

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION DUE TO SOLE SOURCE REQUIREMENT

REQUIRED INFORMATION	
1.	FACILITY NUMBER-NAME- CITY, STATE: <i>Station 502, Alexandria VAHCS, Pineville, LA</i>
2.	VISN OR PROGRAM ACTIVITY: <i>16</i>
3.	POC NAME AND TELEPHONE NUMBER: <i>Paul Moreau, 318-466-2574</i>
4.	PROPOSED ACTION: Brand Name or Sole Source Procurement of: <i>COMMODITY</i>
5.	<p>DESCRIPTION OF REQUIREMENT: <i>Emergency Procurement of Gamunex-C from McKesson Plasma and Biologicals for delivery on 21 Jan 2013 for critical need to sustain patient's life.</i></p> <ul style="list-style-type: none"> Supplies/Equipment: Technical Characteristics can include, but are not limited to model, make, part number, color, size, quantity, delivery date, etc. Services: Refer to the statement of work, statement of objective, or performance work statement for your description.
6.	<p>STATUTORY AUTHORITY PERMITTING OTHER THAN FULL AND OPEN COMPETITION: <i>Unusual and Compelling Urgency</i></p> <ul style="list-style-type: none"> FAR 6.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements FAR 8.405-6 Limited sources justification and approval FAR 13.106-1(B) SAP Requirements – Soliciting From a Single Source. If contracting officer determines that circumstance of contract action deem only one source is considered reasonable available. This is a reference to the part of the Federal Acquisition Regulation that allows an item to be purchased without being fully competed. This statement serves as a point of reference in case the justification is questioned. In this case, it would be reviewed for its relativity to this part of the Federal Acquisition Regulation.
7.	<p>NATURE & BACKGROUND OF ACQUISITION TO JUSTIFY SOLE SOURCE: <i>The prescribed drug is requested from McKesson Plasma and Biologicals based on the following: (1) the Federal Drug Administration (FDA) has deemed this drug so potentially dangerous that it requires special packing and handling as required by the FDA Risk Evaluation and Mitigations Strategies (REMS); (2) The drug is ordered through this VA Vendor to ensure that special safety monitoring procedures are being adhered through the FDA; (3) Telecris (Grifols) will not sell this drug to the VA directly so we are required to purchase from an authorized distributor; (4) McKesson has been the source for this drug for the Alexandria VA; and (5) There is only a small quantity of this drug available through the VA contract so this drug shortage makes it necessary to procure from this source as an open market item.</i></p> <ul style="list-style-type: none"> Describe the minimum salient characteristics that will meet your needs. This is the area where you explain why no other vendor anywhere can supply this requirement for you. Acceptable reasons for "sole source" include (but are not limited to): bound by contract, technical order specification, warranty service, or regional standardization. If the reason for sole source is determined locally, offer what market research or clinical guidelines led to the decision.
8.	<p>PROVIDE INFORMATION SHOWING MARKET RESEARCH WAS CONDUCTED: <i>Past experience with ordering Gamunex on a normal and emergency basis has revealed that ordering from McKesson is most expedient in the event of an emergency. An account has been set up with McKesson for ordering, to include emergency ordering for this specific drug. This drug is an immune globulin injection (human) approved to treat primary humoral immunodeficiency disease (PI) and idiopathic thrombocytopenic purpura (ITP) and chronic inflammatory demyelinating polyneuropathy (CICP). Gamunex-C provides healthy antibodies to block the immune and inflammatory processes that attach and destroy myelin (the protective covering around nerve fibers). The physician has made a determination that this drug is critical for this specific patient.</i></p> <ul style="list-style-type: none"> This justification is for why no other vendor anywhere can supply your item or service and still meet your

needs. Your rationale for barring other vendors is crucial to your justification. If you already cited the statutory reason for a sole source, state, "See paragraph 7". If your rationale for a sole source purchase was determined locally, offer an explanation of the source selection process you went through to determine your sole source requirement. Unacceptable reasons include (but are not limited to) personal taste, good relationship with existing vendor, or one's comfort level with a particular vendor.

- Describe the similarities and differences in vendors for the product that you are aware of that could assist or prevent the purchaser from obtaining the best value for you. Be sure to name the vendors. This section will help the purchaser decide which vendors are available to purchase this item from. If market research was not conducted, state it AND the reason that there was no market research.

9. PRICE ANALYSIS "FAIR AND REASONABLE": *This is the open market pricing of Gamunex 10 and 20 gram from McKesson Plasma and Biologicals for the VA.*

- This section is mandatory. Do not leave this section blank. Even though this must be purchased from only one source, you must still obtain a quote from the vendor for this purchase. This way you are able to verify added costs for delivery, your geographic region, or installation. Cite the pricing here. If you purchased this item before, compare this price to what you paid last time. Cite this as well in your answer.

10. LISTING OF SOURCES EXPRESSING INTEREST IN THIS REQUIREMENT: *None - Urgent (Emergency) Requirement Sole Sourced using existing account.*

- Enter or attach contact information for sources you cited in the description of your source selection. If sole source by statute, regulation, or standard, list contact information for that source here.

11. FUTURE ACTION TO OVERCOME BARRIER TO OTFOC: *Provide sufficient acquisition lead time to compete requirement among authorized distributors.*

- This section fulfills the legal requirement to affirm that the selection of a singular source for this requirement is an anomaly and that action will be taken in the future to ensure full competition in the future. The reason this is needed is to describe how the government will make an effort in the future to fully comply with standard acquisition practices and not resort to creating unnecessary partnerships with few vendors at the risk barring full competition to circumvent the FAR. By signing this, you are telling the contracting officer to avoid the processes that assure best value and fairness in this acquisition. If the reason for sole source purchase is because of statute, standard, or regulation, enter "THE SOURCE FOR THIS PURCHASE IS REQUIRED IAW." Cite this as well in your answer.