Template for a Federal Supply Schedule (FSS)
Limited-Sources Justification

[redacted]

FEDERAL SUPPLY SCHEDULE
LIMITED-SOURCES JUSTIFICATION

Acquisition Title: Product Replacement - Amoxicillin trihydrate 500 mg oral capsules

Agency: ASPR

Acquisition Year (FY): 26

Author: [redacted]

2. Description of Action:

Nature:	☒ New Requirement	☐ Follow-on Requirement	
	☐ Modification to Existing Purchase Order/Contract Number:		
Pricing:	☒ Firm-Fixed Price	☐ Time & Materials	☐ Cost
	☐ Other:		
Funds:	☒ OMA	☐ Other Funds:	

[redacted]

Name of Proposed Contractor(s): US Antibiotics

Street Address: 201 Industrial Drive

City, State, Zip: Bristol, TN 37620

Add Contractor | Remove Contractor

3. Description of Supplies and Services to Include Contract Vehicle/Number Utilized:

The purpose of this acquisition is to purchase [redacted] Amoxicillin trihydrate 500 mg oral capsules – 60 count per bottle, NDC #: 81964-0350-60 and [redacted] Amoxicillin trihydrate 500 mg oral capsules – 100 count per bottle, NDC #:81964-0350-10. This pharmaceutical is available on Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) No. 36F79723D0101. The anticipated order duration for this acquisition is not to exceed 12 months.

The estimated value of the proposed action, including all options, is $ $29,998,678.00

[redacted]

The Strategic National Stockpile (SNS) has an urgent requirement to procure Amoxicillin trihydrate (500 mg) in 60-count and 100-count bottle configurations to support national anthrax preparedness operations. SNS is required under Public Health Emergency Medical Countermeasures Enterprise guidance to maintain stockpiles of Amoxicillin trihydrate as part of the national formulary supporting response to mass exposures to Bacillus anthracis.

Amoxicillin trihydrate is the first-line drug of choice for anthrax post-exposure prophylaxis in pediatric populations, as well as individuals with contraindications to alternative therapies.

Standardized bottle counts are required to support rapid dispensing during emergency response operations. Pre-packaged 60-count and 100-count bottles allow for immediate distribution of complete post-exposure prophylaxis regimens without additional repackaging or counting of capsules during a public health emergency. Any delay caused by repackaging bulk pharmaceutical containers during an emergency response could slow the timely administration of prophylaxis to exposed individuals. Anthrax remains a credible bioterrorism threat due to its ability to be mass-produced and disseminated as aerosolized spores.

4. Authority:

☒ **ORDER AGAINST FSS:** Authority of the Multiple Award Schedule Program, Title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 251, *et seq.*); Title 40 U.S.C. 501, Services for Executive Agencies; and Section 803 of the National Defense Authorization Act of 2002 (PL 107-107) and implemented by FAR 8.405-6. Mark the applicable exception and discuss how the cited authority applies in accordance with **FAR 8.405-6(c)(2)(iv)**.

☒ An urgent and compelling need exists, and following the procedures would result in unacceptable delays (FAR 8.405-6(a)(1)(i)(A));

In accordance with the Revolutionary FAR Overhaul (RFO), FAR Part 8 was revised and RFO 8.401 requires the use of the General Services Administration Manual/Regulation (GSAM/R). GSAM/R 538.7104-3(b)(1)(i), allows for the placement of a sole source order when the "need is of such unusual urgency that following procedures would result in unacceptable delays in fulfilling that need." [redacted]

[redacted]

[redacted]

[redacted] Amoxicillin trihydrate levels [redacted] because of the Amoxicillin ordered under 36F79720D0198/Order 75A50322F80030 not being delivered, [redacted] and the competitive FY25 requirement for Amoxicillin trihydrate 500 mg oral capsules being protested, which led to the termination of 36F79725D0059/ Order 75A50325F80038.

In addition, this created a shortfall, resulting in [redacted] Amoxicillin preparedness capability. This sole source acquisition is necessary to [redacted] operational readiness and ensure continued availability of a critical medical countermeasure. This sole source acquisition is being issued to fulfill the Government's immediate urgent requirement. A subsequent requirement for Amoxicillin trihydrate 500 mg oral capsules will be competed.

Market research confirmed that only one Federal Supply Schedule vendor is capable of meeting the Government's validated operational requirement necessary to [redacted] preparedness capability. The Government's requirement is based on validated mission needs and operational risk associated with [redacted] rather than vendor preference or administrative convenience. The period of performance is twelve (12) months from the date of award. A sole source award is required to ensure timely [redacted] stock levels and mitigate operational risk [redacted] and to ensure SNS can maintain response capability for pediatric anthrax post-exposure prophylaxis.

The delivery requirement was established through readiness assessments, inventory analysis, and technical evaluation of operational risk associated with [redacted]. These analyses concluded that delayed availability of product would [redacted] and [redacted] SNS's ability to support timely response operations during an anthrax emergency event. The required delivery schedule is therefore rationally related to the Government's legitimate need [redacted] as rapidly as practicable.

Due to current [redacted], the Government must obtain products from a vendor capable of providing product availability and delivery support consistent with the Government's urgent operational need in order to [redacted] SNS preparedness capability. The requested quantity represents the [redacted] procurement necessary to [redacted] preparedness capability for pediatric anthrax post-exposure prophylaxis and maintain operational readiness.

The Government documented the operational consequences associated with relaxing the delivery requirement and determined that extending delivery timelines would materially increase performance risk by prolonging [redacted] Continued [redacted] Amoxicillin trihydrate 500 mg oral capsules inventory would reduce SNS's ability to rapidly distribute first-line prophylaxis during a response event and could negatively affect federal, state, and territorial response operations. The total quantity must be delivered within 12 months from date of award. Vendors unable to provide product availability within the Government's urgent delivery requirement were determined not viable for this acquisition, because delayed delivery would [redacted] to national preparedness objectives.

This requirement is supported by market research, technical analysis, and operational readiness assessments demonstrating a logical connection between the delivery requirement and the Government's need to [redacted] and sustain [redacted] preparedness capability.

If this requirement is not fulfilled with sufficient urgency [redacted], federal, state, and territorial response efforts will lack the first-line medical countermeasure necessary to protect pediatric populations following an anthrax exposure event. Delays in administration of anthrax post-exposure prophylaxis significantly increase morbidity and mortality. Immediate procurement is therefore required [redacted] and ensure the United States maintains the capability to respond rapidly to an anthrax incident.

☐ Only one source is capable of providing the supplies or services required at the level or quality required because the supplies or services are unique or highly specialized (FAR 8.405-6(a)(1)(i)(B)).

[redacted]

☐ In the interest of economy and efficiency, 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 or BPA must not have been previously issued under sole-source or limited sources procedures (FAR 8.405-6(a)(1)(i)(C)); or

☐ An item peculiar to one manufacturer can be a particular brand name, product, or a feature of a product, peculiar to one manufacturer). A brand name item, whether available on one or more schedule contracts, is an item peculiar to one manufacturer. (FAR 8.405-6(b)).

[redacted]

5. **Market Research:**

[redacted]

the particular feature, do not meet, or cannot be modified to meet, the agency's needs.

Market research was conducted to identify Federal Supply Schedule vendors capable of supplying Amoxicillin trihydrate in 60-count and 100-count bottle configurations and capable of meeting the Government's required quantities and delivery timeframe necessary [redacted] SNS preparedness capability.

Research included review of the VA Federal Supply Schedule (Schedule 65 I B – Pharmaceuticals), vendor capability inquiries, and evaluation of product availability and delivery timelines. Four vendors were identified as offering Amoxicillin trihydrate on the VA Federal Supply Schedule: US Antibiotics, LLC (Manufacturer), Lovell Government Services, Inc. (Reseller), Chinook Medical Gear Medical Gear Inc. (Reseller), and Chartwell RX, LLC, LLC (Distributor).

Each vendor was reviewed based on product availability, manufacturing capability, delivery timelines, and the ability to meet required quantities, and ability to support the Government's validated operational readiness requirement.

The Government evaluated whether vendors could support the operational need to [redacted] inventory levels and reduce the preparedness risks associated with [redacted]

US Antibiotics represented the ability to provide product availability and delivery support consistent with the Government's urgent operational requirement and demonstrated the manufacturing capability necessary to support [redacted] SNS preparedness capability.

[redacted], based on readiness assessments and operational risk analysis associated with [redacted] the Government determined that [redacted] delivery capability would not adequately support the urgent operational need to rapidly [redacted] DDS preparedness capability.

[redacted]

[redacted]

The Government determined that vendors unable to support the required operational need would introduce unacceptable

performance risk [redacted] preparedness capability and [redacted]

Based on the market research conducted, US Antibiotics, LLC is the only vendor capable of meeting the Government's required quantities and operational delivery requirements necessary to [redacted] SNS preparedness capability; therefore, a sole source award to [redacted], is justified.

6. **Actions to Increase Competition:**

[redacted]

The Government evaluated the factors that resulted in restricted consideration for this procurement and assessed potential actions to promote broader competition in future acquisitions. The primary barrier to competition is the limited number of manufacturers capable of producing Amoxicillin trihydrate 500 mg oral capsules at the required quantity and operational delivery capacity necessary [redacted]

While market research identified vendors on the VA Federal Supply Schedule capable of providing the product, US Antibiotics LLC is the only source that demonstrated the capability to meet the Government's validated

operational requirement necessary [redacted] The Government considered whether relaxing the operational delivery requirement would increase competition; however, technical and readiness analyses concluded that extending delivery timelines would prolong the [redacted] to SNS preparedness capability.

Currently, no further actions are feasible to increase competition for the current requirement due to the immediate operational urgency, existing product expiration, and [redacted] which have resulted in a [redacted] The urgency to [redacted] prevents the Government from extending timelines to allow additional vendors time to build capacity or reconfigure manufacturing processes.

The Government's requirement reflects the [redacted] operational need necessary to [redacted] and is not intended to unnecessarily restrict competition. Supporting market research, technical analysis, and readiness assessments have been documented to substantiate the relationship between the requirement and the Government's mission needs.

This procurement is intended solely to address SNS's immediate operational requirement and [redacted] pending a future competitive acquisition. It is anticipated that future SNS requirements for It is anticipated that future SNS requirements for Amoxicillin trihydrate 500 mg oral capsules will be competed.

7. Any other facts supporting the justification:

[redacted]

8. Technical / Requirements Certification: By my signature below, I certify that the supporting data under my review which is included in this Limited-Sources Justification is accurate and complete.

Program Manager	
Name:	[redacted]
Position Title:	Logistics Management Specialist
Email address:	[redacted]
Phone:	[redacted]
Program Manager Supervisor (or one level above Program Manager)	
Name:	[redacted]
Position Title:	Acting Branch Director
Email address:	[redacted]
Signature:	Anthony K. Nanes -S Digitally signed by Anthony K. Nanes -S Date: 2026.05.15 11:35:20 -04'00'
Date:	

9. Best Value Determination: By my signature below, after review of the relevant documents, I have determined that the order subject to this Limited-Sources Justification represents the best value for the Government as set forth in FAR 8.404(d), and constitutes a fair and reasonable price. The basis for my determination is as follows:

[redacted]

Prices under the VA Federal Supply Schedule have already been determined fair and reasonable by the General Services Administration. The ordering activity will verify that the proposed pricing does not exceed the contractor's awarded Schedule rates and will seek further price discounts in accordance with GSAR 538.7102-2(c)(2). Due to the urgent delivery requirement and [redacted] status, the Government was unable to solicit pricing from multiple Schedule vendors within the required timeframe. However, the use of Schedule pricing mitigates pricing risk, and no premium will be paid for urgency and a discount based on the volume purchased will be sought from the vendor.

10. Contracting Officer's Approval (Required for proposed contract not to exceed $700,000 (value calculated including all options)): I hereby certify that this justification is accurate and complete to the best of my knowledge. I approve this justification subject to the availability of funds, and provided that the services and supplies herein described have otherwise been approved for acquisition.

Name:	[redacted] Lead Contract S	Phone:	
Signature:	Kimberly L. Golden -S	Date: Digitally signed by Kimberly L. Golden -S Date: 2026.05.15 12:57 -04'00'	

11. Legal Review:

[redacted]

A legal review was provided by the General Law Division.

12. OPDIV Competition Advocate Approval (Required for proposed contract over $700,000 but not exceeding $13.5 million (value calculated includi[redacted])

I have reviewed this justification and find that it adequately supports limiting sources.

Name:		Phone:	
Signature:		Date:	

13. Office of Small and Disadvantaged Business Utilization:

I have reviewed this justification and find that it adequately supports limiting sources.

Name:		Phone:	
Signature:		Date:	

14. OPDIV HCA Approval (Required for proposed contract over $13.5 million but not exceeding $68 million (value calculated including all options)):

Name:	[redacted], HCA	Phone:	
Signature:	Makoto P. Braxton -S Digitally signed by Makoto P. Braxton -S Date: 2026.05.15 11:50:36 -04'00'	Date:	

15. Department Competition Advocate:

Concur:	☐	Non-Concur:	☐
Name:	[redacted], CA	Phone:	
Signature:	Makoto P. Braxton -S Digitally signed by Makoto P. Braxton -S Date: 2026.05.15 11:51:05 -04'00'	Date:	

[redacted]

16. HHS Senior Procurement Executive (SPE) Approval:

Based on the foregoing justification, I hereby approve limiting sources for the above stated procurement, subject to the availability of funds, and provided that the services herein described have otherwise been authorized for acquisition.

State supplies/services being procured:

State the full statutory authority and FAR cite and title, consistent with paragraph 4, e.g. 41 U.S.C. 3304:

Name:		Phone:	
Signature:		Date:	