will be placed against that contract.

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(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

(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:

(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.)*

	<u>9/6/17</u>
SIGNATURE	DATE
<u>JUSTIN Simon</u>	<u>Logistics Manager</u>
NAME	TITLE
<u>765</u>	<u>CmOP</u>
FACILITY	SERVICE LINE/SECTION

(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.

<hr/>	<u>09/06/2017</u>
CONTRACTING OFFICER/DESIGNEE'S SIGNATURE	DATE
<u>Josie Manderscheid, Contracting Officer</u>	<hr/>
NAME AND TITLE	FACILITY