

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE	PAGE OF PAGES
				J	1 14
2. AMENDMENT/MODIFICATION NO. P00001		3. EFFECTIVE DATE 01-Sep-2020	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO.(If applicable)
6. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	7. ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA DETROIT 35803 MOUND RD STERLING HEIGHTS MI 48310		CODE S2305A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) GRAND RIVER ASEPTIC MANUFACTURING, INC. GRAM (b) (6) 140 FRONT AVE SW #3 GRAND RAPIDS MI 49504-6426				9A. AMENDMENT OF SOLICITATION NO.	
				9B. DATED (SEE ITEM 11)	
				X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0086	
				X 10B. DATED (SEE ITEM 13) 04-Aug-2020	
CODE 6ZL94		FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.					
<p>Offer 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:</p> <p>(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 telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>					
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
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.					
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a)(3) Mutual Agreement Between Contracting Parties					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 202614 Modification Obligation: (b) (6) The purpose of this Modification is to: 1) Update Milestone Schedule 2) Update Admin DODACC to S2305A 3) Update Payment Office to S2305A 4) Update Service acceptor/approver DODAAC to S2305A in WAWF Clause 5) Add DMCA Contact Info 6) Add COR Contact info. 7) Update H.9 Clause to reflect Security Plan Proposal due in 60 days from contract award. 8) Update Attachment 2 - Security Plan to reflect delivery within 60 days of contract award. 9) Reduce Value and funding from CLIN 0001AB by the amounts not yet invoiced 10) Create CLIN 0001AC for remaining value that was reduced from CLIN 0001AB. 11) Remove incorrect SOW reference in CLIN 0003 extended description. There is no change in Contract Value. All other Terms and Conditions remain in effect.					
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
			(b) (6)		
			TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)			BY (b) (6)		18-Sep-2020
				(Signature of Contracting Officer)	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The 'Payment will be made by' organization has changed from
DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS-INDY VP GFEB
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800
to
DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS - COLUMBUS CENTER (HQ0337)
NORTH ENTITLEMENT OPERATIONS
P.O. BOX 182317
COLUMBUS OH 43218-2266

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 0001AB

The pricing detail quantity has decreased by (b) (4).

The total cost of this line item has decreased by (b) (4) from (b) (4).

CLIN 0003

The CLIN extended description has changed from:

The contractor shall complete the validation of the line at BSL-2 in an accelerated fashion IAW C.3.2.2

To:

The contractor shall complete the validation of the line at BSL-2 in an accelerated fashion.

SUBCLIN 0001AC is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AC	Maintenance and/or Operating FFP Maintenance and/or Operating of Fill/Finish Process-Monthly IAW C.3.1.2 FOB: Destination PURCHASE REQUEST NUMBER: 0011552063 PSC CD: Q999		Job	(b) (4)	(b) (4)

NET AMT

(b) (4)

ACRN AA
CIN: GFEBS001155206300001

(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 0001AC:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for SUBCLIN 0001AA has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
1 hr. ADC	1	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
04-AUG-2020	1	N/A FOB: Destination	

The following Delivery Schedule Item has been deleted from SUBCLIN 0001AB:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

30-SEP-2020	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-JUN-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-MAY-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-APR-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-MAR-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

28-FEB-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-JAN-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-DEC-2020	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-NOV-2020	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-OCT-2020	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

31-JUL-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
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The following Delivery Schedule for SUBCLIN 0001AC has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-SEP-2020	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
31-OCT-2020	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
30-NOV-2020	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
31-DEC-2020	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
31-JAN-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
28-FEB-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
31-MAR-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
30-APR-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
31-MAY-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
30-JUN-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY
31-JUL-2021	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	W911QY

Accounting and Appropriation

Summary for the Payment Office

SUBCLIN 0001AB:

AA: 0212020202120400000664643252 S.0074658.5.9 6100.9000021001 A5XAH (CIN
GFEB001153321000020) was decreased by (b) (4)

SUBCLIN 0001AC:

Funding on SUBCLIN 0001AC is initiated as follows:

ACRN: AA

CIN: GFEB001155206300001

Acctng Data: 0212020202120400000664643252 S.0074658.5.9 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

The following have been modified:

G.1 GOVERNMENT CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

Procuring Contracting Officer:

(b) (6)

Bldg 1, General Greene Avenue
Natick, MA 01760-5011

Contract Specialist:

(b) (6)

Bldg 1, General Greene Avenue
Natick, MA 01760-5011

DCMA:

(b) (6)

Administrative Contracting Officer / DCMA Detroit-Grand Rapids

(b) (6)

(b) (6)
Contract Administrator / DCMA Detroit

(b) (6)
(b) (6)

Contracting Officer's Representative (COR)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)

(b) (6)

(b) (6)
(b) (6)
(b) (6)
(b) (6)
(b) (6)

(b) (6)

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

Primary: (b) (6)

G.4 PLACES OF PERFORMANCE

Primary: (b) (6)

Address: Grand Rapids, MI 22102

CAGE Code 6ZL94

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

[Note: The Contractor may use a WAWF “combo” document type to create some combinations of invoice and receiving report in one step.]

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For fixed price line items—

“Invoice 2in1”

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	S2305A
Inspect By DoDAAC	_____
Ship To Code	_____

Ship From Code	_____
Mark For Code	TBD
Service Approver (DoDAAC)	S2305A
Service Acceptor (DoDAAC)	S2305A
Accept at Other DoDAAC	S2305A
LPO DoDAAC	_____
DCAA Auditor DoDAAC	_____
Other DoDAAC(s)	_____

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

TBD

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies HHS approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. W911QY-20-P-0086."

H.5 Organizational Conflicts of Interest:

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any

unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall:

- (1) enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

H.6 Confidentiality of Information

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all Sub-contractors.

H.7 PAYMENT IN THE EVENT OF TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT

The Government has entered into a contract to acquire BSL2 vial fill-finish capacity for a one-year PoP IAW the contract delivery schedule. In consideration for this contract, the contractor has turned away reservation of this capacity with other customers. In the event of a termination for the convenience of the Government, the Contractor will utilize commercially reasonable efforts to secure a replacement customer. To the extent Contractor cannot secure a replacement customer, the Government will continue to pay the SLIN0001AB and liquidate the advanced payment at SLIN0001AA through the end of the original term of the contract or pay the remainder of the SLIN0001AB as a lump sum if a lump sum payment is determined by the Termination Contracting Officer (TCO) to be in the best interest of the Government. The Contractor shall not be paid for any portion of the reservation fee which reasonably could have been avoided. In no event, shall the sum total of payments made to the Contractor under the Contract and termination settlement exceed the contract's total price.

H.8 Contract Financing

(1) Except as otherwise provided in the contract, delivery payments shall be made only for completed supplies and services accepted by the Government in accordance with the terms of the contract.

(2) This contract provides for commercial advance payments of a reservation fee of (b) (4) following contract award. This is (b) (4) of the Reservation Fee (Sub Line Item Number 0001AA).

(3) Specific conditions of contractor entitlement to those financing payments: Upon contract award, GRAM will become entitled to payment for the Reservation Fee and shall invoice for the advance payment.

(4) Liquidation of those financing payments by delivery payments: The advance payment of the reservation fee will be liquidated at the rate of (b) (4) per month of performance.

(5) In accordance with FAR 32.202-4 (a)(2), the contracting officer has determined the offeror's financial condition to be adequate security, provided the offeror agrees to provide additional security should that financial condition become inadequate as security;

(6) Upon award the contractor shall invoice for the reservation fee.

(7) See Clauses 52.212-4(i) and 52.232-29 for additional payment terms and conditions.

H.9 BARDA Facility Security Requirements.

"Facility Security Plan

1. At the time of issuance of this proposal, (b) (4)

The government acknowledges this constraint, and due to urgency, the government will consider adding additional effort and funding to meet this requirement after contract award and upon receipt of a change proposal provided not later than 60 days after award. In the event that GRAM does not provide an adequate change proposal within 60 days, the Government will withhold payment of CLIN 0001, SLIN 0001AB until an adequate change proposal is accepted by the Government.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The Table of Contents has changed from:

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit A	Appendix A_CDRL		02-AUG-2020
Attachment 1	Milestone Schedule		04-AUG-2020

Attachment 2	Concept of Operations	04-AUG-2020
Attachment 3	OWS Required Content	02-AUG-2020

to:

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit A	Appendix A_CDRL		02-AUG-2020
Attachment 1	Milestone Schedule V1		01-SEP-2020
Attachment 2	Concept of Operations		04-AUG-2020
Attachment 3	OWS Required ContentBARDA Security PLAN V1		01-SEP-2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE J	PAGE OF PAGES 1 4
2. AMENDMENT/MODIFICATION NO. P00002	3. EFFECTIVE DATE 24-Sep-2020	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO.(If applicable)
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			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0086	
			X 10B. DATED (SEE ITEM 13) 04-Aug-2020	
CODE 6ZL94	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
Offer 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 telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter 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 APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
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 date, 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 <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 203006 Modification Obligation: (b) (6) The purpose of this modification is to update DODAAC information only. Admin DODAAC Updated on Contract Pay Office updated on WAWF Clause No other changes to the contract have been made.				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
			(b) (6)	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY (b) (6)		24-Sep-2020
		(Signature of Contracting Officer)		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The 'administered by' organization has changed from

W6QK ACC-APG NATICK
CONTRACTING DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

to

DEFENSE CONTRACT MANAGEMENT AGENCY
DCMA DETROIT
35803 MOUND RD
STERLING HEIGHTS MI 48310

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

[Note: The Contractor may use a WAWF “combo” document type to create some combinations of invoice and receiving report in one step.]

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For fixed price line items—

“Invoice 2in1”

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC**	S2305A
Inspect By DoDAAC	_____
Ship To Code	W911QY
Ship From Code	_____
Mark For Code	TBD
Service Approver (DoDAAC)	S2305A
Service Acceptor (DoDAAC)	S2305A
Accept at Other DoDAAC	S2305A
LPO DoDAAC	_____
DCAA Auditor DoDAAC	_____
Other DoDAAC(s)	_____

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

TBD

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE J	PAGE OF PAGES 1 9
2. AMENDMENT/MODIFICATION NO. P00003	3. EFFECTIVE DATE 25-Oct-2020	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO.(If applicable)
6. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	7. ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA DETROIT 35803 MOUND RD STERLING HEIGHTS MI 48310		CODE S2305A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) GRAND RIVER ASEPTIC MANUFACTURING, INC. GRAM (b) (6) 140 FRONT AVE SW #3 GRAND RAPIDS MI 49504-6426			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0086	
			X 10B. DATED (SEE ITEM 13) 04-Aug-2020	
CODE 6ZL94	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
Offer 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 telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter 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 APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
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.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: 52.243-1				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 21273 Modification Obligation: (b) (4)				
The purpose of this modification is to add CLIN 0006 and associated SubCLINS to add the requirements to meet the OWS Security requirements. Update H.9 to show requirement was satisfied. Add Mandatory Clause 52.204-25 Changes are outlined in the summary of changes:				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
			(b) (6)	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6)		30-Oct-2020
		(Signature of Contracting Officer)		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) [REDACTED].

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0006 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006	OWS Security Upgrades FFP Required Security elements in accordance with GRAM's proposal. Validation to be completed by the imbedded, in-plant government representative.				(b) (4)
NET AMT					(b) (4)

SUBCLIN 0006AA is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006AA	Security Personnel FFP Unarmed Security Personnel and Security Director FOB: Destination PURCHASE REQUEST NUMBER: 0011568272 PROJECT: Operation Warp Speed PSC CD: Q999	[REDACTED]	Months	(b) (4)	(b) (4)
NET AMT					(b) (4)
ACRN AB					(b) (4)
CIN: GFEB001156827200001					

SUBCLIN 0006AB is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006AB	Physical Security Upgrades FFP includes Card Reader Additions, Badge Printing, Photo Back Drop, Camera, Cable Installation, Cage, Freezer Electrical -Validation to be completed by the imbedded, in-plant government representative. Early Delivery Acceptable FOB: Destination PURCHASE REQUEST NUMBER: 0011568272 PROJECT: Operation Warp Speed PSC CD: Q999	1	Job	(b) (4)	(b) (4)
NET AMT					(b) (4)
ACRN AB					(b) (4)
CIN: GFEBS001156827200002					

SUBCLIN 0006AC is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006AC	Generator Fencing and Electrical FFP Validation to be completed by the imbedded, in-plant government representative. Early Delivery Acceptable FOB: Destination PURCHASE REQUEST NUMBER: 0011568272 PROJECT: Operation Warp Speed PSC CD: Q999	1	Job	(b) (4)	(b) (4)
NET AMT					(b) (4)
ACRN AB					(b) (4)
CIN: GFEBS001156827200003					

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0006:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 0006AA:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0006AB:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0006AC:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for SUBCLIN 0006AA has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-OCT-2020	1	N/A FOB: Destination	
30-NOV-2020	1	N/A FOB: Destination	
31-DEC-2020	1	N/A FOB: Destination	
31-JAN-2021	1	N/A FOB: Destination	
28-FEB-2021	1	N/A FOB: Destination	
31-MAR-2021	1	N/A FOB: Destination	
30-APR-2021	1	N/A FOB: Destination	
31-MAY-2021	1	N/A FOB: Destination	
30-JUN-2021	1	N/A FOB: Destination	
31-JUL-2021	1	N/A FOB: Destination	

The following Delivery Schedule for SUBCLIN 0006AB has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-DEC-2020	1	N/A FOB: Destination	

The following Delivery Schedule for SUBCLIN 0006AC has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
28-FEB-2021	1	N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4)

SUBCLIN 0006AA:

Funding on SUBCLIN 0006AA is initiated as follows:

ACRN: AB

CIN: GFEB001156827200001

Acctng Data: 0212020202120400000664643255 S.0074658.5.9 6100.9000021001

Increase: \$(b) (4)

Total: \$(b) (4)

Cost Code: A5XAH

SUBCLIN 0006AB:

Funding on SUBCLIN 0006AB is initiated as follows:

ACRN: AB

CIN: GFEB001156827200002

Acctng Data: 0212020202120400000664643255 S.0074658.5.9 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0006AC:

Funding on SUBCLIN 0006AC is initiated as follows:

ACRN: AB

CIN: GFEB001156827200003

Acctng Data: 0212020202120400000664643255 S.0074658.5.9 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies HHS approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. W911QY-20-P-0086."

H.5 Organizational Conflicts of Interest:

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall:

- (1) enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

H.6 Confidentiality of Information

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all Sub-contractors.

H.7 PAYMENT IN THE EVENT OF TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT

The Government has entered into a contract to acquire BSL2 vial fill-finish capacity for a one-year PoP IAW the contract delivery schedule. In consideration for this contract, the contractor has turned away reservation of this capacity with other customers. In the event of a termination for the convenience of the Government, the Contractor will utilize commercially reasonable efforts to secure a replacement customer. To the extent Contractor cannot secure a replacement customer, the Government will continue to pay the SLIN0001AB and liquidate the advanced payment at SLIN0001AA through the end of the original term of the contract or pay the remainder of the SLIN0001AB as a lump sum if a lump sum payment is determined by the Termination Contracting Officer (TCO) to be in the best interest of the Government. The Contractor shall not be paid for any portion of the reservation fee which reasonably could have been avoided. In no event, shall the sum total of payments made to the Contractor under the Contract and termination settlement exceed the contract's total price.

H.8 Contract Financing

- (1) Except as otherwise provided in the contract, delivery payments shall be made only for completed supplies and services accepted by the Government in accordance with the terms of the contract.
- (2) This contract provides for commercial advance payments of a reservation fee of (b) (4) following contract award. This is (b) (4) of the Reservation Fee (Sub Line Item Number 0001AA).

(3) Specific conditions of contractor entitlement to those financing payments: Upon contract award, GRAM will become entitled to payment for the Reservation Fee and shall invoice for the advance payment.

(4) Liquidation of those financing payments by delivery payments: The advance payment of the reservation fee will be liquidated at the rate of (b) (4) per month of performance.

(5) In accordance with FAR 32.202-4 (a)(2), the contracting officer has determined the offeror's financial condition to be adequate security, provided the offeror agrees to provide additional security should that financial condition become inadequate as security;

(6) Upon award the contractor shall invoice for the reservation fee.

(7) See Clauses 52.212-4(i) and 52.232-29 for additional payment terms and conditions.

H.9 BARDA Facility Security Requirements.

"Facility Security Plan

1. At the time of issuance of this proposal, (b) (4) [REDACTED]

The government acknowledges this constraint, and due to urgency, the government will consider adding additional effort and funding to meet this requirement after contract award and upon receipt of a change proposal provided not later than 60 days after award. In the event that GRAM does not provide an adequate change proposal within 60 days, the Government will withhold payment of CLIN 0001, SLIN 0001AB until an adequate change proposal is accepted by the Government.

2.This has been satisfied in P00003.

SECTION I - CONTRACT CLAUSES

The following have been added by reference:

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. AUG 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE J	PAGE OF PAGES 1 6
2. AMENDMENT/MODIFICATION NO. P00004		3. EFFECTIVE DATE 13-Nov-2020	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO.(If applicable)
6. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	7. ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA DETROIT 35803 MOUND RD STERLING HEIGHTS MI 48310		CODE S2305A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) GRAND RIVER ASEPTIC MANUFACTURING, INC. GRAM (b) (6) 140 FRONT AVE SW #3 GRAND RAPIDS MI 49504-6426				9A. AMENDMENT OF SOLICITATION NO.	
				9B. DATED (SEE ITEM 11)	
				X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0086	
				X 10B. DATED (SEE ITEM 13) 04-Aug-2020	
CODE 6ZL94		FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer 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 telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter 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 APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
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.					
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: 52.243-1					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u> 1 </u> copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 21472 Modification Obligation: (b) (4) The purpose of this modification is to incorporate an Enhanced Labeler and Printer Capability and Enhanced Fill Finish Capabilities required for the identified Janssen Drug Product. This modification eliminates SUBCL N 0002AD for (b) (4) adds SUBCLIN 0002AF for (b) (4) and SUBCL N 0002AG for (b) (4) incorporating the required additional enhanced packaging/labeling capabilities. These changes have been requested by the requiring activity in order to meet mission goals. Changes are as follow s: Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 19-Nov-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) [REDACTED].

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 0002AD

The CLIN extended description has changed from:

The contractor will perform Fully Automated Labeling Machine Capacity Expansion and report of invoice. Early delivery is acceptable.

To:

The contractor will perform Fully Automated Labeling Machine Capacity Expansion and report of invoice. Early delivery is acceptable. P00004 - Decrement (b) (4) [REDACTED] - moved/incorporated into SUBCLIN 00002AF

The pricing detail quantity has decreased by 1.00 from 1.00 to 0.00.

The total cost of this line item has decreased by (b) (4) [REDACTED] to \$0.00.

SUBCLIN 0002AF is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AF	Enhanced Labeler and Printer Capability FFP	1	Job	(b) (4)	(b) (4)
	The contractor will perform Enhanced Fully Automated Labeling and Printing Machine Capacity Expansion and report of invoice in accordance with GRAM's proposal dated 11/02/2020. Early delivery is acceptable. At a minimum, the capacity must support Janssen's Drug Product, including but not limited to high speed labeling and decrease potential for ink smearing associated with thermal transfer printing. Validation to be completed by the embedded, in-plant government representative. FOB: Destination PURCHASE REQUEST NUMBER: 0011533210-0005 PSC CD: Q999				

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEB001153321000093

SUBCLIN 0002AG is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002AG	Enhanced Fill Finish Capabilities FFP	1	Job	(b) (4)	(b) (4)
	The contractor shall provide and complete the installation of enhanced packaging to full operational capability IAW vendor proposal received 11/02/2020. Validation to be completed by the imbedded, in-plant government representative. Early Delivery Acceptable FOB: Destination PURCHASE REQUEST NUMBER: 0011533210-0003 PROJECT: Operation Warp Speed PSC CD: Q999				

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEB001153321000092

SECTION E - INSPECTION AND ACCEPTANCE

The Acceptance/Inspection Schedule for SUBCLIN 0002AE has been changed from:
INSPECT AT INSPECT BY ACCEPT AT

ACCEPT BY

N/A	N/A	N/A	Government
To:			
INSPECT AT N/A	INSPECT BY N/A	ACCEPT AT Origin	ACCEPT BY Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0002AF:

INSPECT AT N/A	INSPECT BY N/A	ACCEPT AT Origin	ACCEPT BY Government
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The following Acceptance/Inspection Schedule was added for SUBCLIN 0002AG:

INSPECT AT Destination	INSPECT BY Government	ACCEPT AT Origin	ACCEPT BY Government
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SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for SUBCLIN 0002AD has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-JAN-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-JAN-2021	0	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY

The following Delivery Schedule for SUBCLIN 0002AF has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
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15-JUN-2021	1	W6QK ACC-APG NATICK DIVISION (b) (6) BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY
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The following Delivery Schedule for SUBCLIN 0002AG has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
15-JUN-2021	1	W6QK ACC-APG NATICK (b) (6) CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 (b) (6) FOB: Destination	W911QY

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4).

SUBCLIN 0002AD:

AA: 0212020202120400000664643252 S.0074658.5.9 6100.9000021001 A5XAH (CIN GFEB001153321000080) was decreased by (b) (4) to (b) (4)

SUBCLIN 0002AF:

Funding on SUBCLIN 0002AF is initiated as follows:

ACRN: AA

CIN: GFEB001153321000093

Acctng Data: 0212020202120400000664643252 S.0074658.5.9 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0002AG:

Funding on SUBCLIN 0002AG is initiated as follows:

ACRN: AA

CIN: GFEBS001153321000092

Acctng Data: 0212020202120400000664643252 S.0074658.5.9 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES
			J	1 11
2. AMENDMENT/MODIFICATION NO. P00005	3. EFFECTIVE DATE 1 April 2021	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE	5. PROJECT NO.(If applicable)	
6. ISSUED BY W60K ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	7. ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA DETROIT 35803 MOUND RD STERLING HEIGHTS MI 48310		CODE S2305A
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) GRAND RIVER ASEPTIC MANUFACTURING, INC. GRAM (b) (6) 140 FRONT AVE SW #3 GRAND RAPIDS MI 49504-6426			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0086	
			X 10B. DATED (SEE ITEM 13) 04-Aug-2020	
CODE 6ZL94	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
<p>Offer 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:</p> <p>(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 telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>				
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
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.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.243-1				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 211688 MODIFICATION OBLIGATION AMOUNT: (b) (4)				
1. The purpose of this modification is to add CLIN 0007 for the increased fill/finish capacity expansion. This modification adds SubCLIN 0007 AA for (b) (4) SubCLIN 0007 AB for (b) (4) SubCLIN 0007 AC for (b) (4) SubCLIN 0007 AD for (b) (4) SubCLIN 0007 AE for (b) (4) and SubCLIN 0007 AF for (b) (4)				
2. This change was requested by the requiring activity in order to meet mission goals.				
3. As a result of this modification, the total cost & funding of this contract was increased by \$538,501.69 from \$162,622,178.10 to \$163,160,679.79.				
Please see below for details. Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print) (b) (6)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
			TEL: _____ EMAIL: _____	
15B. CONTRACTOR/OFFEROR (b) (6) (Signature of person authorized to sign)	15C. DATE SIGNED 04/01/2021	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 1 April 2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0007 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007	Increased Filling Capacity FFP The contractor shall establish increased qualified manufacturing capacity by expanding the available equipment to support a higher throughput of filled doses by offering increased manufacturing process volumes to include, but not limited to, formulation tanks, ancillary equipment for the filling line and larger freezer space to accommodate the storage of the increased number of filled drug product. To the extent required, qualification of the new equipment is required to support the increased capacity.				(b) (4)
NET AMT					(b) (4)

SUBCLIN 0007AA is added as follows:

FOR OFFICIAL USE ONLY - PROCUREMENT SENSITIVE INFORMATION (FAR 2.102 AND 3.104)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007AA	Bulk Vaccine -70 degree Freezer FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011629111 PSC CD: Q999	1	Each	(b) (4)	(b) (4)

NET AMT (b) (4)

ACRN AC (b) (4)
CIN: GFEBS001162911100001

SUBCLIN 0007AB is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007AB	Bulk Vaccine Thaw Carts FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011629111 PSC CD: Q999	3	Each	(b) (4)	(b) (4)

NET AMT (b) (4)

ACRN AC (b) (4)
CIN: GFEBS001162911100002

SUBCLIN 0007AC is added as follows:

FOR OFFICIAL USE ONLY - PROCUREMENT SENSITIVE INFORMATION (FAR 2.102 AND 3.104)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007AC	1000L Power Mix Tanks FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011629111 PSC CD: Q999	2	Each	(b) (4)	(b) (4)

NET AMT

(b) (4)

ACRN AC
CIN: GFEBS001162911100003

(b) (4)

SUBCLIN 0007AD is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007AD	Tank Chillers FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011629111 PSC CD: Q999	2	Each	(b) (4)	(b) (4)

NET AMT

(b) (4)

ACRN AC
CIN: GFEBS001162911100004

(b) (4)

SUBCLIN 0007AE is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007AE	Molded Vial Storage Trays FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011629111 PSC CD: Q999	1,700	Each	(b) (4)	(b) (4)

NET AMT (b) (4)

ACRN AC (b) (4)
CIN: GFEBS001162911100005

SUBCLIN 0007AF is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007AF	-40 degree Blast Freezer FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011629111 PSC CD: Q999	1	Each	(b) (4)	(b) (4)

NET AMT (b) (4)

ACRN AC (b) (4)
CIN: GFEBS001162911100006

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been added by full text:
SOW CLIN 0007

SECTION C: PERFORMANCE WORK STATEMENT

TITLE: MANUFACTURING CAPACITY EXPANSION FOR VACCINES IN RESPONSE TO THE CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC

SCOPE. The United States Government (USG) seeks to expand the domestic aseptic fill and finish manufacturing capacity for critical vaccines at its contractor Grand River Aseptic Manufacturing (GRAM) facilities in response to the COVID-19 pandemic. The USG requires expansion of the contractor's available fill/finish manufacturing domestic capacity.

C.1.1 **Background.** In December 2019, a novel (new) coronavirus known as SARS-CoV-2 (“the virus”) was first detected in Wuhan, Hubei Province, People’s Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under the USG’s COVID-19 response mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 vaccine candidates to maximize probability of having one or more safe and effective vaccines as fast as possible for mass distribution. As such, HHS’s Biomedical Advanced Research and Development Authority (BARDA) has a specific need to increase US domestic aseptic fill and finish manufacturing capacity for critical vaccines and therapeutics in response to the COVID-19 pandemic to ensure adequate and uninterrupted supply throughout the COVID-19 campaign.

C.1.2 **Objective.** The objective of this effort is to increase the contractor’s domestic capacity to perform fill/finish services for a USG-selected COVID-19 BSL-2 vaccine (live virus vaccine).

C.2 APPLICABLE DOCUMENTS.

C.2.1 Federal Documents:

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General. (https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0).

C.3 **REQUIREMENTS.** Independently, and not as an agent of the USG, in accordance with the Proposals submitted by Grand River Aseptic Manufacturing (GRAM) in response to Request for Proposal Number 75A50120R00013 (“COVID-19 Fill and Finish Manufacturing Capacity”), dated May 11, 2020 and June 12, 2020 (and any subsequent revised Proposal submissions), the contractor shall provide all necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, to perform the task set forth below.

C.3.1 Task 1 – Aseptic Fill Manufacturing Capacity Expansion

C.3.1.1.1 To the extent required under the Federal Food, Drug, and Cosmetic Act, the Recipient will ensure that the manufacturing capability established under this contract complies with current good manufacturing practices (cGMPs) under 21 CFR 210 and 211. The contractor agrees to notify the Government of any written cGMP inspection findings from the U.S. Food and Drug Administration (FDA) pertinent to the manufacturing capability established under this contract.

C.3.2.1 CLIN 0007: Increased Filling Capacity. The contractor shall establish increased qualified manufacturing capacity by expanding the available equipment to support a higher throughput of filled doses by offering increased manufacturing process volumes to include, but not limited to, formulation tanks, ancillary equipment for the filling line and larger freezer space to accommodate the storage of the increased number of filled drug product. To the extent required, qualification of the new equipment is required to support the increased capacity.

C.4 Milestone Schedule. The contractor shall comply with the Milestone Schedule

C.5 Listing of Acronyms.

ACRONYM	DEFINITION
BARDA	Biomedical Advanced Research and Development Authority
BSL	Biosafety Level
COVID-19	Coronavirus Disease 2019
FDA	Federal Drug Administration
cGMP	Current Good Manufacturing Practices
HHS	Health and Human Services
USG	United States Government

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0007:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 0007AA:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0007AB:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0007AC:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0007AD:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0007AE:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0007AF:

INSPECT AT Origin	INSPECT BY Government	ACCEPT AT Origin	ACCEPT BY Government
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SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for SUBCLIN 0007AA has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
15-JUN-2021	1	W6QK ACC-APG NATICK DIVISION (b) (6) 1 GENERAL GREENE AVE BLDG 1 NATICK MA 01760 FOB: Destination	W911QY

The following Delivery Schedule for SUBCLIN 0007AB has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
15-JUN-2021	3	W6QK ACC-APG NATICK DIVISION (b) (6) 1 GENERAL GREENE AVE BLDG 1 NATICK MA 01760 FOB: Destination	W911QY

The following Delivery Schedule for SUBCLIN 0007AC has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
15-JUN-2021	2	W6QK ACC-APG NATICK DIVISION (b) (6) 1 GENERAL GREENE AVE BLDG 1 NATICK MA 01760 FOB: Destination	W911QY

The following Delivery Schedule for SUBCLIN 0007AD has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
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15-JUN-2021	2	W6QK ACC-APG NATICK DIVISION (b) (6) 1 GENERAL GREENE AVE BLDG 1 NATICK MA 01760 FOB: Destination	W911QY
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The following Delivery Schedule for SUBCLIN 0007AE has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
15-JUN-2021	1,700	W6QK ACC-APG NATICK DIVISION (b) (6) 1 GENERAL GREENE AVE BLDG 1 NATICK MA 01760 FOB: Destination	W911QY

The following Delivery Schedule for SUBCLIN 0007AF has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
15-JUN-2021	1	W6QK ACC-APG NATICK DIVISION (b) (6) 1 GENERAL GREENE AVE BLDG 1 NATICK MA 01760 FOB: Destination	W911QY

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4).

SUBCLIN 0007AA:

Funding on SUBCLIN 0007AA is initiated as follows:

ACRN: AC

CIN: GFEB001162911100001

Acctng Data: 0212021202220400000665654252 S.0074658.5.53 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0007AB:

Funding on SUBCLIN 0007AB is initiated as follows:

ACRN: AC

CIN: GFEB001162911100002

Acctng Data: 0212021202220400000665654252 S.0074658.5.53 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0007AC:

Funding on SUBCLIN 0007AC is initiated as follows:

ACRN: AC

CIN: GFEB001162911100003

Acctng Data: 0212021202220400000665654252 S.0074658.5.53 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0007AD:

Funding on SUBCLIN 0007AD is initiated as follows:

ACRN: AC

CIN: GFEB001162911100004

Acctng Data: 0212021202220400000665654252 S.0074658.5.53 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0007AE:

Funding on SUBCLIN 0007AE is initiated as follows:

ACRN: AC

CIN: GFEB001162911100005

Acctng Data: 0212021202220400000665654252 S.0074658.5.53 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 0007AF:

Funding on SUBCLIN 0007AF is initiated as follows:

ACRN: AC

CIN: GFEB001162911100006

Acctng Data: 0212021202220400000665654252 S.0074658.5.53 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

(End of Summary of Changes)