

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NUMBER		PAGE OF 1 22	
2. CONTRACT NO.		3. AWARD/ EFFECTIVE DATE		4. ORDER NUMBER		5. SOLICITATION NUMBER 75A50122Q00018	
						6. SOLICITATION ISSUE DATE 08/18/2022	
7. FOR SOLICITATION INFORMATION CALL:		a. NAME KIMBERLY GOLDEN			b. TELEPHONE NUMBER (No collect calls)		8. OFFER DUE DATE/LOCAL TIME 09/6/2022 1400 ET
9. ISSUED BY ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341				10. THIS ACQUISITION IS UNRESTRICTED OR <input checked="" type="checkbox"/> SET ASIDE: % FOR: <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> SMALL BUSINESS HUBZONE SMALL BUSINESS SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS </div> <div> WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM EDWOSB 8(A) NAICS: 325412 SIZE STANDARD: 1,250 </div> </div>			
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED SEE SCHEDULE		12. DISCOUNT TERMS		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING	
						14. METHOD OF SOLICITATION X RFQ IFB RFP	
15. DELIVER TO		CODE		16. ADMINISTERED BY CODE ASPR/SNS US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341			
17a. CONTRACTOR/ OFFEROR		CODE		FACILITY CODE		18a. PAYMENT WILL BE MADE BY CODE	
TELEPHONE NO.							
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED SEE ADDENDUM			
19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES			21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), intends to issue a delivery order for Amoxicillin trihydrate 500 MG and Doxycycline Hyclate 100 MG in configurations of (20ct, 60ct, and 100ct)EA under the FSS VA/Schedule VA Federal Supply Schedule (FSS) 65IB- Drugs, Pharmaceuticals & Hematology 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. <i>(Use Reverse and/or Attach Additional Sheets as Necessary)</i>						
25. ACCOUNTING AND APPROPRIATION DATA						26. TOTAL AWARD AMOUNT (For Govt. Use Only)	
X 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ARE <input checked="" type="checkbox"/> ARE NOT ATTACHED. 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4, FAR 52.212-5 IS ATTACHED. ADDENDA ARE <input type="checkbox"/> ARE NOT ATTACHED.							
X 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.				29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:			
30a. SIGNATURE OF OFFEROR/CONTRACTOR				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)			
30b. NAME AND TITLE OF SIGNER (Type or print)		30c. DATE SIGNED		31b. NAME OF CONTRACTING OFFICER (Type or print)		31c. DATE SIGNED	
				KIMBERLY L. GOLDEN			

19. ITEM NO	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Period of Performance: 09/30/2022 to 09/29/2023 Performance is anticipated to begin September 30, 2022 for a period of 12 months. Period of Performance: 09/30/2022 to 09/29/2023				

32a. QUANTITY IN COLUMN 21 HAS BEEN

RECEIVED

INSPECTED

ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
			32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	37. CHECK NUMBER
PARTIAL FINAL			COMPLETE PARTIAL FINAL	
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT			42a. RECEIVED BY (Print)	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER		41c. DATE	42b. RECEIVED AT (Location)	
			42c. DATE REC'D (YY/MM/DD)	42d. TOTAL CONTAINERS

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65IB- Drugs, Pharmaceuticals & Hematology VA Federal Supply Schedule (FSS)
Delivery Order Purchase Schedule 42-2B Generic & multiple source pharmaceuticals &
drugs, human bloodproducts, & over-the-counter drugs

- a. This is a Delivery Order (DO) awarded under FAR Part 8, VA Federal Supply Schedule (FSS) and is subject to the terms and conditions contained therein as well as in this DO.
- b. The solicitation number is 75A50122Q00018 and is being issued as a request for proposal.
- c. This acquisition is a small business set-aside. The North American Industry Classification System (NAICS) code is 325412.
- d. The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) and Administration for Preparedness and Response (ASPR), intends to purchase doxycycline hyclate and amoxicillin trihydrate. The Government intends to evaluate offers and award a contract without discussions. However, the Government may, in its sole discretion, elect to conduct discussions if determined to be in the best interest of the Government.
- e. Performance is anticipated to begin September 30, 2022. The period of performance is for a period of 12 months.
- f. Offerors shall include a completed copy of FAR 52.212-3, Offeror Representations and Certifications-Commercial Items (Appendix A), with its offer. (Note, if offerors are registered within the System for Award Management (SAM) and certs and reps are up to date, make a statement to that effect in accordance with this clause).

- j. This solicitation is to be competed on the VA NAC, Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. All clauses from the winning vendor(s) applicable VA/FSS schedule contract will be applicable to this award. Additional clauses and instructions are included in Sections (C & E) below.
- k. **Offers are due no later than September 6, 2022 on or before 2:00 PM Eastern Time** by e-mail to the **Subject Line RFQ 75A50122Q00018** attention of Contracting Officer, Kimberly Golden at: **OSContracting@cdc.gov**. The offeror's **complete** proposal (including all information required to be submitted as part of the offeror's quote;
- Volume A - Completed 1449 & Fill-In Docs,
 - Volume B -Technical Proposal,
 - Volume C - Price/Business Proposal,
- l. **Questions are due August 23, 2022 on or before 5:00 PM Eastern Time** by e-mail: **Subject Line QUESTIONS: RFQ 75A50122Q00018** to the attention of Contracting Officer, Kimberly Golden at: **OSContracting@cdc.gov**.
- m. The point of contact for information regarding this solicitation is Kimberly Golden, OSContracting@cdc.gov. No phone calls please.

SECTION B – SCHEDULE OF SUPPLIES/SERVICES

B.1 Itemized Breakdown of Pharmaceutical Supplies for Base Year: 30 Sep 2022 – 29 Sep 2023

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3); 42 U.S.C. § 247d-6b(d)					
Grand Total					

In accordance with FAR 52.217-6, Option for Increased Quantity, the Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within *15 days*. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

B.2. Delivery Schedule

B.3.A. Below is a delivery schedule template for all periods (Base). Offerors shall update this with their proposed delivery schedule and quantities (see example below).

Period of Performance: Sep 30, 2022 through Sep 29, 2023

CLIN	Product Description	Unit of Measure	Oct 22	Nov 23	Dec 23	Jan 23	Feb 23	Mar 23	April 23	May 23	June 23	July 23	Aug 23	Sep 23
0001	Doxycycline hyclate 100 mg 20 ct. Oral Tablets	(EA)												
0002	Doxycycline hyclate 100 mg 100 ct. Oral Tablets	(EA)												
0003	Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules	(EA)												
0004	Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules	(EA)												

B.3.B. Offerors shall provide a breakout detailing the "ramp" timeframe(s) for the optional quantities, required to manufacture and deliver additional quantities. Example Language: Offeror requires a 30-day period, from time of option exercise to ramp production and delivery to XX tablets/capsules per month. At 60 days, production can increase to XX tablets/capsules per month, etc.

SECTION C - CONTRACT CLAUSES

This solicitation is to be competed against the 651B- Drugs, Pharmaceuticals & Hematology VA NAC, Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. All clauses from the winning vendor(s) applicable GSA schedule contract will be applicable to this award.

Additional Contract Clauses and Instructions:

C.1 HHS Acquisition Regulations (HHSAR)

This contract incorporates one or more HHSAR clauses by reference, with the same force and effect as if they were given in full text. The full text of a clause may be accessed electronically at this/these address(es):

<http://www.hhs.gov/>

<https://www.acquisition.gov/hhsar>

HHSAR SOURCE	TITLE AND DATE
352.203-70	Anti-Lobbying (Dec 2015)
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)
352.227-70	Publications and Publicity (Dec 2015)
353.208-70	Printing and Duplication (Dec 2015)
352.224-70	Privacy Act (Dec 2015)
352.233-71	Litigation and Claims (Dec 2015)
352.237-74	Non-Discrimination in Service Delivery (Dec 2015)
352.239-74	Electronic and Information Technology Accessibility (Dec 2015)

C.2 Inspection and acceptance under this contract will be in accordance with FAR 52.212-4 Contract Terms and Conditions - Commercial Items (May 2015).

C.3 FAR 52.217-6 Option for Increased Quantity (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of Clause)

C.4 FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 15 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

C.5 CONTRACTING OFFICER'S REPRESENTATIVE(COR) APPOINTMENT AND AUTHORITY

Performance of work under this contract is subject to the technical direction of the COR or a representative designated by the contracting officer in writing. The term "technical direction" includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, and/or fills in details and otherwise serves to ensure that tasks outlined in the contract are accomplished satisfactorily. Technical direction must be within the scope of the contract specification(s)/work statement.

The COR does not have authority to issue technical direction that: (a) Constitutes additional work outside the contract specification(s) /work statement; (b) Constitutes a change as defined in the "Changes" clause of this contract; (c) Causes an increase or decrease in the contract price, or the time required for contract performance interferes with the contractor's right to perform under the terms and conditions of the contract; or (d) Directs, supervises or otherwise controls the actions of the contractor's employees.

Technical direction may be oral or in writing. The COR must confirm oral direction in writing within five workdays, with a copy to the contracting officer. The contractor shall proceed promptly with performance resulting from the technical direction issued by the COR, if the opinion of the contractor, any direction of the COR or the designated representative falls within the limitations above, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government workday. Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.6 CONTRACTOR PUBLICITY

The Contractor, or any entity or representative acting on behalf of the Contractor, may not refer to the equipment or services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer. Should any reference to such equipment or services appear in any news release or commercial advertising issued by or on behalf of the Contractor without the required consent, the Government will consider institution of all remedies available under the contract and applicable law.in the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.7 INVOICE SUBMISSION

The Department of Health and Human Services has amended the Department's Federal Acquisition Regulation Supplement, the HHS Acquisition Regulation (HHSAR), to support the HHS Electronic Invoicing Implementation Project and HHS's transition to the Department of the Treasury's Invoice Processing Platform (IPP). This complies with Office of Management and Budget (OMB) memorandum M-15-19, Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing, issued on July 17, 2015.

If your company is already registered to use IPP, you will not be required to re-register. Once your contract is transitioned to IPP, your company shall submit invoices for all open and new contracts via the IPP Invoicing Platform.

Your company will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

HHS and the Department of Treasury will enroll your company into IPP. Your company must follow the IPP registration email instructions to register for the Collector Account to be able to submit invoice requests for payment. Your business point of contact as listed in SAM will receive the registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the implementation of IPP. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov.

To request assistance with enrollment, please contact the IPP Production Helpdesk via email IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

INVOICE CLAUSE

HHSAR 352.232-71 Electronic submission of payment requests (Feb 2022)

(a) *Definitions.* As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(e) Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

Statement of Work

Title: Doxycycline hyclate 100 mg tablets & Amoxicillin trihydrate 500 mg capsules

D.1 Background

The Strategic National Stockpile (SNS) is responsible for federal stockpiling and deploying pharmaceuticals, equipment and medical supplies needed during a public health response. During a public health emergency, these supplies of medications and equipment are used to treat or prevent illness may need to be distributed and dispensed to people throughout the country. Currently, distribution and dispensing/administration of pharmaceuticals and supplies/equipment from the SNS relies on the public health system (state and local health departments). SNS in collaboration with ASPR is looking to optimize distribution of SNS pharmaceuticals and supplies/equipment specifically for a pandemic emergency.

The United States Government (USG) across multiple agencies, holds antibiotics intended for use as post-exposure prophylaxis (PEP) for persons suspected of being exposed to aerosolized *Bacillus anthracis* (anthrax) or other disease conditions. These antibiotics may be provided at the time of a suspected event or prior to an event to protect the general public, protect first responders, provide for Continuity of Operations/Continuity of Government (COOP/COG) for select persons, or for other purposes. Operationally, to assure the efficiency of a PEP campaign, the USG plans to provide antibiotics in several formulations and packages as described in this Statement of Work (SOW).

D.2 Purpose/Objective

The United State Government (USG) is interested in establishing award(s) for the purchase of FDA approved Doxycycline hyclate 100 mg Oral Tablets and Amoxicillin trihydrate 500 mg Oral Capsules, in the specified bottle counts noted in D.4. The USG's current plan to provide for oral prophylaxis for a suspected anthrax event relies on the dispensing of antibiotics in two stages.

1. First, the USG these products to be dispensed as a "10-day unit of use" package.
2. Second, the government follows an initial 10-day supply to potentially affected persons with a longer-term supply expected to continue treatment up to an additional 50 days.

D.3 Scope of Work

The government has a need for these drugs in varied configurations. The USG holds product in strict conformance to standards set forth in 21 Code of Federal Regulations (CFR). The Contractor, as an independent organization and not as an agent of the Government, shall procure and furnish all labor, materials, supplies, facilities, equipment, transportation and travel necessary to deliver the acceptable Pharmaceuticals within the prescribed timeframe to the specified location.

D.4 Product Requirements

The products to be acquired under this contract are FDA approved:

1. Doxycycline hyclate 100 mg 20 ct. Oral Tablets
2. Doxycycline hyclate 100 mg 100 ct. Oral Tablets
3. Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules

4. Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules

D.4.1 Product requirements:

1. The medication produced and delivered under this contract must be FDA approved and shall be manufactured in accordance with the conditions approved by the FDA under appropriate patents for the medication.
2. All products shall have storage requirements of controlled room temperature conditions at 15° - 30°Celsius.
3. Offerors shall use the same lot number for both 20 and 100 count bottles (1:1 ratio) for doxycycline tablets. Offerors shall use the same lot number for both 60 and 100 count packs (1:3 ratio) for amoxicillin capsules.
4. Offerors shall maximize the quantity of product of any lot # thus providing the fewest quantity of Lot numbers per contracted amount per contract year for each product.
5. Supplies shall conform to all current FDA regulations at the time of delivery.
6. Manufacturing Lot Size: Offerors shall provide the minimum and maximum lot size for each product proposed.
7. Delivery Schedule: Offerors shall provide a delivery schedule and production timeline to meet CLIN quantity requirements from time of award.

D 4.1.2 Minimum Labeling/Packaging Marking Requirements:

ASPR/DSNS's required bottle labeling includes the following:

1. Product shall be user-friendly. End user must be able to open packaging with ease to access medication. Child-resistant bottles are required.
2. Package inserts are required and can either be affixed to each individual bottle or can supply the equivalent quantity of loose/non-affixed in the master product case.
3. Each bottle must include an RX or unique identifier number on the label plus two pull-off sticker labels that include the drug name, strength, quantity per bottle, NDC number, lot number, and an RX or unique identifier number.
4. The RX or unique identifier number must be specific to each bottle.
5. The two pull-off sticker labels must be affixed to each bottle or on separate larger sticker sheets included inside each packing box.
6. If the separate larger sticker sheets are used, there must be two pull-off sticker labels with the information that corresponds with each bottle included in a packing box. All product and case labels shall require prior approval by ASPR/SNS
7. RX or unique identifier number listed in 1. and 2. above shall be a serialization with unique product code complying with the Drug Supply Chain Security Act (DSCSA).

D.5 Type of Contract

The anticipated contract shall be Firm-Fixed Price.

D.6 Contract Period of Performance:

The period of performance shall be for a single base year:

- Base QTY Sep 30, 2022 –Sep 29, 2023

D.7 Shelf-Life Requirements

It is anticipated that at time of delivery, product under this requirement shall have no less than:

Product	Minimum Acceptable Shelf Life
(b)(3):42 U.S.C. § 247d-6b(d)	

The current Good Manufacturing Practice regulations (cGMP's) (21CFR Parts 210-211) shall be the standard to be applied for manufacturing, processing, and packing of drugs. Product to be packaged while ensuring long-term stability shelf life of product and assuring product quality in accordance with 21 CFR.

D.8 Quality Control Inspections

The Government reserves the right to inspect any contractor or subcontractor facility used for the manufacture, packaging, storage, transportation, or any other handling of products ordered as a result of this solicitation without prior notice. These inspections do not replace any required inspections conducted by the FDA but are in addition to such inspections. The contractor shall be required to respond to any finding(s) resultant from these inspections with remediation plans or an explanation of why no remediation is required.

D.9 Good Manufacturing Practice regulations (cGMP) and licensures

The current Good Manufacturing Practice regulations (cGMP's) 21CFR Parts 210-211 shall be the standard to be applied for manufacturing, processing, and packing of drugs. The medications produced and delivered under this contract shall be FDA licensed and approved and shall be manufactured in accordance with all Federal, State, and local regulations, laws, and statutes. The Contractor shall provide the New Drug Application (NDA) # or (Abbreviated New Drug Application) ANDA # for all product. Contractors shall include all product literature and specifications for all proposed products. Medications delivered under this contract shall be Trade Agreement Act (TAA) compliant.

The Contractor shall advise the Contracting Officer (CO) and the Contracting Officer's Representative (COR) immediately of any proposed or actual relocation of the prime manufacturing facility or the relocation of any subcontractor's facility. If at any time during the life of the contract, the products listed under this contract fails to meet cGMP's and/or a negative FDA Quality Assurance Evaluation is received, the USG may reevaluate continuing the contract with the Offeror.

D.6 Deliverables

Deliverable	Format/Deliver to	Date
Kick-Off Meeting Notes Should contain a detailed overview of the discussion.	Electronic copy of Kick-Off Meeting Notes – COR	Within 5 days of meeting being held
Delivery Documents	Scan and email to COR/POC	2 Business Days Prior to Delivery
Packing Slips	Scan and email to COR/POC	48 hours after delivery
Final Report	Summary of all deliveries under performance of this contract.	Within 5 business days from final delivery or end of contract, whichever comes first.
Contractor delivery schedule	Scan and email to COR/POC	Must be included in the proposal submission.

D.7 Delivery Location & Transportation:

1. Delivery location and schedule will be provided by the Contracting Officer's Representative after award.
2. Delivery locations will be SNS locations within the CONUS. Exact locations will be provided after award due to the sensitive nature of these sites. Final delivery schedule will be defined at time of award and based upon Offeror's capabilities.

SECTION E - INSTRUCTIONS, CONDITIONS, AND NOTICES TO BIDDERS

E.1 SUBMISSION INSTRUCTIONS

Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (FEB 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. The offerors cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov>.

(End of Provision)

E.2 FAR 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a firm fixed price contract resulting from this solicitation. (End of Provision)

E.3 ADDENDUM TO FAR 52.212-1- INSTRUCTIONS TO OFFERORS- COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (NOV 2021)

1. Offerors are invited to submit a proposal in response to this solicitation. Vendors shall provide a delivery schedule, capability details to provide the product on your current VA federal supply schedule or provide a timeline of when the product can be added to the VA schedule, and pricing. All proposals received shall become part of the official file. The proposal shall be signed by an official authorized to bind your organization. The Offeror's transmittal and cover letter for the proposal shall also contain the name, phone number, and email address of the individual to be contacted concerning any matter related to the quote.
2. Offerors shall submit one electronic version of your proposal documents (in PDF) via email to OSContracting@cdc.gov. In the subject line of your response, include in title: RFO 75A503322Q0018 Doxycycline/ Amoxicillin.
3. Any questions or inquiries regarding solicitation shall be addressed via email to OSContracting@cdc.gov. In the subject line of your question, include in title: RFQ Questions Doxycycline tab/ Amoxicillin cap solicitation. All questions must be received within the specified question and answer period to be considered. The Government may or may not respond to any questions received at its discretion.
4. The Government may accept any item or group of items of an offer, unless the Offeror qualifies the offer by specific limitations. The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit prices offered. If there is a correlation between quantity purchased and price offered, then it is the offeror's responsibility to make that clear in its proposal.

5. The Government shall not pay any cost for the preparation and submission of a proposal. All communications concerning this project prior to the award of a contract under this solicitation shall be with the Contract Specialist or Contracting Officer.
6. Proposals "received" means that the submission is in the Government's designated email inbox by the stated deadline. Please note that there may be delays in receiving these electronic submissions through the USG email server system. Please allow for this potential delay. Accordingly, we encourage you to submit your proposal at least an hour before deadline. Furthermore, there may be file size limitations on the Government's email server. Please be prepared to adjust accordingly. Proposals and supporting documentation shall be e-mailed directly to OSContracting@cdc.gov no later than September 6, 2022 at 2pm EST.
7. All proposal parts (Technical Proposal and Business Quote) shall begin with a Cover Page to include, at a minimum, offerors name, FSS Contract No., DUNS#, Point of Contact, RFQ #, RFQ Title, identification of proposal parts, and offeror's address.
8. Evaluation of Contractor Performance Utilizing CPARS
Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on Anniversary dates Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final. Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions. Electronic Access to Contractor Performance Evaluations Contractors may access evaluations through a secure Web site for review and comment at the following address: <http://www.cpars.gov>.

Provide the current CPARS representative information below.

PRINT OR TYPE NAME

EMAIL ADDRESS AND

E.4 TECHNICAL PROPOSAL CONTENT

1. In order for the technical proposal to be evaluated strictly on the merit of the material, **NO PRICE INFORMATION IS TO BE INCLUDED** in the **TECHNICAL PROPOSAL**. The technical proposal shall be no more than 10 pages in length, excluding product literature/information documents.
2. Each page is to be numbered and labeled with the name of the offeror in the header or footer.
3. **TECHNICAL PROPOSAL MUST INCLUDE THE FOLLOWING INFORMATION:** The name of company, NDC, Unit of Measure (UoM), Eaches Per UOM, Organization Type-Manufacturer or Authorized Reseller, Shelf Life, Earliest Delivery Date, Business Size. You must complete (Attachment 1) to include a proposed delivery schedule and ramp-up information.

F.5 TECHNICAL EVALUATION CRITERIA

The Government will perform evaluations based on the offeror's response to the solicitation, as described in Section D, and in accordance with the Evaluation Factors for award as described in this section. The Government will conduct the evaluation based on the proposal being considered the best value to the ASPR/DSNS through the following Evaluation factors listed in descending order and will be evaluated on how it meets the requirements outlined in the SOW.

The following criteria are in descending order of importance.

FACTOR 1-TECHNICAL CAPABILITY

Subfactor 1: Manufacturer/Product

- a. Offerors shall be the manufacturer/or an authorized reseller.
- b. If offeror is a reseller, offeror shall provide the name of the original product manufacturer and the location(s) of the manufacturer for each product, from which the contractor would supply the Government with product.
- c. Offerors must provide FDA Approved products.
- d. Offerors must provide current DEA License Information.
- e. Product must be an exact match for the dosage, quantity, and form (bottles) requirements found in Section D.7.
- f. Proposed product must meet all packaging and other requirements specified in D.4.
- g. Storage conditions shall meet or exceed all label requirements for products identified in this SOW.

Subfactor 2: Production Schedule

Offerors shall provide:

- a. A detailed delivery schedule of the drugs that can be provided in accordance with Section. Offerors shall provide a delivery schedule, capability details to provide the product on its current VA federal supply schedule, or provide a timeline of when the product can be added to the VA schedule.
- b. Provide monthly manufacturing & delivery capabilities, as well as ramp-up capabilities for product at D.7 (See Attachment 1) .

Subfactor 3: Shelf Life

- a. Offerors shall provide the products shelf-life at time of delivery. The Government's overall best value determination will consider the cost of the product as it relates to the shelf-life at time of delivery and the best value determination will also consider the time, effort, and cost to sustain product with lesser shelf-life.
- b. Offerors shall provide the expected remaining shelf-life for product at time of delivery.
- c. The vendor should be able to meet or exceed the shelf-life requirements found in Section D. above.
- d. Sufficient documentation to support the claim is required.
- e. Failure to provide such will result in a technically unacceptable proposal.

Subfactor 4: Label Requirement

- a. Provide details of foldout design.
- b. Provide sample of Label in accordance D. 4.1.2.

FACTOR 2: Past Performance:

The Offeror shall provide a description of at least two (2) projects performed within the past three years that clearly demonstrates the Offeror's experience in performing manufacturing projects of similar scope, size and complexity to the requirements described in the statement of work (SOW). The following information shall be provided for each project reference:

- a. Contract number, customer/agency name and contract title;
- b. Brief narrative description of the work performed for each of those contracts, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the request for proposal (RFQ) and a discussion of any problems encountered/corrective actions and significant accomplishments;
- c. Dollar value, contract type, period of performance, and the quantity and types of product delivered in the performance of the contract;
- d. Demonstrated experience related to subfactors 1-3.

E.6 BUSINESS PROPOSAL INSTRUCTIONS

The Business Proposal shall be comprised of the following elements:

- (a) Contract Form and Representation and Certifications

The Schedule of Supplies/Services found in Section B, and the Representations and Certifications found in (Appendix A) FAR 52.212-3 of this Request for Quote must be executed by an official authorized to bind the offeror.

(b) Business Quote Cover Sheet

- The cover sheet of your Business Quote must contain the following information (as applicable): Solicitation number; FSS Schedule Number, etc.
- Name and address of offeror;
- Name and telephone number of points of contact;
- Name, address, and telephone number of Cognizant Contract Administration Office; Name, address, and telephone number of Cognizant Audit Office;
- Proposed price per year and total for all years, if applicable.
- [Complete Attachment B pg. 6, sign 1449 pg. 1](#)

FACTOR 3: PRICE EVALUATION

The government must evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' Quotes offer the best value to the agency. Risk of excessive pricing is a major concern and Offerors are advised to pay special attention to the instructions related to pricing. The government reserves the right to reject any Quotes that, in its opinion, does not offer fair and reasonable prices.

E.7 INCURRING COSTS

This solicitation does not commit the Government to pay any cost for the preparation and submission of a Quote. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

(End of Provision)

E.8 52.216-32 Task-Order and Delivery-Order Ombudsman (Sept 2019)

a. In accordance with [41 U.S.C. 4106\(g\)](#), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task-order and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of orders, consistent with the procedures in the contract.

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Acquisition Program Oversight
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- b. Consulting an ombudsman does not alter or postpone the timeline for any other process (e.g., protests).
- c. Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested by the Contractor, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

E.9 . BASIS FOR AWARD

- a. This is a best value acquisition conducted in accordance with Federal Acquisition Regulation (FAR) 12.301(b)(2); the Government intends to select the best overall offer, based upon an integrated assessment of Technical and Business Proposals.
- b. The Contract will be awarded to the offeror who is deemed responsible in accordance with the FAR, whose quote conforms to the solicitation's requirements (to include all stated terms, conditions, representations, certifications, and all other information required by Section E of this solicitation); and is judged by an overall assessment of the evaluation factors and subfactors to be most advantageous to the Government.
- c. As part of making the assessment, an analysis to determine whether or not exceeding the minimum requirements at an associated price premium provides the best value to the Government will be performed if necessary. Technical proposals determined to be "Technically Unacceptable" will not be considered for award.
- d. The government reserves the right to make multiple awards.

Appendix A

Complete 1449 & Fill-In Docs

Volume A will consist of the completed and signed RFQ with a cover letter delineating any assumptions regarding the RFQ terms and conditions with accompanying rationale. However, offerors are cautioned that any noncompliance with the terms and conditions of the RFQ may cause their proposal to be determined unacceptable and therefore not eligible for award.

Any fill-in areas must be completed and returned within Volume 1 (e.g., Certifications and Representations, CPARS).

Appendix A.1 **PAST PERFORMANCE QUESTIONNAIRE (Complete Questionnaire) (REMOVED IN ITS ENTIRETY)**

APPENDIX A.2

52.212-3 Offeror Representations and Certifications—Commercial Items (Jun 2020)

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically in the System for Award Management (SAM) accessed through <https://www.sam.gov>. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (v) of this provision. (See attachment 2)

<https://www.acquisition.gov/content/52212-3alternate-i>

OFFEROR REPRESENTATIONS AND CERTIFICATIONS—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (MAY 2022)

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically in the System for Award Management (SAM) accessed through <https://www.sam.gov>. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (v) of this provision.

(a) *Definitions.* As used in this provision—

"Covered telecommunications equipment or services" has the meaning provided in the clause [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business eligible under the WOSB Program.

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

Inverted domestic corporation, means a foreign incorporated entity that meets the definition of an inverted domestic corporation under [6 U.S.C. 395\(b\)](#), applied in accordance with the rules and definitions of [6 U.S.C. 395\(c\)](#).

Manufactured end product means any end product in product and service codes (PSCs) 1000-9999, except—

- (1) PSC 5510, Lumber and Related Basic Wood Materials;
- (2) Product or Service Group (PSG) 87, Agricultural Supplies;
- (3) PSG 88, Live Animals;
- (4) PSG 89, Subsistence;
- (5) PSC 9410, Crude Grades of Plant Materials;
- (6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;
- (7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;
- (8) PSC 9610, Ores;
- (9) PSC 9620, Minerals, Natural and Synthetic; and
- (10) PSC 9630, Additive Metal Materials.

Place of manufacture means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

Reasonable inquiry has the meaning provided in the clause [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

Restricted business operations means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

- (1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;
- (2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended."Sensitive technology"—

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

Service-disabled veteran-owned small business concern—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in [38 U.S.C. 101](#)(2), with a disability that is service connected, as defined in [38 U.S.C. 101](#)(16).

Small business concern—

(1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and size standards in this solicitation.

(2) *Affiliates*, as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

Small disadvantaged business concern, consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Subsidiary means an entity in which more than 50 percent of the entity is owned—

(1) Directly by a parent corporation; or

(2) Through another subsidiary of a parent corporation

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term "successor" does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

Veteran-owned small business concern means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

Women-owned business concern means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women

Women-owned small business concern means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)

(1) *Annual Representations and Certifications.* Any changes provided by the Offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications in SAM.

(2) The offeror has completed the annual representations and certifications electronically in SAM accessed through <http://www.sam.gov>. After reviewing SAM information, the Offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications-Commercial Products and Commercial Services, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard(s) applicable to the NAICS code(s) referenced for this solicitation), at the time this offer is submitted and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs _____.

[Offeror to identify the applicable paragraphs at (c) through (v) of this provision that the offeror has completed for the purposes of this solicitation only, if any.

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted electronically in SAM.]

(c) Offerors must complete the following representations when the resulting contract is for supplies to be delivered or services to be performed in the United States or its outlying areas, or when the contracting officer has applied [part 19](#) in accordance with [19.000\(b\)\(1\)\(ii\)](#). Check all that apply.

(1) *Small business concern.* The offeror represents as part of its offer that it ☐s, ☐s not a small business concern.

(2) *Veteran-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it ☐s, ☐s not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern.* [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.] The offeror represents as part of its offer that it ☐s, ☐s not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, that it ☐s, ☐s not a small disadvantaged business concern as defined in 13 CFR124.1002.

(5) *Women-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it ☐s, ☐s not a women-owned small business concern.

(6) WOSB concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(5) of this provision.] The offeror represents that-

(i) It ☐s, ☐s not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐s, ☐s not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(6)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(7) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a WOSB concern eligible under the WOSB Program in (c)(6) of this provision.] The offeror represents that-

(i) It ☐ is, ☐ is not an EDWOSB concern, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(7)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. *[The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.]* Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

Note: Complete paragraphs (c)(8) and (c)(9) only if this solicitation is expected to exceed the simplified acquisition threshold.

(8) *Women-owned business concern (other than small business concern).* *[Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents that it ☐ is a women-owned business concern.

(9) *Tie bid priority for labor surplus area concerns.* If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:_____

(10) *HUBZone small business concern.* *[Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents, as part of its offer, that-

(i) It ☐ is, ☐ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It ☐ is, ☐ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. *[The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.]* Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order 11246-

(1) Previous contracts and compliance. The offeror represents that-

(i) It ☐has, ☐has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It ☐has, ☐has not filed all required compliance reports.

(2) *Affirmative Action Compliance.* The offeror represents that-

(i) It ☐has developed and has on file, ☐has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or

(ii) It ☐has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions* (31 <http://uscode.house.gov/> U.S.C. 1352). (Applies only if the contract is expected to exceed \$150,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(f) *Buy American Certificate.* (Applies only if the clause at Federal Acquisition Regulation (FAR) [52.225-1](#), Buy American-Supplies, is included in this solicitation.)

(1)

(i) The Offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product.

(ii) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(iii) The terms "domestic end product," "end product," "foreign end product," and "United States" are defined in the clause of this solicitation entitled "Buy American-Supplies."

(2) Foreign End Products:

[List as necessary]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR [part 25](#).

(g)

(1) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate*. (Applies only if the clause at FAR [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act, is included in this solicitation.)

(i)

(A) The Offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (iii) of this provision, is a domestic end product.

(B) The terms "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "Israeli end product," and "United States" are defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act."

(ii) The Offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act."

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

[List as necessary]

(iii) The Offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act." The Offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

Other Foreign End Products:

[List as necessary]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR [part 25](#).

(2) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate 1.* If Alternate 1 to the clause at FAR [52.225-3](#) is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Canadian End Products:

[List as necessary]

(3) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate II.* If Alternate II to the clause at FAR [52.225-3](#) is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Canadian or Israeli End Products:

[List as necessary]

(4) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate III.* If Alternate III to the clause at [52.225-3](#) is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act":

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

[List as necessary]

(5) *Trade Agreements Certificate.* (Applies only if the clause at FAR [52.225-5](#), Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(5)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

[List as necessary]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR [part 25](#). For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer

determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) *Certification Regarding Responsibility Matters (Executive Order 12689)*. (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals–

(1) ☐Are, ☒are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) ☐Have, ☒have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(3) ☐Are, ☒are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses enumerated in paragraph (h)(2) of this clause; and

(4) ☐Have, ☒have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds the threshold at 9.104-5(a)(2) for which the liability remains unsatisfied.

(i) Taxes are considered delinquent if both of the following criteria apply:

(A) *The tax liability is finally determined.* The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(B) *The taxpayer is delinquent in making payment.* A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(ii) *Examples.*

(A) The taxpayer has received a statutory notice of deficiency, under I.R.C. §6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court

review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(B) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. §6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(C) The taxpayer has entered into an installment agreement pursuant to I.R.C. §6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(D) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. §362 (the Bankruptcy Code).

(i) Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126). [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at [22.1503\(b\)](#).]

(1) Listed end products.

(2) Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]

(i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

(ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j) *Place of manufacture.* (Does not apply unless the solicitation is predominantly for the acquisition of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly-

(1) ☒ In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or

(2) ☐ Outside the United States.

(k) *Certificates regarding exemptions from the application of the Service Contract Labor Standards* (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services.) [The contracting officer is to check a box to indicate if paragraph (k)(1) or (k)(2) applies.]

(1) Maintenance, calibration, or repair of certain equipment as described in FAR [22.1003-4\(c\)\(1\)](#). The offeror ☒ does ☐ does not certify that-

(i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR [22.1003-4\(c\)\(2\)\(ii\)](#)) for the maintenance, calibration, or repair of such equipment; and

(iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

(2) Certain services as described in FAR [22.1003-4\(d\)\(1\)](#). The offeror ☒ does ☐ does not certify that-

(i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of

an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR [22.1003-4\(d\)\(2\)\(iii\)](#));

(iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and

(iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.

(3) If paragraph (k)(1) or (k)(2) of this clause applies-

(i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

(ii) The Contracting Officer may not make an award to the offeror if the offeror fails to execute the certification in paragraph (k)(1) or (k)(2) of this clause or to contact the Contracting Officer as required in paragraph (k)(3)(i) of this clause.

(l) *Taxpayer Identification Number (TIN)* ([26 U.S.C. 6109](#), [31 U.S.C. 7701](#)). (Not applicable if the offeror is required to provide this information to the SAM to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (l)(3) through (l)(5) of this provision to comply with debt collection requirements of [31 U.S.C. 7701\(c\) and 3325\(d\)](#), reporting requirements of [26 U.S.C. 6041, 6041A, and 6050M](#), and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government ([31 U.S.C. 7701\(c\)\(3\)](#)). If the resulting contract is subject to the payment reporting requirements described in FAR [4.904](#), the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) *Taxpayer Identification Number (TIN)*.

TIN: _____.

TIN has been applied for.

TIN is not required because:

Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

Offeror is an agency or instrumentality of a foreign government;

Offeror is an agency or instrumentality of the Federal Government.

(4) Type of organization.

Sole proprietorship;

Partnership;

Corporate entity (not tax-exempt);

Corporate entity (tax-exempt);

Government entity (Federal, State, or local);

Foreign government;

International organization per 26 CFR1.6049-4;

Other _____.

(5) Common parent.

Offeror is not owned or controlled by a common parent;

Name and TIN of common parent:

Name _____.

TIN _____.

(m) *Restricted business operations in Sudan.* By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(n) *Prohibition on Contracting with Inverted Domestic Corporations.*

(1) Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of an inverted domestic corporation, unless the exception at [9.108-2\(b\)](#) applies or the requirement is waived in accordance with the procedures at [9.108-4](#).

(2) *Representation*. The Offeror represents that-

(i) It ☐s, ☐s not an inverted domestic corporation; and

(ii) It ☐s, ☐s not a subsidiary of an inverted domestic corporation.

(o) Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.

(1) The offeror shall e-mail questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(2) *Representation and Certifications*. Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror-

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds the threshold at FAR [25.703-2\(a\)\(2\)](#) with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (et seq.) (see OFAC's Specially Designated Nationals and Blocked Persons List at <https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx>).

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if-

(i) This solicitation includes a trade agreements certification (e.g., [52.212-3](#)(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products.

(p) *Ownership or Control of Offeror.* (Applies in all solicitations when there is a requirement to be registered in SAM or a requirement to have a unique entity identifier in the solicitation).

(1) The Offeror represents that it ☐has or ☐does not have an immediate owner. If the Offeror has more than one immediate owner (such as a joint venture), then the Offeror shall respond to paragraph (2) and if applicable, paragraph (3) of this provision for each participant in the joint venture.

(2) If the Offeror indicates "has" in paragraph (p)(1) of this provision, enter the following information:

Immediate owner CAGE code: _____.

Immediate owner legal name: _____.

(Do not use a "doing business as" name)

Is the immediate owner owned or controlled by another entity: ☒Yes or ☐No.

(3) If the Offeror indicates "yes" in paragraph (p)(2) of this provision, indicating that the immediate owner is owned or controlled by another entity, then enter the following information:

Highest-level owner CAGE code: _____.

Highest-level owner legal name: _____.

(Do not use a "doing business as" name)

(q) *Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law.*

(1) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, The Government will not enter into a contract with any corporation that–

(i) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not

being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(ii) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(2) The Offeror represents that-

(i) It is ☐ is not ☒ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and

(ii) It is ☐ is not ☒ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(r) *Predecessor of Offeror.* (Applies in all solicitations that include the provision at [52.204-16](#), Commercial and Government Entity Code Reporting.)

(1) The Offeror represents that it ☐ is or ☒ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(2) If the Offeror has indicated "is" in paragraph (r)(1) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: (or mark "Unknown").

Predecessor legal name:_____.

(Do not use a "doing business as" name).

(s) [Reserved].

(t) *Public Disclosure of Greenhouse Gas Emissions and Reduction Goals.* Applies in all solicitations that require offerors to register in SAM ([12.301\(d\)\(1\)](#)).

(1) This representation shall be completed if the Offeror received \$7.5 million or more in contract awards in the prior Federal fiscal year. The representation is optional if the Offeror received less than \$7.5 million in Federal contract awards in the prior Federal fiscal year.

(2) Representation. [Offeror to check applicable block(s) in paragraph (t)(2)(i) and (ii)].

(i) The Offeror (itself or through its immediate owner or highest-level owner) ☒ does, ☐ does not publicly disclose greenhouse gas emissions, i.e., makes available on a publicly accessible website the results of a greenhouse gas inventory, performed in accordance with an accounting standard with publicly available and consistently applied criteria, such as the Greenhouse Gas Protocol Corporate Standard.

(ii) The Offeror (itself or through its immediate owner or highest-level owner) ☒ does, ☐ does not publicly disclose a quantitative greenhouse gas emissions reduction goal, i.e., make available on a publicly accessible website a target to reduce absolute emissions or emissions intensity by a specific quantity or percentage.

(iii) A publicly accessible website includes the Offeror's own website or a recognized, third-party greenhouse gas emissions reporting program.

(3) If the Offeror checked "does" in paragraphs (t)(2)(i) or (t)(2)(ii) of this provision, respectively, the Offeror shall provide the publicly accessible website(s) where greenhouse gas emissions and/or reduction goals are reported:_____.

(u)

(1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(2) The prohibition in paragraph (u)(1) of this provision does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(3) *Representation.* By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or

subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(v) *Covered Telecommunications Equipment or Services-Representation.* Section 889(a)(1)(A) and section 889 (a)(1)(B) of Public Law 115-232.

(1) The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(2) The Offeror represents that-

(i) It ☐ does, ☐ does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(ii) After conducting a reasonable inquiry for purposes of this representation, that it ☐ does, ☐ does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

(End of Provision)

Alternate I (Oct2014). As prescribed in [12.301](#)(b)(2), add the following paragraph (c)(11) to the basic provision:

(11) (Complete if the offeror has represented itself as disadvantaged in paragraph (c)(4) of this provision.)

___ Black American.

___ Hispanic American.

___ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

___ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, Republic of Palau, Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

___ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

___ Individual/concern, other than one of the preceding.

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NUMBER		PAGE OF 1 38	
2. CONTRACT NO.		3. AWARD/ EFFECTIVE DATE		4. ORDER NUMBER		5. SOLICITATION NUMBER 75A50122Q00018	
						6. SOLICITATION ISSUE DATE 08/12/2022	
7. FOR SOLICITATION INFORMATION CALL:		a. NAME KIMBERLY GOLDEN			b. TELEPHONE NUMBER (No collect calls)		8. OFFER DUE DATE/LOCAL TIME 08/31/2022 1400 ET
9. ISSUED BY ASPR/SNS ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341				CODE ASPR/SNS 10. THIS ACQUISITION IS UNRESTRICTED OR <input checked="" type="checkbox"/> SET ASIDE: % FOR: <input checked="" type="checkbox"/> SMALL BUSINESS WOMEN-OWNED SMALL BUSINESS HUBZONE SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SERVICE-DISABLED SMALL BUSINESS PROGRAM NAICS: 325412 VETERAN-OWNED EDWOSB 8(A) SIZE STANDARD: 1,250 SMALL BUSINESS			
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED SEE SCHEDULE		12. DISCOUNT TERMS		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING	
						14. METHOD OF SOLICITATION <input checked="" type="checkbox"/> RFQ <input type="checkbox"/> IFB <input type="checkbox"/> RFP	
15. DELIVER TO CODE				16. ADMINISTERED BY CODE ASPR/SNS US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341			
17a. CONTRACTOR/ OFFEROR CODE		FACILITY CODE		18a. PAYMENT WILL BE MADE BY CODE			
TELEPHONE NO.							
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED SEE ADDENDUM			
19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES			21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), intends to issue a delivery order for Amoxicillin trihydrate 500 MG and Doxycycline Hyclate 100 MG in configurations of (tablets ad capsules, 20ct, 60ct, and 100ct) under the FSS VA/Schedule VA Federal Supply Schedule (FSS) Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & <i>(Use Reverse and/or Attach Additional Sheets as Necessary)</i>						
25. ACCOUNTING AND APPROPRIATION DATA						26. TOTAL AWARD AMOUNT (For Govt. Use Only)	
X 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ARE <input checked="" type="checkbox"/> ARE NOT ATTACHED. 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ARE <input type="checkbox"/> ARE NOT ATTACHED.							
X 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.				29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:			
30a. SIGNATURE OF OFFEROR/CONTRACTOR				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)			
30b. NAME AND TITLE OF SIGNER (Type or print)		30c. DATE SIGNED		31b. NAME OF CONTRACTING OFFICER (Type or print)		31c. DATE SIGNED	
				KIMBERLY L. GOLDEN			

19. ITEM NO	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	over-the-counter drugs Period of Performance: 09/30/2022 to 09/29/2027 Performance is anticipated to begin September 30, 2022 for a period of 5 years. Period of Performance: 09/30/2022 to 09/29/2027				

32a. QUANTITY IN COLUMN 21 HAS BEEN

RECEIVED

INSPECTED

ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
			32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	37. CHECK NUMBER
PARTIAL FINAL			COMPLETE PARTIAL FINAL	
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY (<i>Print</i>)		
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER		42b. RECEIVED AT (<i>Location</i>)		
		42c. DATE REC'D (YY/MM/DD)		42d. TOTAL CONTAINERS

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VA Federal Supply Schedule (FSS) Delivery Order Purchase
Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood
products, & over-the-counter drugs

- a. This is a Delivery Order (DO) awarded under FAR Part 8, VA Federal Supply Schedule (FSS) and is subject to the terms and conditions contained therein as well as in this DO.
- b. The solicitation number is 75A50122Q00018 and is being issued as a request for proposal.
- c. This acquisition is a small business set-aside. The North American Industry Classification System (NAICS) code is 325412.
- d. The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), intends to purchase doxycycline hyclate and amoxicillin trihydrate. The Government intends to evaluate offers and award a contract without discussions. However, the Government may, in its sole discretion, elect to conduct discussions if determined to be in the best interest of the Government.
- e. Performance is anticipated to begin September 30, 2022. The period of performance is for a period of 60 months.
- f. Offerors shall include a completed copy of FAR 52.212-3, Offeror Representations and Certifications-Commercial Items (Appendix A), with its offer. (Note, if offerors are registered within the System for Award Management (SAM) and certs and reps are up to date, make a statement to that effect in accordance with this clause).

- j. This solicitation is to be competed on the VA NAC, Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. All clauses from the winning vendor(s) applicable GSA schedule contract will be applicable to this award. Additional clauses and instructions are included in Section C below.
- k. **Offers are due no later than August 31, 2022 on or before 2:00 PM Eastern Time** by e-mail to the **Subject Line RFP 75A50122Q00018** attention of Contracting Officer, Kimberly Golden at: **OSContracting@cdc.gov**. The offeror's **complete** proposal (including all information required to be submitted as part of the offeror's;
- Volume A - Completed 1449 & Fill-In Docs,
 - Volume B -Technical Proposal,
 - Volume C - Price/Business Proposal,
- l. **Questions are due August 17, 2022 on or before 5:00 PM Eastern Time** by e-mail: **Subject Line QUESTIONS: RFP 75A50122Q00018** to the attention of Contracting Officer, Kimberly Golden at: **OSContracting@cdc.gov**.
- m. The point of contact for information regarding this combined synopsis/solicitation is Kimberly Golden, OSContracting@cdc.gov. No phone calls please.

SECTION B – SCHEDULE OF SUPPLIES/SERVICES

B.1 Itemized Breakdown of Pharmaceutical Supplies for Base Year: 30 Sep 2022 – 29 Sep 2023

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3); 42 U.S.C. § 247d-6b(d)					
Grand Total					

B.2 Itemized Breakdown of Pharmaceutical Supplies for Option Year 1: 30 Sep 2023 – 29 Sep 2024 (OPTIONAL)

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3); 42 U.S.C. § 247d-6b(d)					
Grand Total					

B.3 Itemized Breakdown of Pharmaceutical Supplies for Option Year 2: 30 Sep 2023 – 29 Sep 2024 (OPTIONAL)

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3)-42 U.S.C. § 247d-6b(d)					
Grand Total					

B.4 Itemized Breakdown of Pharmaceutical Supplies for Option Year 3: 30 Sep 2025 – 29 Sep 2026

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3)-42 U.S.C. § 247d-6b(d)					
Grand Total					

B.5 Itemized Breakdown of Pharmaceutical Supplies for Option Year 4: 30 Sep 2026 – 29 Sep 2027

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
------	---------------------	-----------------	----------	------------	-------------

(b)(3):42 U.S.C. § 247d-6b(d)

	Grand Total	
--	-------------	--

B.6 (B.1 – B.5 Quantity)

Quantities listed in CLINs B.1 – B.5 are maximum quantities to be procured based yearly (based on fiscal year funding). The quantities listed in B.1 – B.5 are in specific quantity ratios of 1 bottle of Doxycycline hyclate 100mg 20 ct. to 1 bottle of Doxycycline hyclate 100 mg 100 ct. Oral Tablets. The Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules are to be in a 1 bottle to 3 bottles ratio to the Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules. Therefore, the actual quantities ordered will always maintain the same ratios between bottle count sizes, even if the Government does not order maximum amount(s).

B.7 Option for Increased Quantity – Separately Priced Line Items

The Government may require the delivery of the numbered line items, identified in the schedule in Section B.2 – B.5 as option items, in incremental quantities at the price stated in the award, up to the maximum quantity identified for each numbered line item, in accordance with FAR 52.217-7 Option for Increased Quantity– Separately Priced Line Items found in Section D.4. Each option line item may be exercised more than once, until the cumulative number of units to be delivered under each option is delivered. The Contractor shall not be required to make any deliveries under this contract beyond six (6) months following the end of the ordering period. The total units hereunder shall not exceed the respective line-item unit maximums over the 5-year ordering period, unless changed by formal modification to the contract.

The Contracting Officer shall exercise the option by written notice to the Contractor. The Contractor shall be notified in writing, by letter or email, at least thirty (30) days before the option to acquire more product is exercised. After that written notification, a funded, unilateral modification shall be issued to formally exercise the option and order items contained within this SOW

The Government may exercise option CLINs for only part of the quantity or may choose not to exercise optional CLINs at all if no additional product is required during that portion of the contract.

B.8 Increased Quantity Limitations

In response to a natural disaster or other unpredictable public health event, the Government may have a need to seek additional product beyond what is contemplated above.

In accordance with FAR 52.217-6, Option for Increased Quantity, the Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within *15 days*. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

B.9. Delivery Schedule

B.9.A. Below is a delivery schedule template for CLINs 0001 - 0004. Offerors shall update this with their proposed delivery schedule and quantities.

Period of Performance: Sep 30, 2022 through Sep 29, 2023

CLIN	Product Description	Unit of Measure	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	April 24	May 24	June 24	July 24	Aug 24	Sep 24
(b)(3)-42 U.S.C. § 247d-6b(d)														

B.9.B. Offerors shall provide a breakout detailing the "ramp" timeframe(s) for the optional quantities, required to manufacture and deliver additional quantities. Example Language: Offeror requires a 30-day period, from time of option exercise to ramp production and delivery to XX tablets/capsules per month. At 60 days, production can increase to XX tablets/capsules per month, etc.

SECTION C - CONTRACT CLAUSES

This solicitation is to be competed against the VA NAC, Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. All clauses from the winning vendor(s) applicable GSA schedule contract will be applicable to this award.

Additional Contract Clauses and Instructions:

C.1 HHS Acquisition Regulations (HHSAR)

This contract incorporates one or more HHSAR clauses by reference, with the same force and effect as if they were given in full text. The full text of a clause may be accessed electronically at this/these address(es):

<http://www.hhs.gov/>

<https://www.acquisition.gov/hhsar>

HHSAR SOURCE	TITLE AND DATE
352.203-70	Anti-Lobbying (Dec 2015)
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)
352.227-70	Publications and Publicity (Dec 2015)
353.208-70	Printing and Duplication (Dec 2015)
352.224-70	Privacy Act (Dec 2015)
352.233-71	Litigation and Claims (Dec 2015)
352.237-74	Non-Discrimination in Service Delivery (Dec 2015)
352.239-74	Electronic and Information Technology Accessibility (Dec 2015)

C.2 Inspection and acceptance under this contract will be in accordance with FAR 52.212-4 Contract Terms and Conditions - Commercial Items (May 2015).

C.3 FAR 52.217-6 Option for Increased Quantity (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of Clause)

C.4 FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of expiration of the contract

C.5 FAR 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of expiration of the contract.

(End of Clause)

C.6 CONTRACTING OFFICER'S REPRESENTATIVE(COR) APPOINTMENT AND AUTHORITY

Performance of work under this contract is subject to the technical direction of the COR or a representative designated by the contracting officer in writing. The term "technical direction" includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, and/or fills in details and otherwise serves to ensure that tasks outlined in the contract are accomplished satisfactorily. Technical direction must be within the scope of the contract specification(s)/work statement.

The COR does not have authority to issue technical direction that: (a) Constitutes additional work outside the contract specification(s) /work statement; (b) Constitutes a change as defined in the "Changes" clause of this contract; (c) Causes an increase or decrease in the contract price, or the time required for contract performance interferes with the contractor's right to perform under the terms and conditions of the contract; or (d) Directs, supervises or otherwise controls the actions of the contractor's employees.

Technical direction may be oral or in writing. The COR must confirm oral direction in writing within five workdays, with a copy to the contracting officer. The contractor shall proceed promptly with performance resulting from the technical direction issued by the COR, if the opinion of the contractor, any direction of the COR or the designated representative falls within the limitations above, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government workday. Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.7 CONTRACTOR PUBLICITY

The Contractor, or any entity or representative acting on behalf of the Contractor, may not refer to the equipment or services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer. Should any reference to such equipment or services appear in any news release or commercial advertising issued by or on behalf of the Contractor without the required consent, the Government will consider institution of all remedies available under the contract and applicable law. in the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.8 INVOICE SUBMISSION

The Department of Health and Human Services has amended the Department's Federal Acquisition Regulation Supplement, the HHS Acquisition Regulation (HHSAR), to support the HHS Electronic Invoicing Implementation Project and HHS's transition to the Department of the Treasury's Invoice Processing Platform (IPP). This complies with Office of Management and Budget (OMB) memorandum M-15-19, Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing, issued on July 17, 2015.

If your company is already registered to use IPP, you will not be required to re-register. Once your contract is transitioned to IPP, your company shall submit invoices for all open and new contracts via the IPP Invoicing Platform.

Your company will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

HHS and the Department of Treasury will enroll your company into IPP. Your company must follow the IPP registration email instructions to register for the Collector Account to be able to submit invoice requests for payment. Your business point of contact as listed in SAM will receive the registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the implementation of IPP. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov.

To request assistance with enrollment, please contact the IPP Production Helpdesk via email IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

INVOICE CLAUSE

HHSAR 352.232-71 Electronic submission of payment requests (Feb 2022)

(a) *Definitions.* As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

SECTION D - CONTRACT DOCUMENTS, EXHIBITS OR ATTACHMENTS

Statement of Work

Title: Doxycycline hyclate 100 mg tablets & Amoxicillin trihydrate 500 mg capsules

D.1 Background

The Strategic National Stockpile (SNS) is responsible for federal stockpiling and deploying pharmaceuticals, equipment and medical supplies needed during a public health response. During a public health emergency, these supplies of medications and equipment are used to treat or prevent illness may need to be distributed and dispensed to people throughout the country. Currently, distribution and dispensing/administration of pharmaceuticals and supplies/equipment from the SNS relies on the public health system (state and local health departments). SNS in collaboration with ASPR is looking to optimize distribution of SNS pharmaceuticals and supplies/equipment specifically for a pandemic emergency.

The United States Government (USG) across multiple agencies, holds antibiotics intended for use as post-exposure prophylaxis (PEP) for persons suspected of being exposed to aerosolized *Bacillus anthracis* (anthrax) or other disease conditions. These antibiotics may be provided at the time of a suspected event or prior to an event to protect the general public, protect first responders, provide for Continuity of Operations/Continuity of Government (COOP/COG) for select persons, or for other purposes. Operationally, to assure the efficiency of a PEP campaign, the USG plans to provide antibiotics in several formulations and packages as described in this Statement of Work (SOW).

D.2 Purpose/Objective

The United State Government (USG) is interested in establishing award(s) for the purchase of FDA approved Doxycycline hyclate 100 mg Oral Tablets and Amoxicillin trihydrate 500 mg Oral Capsules, in the specified bottle counts noted in D.4. The USG's current plan to provide for oral prophylaxis for a suspected anthrax event relies on the dispensing of antibiotics in two stages.

1. First, the USG these products to be dispensed as a "10-day unit of use" package.
2. Second, the government follows an initial 10-day supply to potentially affected persons with a longer-term supply expected to continue treatment up to an additional 50 days.

D.3 Scope of Work

The government has a need for these drugs in varied configurations. The USG holds product in strict conformance to standards set forth in 21 Code of Federal Regulations (CFR). The Contractor, as an independent organization and not as an agent of the Government, shall procure and furnish all labor, materials, supplies, facilities, equipment, transportation and travel necessary to deliver the acceptable Pharmaceuticals within the prescribed timeframe to the specified location.

D.4 Product Requirements

The products to be acquired under this contract are FDA approved:

1. Doxycycline hyclate 100 mg 20 ct. Oral Tablets

2. Doxycycline hyclate 100 mg 100 ct. Oral Tablets
3. Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules
4. Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules

D.4.1 Product requirements:

1. The medication produced and delivered under this contract must be FDA approved and shall be manufactured in accordance with the conditions approved by the FDA under appropriate patents for the medication.
2. All products shall have storage requirements of controlled room temperature conditions at 15° - 30°Celsius.
3. Offerors shall use the same lot number for both 20 and 100 count bottles (1:1 ratio) for doxycycline tablets. Offerors shall use the same lot number for both 60 and 100 count packs (1:3 ratio) for amoxicillin capsules.
4. Offerors shall maximize the quantity of product of any lot # thus providing the fewest quantity of Lot numbers per contracted amount per contract year for each product.
5. Supplies shall conform to all current FDA regulations at the time of delivery.
6. Manufacturing Lot Size: Offerors shall provide the minimum and maximum lot size for each product proposed.
7. Delivery Schedule: Offerors shall provide a delivery schedule and production timeline to meet CLIN quantity requirements from time of award.

D 4.1.2 Minimum Labeling/Packaging Marking Requirements:

ASPR/DSNS's required bottle labeling includes the following:

1. Product shall be user-friendly. End user must be able to open packaging with ease to access medication. Child-resistant bottles are required.
2. Products must include a foldout providing specific directions for use of the product. Design of how foldout will be incorporated must be described. Must cover the following:
3. Package inserts and Patient Instruction Leaflets are required and can either be affixed to each individual bottle or can supply the equivalent quantity of loose/non-affixed in the master product case.
4. Each bottle must include an RX or unique identifier number on the label plus two pull-off sticker labels that include the drug name, strength, quantity per bottle, NDC number, lot number, and an RX or unique identifier number.
5. The RX or unique identifier number must be specific to each bottle.
6. The two pull-off sticker labels must be affixed to each bottle or on separate larger sticker sheets included inside each packing box.
7. If the separate larger sticker sheets are used, there must be two pull-off sticker labels with the information that corresponds with each bottle included in a packing box. All product and case labels shall require prior approval by ASPR/SNS
8. RX or unique identifier number listed in 1. and 2. above shall be a serialization with unique product code complying with the Drug Supply Chain Security Act (DSCSA).

D.5 Type of Contract

The anticipated contract shall be Firm-Fixed Price.

D.6 Contract Period of Performance:

The period of performance shall be a base year and four one-year options:

- Base QTY Sep 30, 2022 –Sep 29, 2023
- Optional QTY Sep 30, 2022- Sep 29, 2027

D.7 Shelf-Life Requirements

It is anticipated that at time of delivery, product under this requirement shall have no less than:

Product	Minimum Acceptable Shelf Life
(b)(3):42 U.S.C. § 247d-6b(d)	

The current Good Manufacturing Practice regulations (cGMP's) (21CFR Parts 210-211) shall be the standard to be applied for manufacturing, processing, and packing of drugs. Product to be packaged while ensuring long-term stability shelf life of product and assuring product quality in accordance with 21 CFR.

D.8 Quality Control Inspections

The Government reserves the right to inspect any contractor or subcontractor facility used for the manufacture, packaging, storage, transportation, or any other handling of products ordered as a result of this solicitation without prior notice. These inspections do not replace any required inspections conducted by the FDA but are in addition to such inspections. The contractor shall be required to respond to any finding(s) resultant from these inspections with remediation plans or an explanation of why no remediation is required.

D.9 Good Manufacturing Practice regulations (cGMP) and licensures

The current Good Manufacturing Practice regulations (cGMP's) 21CFR Parts 210-211 shall be the standard to be applied for manufacturing, processing, and packing of drugs. The medications produced and delivered under this contract shall be FDA licensed and approved and shall be manufactured in accordance with all Federal, State, and local regulations, laws, and statutes. The Contractor shall provide the New Drug Application (NDA) # or (Abbreviated New Drug Application) ANDA # for all product. Contractors shall include all product literature and specifications for all proposed products. Medications delivered under this contract shall be Trade Agreement Act (TAA) compliant.

The Contractor shall advise the Contracting Officer (CO) and the Contracting Officer's Representative (COR) immediately of any proposed or actual relocation of the prime manufacturing facility or the relocation of any subcontractor's facility. If at any time during the life of the contract, the products listed under this contract fails to meet cGMP's and/or a negative FDA Quality Assurance Evaluation is received, the USG may reevaluate continuing the contract with the Offeror.

D.10 Deliverables

Deliverable	Format/Deliver to	Date
Kick-Off Meeting Notes Should contain a detailed overview of the discussion.	Electronic copy of Kick-Off Meeting Notes – COR	Within 5 days of meeting being held
Delivery Documents	Scan and email to COR/POC	2 Business Days Prior to Delivery
Packing Slips	Scan and email to COR/POC	48 hours after delivery
Final Report	Summary of all deliveries under performance of this contract.	Within 5 business days from final delivery or end of contract, whichever comes first.
Contractor delivery schedule	Scan and email to COR/POC	Must be included in the proposal submission.

D.11 Delivery Location & Transportation:

1. Delivery location and schedule will be provided by the Contracting Officer's Representative after award.
2. Delivery locations will be SNS locations within the CONUS. Exact locations will be provided after award due to the sensitive nature of these sites. Final delivery schedule will be defined at time of award and based upon Offeror's capabilities.

SECTION E - INSTRUCTIONS, CONDITIONS, AND NOTICES TO BIDDERS

E.1 SUBMISSION INSTRUCTIONS

Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (FEB 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. The offerors cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov>.

(End of Provision)

E.2 FAR 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a firm fixed price contract resulting from this solicitation. (End of Provision)

E.3 ADDENDUM TO FAR 52.212-1- INSTRUCTIONS TO OFFERORS- COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (NOV 2021)

1. Offerors are invited to submit a proposal in response to this solicitation. All proposals received shall become part of the official file. The proposal shall be signed by an official authorized to bind your organization. The Offeror's transmittal and cover letter for the proposal shall also contain the name, phone number, and email address of the individual to be contacted concerning any matter related to the quote.
2. Offerors shall submit one electronic version of your proposal documents (in PDF) via email to OSContracting@cdc.gov. In the subject line of your response, include in title: RFP 75A503322Q0018 Doxycycline/ Amoxicillin.
3. Any questions or inquiries regarding solicitation shall be addressed via email to OSContracting@cdc.gov. In the subject line of your question, include in title: RFP Questions Doxycycline tab/ Amoxicillin cap solicitation. All questions must be received within the specified question and answer period to be considered. The Government may or may not respond to any questions received at its discretion.
4. The Government may accept any item or group of items of an offer, unless the Offeror qualifies the offer by specific limitations. The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit prices offered. If there is a correlation between quantity purchased and price offered, then it is the offeror's responsibility to make that clear in its proposal.

5. The Government shall not pay any cost for the preparation and submission of a proposal. All communications concerning this project prior to the award of a contract under this solicitation shall be with the Contract Specialist or Contracting Officer.
6. Proposals "received" means that the submission is in the Government's designated email inbox by the stated deadline. Please note that there may be delays in receiving these electronic submissions through the USG email server system. Please allow for this potential delay. Accordingly, we encourage you to submit your proposal at least an hour before deadline. Furthermore, there may be file size limitations on the Government's email server. Please be prepared to adjust accordingly. Proposals and supporting documentation shall be e-mailed directly to OSContracting@cdc.gov no later than Wednesday, August 31st, 2022 at 3pm EST.
7. All proposal parts (Technical Proposal and Business Quote) shall begin with a Cover Page to include, at a minimum, offerors name, FSS Contract No., DUNS#, Point of Contact, RFP #, RFP Title, identification of proposal parts, and offeror's address.
8. Evaluation of Contractor Performance Utilizing CPARS

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on Anniversary dates Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final. Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions. Electronic Access to Contractor Performance Evaluations Contractors may access evaluations through a secure Web site for review and comment at the following address:
<http://www.cpars.gov>.

Provide the current CPARS representative information below.

 PRINT OR TYPE NAME

 EMAIL ADDRESS AND

E.4 TECHNICAL PROPOSAL CONTENT

1. In order for the technical proposal to be evaluated strictly on the merit of the material, **NO PRICE INFORMATION IS TO BE INCLUDED** in the **TECHNICAL PROPOSAL**. The technical proposal shall be no more than 10 pages in length, excluding product literature/information documents.
2. Each page is to be numbered and labeled with the name of the offeror in the header or footer.
3. **TECHNICAL PROPOSAL MUST INCLUDE THE FOLLOWING INFORMATION:** The name of company, NDC, Unit of Measure (UoM), Eaches Per UOM, Organization Type- Manufacturer or Authorized Reseller? Shelf Life, Earliest Delivery Date, Business Size. You must complete (Attachment 1) to include a proposed delivery schedule and ramp-up information.

E.5 TECHNICAL EVALUATION CRITERIA

The Government will perform evaluations based on the offeror's response to the solicitation, as described in Section D, and in accordance with the Evaluation Factors for award as described in this section. The Government will conduct the evaluation based on the proposal being considered the best value to the ASPR/DSNS through the following Evaluation factors listed in descending order and will be evaluated on how it meets the requirements outlined in the SOW.

The following criteria are in descending order of importance.

FACTOR 1-TECHNICAL CAPABILITY

Subfactor 1: Manufacturer/Product

- a. Offerors shall be the manufacturer/or an authorized reseller.
- b. If offeror is a reseller, offeror shall provide the name of the original product manufacturer and the location(s) of the manufacturer for each product, from which the contractor would supply the Government with product.
- c. Offerors must provide FDA Approved products.
- d. Offerors must provide current DEA License Information.
- e. Product must be an exact match for the dosage, quantity, and form (capsule or tablet) requirements found in Section D.7.
- f. Proposed product must meet all packaging and other requirements specified in D.4.
- g. Storage conditions shall meet or exceed all label requirements for products identified in this SOW.

Subfactor 2: Production Schedule

Offerors shall provide:

- a. A detailed delivery schedule of the drugs that can be provided in accordance with Section D.7
- b. Provide monthly manufacturing & delivery capabilities, as well as ramp-up capabilities for product at D.7 (See Attachment 1) .

Subfactor 3: Shelf Life

- a. Offerors shall provide the products shelf-life at time of delivery. The Government's overall best value determination will consider the cost of the product as it relates to the shelf-life at time of delivery and the best value determination will also consider the time, effort, and cost to sustain product with lesser shelf-life.
- b. Offerors shall provide the expected remaining shelf-life for product at time of delivery.
- c. The vendor should be able to meet or exceed the shelf-life requirements found in Section D. above.
- d. Sufficient documentation to support the claim is required.
- e. Failure to provide such will result in a technically unacceptable proposal.

Subfactor 4: Label Requirement

- a. Provide details of foldout design.
- b. Provide sample of Label in accordance D. 4.1.2.

FACTOR 2: Past Performance:

The Offeror shall provide a description of at least two (2) projects performed within the past three years that clearly demonstrates the Offeror's experience in performing manufacturing projects of similar scope, size and complexity to the requirements described in the statement of work (SOW). The following information shall be provided for each project reference:

- a. Contract number, customer/agency name and contract title;
- b. Brief narrative description of the work performed for each of those contracts, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the request for proposal (RFP) and a discussion of any problems encountered/corrective actions and significant accomplishments;
- c. Dollar value, contract type, period of performance, and the quantity and types of product delivered in the performance of the contract;
- d. Demonstrated experience related to subfactors 1-3.

E.6 BUSINESS PROPOSAL INSTRUCTIONS

The Business Proposal shall be comprised of the following elements:

- (a) Contract Form and Representation and Certifications

The Schedule of Supplies/Services found in Section B, and the Representations and Certifications found in (Appendix A) FAR 52.212-3 of this Request for Quote must be executed by an official authorized to bind the offeror.

This acquisition is subject to the requirements of FAR Subpart 19.7 (The Small Business Subcontracting Program). A Subcontracting Plan shall be submitted by offerors who are large business concerns only. Offerors must comply with FAR 52.219-9 Small Business Subcontracting Plan (Nov. 2022) (See Appendix A).

The HHS current subcontracting goal is 33.25% for Small Business (hereafter referred to as SB), 5.00% for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), 5.00% for Women-Owned Small Business and Economically Disadvantaged. Offerors shall provide past experience in meeting proposed subcontracting goals along with processes that have been implemented to correct inabilities to meet subcontracting goals will also be evaluated. Past performance in meeting or exceeding SB subcontracting goals shall be demonstrated utilizing copies of Electronic Subcontracting Reporting System (eSRS) reports. Offerors shall include most recent eSRS reports covering the last three (3) years.

The eSRS reports shall include contracts of similar size and scope to this requirement. In order to be considered for award the "successful offeror", SHALL have a subcontracting plan that comply with HHS Agency subcontracting goals for each socioeconomic category in order to receive award. If the apparent successful offeror fails to negotiate a subcontracting plan acceptable to the contracting officer within 30 days or the time limit prescribed by the contracting officer, the offeror will be ineligible for award.

(b) Business Quote Cover Sheet

- The cover sheet of your Business Quote must contain the following information (as applicable): Solicitation number; FSS Schedule Number, etc.
- Name and address of offeror;
- Name and telephone number of points of contact;
- Name, address, and telephone number of Cognizant Contract Administration Office; Name, address, and telephone number of Cognizant Audit Office;
- Proposed price per year and total for all years, if applicable.
- A breakdown of the end product demonstrating that the cost of domestic components is 100% of the cost of all the components.
- Complete Attachment B

FACTOR 3: PRICE EVALUATION

The government must evaluate each Offeror's prices to determine that those prices are fair and reasonable and to determine which Offerors' Quotes offer the best value to the agency. Risk of excessive pricing is a major concern and Offerors are advised to pay special attention to the instructions related to pricing. The government reserves the right to reject any Quotes that, in its opinion, does not offer fair and reasonable prices.

- (a) Options. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may

determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

- (b) A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

(End of provision)

E.7 INCURRING COSTS

This solicitation does not commit the Government to pay any cost for the preparation and submission of a Quote. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

(End of Provision)

E.8 52.216-32 Task-Order and Delivery-Order Ombudsman (Sept 2019)

- a. In accordance with 41 U.S.C. 4106(g), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task-order and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of orders, consistent with the procedures in the contract.

Steven Green
Acquisition Program Oversight
MFHC\DAAPPO
HHS\ASPR
steven.green@hhs.gov

- b. Consulting an ombudsman does not alter or postpone the timeline for any other process (e.g., protests).
- c. Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested by the Contractor, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

E.9 . BASIS FOR AWARD

- a. This is a best value acquisition conducted in accordance with Federal Acquisition Regulation (FAR) 12.301(b)(2); the Government intends to select the best overall offer, based upon an integrated assessment of Technical and Business Proposals.
- b. The Contract will be awarded to the offeror who is deemed responsible in accordance with the FAR, whose quote conforms to the solicitation's requirements (to include all stated terms, conditions, representations, certifications, and all other

information required by Section E of this solicitation); and is judged by an overall assessment of the evaluation factors and subfactors to be most advantageous to the Government.

- c. As part of making the assessment, an analysis to determine whether or not exceeding the minimum requirements at an associated price premium provides the best value to the Government will be performed if necessary. Technical proposals determined to be **“Technically Unacceptable”** will not be considered for award.
- d. The government reserves the right to make multiple awards.

Appendix A

Complete 1449 & Fill-In Docs

Volume A will consist of the completed and signed RFP with a cover letter delineating any assumptions regarding the RFP terms and conditions with accompanying rationale. However, offerors are cautioned that any noncompliance with the terms and conditions of the RFP may cause their proposal to be determined unacceptable and therefore not eligible for award.

Any fill-in areas must be completed and returned within Volume 1 (e.g., Certifications and Representations, CPARS, Subcontracting Plan information, if applicable).

Appendix A.1

PAST PERFORMANCE QUESTIONNAIRE (Complete Questionnaire)

PAST PERFORMANCE QUESTIONNAIRE	
1. Contractor Name and Address:	2. Contract Number &/or Task Order Number: 3. Contract or Task Order Value (Base Plus Options): 4. Contract/Task Order Award Date: Contract/Task Order Completion Date: 5. Name of Contracting Entity:
5. Type of Contract: (Check all that apply) <input type="checkbox"/> FP <input type="checkbox"/> FP-EPA <input type="checkbox"/> CPFF-Completion <input type="checkbox"/> CPFF-Term <input type="checkbox"/> CPIF <input type="checkbox"/> CPAF <input type="checkbox"/> ID/IQ <input type="checkbox"/> BOA <input type="checkbox"/> Requirements <input type="checkbox"/> Labor Hour <input type="checkbox"/> T&M <input type="checkbox"/> SBSA 8(a) <input type="checkbox"/> SBIR <input type="checkbox"/> Sealed Bid <input type="checkbox"/> Negotiated <input type="checkbox"/> Competitive <input type="checkbox"/> Non-Competitive <input type="checkbox"/> Other (Specify)	
6. Description of Requirement:	

<p>7. Rep Name: _____ (Individual completing or responding to questionnaire)</p>

Insert a rating for each of the 4 categories in bold. To facilitate a full assessment of the contractor's past performance, please include comments as appropriate.

QUALITY OF PRODUCT OR SERVICE _____

[U] Unsatisfactory [P] Poor [F] Fair [G] Good [E] Excellent
--

Examples:

Quality of deliverables and performance.

The contractor performed all tasks as proposed.

Comments:

COST/VALUE CONTROL _____

[U] Unsatisfactory [P] Poor [F] Fair [G] Good [E] Excellent
--

Examples:

The contractor was effective in forecasting, managing, and controlling contract cost.

The contractor provided accurate and reasonable estimates of cost.

Comments:

TIMELINESS OF PERFORMANCE _____

[U] Unsatisfactory	[P] Poor	[F] Fair	[G] Good	[E] Excellent
--------------------	----------	----------	----------	---------------

Examples:

The contractor adhered to contract delivery schedules.

The contractor responded positively and promptly to technical directions, contract change orders, etc.

Comments:

BUSINESS RELATIONS

[U] Unsatisfactory	[P] Poor	[F] Fair	[G] Good	[E] Excellent
--------------------	----------	----------	----------	---------------

Examples:

The contractor adhered to contract terms to include administrative aspects of performance.

The contractor had a business-like concern for the interest of the customer.

The contractor was reasonable and cooperative in behavior

Comments:

OVERALL RATING

[U] Unsatisfactory	[P] Poor	[F] Fair	[G] Good	[E] Excellent
--------------------	----------	----------	----------	---------------

With respect to capability, quality of service and overall technical performance, I would do business with this contractor again and would recommend them for similar contracts. Yes No If no, explain.

Comments:

APPENDIX A.2

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically in the System for Award Management (SAM) accessed through <https://www.sam.gov>. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (v) of this provision.

<https://www.acquisition.gov/content/52212-3alternate-i>

APPENDIX A.3

HHS SUBCONTRACTING PLAN TEMPLATE

A Subcontracting Plan is required if the estimated cost of the contract **may exceed \$750,000 (\$1,500,000 for construction)** Small businesses are excluded.

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommends that offerors use the following format to submit proposed Individual Subcontracting Plans. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive.

Questions shall be forwarded to the Contracting Officer and/or Small Business Subcontracting Program Manager.

PROJECT INFORMATION					
Solicitation/Contract No.:		MOD No. (if applicable):			
Title of Acquisition:					
Contractor's Name:					
Period of Performance:		Total Contract Amount (including options, and any modifications if this submission is due to a modification): \$			
Total Modification Amount: (if applicable)	\$	Base Period (if there are options):	\$		
Option 1 (if applicable):	\$	Option 2 (if applicable):	\$		
Option 3 (if applicable):	\$	Option 4 (if applicable):	\$		
FAR 52.217-8 (if applicable):	\$				
Contracting Officer/Specialist Name:		Tel & Fax:			
OPDIV/Division/Branch (including location):		Email:			
<p>SUBCONTRACT PLAN REQUIREMENTS- Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.</p> <p>If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/about/smallbusiness/osdbustaff.html) or you may contact the OSDBU headquarters at (202) 690-7300.</p> <p>HHS currently has the following subcontracting goals for Fiscal Year 2022:</p> <table border="1"> <thead> <tr> <th>Type of Concern</th> <th>Goal (%)</th> </tr> </thead> </table>				Type of Concern	Goal (%)
Type of Concern	Goal (%)				

Small Business	26.00%
Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes	5.00%
Women Owned Small Business	5.00%
Service-Disabled Veteran Owned Small Business	3.00%
HUBZone	3.00%

For this procurement, or modification, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages.

1. Type of Plan (check one):	Individual <input type="checkbox"/> *Master (Addendum) <input type="checkbox"/> *Commercial <input type="checkbox"/> <small>*When Master is checked, Individual must also be checked, and submission must include both. *If Commercial is checked, please stop here and attach a copy of your commercial plan.</small>
	For Informational Purposes: Individual plan - all elements developed specifically for this contract and applicable for the full term of this contract. Master plan - goals developed for this contract, all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval. Commercial products/service plan - goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts; this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year.
2. Subcontracting Goal Data: (FAR19.702(a)(1-3) & FAR 52.219-9(d)(1)) Below indicate the dollar and percentage goals for Small Business (SB), Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Women-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Veteran Owned Small Business (VOSB), Service-Disabled Veteran-Owned (SDVOSB) Small Businesses and "Other than Small Business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704. If any contract has more than four options, please attach additional sheets which illustrate dollar amounts and percentages.	
PLEASE NOTE: Zero dollars is not an acceptable goal for the SB, SDB, WOSB, HUBZone, VOSB or SDVOSB categories since this does not demonstrate a good faith effort throughout the period of performance of the contract.	
For Individual Plans complete a(1): (FAR 52.219-9(d)(2)(i)) a(1). Total dollars planned to be subcontracted under this contract is: \$ _____ =2b+2h	% of Total Contract \$ If required by CO For Individual Plan _____ %

<p>If your contract includes options, please include the break down here:</p> <p>Base Period: \$ <input type="text"/> Option Period 3: \$ <input type="text"/></p> <p>Option Period 1: \$ <input type="text"/> Option Period 4: \$ <input type="text"/></p> <p>Option Period 2: \$ <input type="text"/></p>	<p>If options are applicable:</p> <p>Base: <input type="text"/> %</p> <p>OPT 1: <input type="text"/> %</p> <p>OPT 2: <input type="text"/> %</p> <p>OPT 3: <input type="text"/> %</p> <p>OPT 4: <input type="text"/> %</p>
<p>b. Total dollars planned to be subcontracted to small business concerns (including ANC and Indian tribes)- [Percentage of 2a.]: (FAR 52.219-9(d)(2)(ii))</p> <p>\$ <input type="text"/> and <input type="text"/> %</p> <p>If your contract includes options, please include the break down here:</p> <p>Base: \$ <input type="text"/> and <input type="text"/> %</p> <p>OPT 1: \$ <input type="text"/> and <input type="text"/> %</p> <p>2: \$ <input type="text"/> \$ O and <input type="text"/> %</p> <p>OPT 3: \$ <input type="text"/> and <input type="text"/> %</p> <p>4: \$ <input type="text"/> \$ C and <input type="text"/> %</p>	<p><input type="text"/> %</p> <p>If options are applicable:</p> <p>Base: <input type="text"/> %</p> <p>OPT 1: <input type="text"/> %</p> <p>OPT 2: <input type="text"/> %</p> <p>OPT 3: <input type="text"/> %</p> <p>OPT 4: <input type="text"/> %</p>
<p>c. Total dollars planned to be subcontracted to veteran-owned small business concerns- [Percentage of 2.a.]: (FAR 52.219-9(d)(2)(iii))</p> <p>\$ <input type="text"/> and <input type="text"/> %</p> <p>If your contract includes options, please include the break down here:</p> <p>Base: \$ <input type="text"/> and <input type="text"/> %</p> <p>OPT 1: \$ <input type="text"/> and <input type="text"/> %</p> <p>2: \$ <input type="text"/> \$ O and <input type="text"/> %</p> <p>OPT 3: \$ <input type="text"/> and <input type="text"/> %</p> <p>4: \$ <input type="text"/> \$ C and <input type="text"/> %</p>	<p><input type="text"/> %</p> <p>If options are applicable:</p> <p>Base: <input type="text"/> %</p> <p>OPT 1: <input type="text"/> %</p> <p>OPT 2: <input type="text"/> %</p> <p>OPT 3: <input type="text"/> %</p> <p>OPT 4: <input type="text"/> %</p>
<p>d. Total dollars planned to be subcontracted to service-disabled veteran-owned small business - [Percentage of 2.a.]: (FAR 52.219-9(d)(2)(iv))</p> <p>\$ <input type="text"/> and <input type="text"/> %</p>	<p><input type="text"/> %</p>

<p>If your contract includes options, please include the break down here:</p> <p>Base: \$ _____ and _____ %</p> <p>_____ and _____ %</p> <p>OPT 1: \$ _____ and _____ %</p> <p>_____ \$ O and _____ %</p> <p>2: \$ _____ and _____ %</p> <p>OPT 3: \$ _____ and _____ %</p> <p>_____ \$ C and _____ %</p> <p>4: \$ _____</p>	<p>If options are applicable:</p> <p>Base: _____ %</p> <p>OPT 1: _____ %</p> <p>OPT 2: _____ %</p> <p>OPT 3: _____ %</p> <p>OPT 4: _____ %</p>
<p>e. Total dollars planned to be subcontracted to HUBZone small business concerns - [Percentage of 2.a.]: (FAR 52.219-9(d)(2)(v))</p> <p>\$ _____ and _____ %</p> <p>If your contract includes options, please include the break down here:</p> <p>Base: \$ _____ and _____ %</p> <p>_____ and _____ %</p> <p>OPT 1: \$ _____ and _____ %</p> <p>_____ \$ O and _____ %</p> <p>2: \$ _____ and _____ %</p> <p>OPT 3: \$ _____ and _____ %</p> <p>_____ \$ C and _____ %</p> <p>4: \$ _____</p>	<p>_____ %</p> <p>If options are applicable:</p> <p>Base: _____ %</p> <p>OPT 1: _____ %</p> <p>OPT 2: _____ %</p> <p>OPT 3: _____ %</p> <p>OPT 4: _____ %</p>
<p>f. Total dollars planned to be subcontracted to small disadvantaged business concerns (including ANCs and Indian tribes) - [Percentage of 2.a.]: (FAR 52.219-9(d)(2)(vi))</p> <p>\$ _____ and _____ %</p> <p>If your contract includes options, please include the break down here:</p> <p>Base: \$ _____ and _____ %</p> <p>_____ and _____ %</p> <p>OPT 1: \$ _____ and _____ %</p> <p>_____ \$ O and _____ %</p> <p>2: \$ _____ and _____ %</p> <p>OPT 3: \$ _____ and _____ %</p> <p>_____ \$ C and _____ %</p> <p>4: \$ _____</p>	<p>_____ %</p> <p>If options are applicable:</p> <p>Base: _____ %</p> <p>OPT 1: _____ %</p> <p>OPT 2: _____ %</p> <p>OPT 3: _____ %</p> <p>OPT 4: _____ %</p>
<p>g. Total dollars planned to be subcontracted to women-owned small business concerns- [Percentage of 2.a.]: (FAR 52.219-9(d)(2)(vii))</p> <p>\$ _____ and _____ %</p>	<p>_____ %</p>

If your contract includes options, please include the break down here:

Base: \$ _____ and _____ %
 _____ and _____ %
 OPT 1: \$ _____ and _____ %
 _____ and _____ %
 2: \$ _____ and _____ %
 OPT 3: \$ _____ and _____ %
 _____ and _____ %
 4: \$ _____ and _____ %

If options are applicable:

Base: _____ %
 OPT 1: _____ %
 OPT 2: _____ %
 OPT 3: _____ %
 OPT 4: _____ %

h. Total Subcontracting Dollars & Percentage with "Other" than Small Businesses (i.e., large companies, non profits, etc.) [Percentage of 2.a.]: (HHS OSDBU)

\$ _____ and _____ %
 If your contract includes options, please include the break down here:
 Base: \$ _____ and _____ %
 _____ and _____ %
 OPT 1: \$ _____ and _____ %
 _____ and _____ %
 2: \$ _____ and _____ %
 OPT 3: \$ _____ and _____ %
 _____ and _____ %
 4: \$ _____ and _____ %

If options are applicable:

Base: _____ %
 OPT 1: _____ %
 OPT 2: _____ %
 OPT 3: _____ %
 OPT 4: _____ %

i. Subcontracting Opportunities (description of all principal products/services to be subcontracted to all types of concerns listed in 2.b.-2.f.) (FAR 52.219-9(d)(3)):

Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (include all that apply):

Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	VOSB	SDVOSB
1							
2							
3							

4							
5							
6							

j. Please describe the methodology used to develop goals & identify potential sources (e.g. historical trends, information on technical and competitive bidding, formula for calculating goals, etc.) (FAR 52.219-9(d)(4-5)):

k. Indirect costs have ☐ have not ☐ been included in the dollar and percentage subcontracting goals above (check one).

If indirect costs have been included in establishing subcontracting goals, please provide a description of the method used to determine the proportionate share of indirect costs to be incurred with all types of concerns listed in 2.b.-2.f. (FAR 52.219-9(d)(6)):

SUBCONTRACTING PLAN REQUIREMENTS (con't)

3. Please enter the following information for the individual who will administer your Subcontracting Program: (FAR 52.219-9(d)(7))

Name: Title:

Address:

Telephone: Email:

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? ☐yes ☐no

Additionally, please respond whether or not the individual who will administer your subcontracting program conducts the following:

1. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing; ☐yes ☐no
2. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns from all possible sources; ☐yes ☐no
3. Ensuring periodic rotation of potential subcontractors on bidder's lists; ☐yes ☐no
4. Assuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing. ☐yes ☐no
5. Ensuring that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns. ☐yes ☐no

6. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, HUBZone, VOSB and SDVOSB small business participation. ☐yes ☐no
7. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns to include the System for Award Management (<http://sam.gov>), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; ☐yes ☐no
8. Establishing and maintaining contract and subcontract award records; ☐yes ☐no
9. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; ☐yes ☐no
10. Ensuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; ☐yes ☐no
11. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; ☐yes ☐no
12. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; ☐yes ☐no
13. Preparing and submitting timely, required subcontract reports; ☐yes ☐no
14. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures;and ☐yes ☐no
15. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies. ☐yes ☐no

(If **NO** is checked for any of the duties above, please provide who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

Additional duties of the individual: _____

4. Please describe your efforts to ensure that Small Businesses (incl. SDB, WOSB, HUBZone, SDVOSB) have an equitable opportunity to compete for subcontracts: (FAR 52.219-9(d)(8))

These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources: (1) Contact minority and small business trade associations; (2) contact business development organizations and local chambers of commerce; (3) attend SB, SDB, WOSB, HUBZone, VOSB and SDVOSB procurement conferences and trade fairs; (4) review sources from the System for Award Management (<http://www.sam.gov>); (5) review sources from the Small Business Administration (SBA), Dynamic Small Business Search database (DSBS) <http://dsbs.sba.gov/>; (6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (<http://epic.od.nih.gov/>). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and (7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel: (1) Conduct workshops, seminars and training programs; (2) Establish, maintain, and utilize SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides, and other data for soliciting subcontractors; and (3) Monitor activities to evaluate compliance with the subcontracting plan.

Efforts Described: _____

5. Flow Down Clause: (FAR 52.219-9(d)(8))

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of \$700,000 (\$1,500,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c)(2) the contractor is not required to include flow-down clause FAR 52.219-9 if it is subcontracting commercial items.

6. Reporting and Cooperation: (FAR 52.219-9(d)(10)); (FAR 19.704(a)(10))

The contractor gives assurance of 1) cooperation in any studies or surveys that may be required; 2) submission of periodic reports which illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors submission of ISRs and SSRs. ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website

<https://esrs.symplicity.com/index?tab=signin&cck=1>

Please refer to FAR Part 19.7 or contact the Contracting Officer for regulatory reporting requirements and other obligations you are accepting as part of your signing of this document and acceptance of any subsequent contract award that may be granted.

7. Record keeping: (FAR 52.219-9(d)(11))

FAR 52.219-9(d)(11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan.

Contractor acknowledges and agrees to record keeping obligation expressed at FAR 52.219-9(d)(11). yes ☐ no ☐

8. Assurances of Good Faith Effort, and the submission of explanations when failing to acquire as stated in Good Faith Effort: (FAR 52.219-9(d)(12-13))

Contractor hereby makes the following assurances:

(1) that contractor will make a good faith effort to acquire articles, equipment, supplies, services, or materials, or obtain the performance of construction work from the small business concerns that it used in preparing the bid or proposal, in the same or greater scope, amount, and quality used in preparing and submitting the bid or proposal yes ☐ no ☐; and

(2) that the Contractor will provide the Contracting Officer with a written explanation if the Contractor fails to acquire articles, equipment, supplies, services or materials or obtain the performance of construction work within 30 days of contract completion and as required under FAR 19.7. yes ☐ no ☐

9. Assurances that the Contractor will not prohibit a subcontractor from discussing with the Contracting Officer any material matter pertaining to payment to or utilization of a subcontractor: (FAR 52.219-9(d)(14))

Contractor hereby makes the assurance that the Contractor will not prohibit a subcontractor from discussing with the Contracting Officer any material matter pertaining to payment to or utilization of a subcontractor. yes ☐ no ☐

10. Assurances of Timely Payments to Subcontractors: (FAR 52.219-9(d)(15))

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with SB concerns, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns.

Your company has established and use such procedures yes ☐ no ☐. Additionally, Contractor makes an assurance that Contractor will pay its small business subcontractors on time and in accordance with the terms and conditions of the underlying subcontract, and notify the contracting officer when the prime contractor makes either a reduced or an untimely payment to a small business subcontractor yes ☐ no ☐.

Signature Page

1. Contractor makes the following representation: I have reviewed FAR Part 19.704 and FAR Clause 52.219-9, and this Subcontracting Plan is in compliance. yes ☐ no ☐

This Subcontracting Plan was submitted by:

Name:

Title:

Signature:

Address:

Telephone:

Email:

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NUMBER		PAGE OF 1 22	
2. CONTRACT NO.		3. AWARD EFFECTIVE DATE		4. ORDER NUMBER		5. SOLICITATION NUMBER 75A50122Q00018	
7. FOR SOLICITATION INFORMATION CALL:		3. NAME KIMBERLY GOLDEN		6. TELEPHONE NUMBER (No collect calls)		8. OFFER DUE DATE/LOCAL TIME 09/02/2022 1400 ET	
9. ISSUED BY ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341				10. THIS ACQUISITION IS UNRESTRICTED OR <input checked="" type="checkbox"/> SET ASIDE % FOR WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM NAICS 325412 EDWOSB B(A) SIZE STANDARD 1,250			
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED SEE SCHEDULE		12. DISCOUNT TERMS		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING	
15. DELIVER TO		CODE		16. ADMINISTERED BY		CODE ASPR/SNS	
17a. CONTRACTOR OFFEROR		Unique ID: (b)(4)		FACILITY CODE CAGE: (b)(4)		18a. PAYMENT WILL BE MADE BY	
Chartwell RX, LLC 77 Brenner Drive Congers, NY 10920 Rockland County						US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED SEE ADDENDUM			
19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES			21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), intends to issue a delivery order for Amoxicillin trihydrate 500 MG and Doxycycline Hyclate 100 MG in configurations of (20ct, 60ct, and 100ct)EA under the FSS VA/Schedule VA Federal Supply Schedule (FSS) 651B- Drugs, Pharmaceuticals & Hematology 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, over-the-counter drugs. (Use Reverse and/or Attach Additional Sheets as Necessary)						
25. ACCOUNTING AND APPROPRIATION DATA						26. TOTAL AWARD AMOUNT (For Govt Use Only)	
27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED ADDENDA ARE X ARE NOT ATTACHED.						27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4, FAR 52.212-5 IS ATTACHED ADDENDA ARE ARE NOT ATTACHED.	
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.				29. AWARD OF CONTRACT OFFER DATED YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN IS ACCEPTED AS TO ITEMS:			
30a. SIGNATURE OF OFFEROR/CONTRACTOR (b) (6)				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)			
30b. NAME AND TITLE OF SIGNER (Type or print) Jack Goldenberg, Managing Member		30c. DATE SIGNED 9/6/22		31b. NAME OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN		31c. DATE SIGNED	

19. ITEM NO	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Period of Performance: 09/30/2022 to 09/29/2023 Performance is anticipated to begin September 30, 2022 for a period of 12 months. Period of Performance: 09/30/2022 to 09/29/2023				

32a. QUANTITY IN COLUMN 21 HAS BEEN

RECEIVED

INSPECTED

ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
			32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	
PARTIAL FINAL			COMPLETE PARTIAL FINAL	
37. CHECK NUMBER				
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT			42a. RECEIVED BY (Print)	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER		41c. DATE	42b. RECEIVED AT (Location)	
			42c. DATE REC'D (YY/MM/DD)	
			42d. TOTAL CONTAINERS	

Statement of Work

Title: Doxycycline hyclate 100 mg tablets & Amoxicillin trihydrate 500 mg capsules

D.1 Background

The Strategic National Stockpile (SNS) is responsible for federal stockpiling and deploying pharmaceuticals, equipment and medical supplies needed during a public health response. During a public health emergency, these supplies of medications and equipment are used to treat or prevent illness may need to be distributed and dispensed to people throughout the country. Currently, distribution and dispensing/administration of pharmaceuticals and supplies/equipment from the SNS relies on the public health system (state and local health departments). SNS in collaboration with ASPR is looking to optimize distribution of SNS pharmaceuticals and supplies/equipment specifically for a pandemic emergency.

The United States Government (USG) across multiple agencies, holds antibiotics intended for use as post-exposure prophylaxis (PEP) for persons suspected of being exposed to aerosolized *Bacillus anthracis* (anthrax) or other disease conditions. These antibiotics may be provided at the time of a suspected event or prior to an event to protect the general public, protect first responders, provide for Continuity of Operations/Continuity of Government (COOP/COG) for select persons, or for other purposes. Operationally, to assure the efficiency of a PEP campaign, the USG plans to provide antibiotics in several formulations and packages as described in this Statement of Work (SOW).

D.2 Purpose/Objective

The United State Government (USG) is interested in establishing award(s) for the purchase of FDA approved Doxycycline hyclate 100 mg Oral Tablets and Amoxicillin trihydrate 500 mg Oral Capsules, in the specified bottle counts noted in D.4. The USG's current plan to provide for oral prophylaxis for a suspected anthrax event relies on the dispensing of antibiotics in two stages.

1. First, the USG these products to be dispensed as a "10-day unit of use" package.
2. Second, the government follows an initial 10-day supply to potentially affected persons with a longer-term supply expected to continue treatment up to an additional 50 days.

D.3 Scope of Work

The government has a need for these drugs in varied configurations. The USG holds product in strict conformance to standards set forth in 21 Code of Federal Regulations (CFR). The Contractor, as an independent organization and not as an agent of the Government, shall procure and furnish all labor, materials, supplies, facilities, equipment, transportation and travel necessary to deliver the acceptable Pharmaceuticals within the prescribed timeframe to the specified location.

D.4 Product Requirements

The products to be acquired under this contract are FDA approved:

1. Doxycycline hyclate 100 mg 20 ct. Oral Tablets
2. Doxycycline hyclate 100 mg 100 ct. Oral Tablets
3. Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules

4. Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules

D.4.1 Product requirements:

1. The medication produced and delivered under this contract must be FDA approved and shall be manufactured in accordance with the conditions approved by the FDA under appropriate patents for the medication.
2. All products shall have storage requirements of controlled room temperature conditions at 15° - 30°Celsius.
3. Offerors shall use the same lot number for both 20 and 100 count bottles (1:1 ratio) for doxycycline tablets. Offerors shall use the same lot number for both 60 and 100 count packs (1:3 ratio) for amoxicillin capsules.
4. Offerors shall maximize the quantity of product of any lot # thus providing the fewest quantity of Lot numbers per contracted amount per contract year for each product.
5. Supplies shall conform to all current FDA regulations at the time of delivery.
6. Manufacturing Lot Size: Offerors shall provide the minimum and maximum lot size for each product proposed.
7. Delivery Schedule: Offerors shall provide a delivery schedule and production timeline to meet CLIN quantity requirements from time of award.

D 4.1.2 Minimum Labeling/Packaging Marking Requirements:

ASPR/DSNS's required bottle labeling includes the following:

1. Product shall be user-friendly. End user must be able to open packaging with ease to access medication. Child-resistant bottles are required.
2. Package inserts are required and can either be affixed to each individual bottle or can supply the equivalent quantity of loose/non-affixed in the master product case.
3. Each bottle must include an RX or unique identifier number on the label plus two pull-off sticker labels that include the drug name, strength, quantity per bottle, NDC number, lot number, and an RX or unique identifier number.
4. The RX or unique identifier number must be specific to each bottle.
5. The two pull-off sticker labels must be affixed to each bottle or on separate larger sticker sheets included inside each packing box.
6. If the separate larger sticker sheets are used, there must be two pull-off sticker labels with the information that corresponds with each bottle included in a packing box. All product and case labels shall require prior approval by ASPR/SNS
7. RX or unique identifier number listed in 1. and 2. above shall be a serialization with unique product code complying with the Drug Supply Chain Security Act (DSCSA).

D.5 Type of Contract

The anticipated contract shall be Firm-Fixed Price.

D.6 Contract Period of Performance:

The period of performance shall be for a single base year:

- Base QTY Sep 30, 2022 –Sep 29, 2023

D.7 Shelf-Life Requirements

It is anticipated that at time of delivery, product under this requirement shall have no less than:

Product	Minimum Acceptable Shelf Life
(b)(3); 42 U.S.C. § 247d-6b(d)	

The current Good Manufacturing Practice regulations (cGMP's) (21CFR Parts 210-211) shall be the standard to be applied for manufacturing, processing, and packing of drugs. Product to be packaged while ensuring long-term stability shelf life of product and assuring product quality in accordance with 21 CFR.

D.8 Quality Control Inspections

The Government reserves the right to inspect any contractor or subcontractor facility used for the manufacture, packaging, storage, transportation, or any other handling of products ordered as a result of this solicitation without prior notice. These inspections do not replace any required inspections conducted by the FDA but are in addition to such inspections. The contractor shall be required to respond to any finding(s) resultant from these inspections with remediation plans or an explanation of why no remediation is required.

D.9 Good Manufacturing Practice regulations (cGMP) and licensures

The current Good Manufacturing Practice regulations (cGMP's) 21CFR Parts 210-211 shall be the standard to be applied for manufacturing, processing, and packing of drugs. The medications produced and delivered under this contract shall be FDA licensed and approved and shall be manufactured in accordance with all Federal, State, and local regulations, laws, and statutes. The Contractor shall provide the New Drug Application (NDA) # or (Abbreviated New Drug Application) ANDA # for all product. Contractors shall include all product literature and specifications for all proposed products. Medications delivered under this contract shall be Trade Agreement Act (TAA) compliant.

The Contractor shall advise the Contracting Officer (CO) and the Contracting Officer's Representative (COR) immediately of any proposed or actual relocation of the prime manufacturing facility or the relocation of any subcontractor's facility. If at any time during the life of the contract, the products listed under this contract fails to meet cGMP's and/or a negative FDA Quality Assurance Evaluation is received, the USG may reevaluate continuing the contract with the Offeror.

D.6 Deliverables

Deliverable	Format/Deliver to	Date
Kick-Off Meeting Notes Should contain a detailed overview of the discussion.	Electronic copy of Kick-Off Meeting Notes – COR	Within 5 days of meeting being held
Delivery Documents	Scan and email to COR/POC	2 Business Days Prior to Delivery
Packing Slips	Scan and email to COR/POC	48 hours after delivery
Final Report	Summary of all deliveries under performance of this contract.	Within 5 business days from final delivery or end of contract, whichever comes first.
Contractor delivery schedule	Scan and email to COR/POC	Must be included in the proposal submission.

D.7 Delivery Location & Transportation:

1. Delivery location and schedule will be provided by the Contracting Officer's Representative after award.
2. Delivery locations will be SNS locations within the CONUS. Exact locations will be provided after award due to the sensitive nature of these sites. Final delivery schedule will be defined at time of award and based upon Offeror's capabilities.

[illegible]

Project 1	
Contract #	
Customer/Agency Name	
Contract Title	
Contract Type	
Period of Performance	
Value	
Product Name	
Quantity	
Brief narrative description of the work performed, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the request for proposal (RFQ) and a discussion of any problems encountered/corrective actions and significant accomplishments	

Project 2	
Contract #	
Customer/Agency Name	
Contract Title	
Contract Type	
Period of Performance	
Value	
Product Name	
Quantity	
Brief narrative description of the work performed, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the request for proposal (RFQ) and a discussion of any problems encountered/corrective actions and significant accomplishments	

MARKET RESEARCH REPORT

Division of Strategic National Stockpile (DDSNS), the
Administration for Strategic Preparedness and Response (ASPR), the
U. S. Department of Health and Human Services (HHS)

(b)(5)

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

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of the Freedom of Information Act

Withheld pursuant to exemption

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of the Freedom of Information Act

Withheld pursuant to exemption

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of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act



Acquisition Plan (AP) Template

Revised July 2020

(b)(5)

Acquisition Plan (AP) Template

(b)(5)

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

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of the Freedom of Information Act

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of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Company Name	Item No.	Product Description	NDC #	Quantity in Eaches	Unit of Measure (UoM)	Eaches Per UoM	Quantity in UoM	UoM Price per product	Total Cost
(b)(5)									

DELETED ATTACHMENT 2

Company Name	Item No.	Product Description	NDC #	Quantity in Eaches	Unit of Measure (UoM)	Eaches Per UoM	Quantity in UoM	UoM Price per product	Total Cost
(b)(5)									

Total for All Products:

Company Name	Item No.	Product Description	NDC #	Quantity in Eaches	Unit of Measure (UoM)	Eaches Per UoM	Quantity in UoM	UoM Price per product	Total Cost
(b)(5)									

Total for All Products:

Company Name	Item No.	Product Description	NDC #	Quantity in Eaches	Unit of Measure (UoM)	Eaches Per UoM	Quantity in UoM	UoM Price per product	Total Cost
(b)(5)									

Total for All Products:

SPENDING TRANSACTIONS

Company Name	Item No.	Product Description	NDC #	Quantity in Eaches	Unit of Measure (UoM)	Eaches Per UoM	Quantity in UoM	UoM Price per product	Total Cost
(b)(5)									

Total for All Products:

FOR OFFICIAL USE ONLY / SOURCE SELECTION INFORMATION - SEE FAR 2.101, 3.104, AND 42.1503

CONTRACTOR PERFORMANCE ASSESSMENT REPORT (CPAR)

INCOMPLETE-RATED

Nonsystems**Name/Address of Contractor:**

Vendor Name: CHARTWELL RX LLC

Division Name: DLA TROOP SUPPORT

Street: 77 BRENNER DR

City: CONGERS

State: NY Zip: 109201307

Country: USA

CAGE Code: (b)(4)

Unique Entity ID (DUNS): (b)(4) Unique Entity ID (SAM): (b)(4)

Product/Service Code: 6505 Principal NAICS Code: 325411

Evaluation Type: Interim**Contract Percent Complete:****Period of Performance Being Assessed:** 03/19/2021 - 03/18/2022**Contract Number:** SPE2D020D0005 **Business Sector & Sub-Sector:** Nonsystems - Personnel Support**Contracting Office:** DLA TROOP SUPPORT **Contracting Officer:** ROSEMARY ADAMS **Phone Number:** 2157373947**Location of Work:**

77 Brenner Dr

Congers, NY, 10920-1307 ,

UNITED STATES

Date Signed: 03/19/2020 **Period of Performance Start Date:** 03/19/2020**Est. Ultimate Completion Date/Last Date to Order:** 03/18/2030 **Estimated/Actual Completion Date:****Funding Office ID:****Base and All Options Value :** \$7,074,642 **Action Obligation:** \$0**Complexity:** Low **Termination Type:** None**Extent Competed:** Full and Open Competition **Type of Contract:** Fixed Price with Economic Price Adjustment**Key Subcontractors and Effort Performed:****Unique Entity ID (DUNS):** **Unique Entity ID (SAM):****Effort:****Unique Entity ID (DUNS):** **Unique Entity ID (SAM):****Effort:****Unique Entity ID (DUNS):** **Unique Entity ID (SAM):****Effort:****Project Number:****Project Title:**

(b)(3):42 U.S.C. § 247d-6b(d)

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(b)(4); (b)(3):42 U.S.C. § 247d-6b(d)

Small Business Subcontracting:

Does this contract include a subcontracting plan? No

Date of last Individual Subcontracting Report (ISR) / Summary Subcontracting Report (SSR): N/A

Evaluation Areas**Past Rating****Rating**

Quality:

Schedule:

Cost Control:

Management:

Small Business Subcontracting:

Regulatory Compliance:

Other Areas:

(1):

(2):

(3):

(b)(4); (b)(3):42 U.S.C. § 247d-6b(d)

Variance (Contract to Date):

Current Cost Variance (%): Variance at Completion (%):

Current Schedule Variance (%):

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Assessing Official Comments:

(b)(4); (b)(5)

Name and Title of Assessing Official:

Name: Wendy Liang

Title:

Organization: DLA Troop Support

Phone Number: Email Address: wendy.liang@dla.mil

Date: 03/30/2022

Contractor Comments:**Name and Title of Contractor Representative:**

Name:

Title:

Phone Number: Email Address:

Date:

Review by Reviewing Official:

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Name and Title of Reviewing Official:

Name:

Title:

Organization:

Phone Number: Email Address:

Date:

FOR OFFICIAL USE ONLY

Company Name	Business Size	Item No.	Product Description	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Delivery Order Expiry Date: 30 days September 20 2022	Remaining Orders to Deliver Vs. Remanufactured	Actual Months needed to Finish Remanufactured
(b)(3).42 U.S.C. § 247d-6b(d)															

Project 1
Contract #
Customer/Agency Name
Contract Title
Contract Type
Period of Performance
Value
Product Name
Quantity

(b)(4); (b)(3); 42 U.S.C. § 247d-6b(d)

Brief narrative description of the work performed, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the request for proposal (RFQ) and a discussion of any problems encountered/corrective actions and significant accomplishments

July, 2020 - August, 2022

Total Sum of Qty

Total Sum of Amount

(b)(4); (b)(3); 42 U.S.C. § 247d-6b(d)

Project 2
Contract #
Customer/Agency Name
Contract Title
Contract Type
Period of Performance
Value
Product Name
Quantity

(b)(4); (b)(3); 42 U.S.C. § 247d-6b(d)

Brief narrative description of the work performed, including a description of how the previous work demonstrates the Offeror's capacity to successfully meet the requirements described in the request for proposal (RFQ) and a discussion of any problems encountered/corrective actions and significant accomplishments

Purchases to Date

Product Purchased

Bottles

Total Amount of Purchase

(b)(4); (b)(3);42 U.S.C. § 247d-6b(d)



VOLUME A: Completed 1449 and Fill In Docs

(b)(4)



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(b)(4)



VOLUME B: TECHNICAL PROPOSAL

(b)(4)



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VOLUME C: PRICE/BUSINESS PROPOSAL

(b)(4)



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(b)(4)



(b)(4)



(b)(4)



(b)(4)



(b)(4)



(b)(4)



(b)(4)

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS <i>OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30</i>				1. REQUISITION NUMBER OS300788		PAGE OF 1 15	
2. CONTRACT NO. 36F79720D0198		3. AWARD/EFFECTIVE DATE 09/30/2022		4. ORDER NUMBER 75A50322F80030		5. SOLICITATION NUMBER	
6. SOLICITATION ISSUE DATE		7. FOR SOLICITATION INFORMATION CALL:		a. NAME KIMBERLY GOLDEN		b. TELEPHONE NUMBER (No collect calls)	
8. OFFER DUE DATE/LOCAL TIME		9. ISSUED BY ASPR/SNS		CODE ASPR/SNS		10. THIS ACQUISITION IS <input type="checkbox"/> UNRESTRICTED OR <input checked="" type="checkbox"/> SET ASIDE % FOR: <input checked="" type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS <input type="checkbox"/> HUBZONE SMALL BUSINESS <input type="checkbox"/> (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM NAICS 325412 <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS <input type="checkbox"/> EDWOSB <input type="checkbox"/> 8(A) SIZE STANDARD 1,250	
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input checked="" type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) <input type="checkbox"/> 13a		13b. RATING	
15. DELIVER TO ASPR-SNS US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA GA 30341		CODE ASPR-SNS		16. ADMINISTERED BY US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341		14. METHOD OF SOLICITATION <input type="checkbox"/> RFO <input type="checkbox"/> IFB <input type="checkbox"/> RFP	
17a. CONTRACTOR/OFFEROR CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194 77 BRENNER DR CONGERS NY 10920		CODE 1620194 FACILITY CODE		18a. PAYMENT WILL BE MADE BY PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814		CODE PSC	
TELEPHONE NO 845-2685000		17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED <input type="checkbox"/> SEE ADDENDUM			
19. ITEM NO	20. SCHEDULE OF SUPPLIES/SERVICES			21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Tax ID Number: (b)(4) DUNS Number: (b)(4) Doxycycline Hyclate 100 mg 20 ct 100 ct Oral Tablets and Amoxicillin trihydrate 500 mg 60 ct and 100 ct Oral Capsules The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), <i>(Use Reverse and/or Attach Additional Sheets as Necessary)</i>						
25. ACCOUNTING AND APPROPRIATION DATA See schedule						26. TOTAL AWARD AMOUNT (For Govt. Use Only) \$139,676,048.00	
<input type="checkbox"/> 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED. <input checked="" type="checkbox"/> 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA <input type="checkbox"/> ARE <input checked="" type="checkbox"/> ARE NOT ATTACHED.							
<input checked="" type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN <u>1</u> COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.				<input checked="" type="checkbox"/> 29. AWARD OF CONTRACT: _____ OFFER DATED 09/23/2022 YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS.			
30a. SIGNATURE OF OFFEROR/CONTRACTOR Jack Goldenberg Digitally signed by Jack Goldenberg Date: 2022.09.26 12:58:18 -04'00'				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) Kimberly L. Golden -S Digitally signed by Kimberly L. Golden -S Date: 2022.09.26 13:04:46 -04'00'			
30b. NAME AND TITLE OF SIGNER (Type or print) Jack Goldenberg, Managing Member		30c. DATE SIGNED 9/26/22		31b. NAME OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN		31c. DATE SIGNED	

19 ITEM NO	20 SCHEDULE OF SUPPLIES/SERVICES	21 QUANTITY	22 UNIT	23 UNIT PRICE	24 AMOUNT
	<p>issued a delivery order for Amoxicillin trihydrate 500 MG and Doxycycline Hyclate 100 MG in configurations of (b) (3):42 U.S.C. EA under the FSS VA/Schedule VA Federal Supply Schedule (FSS) 651B- Drugs, Pharmaceuticals & Hematology 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs.</p> <p>This is a Delivery Order (DO) awarded under FAR Part 8, VA Federal Supply Schedule (FSS) and is subject to the terms and conditions contained therein as well as in this DO.</p> <p>Period of Performance: 09/30/2022 to 09/29/2024</p>				
1	<p>Doxo hyclate 100mg 20 ct oral tablets</p> <p>Accounting Info: (b) (4)</p> <p>Funded: \$24,762,512.00</p>				(b)(3):42 U.S.C. § 247d.5b(4)
2	<p>Doxo hyclate 100mg 100 ct oral tablets</p> <p>Accounting Info: (b) (4)</p> <p>Continued ...</p>				(b)(3):42 U.S.C. § 247d.5b(4)

32a QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED

32b SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c DATE	32d PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
32e MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			32f TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
			32g E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
33 SHIP NUMBER	34 VOUCHER NUMBER	35 AMOUNT VERIFIED CORRECT FOR	36 PAYMENT <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL	37 CHECK NUMBER
<input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL				
38 S/R ACCOUNT NUMBER	39 S/R VOUCHER NUMBER	40 PAID BY		
41a I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT			42a RECEIVED BY (Print)	
41b SIGNATURE AND TITLE OF CERTIFYING OFFICER		41c DATE	42b RECEIVED AT (Location)	
			42c DATE RECD (Y/M/D)	42d TOTAL CONTAINERS

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
26F7972GD0198/75A50222F80030PAGE OF
3 15

NAME OF OFFEROR OR CONTRACTOR

CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194

ITEM NO (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
3	(b)(4) Funded: \$74,287,536.00 FOB: Destination Amoxicillin trihydrate 500mg 60 ct Oral Capsules Accounting Info: (b)(4) Funded: \$7,686,000.00 FOB: Destination				(b)(3); 42 U.S.C. § 247d-6b(d)
4	Amoxicillin trihydrate 500mg 100 ct Oral Capsules Accounting Info: (b)(4) Funded: \$32,940,000.00 FOB: Destination The total amount of award: \$139,676,048.00. The obligation for this award is shown in box 26. Name: Kimberly Golden, CO Phone: (b)(6) Email: kxm9@cdc.gov Name: Scott Andrews, COE Phone: (b)(6) (cell) Email: svl4@cdc.gov Name: Vendor Point of Contact Kerry Collias, EVP Sales & Marketing Email: (b)(6)@Chartwellpharma.com Phone: (b)(6) Continued ...				

NAME OF OFFEROR OR CONTRACTOR
CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194

ITEM NO (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Name: Jestine Mathis, Contract Administrator Phone: Cell # (b) (6) Email qvb3@cac.gov				

SECTION B – SCHEDULE OF SUPPLIES/SERVICES**B.1 Itemized Breakdown of Pharmaceutical Supplies for 24 Months Base Year: 30 Sep 2022–29 Sep 2024**

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3)-42 U.S.C. § 247d-6b(d)					

In accordance with FAR 52.217-6, Option for Increased Quantity, the Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within *15 days*. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

B.2. Delivery Schedule

B.3.A. Below is a delivery schedule template for 24 Month (Base Period). (See attachment 1)

Period of Performance: Sep 30, 2022 through Sep 29, 2024

B.3.B. Offerors shall provide a breakout detailing the "ramp" timeframe(s) for all quantities, required to manufacture and deliver the requested quantities above.

SECTION C - CONTRACT CLAUSES

This solicitation is to be competed against the 65IB- Drugs, Pharmaceuticals & Hematology VA NAC, Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. All clauses from the winning vendor(s) applicable GSA schedule contract will be applicable to this award.

Additional Contract Clauses and Instructions:

C.1 HHS Acquisition Regulations (HHSAR)

This contract incorporates one or more HHSAR clauses by reference, with the same force and effect as if they were given in full text. The full text of a clause may be accessed electronically at this/these address(es):

<http://www.hhs.gov/>

<https://www.acquisition.gov/hhsar>

HHSAR SOURCE	TITLE AND DATE
352.203-70	Anti-Lobbying (Dec 2015)
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)
352.227-70	Publications and Publicity (Dec 2015)
353.208-70	Printing and Duplication (Dec 2015)
352.224-70	Privacy Act (Dec 2015)
352.233-71	Litigation and Claims (Dec 2015)
352.237-74	Non-Discrimination in Service Delivery (Dec 2015)
352.239-74	Electronic and Information Technology Accessibility (Dec 2015)

C.2 Inspection and acceptance under this contract will be in accordance with FAR 52.212-4 Contract Terms and Conditions - Commercial Items (May 2015).

C.3 FAR 52.217-6 Option for Increased Quantity (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of Clause)

C.4 FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 15 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

C.5 CONTRACTING OFFICER'S REPRESENTATIVE(COR) APPOINTMENT AND AUTHORITY

Performance of work under this contract is subject to the technical direction of the COR or a representative designated by the contracting officer in writing. The term "technical direction" includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, and/or fills in details and otherwise serves to ensure that tasks outlined in the contract are accomplished satisfactorily. Technical direction must be within the scope of the contract specification(s)/work statement.

The COR does not have authority to issue technical direction that: (a) Constitutes additional work outside the contract specification(s) /work statement; (b) Constitutes a change as defined in the "Changes" clause of this contract; (c) Causes an increase or decrease in the contract price, or the time required for contract performance interferes with the contractor's right to perform under the terms and conditions of the contract; or (d) Directs, supervises or otherwise controls the actions of the contractor's employees.

Technical direction may be oral or in writing. The COR must confirm oral direction in writing within five workdays, with a copy to the contracting officer. The contractor shall proceed promptly with performance resulting from the technical direction issued by the COR, if the opinion of the contractor, any direction of the COR or the designated representative falls within the limitations above, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government workday. Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.6 CONTRACTOR PUBLICITY

The Contractor, or any entity or representative acting on behalf of the Contractor, may not refer to the equipment or services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer. Should any reference to such equipment or services appear in any news release or commercial advertising issued by or on behalf of the Contractor without the required consent, the Government will consider institution of all remedies available under the contract and applicable law.in the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.7 INVOICE SUBMISSION

The Department of Health and Human Services has amended the Department's Federal Acquisition Regulation Supplement, the HHS Acquisition Regulation (HHSAR), to support the HHS Electronic Invoicing Implementation Project and HHS's transition to the Department of the Treasury's Invoice Processing Platform (IPP). This complies with Office of Management and Budget (OMB) memorandum M-15-19, Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing, issued on July 17, 2015.

If your company is already registered to use IPP, you will not be required to re-register. Once your contract is transitioned to IPP, your company shall submit invoices for all open and new contracts via the IPP Invoicing Platform.

Your company will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

HHS and the Department of Treasury will enroll your company into IPP. Your company must follow the IPP registration email instructions to register for the Collector Account to be able to submit invoice requests for payment. Your business point of contact as listed in SAM will receive the registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the implementation of IPP. Registration emails are sent via email from ipp.noreply@mail.ero.ctwai.gov.

To request assistance with enrollment, please contact the IPP Production Helpdesk via email IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

INVOICE CLAUSE

HHSAR 352.232-71 Electronic submission of payment requests (Feb 2022)

(a) *Definitions.* As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(e) Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

Statement of Work

Title: Doxycycline hyclate 100 mg tablets & Amoxicillin trihydrate 500 mg capsules

D.1 Background

The Strategic National Stockpile (SNS) is responsible for federal stockpiling and deploying pharmaceuticals, equipment and medical supplies needed during a public health response. During a public health emergency, these supplies of medications and equipment are used to treat or prevent illness may need to be distributed and dispensed to people throughout the country. Currently, distribution and dispensing/administration of pharmaceuticals and supplies/equipment from the SNS relies on the public health system (state and local health departments). SNS in collaboration with ASPR is looking to optimize distribution of SNS pharmaceuticals and supplies/equipment specifically for a pandemic emergency.

The United States Government (USG) across multiple agencies, holds antibiotics intended for use as post-exposure prophylaxis (PEP) for persons suspected of being exposed to aerosolized *Bacillus anthracis* (anthrax) or other disease conditions. These antibiotics may be provided at the time of a suspected event or prior to an event to protect the general public, protect first responders, provide for Continuity of Operations/Continuity of Government (COOP/COG) for select persons, or for other purposes. Operationally, to assure the efficiency of a PEP campaign, the USG plans to provide antibiotics in several formulations and packages as described in this Statement of Work (SOW).

D.2 Purpose/Objective

The United State Government (USG) is interested in establishing award(s) for the purchase of FDA approved Doxycycline hyclate 100 mg Oral Tablets and Amoxicillin trihydrate 500 mg Oral Capsules, in the specified bottle counts noted in D.4. The USG's current plan to provide for oral prophylaxis for a suspected anthrax event relies on the dispensing of antibiotics in two stages.

1. First, the USG these products to be dispensed as a "10-day unit of use" package.
2. Second, the government follows an initial 10-day supply to potentially affected persons with a longer-term supply expected to continue treatment up to an additional 50 days.

D.3 Scope of Work

The government has a need for these drugs in varied configurations. The USG holds product in strict conformance to standards set forth in 21 Code of Federal Regulations (CFR). The Contractor, as an independent organization and not as an agent of the Government, shall procure and furnish all labor, materials, supplies, facilities, equipment, transportation and travel necessary to deliver the acceptable Pharmaceuticals within the prescribed timeframe to the specified location.

D.4 Product Requirements

The products to be acquired under this contract are FDA approved:

1. Doxycycline hyclate 100 mg 20 ct. Oral Tablets
2. Doxycycline hyclate 100 mg 100 ct. Oral Tablets
3. Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules

4. Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules

D.4.1 Product requirements:

1. The medication produced and delivered under this contract must be FDA approved and shall be manufactured in accordance with the conditions approved by the FDA under appropriate patents for the medication.
2. All products shall have storage requirements of controlled room temperature conditions at at 20° to 25°C (68° to 77°F).
3. Offerors shall use the same lot number for both 20 and 100 count bottles (1:1 ratio) for doxycycline tablets. Offerors shall use the same lot number for both 60 and 100 count packs (1:3 ratio) for amoxicillin capsules.
4. Offerors shall maximize the quantity of product of any lot # thus providing the fewest quantity of Lot numbers per contracted amount per contract year for each product.
5. Supplies shall conform to all current FDA regulations at the time of delivery.
6. Manufacturing Lot Size: Offerors shall provide the minimum and maximum lot size for each product proposed.
7. Delivery Schedule: Offerors shall provide a delivery schedule and production timeline to meet CLIN quantity requirements from time of award.

D 4.1.2 Minimum Labeling/Packaging Marking Requirements:

ASPR/DSNS's required bottle labeling includes the following:

1. Product shall be user-friendly. End user must be able to open packaging with ease to access medication. Child-resistant bottles are required.
2. Package inserts are required and can either be affixed to each individual bottle or can supply the equivalent quantity of loose/non-affixed in the master product case.
3. Each bottle must include an RX or unique identifier number on the label which must be specific to each bottle. The RX or unique identifier number shall be a serialization with unique product code complying with the Drug Supply Chain Security Act (DSCSA).

D 4.2 Product Packaging & Shipping Requirements

1. No partial case, bottle, or package quantities shall be accepted.
2. No mixed lot numbers per case or per package shall be accepted.
3. No mixed bottle counts on one pallet shall be accepted.
4. One lot number shall be used per pallet.
5. Case labels must face outward on pallet for material handlers to see.
6. Duplicate lots should only have one expiration date (i.e. the same two lot numbers should not have different expiry dates).
7. Pallets with the same lot number of an individual product description and bottle shall have the same expiry date. Different expiry dates for the same Lot # shall not be accepted. For example, Doxy #20 CT and Doxy #100 CT of the same lot # shall be on different pallets but require the same expiry date.
8. Contractor shall contact designated POC (for the respective address items are being delivered to) to schedule delivery appointments NLT 48 hours prior to shipping any product but as far in advance as possible (delivery times are Mon – Fri 8:00 AM – 3:30 PM).
9. All product to be delivered on a Heat Treated 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, and secured to pallet for safe and future multiple transports.
10. Product cases shall not overlap any portion of the pallet.
11. Shall maintain identical case product counts, Case packaging configuration and TI-Hi pallet stacking configurations for all deliveries throughout contract per product and bottle count.
12. Vendor is responsible for all product delivery damages that occurred in transport and is expected to issue a Return Material Authorization (RMA) within 5 business days of receipt. Vendor will provide product replacement for damages on future production run
13. Lot numbers, quantity per lot # / Product description, Purchase Order #, Vendor Name & address, Unit of Measure in eaches (per capsule or Tablet), in total bottle count per Case, total each case, total bottle count per pallet, total each per pallet and total case count per pallet. This info shall be on all product deliveries and on each shippers Bill of Lading / Shipping Manifest for all product deliveries.

D.5 Type of Contract

The anticipated contract shall be Firm-Fixed Price.

D.6 Contract Period of Performance:

The period of performance shall be for a single base year:

- Base QTY Sep 30, 2022 –Sep 29, 2024

D.7 Shelf-Life Requirements

It is anticipated that at time of delivery, product under this requirement shall have no less than:

Product	Minimum Acceptable Shelf Life
(b)(3):42 U.S.C. § 247d-6b(d)	

The current Good Manufacturing Practice regulations (cGMP's) (21CFR Parts 210-211) shall be the standard to be applied for manufacturing, processing, and packing of drugs. Product to be packaged while ensuring long-term stability shelf life of product and assuring product quality in accordance with 21 CFR.

D.8 Quality Control Inspections

The Government reserves the right to inspect any contractor or subcontractor facility used for the manufacture, packaging, storage, transportation, or any other handling of products ordered as a result of this solicitation without prior notice. These inspections do not replace any required inspections conducted by the FDA but are in addition to such inspections. The contractor shall be required to respond to any finding(s) resultant from these inspections with remediation plans or an explanation of why no remediation is required.

D.9 Good Manufacturing Practice regulations (cGMP) and licensures

The current Good Manufacturing Practice regulations (cGMP's) 21CFR Parts 210-211 shall be the standard to be applied for manufacturing, processing, and packing of drugs. The medications produced and delivered under this contract shall be FDA licensed and approved and shall be manufactured in accordance with all Federal, State, and local regulations, laws, and statutes. The Contractor shall provide the New Drug Application (NDA) # or (Abbreviated New Drug Application) ANDA # for all product. Contractors shall include all product literature and specifications for all proposed products. Medications delivered under this contract shall be Trade Agreement Act (TAA) compliant.

The Contractor shall advise the Contracting Officer (CO) and the Contracting Officer's Representative (COR) immediately of any proposed or actual relocation of the prime manufacturing facility or the relocation of any subcontractor's facility. If at any time during the life of the contract, the products listed under this contract fails to meet cGMP's and/or a negative FDA Quality Assurance Evaluation is received, the USG may reevaluate continuing the contract with the Offeror.

D.10 Deliverables

Deliverable	Format/Deliver to	Date
Kick-Off Meeting Notes Should contain a detailed overview of the discussion.	Electronic copy of Kick-Off Meeting Notes – COR	Within 5 days of meeting being held
Delivery Documents	Scan and email to COR/POC	2 Business Days Prior to Delivery
Packing Slips	Scan and email to COR/POC	48 hours after delivery
Final Report	Summary of all deliveries under performance of this contract.	Within 5 business days from final delivery or end of contract, whichever comes first.
Contractor delivery schedule	Scan and email to COR/POC	Must be included in the proposal submission.

D.11 Delivery Location & Transportation:

1. Delivery location and schedule will be provided by the Contracting Officer's Representative after award.
2. Delivery locations will be SNS locations within the CONUS. Exact locations will be provided after award due to the sensitive nature of these sites. Final delivery schedule will be defined at time of award and based upon Offeror's capabilities.

D.12 CPAR POC Information:

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on Anniversary dates Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final. Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions. Electronic Access to Contractor Performance Evaluations Contractors may access evaluations through a secure Web site for review and comment at the following address: <http://www.cpars.gov>.

Provide the current CPARS representative information below.

Name Kerry D Collias

POC Email (b)(6)@ChartwellPharma.com

POC Phone: (b)(6) or (b)(4)

52.216-32 Task-Order and Delivery-Order Ombudsman (Sept 2019)

a. In accordance with 41 U.S.C. 4106(g), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task-order and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of orders, consistent with the procedures in the contract.

Steven Green
Acquisition Program Oversight
MFHC|DAAPPO
HHS|ASPR
steven.green@hhs.gov

b. Consulting an ombudsman does not alter or postpone the timeline for any other process (e.g., protests).

c. Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested by the Contractor, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

Product Description	NDC #	Quantity In Eaches	Unit of Measure (Eaches Per UOM)	Shelf-Life at Time of Delivery (Months)	Delivery Schedule QTY & Ramp UP (RU)	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Total	
(b)(4); (b)(3);42 U.S.C. § 247d-6b(d)																															

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act



September 26, 2022

RE: Congressional Notice of Contract 36F79720D0198 Order No. 75A50322F80030 Award

VIA Email: grantfax@hhs.gov

To: HHS Congressional Liaison Office ASL, OS

cc: Tijuana Triplet, Congressional Communications Officer

Email: Tijuana.Triplet@hhs.gov

From: Kimberly Golden, Contract Officer, OS/ASPR/ORM/SNS Contracts and Grants

Phone: (b)(6)

E-Mail: ixm9@cdc.gov

Subject: Notice of Contract Award of More than \$4 million

As required by HHSAR 305.303, the purpose of this memo is to provide for a public announcement of an acquisition whose value exceeds \$4 million. Enclosed is a copy of the face page of contract no. Contract 36F79720D0198 Order No. 75A50322F80030.

The United States Government (USG) across multiple agencies, holds antibiotics intended for use as post-exposure prophylaxis (PEP) for persons suspected of being exposed to aerosolized *Bacillus anthracis* (anthrax) or other disease conditions. These antibiotics may be provided at the time of a suspected event or prior to an event to protect the general public, protect first responders, provide for Continuity of Operations/Continuity of Government (COOP/COG) for select persons, or for other purposes. Operationally, to assure the efficiency of a PEP campaign, the USG plans to provide antibiotics in several formulations and packages. The purpose of this contract is to procure FDA approved Amoxicillian trihydrate 100mg. and Doxycycline Hyclate 500 mg.

Contractor:

CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC
77 Brenner Drive
Congers, NY 10920

Total Funded Amount: \$139,676,048.00

This award has an effective date of September 30, 2020. The period of Performance is for a Base Period of 24 Months.

If you have any questions, please feel free to contact me, at (b)(6) or KGolden1@cdc.gov.

Sincerely,

(b)(6)

Kimberly Golden
Contracting Officer
OS/ASPR/ORM/SNS Contracts and Grants

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE		PAGE OF PAGES 1 2	
2. AMENDMENT/MODIFICATION NO P00001		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO.	
5. PROJECT NO. (If applicable)		6. ISSUED BY ASPR/SNS ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341		7. ADMINISTERED BY (If other than item 6) US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) CHARTWELL RX LLC 1622676 JACK GOLDBERG 77 BRENNER DR CONGERS NY 10920		(x)		9A. AMENDMENT OF SOLICITATION NO.	
CODE 1622676		FACILITY CODE		9B. DATED (SEE ITEM 11)	
		X		10A. MODIFICATION OF CONTRACT/ORDER NO. 36F79720D0198 75A50322F80030	
				10B. DATED (SEE ITEM 13) 09/26/2022	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers is extended. is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT. Contractor is not X is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: (b)(4)

DUNS Number: (b)(4)

UEI: ER5UA9TYBGH4

- The purpose for this administrative modification is to correct the vendor information from Chartwell Governmental Specialty RX LLC to Chartwell RX, LLC.
- All other terms and conditions remain unchanged.

Period of Performance: 09/30/2022 to 09/29/2024

Continued ...

Except as provided herein, all terms and conditions of the document referenced in item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) JACK GOLDBERG		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN	
15B. CONTRACTOR/OFFEROR (b)(6) (Signature of person authorized to sign)	15C. DATE SIGNED 11/8/2022	16B. UNITED STATES OF AMERICA (b)(6) (Signature of Contracting Officer)	16C. DATE SIGNED 11-9-2022

Previous edition unusable

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
36F79720D0198/75A50322F80030/P00001PAGE OF
2 2NAME OF OFFEROR OR CONTRACTOR
CHARTWELL RX LLC 1622676

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Name: Kimberly Golden, CO Phone: (b)(6) Email: ikm9@cdc.gov Name: Scott Andrews, COR Phone: (b)(6) (cell) Email: evl4@cdc.gov Name: Vendor Point of Contact Kerry Collias, EVP Sales & Marketing Email: (b)(6)@Chartwellpharma.com Phone: (b)(6) Name: Jestine Mathis, Contract Administrator Phone: Cell # (b)(6) Email: qvb3@cdc.gov				

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NUMBER (b) (4)		PAGE OF 1 15					
2. CONTRACT NO. 36F79720D0198		3. AWARD/ EFFECTIVE DATE 09/30/2022		4. ORDER NUMBER 75A50322F80030		5. SOLICITATION NUMBER		6. SOLICITATION ISSUE DATE			
7. FOR SOLICITATION INFORMATION CALL:		a. NAME KIMBERLY GOLDEN				b. TELEPHONE NUMBER (No collect calls)		8. OFFER DUE DATE/LOCAL TIME			
9. ISSUED BY ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341		CODE ASPR/SNS		10. THIS ACQUISITION IS UNRESTRICTED OR <input checked="" type="checkbox"/> SET ASIDE % FOR a. SMALL BUSINESS b. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM EDWOSB NAICS 325412 c. SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS H(A) SIZE STANDARD 1,250							
11. DELIVERY FOR FOB DESTINA- TION UNLESS BLOCK IS MARKED <input checked="" type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS		13a. THIS CONTRACT IS A RATED ORDER UNDER (FAS 115 CFR 700)		13b. RATING		14. METHOD OF SOLICITATION <input type="checkbox"/> RFQ <input type="checkbox"/> IFB <input type="checkbox"/> RFP			
15. DELIVER TO ASPR-SNS US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA GA 30341		CODE ASPR-SNS		16. ADMINISTERED BY US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341		CODE ASPR/SNS					
17a. CONTRACTOR/ OFFEROR CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194 77 BRENNER DR CONGERS NY 10920 TELEPHONE NO. 845-2685000		CODE 1620194 FACILITY CODE		18a. PAYMENT WILL BE MADE BY PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814		CODE PSC					
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED		SEE ADDENDUM							
19. ITEM NO		20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY		22. UNIT		23. UNIT PRICE		24. AMOUNT	
		Tax ID Number: (b)(4) DUNS Number: (b)(4) Doxycycline Hyclate 100 mg 20 ct 100 ct Oral Tablets and Amoxicillin trihydrate 500 mg 60 ct and 100 ct Oral Capsules The Division of Strategic National Stockpile (DSNS), of the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR), (Use Reverse and/or Attach Additional Sheets as Necessary)									
25. ACCOUNTING AND APPROPRIATION DATA See schedule						26. TOTAL AWARD AMOUNT (For Govt. Use Only) \$139,676,048.00					
27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA						ARE <input type="checkbox"/> ARE NOT ATTACHED					
27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4, FAR 52.212-5 IS ATTACHED. ADDENDA						ARE <input type="checkbox"/> ARE NOT ATTACHED					
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED				29. AWARD OF CONTRACT: DATED 09/23/2022 YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS.							
30a. SIGNATURE OF OFFEROR/CONTRACTOR Jack Goldenberg Digitally signed by Jack Goldenberg Date: 2022.09.26 12:58:18 -04'00'				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) Kimberly L. Golden -S Digitally signed by Kimberly L. Golden -S Date: 2022.09.26 13:04:46 -04'00'							
30b. NAME AND TITLE OF SIGNER (Type or print) Jack Goldenberg, Managing Member				30c. DATE SIGNED 9/26/22		31b. NAME OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN				31c. DATE SIGNED	
AUTHORIZED FOR LOCAL REPRODUCTION PREVIOUS EDITION IS NOT USABLE						STANDARD FORM 1449 (REV. 2/2012) Prescribed by GSA - FAR (48 CFR) 53.212					

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	<p>issued a delivery order for Amoxicillin trihydrate 500 MG and Doxycycline Hyclate 100 MG in configurations of (b)(3)-42 U.S.C. § EA under the FSS VA/Schedule VA Federal Supply Schedule (FSS) 65IB- Drugs, Pharmaceuticals & Hematology 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs.</p> <p>This is a Delivery Order (DO) awarded under FAR Part 8, VA Federal Supply Schedule (FSS) and is subject to the terms and conditions contained therein as well as in this DO. Period of Performance: 09/30/2022 to 09/29/2024</p>				
1	<p>Doxy hyclate 100mg 20 ct oral tablets</p> <p>Accounting Info: (b)(4)</p>				(b)(3)-42 U.S.C. § 247d-6b(d)
2	<p>Doxy hyclate 100mg 100 ct oral tablets</p> <p>Accounting Info: (b)(4)</p>				

32a. QUANTITY IN COLUMN 21 HAS BEEN

RECEIVED

INSPECTED

ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE			32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
			32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE	
33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	37. CHECK NUMBER
PARTIAL FINAL			COMPLETE PARTIAL FINAL	
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY (Print)		
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER		41c. DATE		
		42b. RECEIVED AT (Location)		
		42c. DATE REC'D (YY/MM/DD)		42d. TOTAL CONTAINERS

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
36F79720D0198/75A50322F80030

PAGE 3 OF 15

NAME OF OFFEROR OR CONTRACTOR

CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	(b)(4) Funded: \$74,287,536.00 FOB: Destination				
3	Amoxicillin trihydrate 500mg 60 ct Oral Capsules Accounting Info: (b)(4)				(b)(4); (b)(3):42 U.S.C. § 247d-6b(d)
4	Amoxicillin trihydrate 500mg 100 ct Oral Capsules Accounting Info: (b)(4)				
The total amount of award: \$139,676,048.00. The obligation for this award is shown in box 26.					
Name: Kimberly Golden, CO Phone: (b)(6) Email: ixm9@cdc.gov					
Name: Scott Andrews, COR Phone: (b)(6) (cell) Email: evl4@cdc.gov					
Name: Vendor Point of Contact Kerry Collias, EVP Sales & Marketing Email: (b)(6)@Chartwellpharma.com Phone: (b)(6)					
Continued ...					

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	36F79720D0198/75A50322F80030	4	15

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	36F79720D0198/75A50322F80030	4	15

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
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NAME OF OFFEROR OR CONTRACTOR
CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194

NAME OF OFFEROR OR CONTRACTOR
CHARTWELL GOVERNMENTAL & SPECIALTY RX LLC 1620194

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
Name: Jestine Mathis, Contract Administrator Phone: Cell # (b)(6) Email qvb3@cdc.gov					

SECTION B – SCHEDULE OF SUPPLIES/SERVICES**B.1 Itemized Breakdown of Pharmaceutical Supplies for 24 Months Base Year: 30 Sep 2022–29 Sep 2024**

CLIN	Product Description	Unit of Measure	Quantity	Unit Price	Total Price
(b)(3):42 U.S.C. § 247d-6b(d)					

In accordance with FAR 52.217-6, Option for Increased Quantity, the Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within *15 days*. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

B.2. Delivery Schedule

B.3.A. Below is a delivery schedule template for 24 Month (Base Period). (See attachment 1)

Period of Performance: Sep 30, 2022 through Sep 29, 2024

B.3.B. Offerors shall provide a breakout detailing the "ramp" timeframe(s) for all quantities, required to manufacture and deliver the requested quantities above.

SECTION C - CONTRACT CLAUSES

This solicitation is to be competed against the 65IB- Drugs, Pharmaceuticals & Hematology VA NAC, Schedule 42-2B Generic & multiple source pharmaceuticals & drugs, human blood products, & over-the-counter drugs. All clauses from the winning vendor(s) applicable GSA schedule contract will be applicable to this award.

Additional Contract Clauses and Instructions:

C.1 HHS Acquisition Regulations (HHSAR)

This contract incorporates one or more HHSAR clauses by reference, with the same force and effect as if they were given in full text. The full text of a clause may be accessed electronically at this/these address(es):

<http://www.hhs.gov/>

<https://www.acquisition.gov/hhsar>

HHSAR SOURCE	TITLE AND DATE
352.203-70	Anti-Lobbying (Dec 2015)
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)
352.227-70	Publications and Publicity (Dec 2015)
353.208-70	Printing and Duplication (Dec 2015)
352.224-70	Privacy Act (Dec 2015)
352.233-71	Litigation and Claims (Dec 2015)
352.237-74	Non-Discrimination in Service Delivery (Dec 2015)
352.239-74	Electronic and Information Technology Accessibility (Dec 2015)

C.2 Inspection and acceptance under this contract will be in accordance with FAR 52.212-4 Contract Terms and Conditions - Commercial Items (May 2015).

C.3 FAR 52.217-6 Option for Increased Quantity (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of Clause)

C.4 FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 15 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

C.5 CONTRACTING OFFICER'S REPRESENTATIVE(COR) APPOINTMENT AND AUTHORITY

Performance of work under this contract is subject to the technical direction of the COR or a representative designated by the contracting officer in writing. The term "technical direction" includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, and/or fills in details and otherwise serves to ensure that tasks outlined in the contract are accomplished satisfactorily. Technical direction must be within the scope of the contract specification(s)/work statement.

The COR does not have authority to issue technical direction that: (a) Constitutes additional work outside the contract specification(s) /work statement; (b) Constitutes a change as defined in the "Changes" clause of this contract; (c) Causes an increase or decrease in the contract price, or the time required for contract performance interferes with the contractor's right to perform under the terms and conditions of the contract; or (d) Directs, supervises or otherwise controls the actions of the contractor's employees.

Technical direction may be oral or in writing. The COR must confirm oral direction in writing within five workdays, with a copy to the contracting officer. The contractor shall proceed promptly with performance resulting from the technical direction issued by the COR, if the opinion of the contractor, any direction of the COR or the designated representative falls within the limitations above, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government workday. Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.6 CONTRACTOR PUBLICITY

The Contractor, or any entity or representative acting on behalf of the Contractor, may not refer to the equipment or services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer. Should any reference to such equipment or services appear in any news release or commercial advertising issued by or on behalf of the Contractor without the required consent, the Government will consider institution of all remedies available under the contract and applicable law.in the scope of the contract shall be subjected the terms of the "Disputes" clause of this contract.

C.7 INVOICE SUBMISSION

The Department of Health and Human Services has amended the Department's Federal Acquisition Regulation Supplement, the HHS Acquisition Regulation (HHSAR), to support the HHS Electronic Invoicing Implementation Project and HHS's transition to the Department of the Treasury's Invoice Processing Platform (IPP). This complies with Office of Management and Budget (OMB) memorandum M-15-19, Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing, issued on July 17, 2015.

If your company is already registered to use IPP, you will not be required to re-register. Once your contract is transitioned to IPP, your company shall submit invoices for all open and new contracts via the IPP Invoicing Platform.

Your company will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

HHS and the Department of Treasury will enroll your company into IPP. Your company must follow the IPP registration email instructions to register for the Collector Account to be able to submit invoice requests for payment. Your business point of contact as listed in SAM will receive the registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the implementation of IPP. Registration emails are sent via email from ipp.noreply@mail.ero.c.twai.gov.

To request assistance with enrollment, please contact the IPP Production Helpdesk via email IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

INVOICE CLAUSE

HHSAR 352.232-71 Electronic submission of payment requests (Feb 2022)

(a) *Definitions.* As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(e) Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

Statement of Work

Title: Doxycycline hyclate 100 mg tablets & Amoxicillin trihydrate 500 mg capsules

D.1 Background

The Strategic National Stockpile (SNS) is responsible for federal stockpiling and deploying pharmaceuticals, equipment and medical supplies needed during a public health response. During a public health emergency, these supplies of medications and equipment are used to treat or prevent illness may need to be distributed and dispensed to people throughout the country. Currently, distribution and dispensing/administration of pharmaceuticals and supplies/equipment from the SNS relies on the public health system (state and local health departments). SNS in collaboration with ASPR is looking to optimize distribution of SNS pharmaceuticals and supplies/equipment specifically for a pandemic emergency.

The United States Government (USG) across multiple agencies, holds antibiotics intended for use as post-exposure prophylaxis (PEP) for persons suspected of being exposed to aerosolized *Bacillus anthracis* (anthrax) or other disease conditions. These antibiotics may be provided at the time of a suspected event or prior to an event to protect the general public, protect first responders, provide for Continuity of Operations/Continuity of Government (COOP/COG) for select persons, or for other purposes. Operationally, to assure the efficiency of a PEP campaign, the USG plans to provide antibiotics in several formulations and packages as described in this Statement of Work (SOW).

D.2 Purpose/Objective

The United State Government (USG) is interested in establishing award(s) for the purchase of FDA approved Doxycycline hyclate 100 mg Oral Tablets and Amoxicillin trihydrate 500 mg Oral Capsules, in the specified bottle counts noted in D.4. The USG's current plan to provide for oral prophylaxis for a suspected anthrax event relies on the dispensing of antibiotics in two stages.

1. First, the USG these products to be dispensed as a "10-day unit of use" package.
2. Second, the government follows an initial 10-day supply to potentially affected persons with a longer-term supply expected to continue treatment up to an additional 50 days.

D.3 Scope of Work

The government has a need for these drugs in varied configurations. The USG holds product in strict conformance to standards set forth in 21 Code of Federal Regulations (CFR). The Contractor, as an independent organization and not as an agent of the Government, shall procure and furnish all labor, materials, supplies, facilities, equipment, transportation and travel necessary to deliver the acceptable Pharmaceuticals within the prescribed timeframe to the specified location.

D.4 Product Requirements

The products to be acquired under this contract are FDA approved:

1. Doxycycline hyclate 100 mg 20 ct. Oral Tablets
2. Doxycycline hyclate 100 mg 100 ct. Oral Tablets
3. Amoxicillin trihydrate 500 mg 60 ct. Oral Capsules

4. Amoxicillin trihydrate 500 mg 100 ct. Oral Capsules

D.4.1 Product requirements:

1. The medication produced and delivered under this contract must be FDA approved and shall be manufactured in accordance with the conditions approved by the FDA under appropriate patents for the medication.
2. All products shall have storage requirements of controlled room temperature conditions at at 20° to 25°C (68° to 77°F).
3. Offerors shall use the same lot number for both 20 and 100 count bottles (1:1 ratio) for doxycycline tablets. Offerors shall use the same lot number for both 60 and 100 count packs (1:3 ratio) for amoxicillin capsules.
4. Offerors shall maximize the quantity of product of any lot # thus providing the fewest quantity of Lot numbers per contracted amount per contract year for each product.
5. Supplies shall conform to all current FDA regulations at the time of delivery.
6. Manufacturing Lot Size: Offerors shall provide the minimum and maximum lot size for each product proposed.
7. Delivery Schedule: Offerors shall provide a delivery schedule and production timeline to meet CLIN quantity requirements from time of award.

D 4.1.2 Minimum Labeling/Packaging Marking Requirements:

ASPR/DSNS's required bottle labeling includes the following:

1. Product shall be user-friendly. End user must be able to open packaging with ease to access medication. Child-resistant bottles are required.
2. Package inserts are required and can either be affixed to each individual bottle or can supply the equivalent quantity of loose/non-affixed in the master product case.
3. Each bottle must include an RX or unique identifier number on the label which must be specific to each bottle. The RX or unique identifier number shall be a serialization with unique product code complying with the Drug Supply Chain Security Act (DSCSA).

D 4.2 Product Packaging & Shipping Requirements

1. No partial case, bottle, or package quantities shall be accepted.
2. No mixed lot numbers per case or per package shall be accepted.
3. No mixed bottle counts on one pallet shall be accepted.
4. One lot number shall be used per pallet.
5. Case labels must face outward on pallet for material handlers to see.
6. Duplicate lots should only have one expiration date (i.e. the same two lot numbers should not have different expiry dates).
7. Pallets with the same lot number of an individual product description and bottle shall have the same expiry date. Different expiry dates for the same Lot # shall not be accepted. For example, Doxy #20 CT and Doxy #100 CT of the same lot # shall be on different pallets but require the same expiry date.
8. Contractor shall contact designated POC (for the respective address items are being delivered to) to schedule delivery appointments NLT 48 hours prior to shipping any product but as far in advance as possible (delivery times are Mon – Fri 8:00 AM – 3:30 PM).
9. All product to be delivered on a Heat Treated 48" by 40" pallet, not to exceed 60" in height, stretch wrapped, and secured to pallet for safe and future multiple transports.
10. Product cases shall not overlap any portion of the pallet.
11. Shall maintain identical case product counts, Case packaging configuration and TI-Hi pallet stacking configurations for all deliveries throughout contract per product and bottle count.
12. Vendor is responsible for all product delivery damages that occurred in transport and is expected to issue a Return Material Authorization (RMA) within 5 business days of receipt. Vendor will provide product replacement for damages on future production run
13. Lot numbers, quantity per lot # / Product description, Purchase Order #, Vendor Name & address, Unit of Measure in eaches (per capsule or Tablet), in total bottle count per Case, total each case, total bottle count per pallet, total each per pallet and total case count per pallet. This info shall be on all product deliveries and on each shippers Bill of Lading / Shipping Manifest for all product deliveries.

D.5 Type of Contract

The anticipated contract shall be Firm-Fixed Price.

D.6 Contract Period of Performance:

The period of performance shall be for a single base year:

- Base QTY Sep 30, 2022 –Sep 29, 2024

D.7 Shelf-Life Requirements

It is anticipated that at time of delivery, product under this requirement shall have no less than:

Product	Minimum Acceptable Shelf Life
(b)(3);42 U.S.C. § 247d-6b(d)	

The current Good Manufacturing Practice regulations (cGMP's) (21CFR Parts 210-211) shall be the standard to be applied for manufacturing, processing, and packing of drugs. Product to be packaged while ensuring long-term stability shelf life of product and assuring product quality in accordance with 21 CFR.

D.8 Quality Control Inspections

The Government reserves the right to inspect any contractor or subcontractor facility used for the manufacture, packaging, storage, transportation, or any other handling of products ordered as a result of this solicitation without prior notice. These inspections do not replace any required inspections conducted by the FDA but are in addition to such inspections. The contractor shall be required to respond to any finding(s) resultant from these inspections with remediation plans or an explanation of why no remediation is required.

D.9 Good Manufacturing Practice regulations (cGMP) and licensures

The current Good Manufacturing Practice regulations (cGMP's) 21CFR Parts 210-211 shall be the standard to be applied for manufacturing, processing, and packing of drugs. The medications produced and delivered under this contract shall be FDA licensed and approved and shall be manufactured in accordance with all Federal, State, and local regulations, laws, and statues. The Contractor shall provide the New Drug Application (NDA) # or (Abbreviated New Drug Application) ANDA # for all product. Contractors shall include all product literature and specifications for all proposed products. Medications delivered under this contract shall be Trade Agreement Act (TAA) compliant.

The Contractor shall advise the Contracting Officer (CO) and the Contracting Officer's Representative (COR) immediately of any proposed or actual relocation of the prime manufacturing facility or the relocation of any subcontractor's facility. If at any time during the life of the contract, the products listed under this contract fails to meet cGMP's and/or a negative FDA Quality Assurance Evaluation is received, the USG may reevaluate continuing the contract with the Offeror.

D.10 Deliverables

Deliverable	Format/Deliver to	Date
Kick-Off Meeting Notes Should contain a detailed overview of the discussion.	Electronic copy of Kick-Off Meeting Notes – COR	Within 5 days of meeting being held
Delivery Documents	Scan and email to COR/POC	2 Business Days Prior to Delivery
Packing Slips	Scan and email to COR/POC	48 hours after delivery
Final Report	Summary of all deliveries under performance of this contract.	Within 5 business days from final delivery or end of contract, whichever comes first.
Contractor delivery schedule	Scan and email to COR/POC	Must be included in the proposal submission.

D.11 Delivery Location & Transportation:

1. Delivery location and schedule will be provided by the Contracting Officer's Representative after award.
2. Delivery locations will be SNS locations within the CONUS. Exact locations will be provided after award due to the sensitive nature of these sites. Final delivery schedule will be defined at time of award and based upon Offeror's capabilities.

D.12 CPAR POC Information:

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on Anniversary dates Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final. Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions. Electronic Access to Contractor Performance Evaluations Contractors may access evaluations through a secure Web site for review and comment at the following address: <http://www.cpars.gov>.

Provide the current CPARS representative information below.

Name Kerry D Collias

POC Email : (b)(6)@ChartwellPharma.com

POC Phone: (b)(6) or (b)(6)

52.216-32 Task-Order and Delivery-Order Ombudsman (Sept 2019)

a. In accordance with 41 U.S.C. 4106(g), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task-order and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of orders, consistent with the procedures in the contract.

Steven Green
Acquisition Program Oversight
MFHC|DAAPPO
HHS|ASPR
steven.green@hhs.gov

b. Consulting an ombudsman does not alter or postpone the timeline for any other process (e.g., protests).

c. Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested by the Contractor, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

Product Description	NDC #	Quantity in Eaches	Unit of Measure (UOM)	Shelf-Life at Time of Delivery (Months)	Delivery Schedule, QTY & Ramp UP (RU)	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Total
(b)(4); (b)(3); 42 U.S.C. § 247d-6b(d)																														