

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

REQUIRED INFORMATION	
1.	FACILITY NUMBER-NAME- CITY, STATE: 437 Fargo HCS Fargo ND
2.	VISN OR PROGRAM ACTIVITY: 23
3.	POC NAME AND TELEPHONE NUMBER: Anne Gossett x3800
4.	PROPOSED ACTION: Sole Source Procurement of COMMODITY
5.	<p>DESCRIPTION OF REQUIREMENT: special order medication-Xenazine (tetra benazine) for the treatment of corea associated with Huntington's Disease</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: Only One Responsible Source Available</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 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: Technical requirements of FDA limit source to single entity due to extensive drug monitoring requirements imposed by FDA</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. If this item is included in an allowance standard for War Reserve Materiel (WRM), cite the allowance standard, required source, and stock number for this item. NOTE FOR WRM PURCHASES: The Defense Logistics Agency is your primary source for WRM equipment. Be sure to determine availability from a DLA item manager before contracting for WRM equipment. If DLA cannot meet your timelines for WRM equipment, your urgency may be further justification for other than full and open competition. See your Medical Logistics Flight Commander for more details.
8.	<p>PROVIDE INFORMATION SHOWING MARKET RESEARCH WAS CONDUCTED: No market research was conducted as this is an FDA Risk Revaluation Mitigation Strategy (REMS) medication and distribution is limited to Caremark.</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": *It is a commercially available drug and available to private healthcare entities.*

- 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 here as well.

10. LISTING OF SOURCES EXPRESSING INTEREST IN THIS REQUIREMENT: *see Pharmacy Benefits Management flowchart*

- 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: *If the FDA REMS monitoring requirement is suspended, future acquisitions for this medication will be solicited.*

- 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 the standard here]."

SUBMITTED BY:

Signature: 

Department/Requestor

Date: 1/17/13

SIGNED BY:

Signature: 

Warranted Contracting Officer

Date: 1/17/13

APPROVED BY:

Signature: 

NCM or Product Line Supervisor

Date: 1/17/2013

Note: Anything that is over 500K will need to strictly follow the SOP J&A Attachment.