

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			RATING	PAGE OF PAGES 1 36	
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY21C0016		3. EFFECTIVE DATE 27 Oct 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011565573			
5. ISSUED BY WBQK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	6. ADMINISTERED BY (If other than Item 5) See Item 5			CODE	
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) ELI LILLY AND COMPANY (b) (6) 1 LILLY CORPORATE CTR. INDIANAPOLIS IN 46285				8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT			
				10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM Section G	
CODE 75602		FACILITY CODE		12. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS - COLUMBUS CENTER (HQ0337) NORTH ENTITLEMENT OPERATIONS P.O. BOX 182317 COLUMBUS OH 43218-2266			
11. SHIP TO/MARK FOR See Schedule		CODE		CODE HQ0337			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [X] 10 U.S.C. 2304(c)(2) [] 41 U.S.C. 253(c)()				14. ACCOUNTING AND APPROPRIATION DATA See Schedule			
15A. ITEM NO.	15B. SUPPLIES/ SERVICES		15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT	
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT						\$1,187,500,000.00	
16. TABLE OF CONTENTS							
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X	E	INSPECTION AND ACCEPTANCE	10	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17 [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office). Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein)				18 [] SEALED-BID AWARD (Contractor is not required to sign this document) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract)			
19A. NAME AND TITLE OF SIGNER (Type or print) (b) (6)				20A. NAME OF CONTRACTING OFFICER			
19B. NAME OF CONTRACTOR (b) (6)				19C. DATE SIGNED 10/26/20		20B. UNITED STATES OF AMERICA	
BY _____ (Signature of person authorized to sign)				BY _____ (Signature of Contracting Officer)			
				20C. DATE SIGNED			

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19A. NAME AND TITLE OF SIGNER (Type or print)			20A. NAME OF CONTRACTING OFFICER (b) (6) / BRANCH CHIEF TEL: _____ EMAIL: (b) (6)				
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)		19C. DATE SIGNED	20B. UNITED STATES OF AMERICA (b) (6) BY _____ (Signature of Contracting Officer)		20C. DATE SIGNED 27-Oct-2020		

Section A - Solicitation/Contract Form

A.1 The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for acquisition of the monoclonal antibody (mAb) therapeutic, LY-CoV555 (a monotherapy) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All vials referenced herein are 700 milligrams.

CLIN	Ab name	Patient setting	Dose (g)	# of vials per dose (0.7g/vial)
0001	LY-CoV555	outpatient	0.7g	1

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Monoclonal Antibody LY-CoV555 COST	950,000	Vial	(b) (4)	(b) (4) NTE
	<p>The contractor shall produce and deliver 300,000 vials of the monoclonal antibody (mAb) therapeutic, LY-CoV555 at a fixed unit price of (b) (4) per vial for a total price of (b) (4)</p> <p>The contractor may deliver up to an additional 650,000 vials of LY-CoV555 at the fixed unit price per vial of (b) upon bilateral agreement on the quantity with the government. Any additional doses will be acquired in increments of 10,000 vials.</p> <p>The not to exceed (NTE) price of this CLIN represents the fixed unit price at the maximum quantity of 950,000 vials.</p> <p>This is a fixed unit price contract. This cost reimbursement structure is only a mechanism which allows for invoicing of variable quantities delivered IAW Lilly's allocation model.</p> <p>This CLIN shall be executed IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract</p> <p>FOB: Origin (Shipping Point) PROJECT: Operation Warp Speed PSC CD: 6505</p>				

ESTIMATED COST (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101	ACRN AA @ \$312,500,000 FFP PURCHASE REQUEST NUMBER: 0011565573				\$0.00
				NET AMT	\$0.00
	ACRN AA CIN: GFEB001156557300001				\$312,500,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Technical Data COST The contractor shall deliver technical Data IAW Contract Data Requirements List (CDRL) IAW deliverables in Section J, Exhibit A. FOB: Destination PROJECT: Operation Warp Speed MFR PART NR: 1 PSC CD: 6505	1	Job		NSP
				ESTIMATED COST	\$0.00

Section C - Descriptions and Specifications

Statement of Work**C.1 EXECUTIVE SUMMARY (Scope of Project):**

Manufacturing shall occur using cGMP validated manufacturing processes for bulk drug substance and fill and finished drug product. The specific objective is the acquisition of a minimum of 300,000 treatment courses (defined as 0.7g/dose/vial) for a targeted US population for delivery during the first two months after EUA or Contract Award date, whichever is later, with the possibility to acquire additional doses up to a maximum of 950,000. Any additional quantities above the minimum are dependent upon available supply to USG as determined by Lilly and need for additional product as determined by USG. The contractor shall also provide storage and distribution.

The product to be produced and delivered include the monoclonal antibody (mAb) therapeutic, LY-CoV555 (a monotherapy), subject to EUA approval.

C.2 TASKS

Task 1: The contractor shall establish a quality agreement (CDRL A018) with the US Government on requirements for the US Government to accept packaged drug product as a completed deliverable. Quality agreement must be negotiated within the first 30 days of award and prior to Government acceptance of drug product. The drug will not transfer to US Government unless there is an active EUA for the product.

Task 2: The contractor shall provide a Product Development Source Material and Manufacturing Plan within 30 days of award to fulfill the US Government order. The manufacturing plan should include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the US Government.

Task 3: The contractor shall manufacture the therapeutic product(s) using an established manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity plan that provides enough doses to meet the desired number of treatment courses.

Task 4: Storage. The contractor shall store the packaged drug product under cGMP conditions until the U.S. Government has directed the allocation of the product.

Task 5: Distribution. The contractor shall distribute the product as directed by the U.S. Government (USG) through the contractor's commercial distribution network with the contractor insuring against any supply loss from time of title transfer at origin through to end destination (site of administration) with replacement product transferred to the US government. Transfer of product to USG and distribution will not occur unless there is an active EUA or FDA approval/licensure for the product. Once the minimum dose requirement is met, the contractor shall communicate to USG in writing to the KO every month how many additional doses, if any, are available for acquisition along with the input data and other documentation used to run the global allocation model to allow review of how the available dose number was derived. Additional doses will only transfer to USG if Lilly has supply available and if USG determines need.

Task 6: Program Management Activities: The contractor shall establish the capacity in compliance with Food and Drug Administration (FDA) current good manufacturing practices (cGMP) regulations, and Biosafety Level standards if applicable. The contractor shall be responsible for management of all activities, including but not limited to, subcontractors to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the contractor shall provide a monthly report that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

The contractor shall provide minutes and reports in accordance with the following deliverables and the Contract Data Requirements List (CDRL), Section J, Exhibit A.

Post Award Teleconference. The contractor shall complete an initial teleconference after contract award in accordance with CDRL A001. The goal of this teleconference is to outline activities for the next 30 days and discuss agenda items for the post-award Kickoff Meeting (CDRL A002).

Kickoff Meeting. The Contractor shall complete a Kickoff meeting after contract award in accordance with CDRL A002. This will occur within a month of contract award, pending concurrence by the contracting officer.

Every 2 weeks Teleconference. The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract in accordance with CDRL A003. Meeting frequency can be increased with agreement between both parties as needed during the course of the Project.

Quarterly Meetings. At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in either Washington D.C or at work sites of the Contractor or subcontractors in accordance with CDRL A004.

FDA Meeting Minutes and other communications with FDA. All formal and informal communications with the FDA should be provided to BARDA in accordance with CDRL A005. Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.

Daily check in with project staff for COVID-19 Contract. Contractor shall participate in a daily check-in update if necessary with the Project Managers and additional project staff as needed (via teleconference or email) in accordance with CDRL A006. Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery,

Monthly Progress Reports. A consolidated submission of all slides and data presented at the biweekly telecons will serve as the monthly report in accordance with CDRL A007. The report only consists of a summary of quantity of product delivered, when and location of the delivery.

Milestone Reports. Milestone reports shall be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW) and Integrated Master Schedule (IMS). As applicable, an Executive Summary highlighting the progress, issues and relevant manufacturing activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages. This should be submitted in accordance with CDRL A008.

Draft and Final Technical Progress Report. A draft Final Technical Progress Report containing a summation of the work performed over the entire Contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' in accordance with CDRL A009. The final report should be submitted in accordance with CDRL A010. This report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where.

Product Development Source Material and Manufacturing Reports. The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites in accordance with CDRL A011. The contract will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar.

Contractor Locations. The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors in accordance with CDRL A012.

Pandemic Management Plan. A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations. Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency in accordance with CDRL A013.

Supply Chain and Distribution Tracking. Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using a dose tracking templates. Contractor will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the contractor and distributor. Distributors will use that information to ship therapeutics in bulk to sites of administration/end user. This will be done in accordance with CDRL A014.

Distribution Plan. This plan shall describe the Contractor's process to allocate (the global allocation model) and distribute EUA-or BLA-approved product to point of care facilities, necessary to meet the Government's need for administration. The plan shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response. This will be done in accordance with CDRL A015.

Manufacturing Development Plan. This plan shall describe describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks." This will be done in accordance with CDRL A016.

Quality Management Plan. Plan may include, but is not limited to the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation. This will done in accordance with CDRL A017.

Quality Agreement. Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place in accordance with CDRL A018.

Release documentation for doses to be delivered. In accordance with CDRL A019 contractor will deliver Certificate of Analysis and Certificate of Compliance as soon as practicable, prior to delivery.

Manufacturing and Distribution Records. In accordance with CDRL A020 contractor will timely deliver the following records for drug substance and drug product for USG review and comment: (1) Certificate of Analysis; (2) Certificate of Conformance/Compliance; and (3) a sample label and carton from production run.

Security Plan. In accordance with CDRL A021 the contractor will deliver a security plan within 30 days of

award.

Supply Chain Resiliency Plan. In accordance with CDRL A022 the contractor will deliver a supply chain resiliency plan within 30 days of award.

Manufacturing Data Requirements. In accordance with CDRL A023 the contractor will deliver manufacturing data requirements within 30 days of award.

BARDA Audit. Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA in accordance with CDRL A024.

FDA Inspections. In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and KO with copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector in accordance with CDRL A025.

QA Audits. BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action in accordance with CDRL A026.

FDA Submissions. The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final." This will be done in accordance with CDRL A027.

EUA Filing. The Contractor shall provide a copy of any request for EUA submitted to the FDA in accordance with CDRL A028.

Provision of Public Law 115-92 Sponsor Authorization Letter. The Contractor shall submit Public Law 115-92 Sponsor Authorization Letter in the Contractor's format that will be delivered to the designated OWS POC(s). This will be done in accordance with CDRL A029.

Press Releases. Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases in accordance with CDRL A030.

C.3 SECURITY

The contractor shall comply with all Operation Warp Speed Security requirements in Section J Attachment 0001, OWS Security Requirements.

Section D - Packaging and Marking

D.1 Marking and labeling TBD

Section E - Inspection and Acceptance

E.1 INSPECTION AND ACCEPTANCE

Inspection shall be at origin at the contractor's plant, conducted by the USG technical representative in accordance with the Quality Assurance (QA) plan. Acceptance shall be at origin by the ACC-APG Contracting Officer. All documentation required for both Inspection and Acceptance shall be uploaded into Wide Area Workflow (WAWF) by the contractor.

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Origin	Government	Origin	Government
000101	N/A	N/A	N/A	N/A
0002	Destination	Government	Destination	Government

Section F - Deliveries or Performance

F.1 Distribution. The contractor shall distribute the product as directed by the US Government through the contractor's commercial distribution network. Distribution will not occur until an EUA or FDA approval/licensure is achieved.

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 27-OCT-2020 TO 30-JUN-2021	N/A	N/A FOB: Origin (Shipping Point)	
000101	N/A	N/A	N/A	N/A
0002	POP 27-OCT-2020 TO 30-JUN-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

CLAUSES INCORPORATED BY REFERENCE

52.247-29

F.O.B. Origin

FEB 2006

Section G - Contract Administration Data

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)
[Redacted]
[Redacted]

Contract Specialist:

(b) (6)
[Redacted]
[Redacted]

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)
[Redacted]
[Redacted]
[Redacted]

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)
[Redacted]
[Redacted]
[Redacted]

G.4 PLACES OF PERFORMANCE

Eli Lilly and Company
1 Lilly Corporate Ctr
Indianapolis, IN 46285

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.

G.6 INVOICING INSTRUCTIONS

The contractor shall invoice for the quantity delivered at the fixed unit price. The total quantity delivered and invoiced shall not exceed the ceiling value of the CLIN(s).

The unit of measure is "vial." The negotiated firm-fixed unit price is (b) (4) The maximum quantities to be delivered are variable based on the contractor's global allocation model.

ACCOUNTING AND APPROPRIATION DATA

AA: 0212021202220400000665654255 S.0074658.5.26 6100.9000021001
 COST CODE: A5XAH
 AMOUNT: \$312,500,000.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001156557300001	\$312,500,000.00

CLAUSES INCORPORATED BY REFERENCE

252.204-7006	Billing Instructions	OCT 2005
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018

CLAUSES INCORPORATED BY FULL TEXT

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:

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

COMBO

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(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.

N/A

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(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**	W911QY
Inspect By DoDAAC	S3605A/BARDA
Ship To Code	7BM13 – Amerisource Bergen Corporation

(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)

FOR REFERENCE:DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_htm/current/PGI204_71.htm#payment_instructions

Section H - Special Contract Requirements

H.1 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to 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 that is both developed or obtained under performance of this contract, and identified by the Government in writing as confidential except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. 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. The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government'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. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.2 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.

- (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 DoD 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 DoD approval or endorsement of the product(s) or service(s) provided.

H.3 Confidentiality of Information

1. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

2. 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.

3. 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.

4. 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.

5. 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.

6. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

7. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.4 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of SARS-CoV2-MCM neutralizing monoclonal antibodies designated as LY-CoV555. The Contractor will be the Sponsor of a Regulatory Application and as such, the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

- (a) DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter to permit DoD to have Government-only access to regulatory filings that the contractor submits to the FDA for LY-CoV555 during the period of performance of this contract. This Letter will be delivered to the designated OWS POC(s) within 30 days of award.
- (b) FDA Communications and Engagement. The contractor will provide to the Government top-line summaries and key conclusions from all studies supporting the FDA regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are submitted, generated, or made during the period of performance of this contract. In addition, unless the timeline for submission is insufficient to allow for Government review, the contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions made during the period of performance of this contract. The Government will review any such submissions promptly upon receipt. The contractor will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The contractor will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities that take place during the period of performance of this Agreement. The contractor shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA during

the period of performance of this contract regarding LY-CoV555 as soon as possible but not later than within 48 hours. The contractor shall notify the FDA that the Government has the right to discuss with FDA any development efforts regarding this product consistent with the terms of this contract.

H.5 Regulatory Compliance

1. The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211 subject to any guidance, exemptions, or waivers issued by the FDA. Production shall occur using cGMP validated manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product subject to any guidance, exemptions, or waivers issued by the FDA.

2. Production and distribution shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response.

H.6 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

- (i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and
- (iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Lilly prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1).

The items and technology covered by this Contract are being developed for both civil and military applications.

H.7 Sales to Covered Nations

- (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 June 2021 sell any COVID-19 therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a

member of the Group of Seven plus Switzerland (“Covered Nation”) at a lower price than the prices set forth in this contract.

(ii) If, at any time prior to 30 June 2021, Lilly enters into any agreement with a Covered Nation to sell the COVID-19 therapeutic supplied to the Government under this Agreement at a price lower than the price currently paid by the U.S. Government for the same COVID-19 therapeutic doses under this contract, Lilly shall provide notice within 30 days to the U.S. Government and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and receive such COVID-19 therapeutic doses at that lower price.

(iii) Upon any such election by the U.S. Government, this contract shall be deemed to have been amended and modified such that, from the date on which the more favorable pricing was first provided to any Covered Nation (the “Amended Pricing Effective Date”), the U.S. Government will receive that lower price for all orders of COVID-19 therapeutic doses following that Amended Pricing Effective Date.

(iv) Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the U.S. Government of any Lilly product.

H.8 Ensuring Sufficient Supply of the Product

1. In recognition of the Government’s need to provide sufficient quantities of a COVID-19 therapeutic to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

(a) Lilly gives written notice, required to be submitted to the Government no later than 15 business days, of:

- i. any formal management decision to terminate manufacturing of this product therapeutic prior to delivery of the minimum required doses to USG under this contract, well as all additional orders accepted by Contractor, other than as a result of clinical failure, or serious technical or safety reasons or;
- ii. any formal management decision to discontinue sale of this product therapeutic to the Government prior to delivery of the minimum required doses to USG under this contract, as well as all additional orders accepted by Contractor, other than as a result of clinical failure, or serious technical or safety reasons; or any filing that anticipates Federal bankruptcy protection; and

(b) Lilly has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Lilly, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product therapeutic with a third party for exclusive sale to the U.S. Government:

(a) a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Lilly Background Patent, Copyright, other Lilly Intellectual Property, Lilly Know-How, Lilly Technical Data rights necessary to manufacture doses of the SARS-CoV2-MCM neutralizing monoclonal antibodies designated as LY-CoV555 and the combination therapy LY-CoV555 and LY-CoV016 therapeutic; b. necessary FDA regulatory filings or authorizations owned or controlled by Lilly related to this product therapeutic and any confirmatory instrument pertaining thereto; and

(b) any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract and the license rights and items may only be used by the Government and its contractors to the extent needed to manufacture the number of doses that are not received under this contract, including with respect to any additional orders that are accepted by Contractor.

H.9 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the drug product before delivery to the final government location. In these circumstances, the Government will accept the drug product at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the therapeutic to its final destination as identified on this contract for up to sixty (60) calendar days after acceptance. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the contractor until delivery of final product to a government facility or a third-party delivery location identified by the Government.

H.10 Validation of IP/Data

The Parties acknowledge that the following background intellectual property and technical data assertions have been made:

List of Lilly Patent Applications Related to LY-CoV555 (bamlinivimab)
Asserted October 19, 2020

1. Patent Family Titled: "Anti-Coronavirus Antibodies and Methods of Use"

- (b) (4)

2. Patent Family Titled: "Methods for Reducing Host Cell Protein Content in Protein Purification Processes"

- (b) (4)

The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

H.11 Combination Therapy Negotiation

It is the intention of the parties that Lilly and the government enter into this contract for the monoclonal antibody therapeutic, while awaiting EUA on the combination therapy LY-CoV016. In the event that the combination therapy receives EUA, the parties agree to negotiate in good faith a separate contract for the combination therapy.

H.12 Buy Back

It is the intention of the parties that Lilly does not want to sell, nor does the Government want to purchase, therapeutics that are not FDA-authorized or approved or for which an EUA has been revoked. In the event that the EUA for the monoclonal antibody therapeutic is revoked, Lilly agrees to buy back from the Government all treatments (as defined in the CLIN) accepted by the Government. Lilly shall notify the contracting officer immediately upon notification of revocation. Lilly shall repurchase the treatments within (30) days of the EUA revocation at the same price as purchased by the Government unless otherwise agreed.

H.13 Modification to Contract

This contract contemplates acquisition of the monoclonal antibody therapeutic LY-CoV555 as long as there is approval and utility of this product. In the event of unforeseen circumstances including, but not limited to, delays in manufacturing, unforeseen U.S. regulatory actions, or revocation of EUA, the parties agree to negotiate in good faith, a modification to the contract to revise the minimum and/or maximum quantities and/or the period of performance.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUN 2020
52.203-3	Gratuities	APR 1984
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	JUN 2020
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-18	Commercial and Government Entity Code Maintenance	AUG 2020
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.212-4	Contract Terms and Conditions--Commercial Items	OCT 2018
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.219-9 (Dev)	Small Business Subcontracting Plan (Deviation 2018-00018)	JUN 2020
52.222-3	Convict Labor	JUN 2003
52.222-19	Child Labor -- Cooperation with Authorities and Remedies	JAN 2020
52.222-36	Equal Opportunity for Workers with Disabilities	JUN 2020
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	JAN 2019
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	JUN 2020
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	JUN 2020
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	JUN 2020
52.227-3	Patent Indemnity	APR 1984
52.229-3	Federal, State And Local Taxes	FEB 2013
52.232-17	Interest	MAY 2014
52.232-22	Limitation Of Funds	APR 1984
52.232-23	Assignment Of Claims	MAY 2014
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.242-5	Payments to Small Business Subcontractors	JAN 2017
52.242-13	Bankruptcy	JUL 1995
52.244-5	Competition In Subcontracting	DEC 1996
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.204-7002	Payment For Contract Line or Subline Items Not Separately Priced	APR 2020
252.204-7006	Billing Instructions	OCT 2005
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7015	Technical Data--Commercial Items	FEB 2014
252.244-7000	Subcontracts for Commercial Items	JUN 2013

CLAUSES INCORPORATED BY FULL TEXT

52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2020)

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "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" in the provision at 52.204-26, Covered Telecommunications Equipment or Services--Representation, or in paragraph (v) of the provision at 52.212-3, Offeror Representations and Certifications-Commercial Items.

(a) Definitions. As used in this provision-

Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, and substantial or essential component have the meanings provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Prohibition.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Nothing in the prohibition shall be construed to--

(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(ii) Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract or extending or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract. Nothing in the prohibition shall be construed to--

(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(ii) Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) Procedures. 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."

(d) Representations. The Offeror represents that--

(1) It [] will, [] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that--

It [] does, [] does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds "does" in paragraph (d)(2) of this section.

(e) Disclosures.

(1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has responded "will" in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment--

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(ii) For covered services--

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded "does" in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:

(i) For covered equipment--

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(ii) For covered services--

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(End of provision)

52.204-25 PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2020)

(a) Definitions. As used in this clause--

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means--

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means--

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled--

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) Exceptions. This clause does not prohibit contractors from providing--

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at <https://dibnet.dod.mil>. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at <https://dibnet.dod.mil>.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

(i) Within one business day from the date of such identification or notification: The contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: Any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (AUG 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (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)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: (Contracting Officer check as appropriate.)

X (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUN 2020), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

X (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

___ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

X (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

___ (5) [Reserved]

___ (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

___ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

X (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).

___ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).

___ (10) [Reserved]

___ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).

___ (ii) Alternate I (MAR 2020) of 52.219-3.

___ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

___ (ii) Alternate I (MAR 2020) of 52.219-4.

___ (13) [Reserved]

___ (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).

___ (ii) Alternate I (MAR 2020) of 52.219-6.

- ___ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).
- ___ (ii) Alternate I (MAR 2020) of 52.219-7.
- ___ (16) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)).
- X** (17)(i) 52.219-9, Small Business Subcontracting Plan (JUN 2020) (15 U.S.C. 637(d)(4)).
- ___ (ii) Alternate I (NOV 2016) of 52.219-9.
- ___ (iii) Alternate II (NOV 2016) of 52.219-9.
- ___ (iv) Alternate III (JUN 2020) of 52.219-9.
- ___ (v) Alternate IV (JUN 2020) of 52.219-9.
- ___ (18) (i) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
- ___ (ii) Alternate I (MAR 2020) of 52.219-13.
- ___ (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).
- ___ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ___ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).
- X** (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (MAY 2020) (15 U.S.C. 632(a)(2)).
- ___ (ii) Alternate I (MAR 2020) of 52.219-28.
- ___ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).
- ___ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).
- ___ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).
- ___ (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).
- X** (27) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).
- x** (28) 52.222-19, Child Labor--Cooperation with Authorities and Remedies (JAN 2020) (E.O. 13126).
- X** (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- ___ (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).
- ___ (ii) Alternate I (FEB 1999) of 52.222-26.
- ___ (31)(i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- ___ (ii) Alternate I (JUL 2014) of 52.222-35.
- ___ (32)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

____ (ii) Alternate I (JUL 2014) of 52.222-36.

____ (33) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

X (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

X (35)(i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

____ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

X (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

____ (37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

____ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

____ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).

____ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

____ (40) (i) 52.223-13, Acquisition of EPEAT® Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

____ (ii) Alternate I (OCT 2015) of 52.223-13.

____ (41)(i) 52.223-14, Acquisition of EPEAT® Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

____ (ii) Alternate I (JUN 2014) of 52.223-14.

____ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (MAY 2020) (42 U.S.C. 8259b).

____ (43)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

____ (ii) Alternate I (JUN 2014) of 52.223-16.

____ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

____ (45) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).

____ (46) 52.223-21, Foams (JUN 2016) (E.O. 13693).

____ (47)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

____ (ii) Alternate I (JAN 2017) of 52.224-3.

___ (48) 52.225-1, Buy American--Supplies (MAY 2014) (41 U.S.C. chapter 83).

___ (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

___ (ii) Alternate I (MAY 2014) of 52.225-3.

___ (iii) Alternate II (MAY 2014) of 52.225-3.

___ (iv) Alternate III (MAY 2014) of 52.225-3.

___ (50) 52.225-5, Trade Agreements (OCT 2019) 19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

X (51) 52.225-13, Restrictions on Certain Foreign Purchases (JUN 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

___ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

___ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (NOV 2007) (42 U.S.C. 5150

___ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (NOV 2007) (42 U.S.C. 5150).

___ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

___ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

___ (57) 52.232-30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

X (58) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (OCT 2018) (31 U.S.C. 3332).

___ (59) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).

___ (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

___ (61) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).

X (62) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).

___ (63)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

___ (ii) Alternate I (APR 2003) of 52.247-64.

___ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: (Contracting Officer check as appropriate.)

_____ (1) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).

_____ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

_____ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

_____ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

_____ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

_____ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

_____ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (E.O. 13658).

_____ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

_____ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records--Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (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)).

- (iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
- (iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- (vii) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
- (viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- (ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- (x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- (xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (xii) 52.222-41, Service Contract Labor Standards (Aug 2018), (41 U.S.C. chapter 67).
- (xiii) _____ (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).
 _____ (B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)
- (xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)
- (xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).
- (xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).
- (xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xix) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
 (B) Alternate I (Jan 2017) of [52.224-3](#).
- (xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<https://www.acquisition.gov/content/regulations>

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

Document Type	Description	Page #	Date
Exhibit A	CDRLs	32	26 October 2020
Attachment 0001	Security Requirements	6	11 October 2020

Exhibit A
Contract Data Requirements List (CDRL)

Data Item #	Title of Data Item	Date
A001	Post Award Teleconference Minutes	26 October 2020
A002	Kickoff Meeting Agenda and Minutes	26 October 2020
A003	Teleconference Minutes	26 October 2020
A004	Quarterly Meeting Minute	26 October 2020
A005	FDA Meeting Minutes	26 October 2020
A006	Daily Check-in Updates	26 October 2020
A007	Monthly/Annual Tech Progress Reports/Annual Meeting	26 October 2020
A008	Milestone Reports	26 October 2020
A009	Draft Technical Progress Report	26 October 2020
A010	Final Technical Progress Report	26 October 2020
A011	Product Development Source Material and Manufacturing Reports	26 October 2020
A012	Contractor Locations	26 October 2020
A013	Pandemic Management Plan	26 October 2020
A014	Supply Chain and Distribution Tracking	26 October 2020
A015	Distribution Plan	26 October 2020
A016	Manufacturing Development Plan	26 October 2020
A017	Quality Management Plan	26 October 2020
A018	Quality Agreement	26 October 2020
A019	Release Documentation for Doses to be Delivered	26 October 2020
A020	Manufacturing and Distribution Records	26 October 2020
A021	Security Plan	26 October 2020
A022	Supply Chain Resiliency Plan	26 October 2020
A023	Manufacturing Data Requirements	26 October 2020
A024	BARDA Audit Report	26 October 2020
A025	FDA Inspections	26 October 2020
A026	QA Audit Reports	26 October 2020
A027	FDA Submissions	26 October 2020
A028	EUA Filing	26 October 2020
A029	Provision of Public Law 115-92 Sponsor Authorization Letter	26 October 2020
A030	Press Releases	26 October 2020

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES	
			S	1	6
2 AMENDMENT/MODIFICATION NO P00001	3 EFFECTIVE DATE 09-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)		CODE	
		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LULLY AND COMPANY 111 (b) (6) 1 LULLY CORPORATE CTR INDIANAPOLIS IN 46285			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016		
			X 10B. DATED (SEE ITEM 13) 27-Oct-2020		
CODE 75602	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.					
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: jpapa21420 MODIFICATION OBLIGATION AMOUNT: \$62,500,000.00					
1. The purpose of this modification is to add incremental funding in the amount of \$62,500,000.00 via SubCLIN 0001 02, update the Contract Specialist information in Section G.1, change the payment office DoDAAC from HQ0337 to HQ0490, and to update the payment office DoDAAC from HQ0337 to HQ0490 in WAWF clause 252.232-7006.					
2. These changes were requested by the requiring activity in order to meet mission goals.					
3. As a result of this modification, the total funded amount for this document was increased by \$62,500,000.00 from \$312,500,000.00 to \$375,000,000.00. The total value and all other terms and conditions remain unchanged.					
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) / CONTRACTING OFFICER		
			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)		09-Nov-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 - COLUMBUS CENTER (HQ0337)
NORTH ENTITLEMENT OPERATIONS
P.O. BOX 182317
COLUMBUS OH 43218-2266
to
DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS-INDY VP GFEB
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000102 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102	ACRN AA @ \$62,500,000.00 FFP PR #0011565573-0001 PURCHASE REQUEST NUMBER: 0011565573-0001				\$0.00
NET AMT					\$0.00
ACRN AA CIN: GFEB001156557300002					\$62,500,000.00

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000102:

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

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 \$62,500,000.00 from \$312,500,000.00 to \$375,000,000.00.

SUBCLIN 000102:

Funding on SUBCLIN 000102 is initiated as follows:

ACRN: AA

CIN: GFEB001156557300002

Acctng Data: 0212021202220400000665654255 S.0074658.5.26 6100.9000021001

Increase: \$62,500,000.00

Total: \$62,500,000.00

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

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)

Project Officer
200 C Street, SW
Washington, DC 20024

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)

Eli Lilly and Company

1 Lilly Corporate Ctr
Indianapolis, IN 46285

G.4 PLACES OF PERFORMANCE

Eli Lilly and Company
1 Lilly Corporate Ctr
Indianapolis, IN 46285

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.

G.6 INVOICING INSTRUCTIONS

The contractor shall invoice for the quantity delivered at the fixed unit price. The total quantity delivered and invoiced shall not exceed the ceiling value of the CLIN(s).

The unit of measure is "vial." The negotiated firm-fixed unit price is (b) . The maximum quantities to be delivered are variable based on the contractor's global allocation model.

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:

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

COMBO

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(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.

N/A

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(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**	W911QY
Inspect By DoDAAC	S3605A/BARDA
Ship To Code	7BM13 – Amerisource Bergen Corporation

(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)

FOR REFERANCE:DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_htm/current/PGI204_71.htm#payment_instructions

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE	PAGE OF PAGES	
				S	1	4
2 AMENDMENT/MODIFICATION NO P00002	3 EFFECTIVE DATE 18-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) See Item 6		CODE		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LILLY AND COMPANY (b) (6) 1 LILLY CORPORATE CTR INDIANAPOLIS IN 46285				9A. AMENDMENT OF SOLICITATION NO.		
				9B. DATED (SEE ITEM 11)		
				X 10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016		
				X 10B. DATED (SEE ITEM 13) 27-Oct-2020		
CODE 75602	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)						
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) 21514 MODIFICATION OBLIGATION AMOUNT: \$0.00						
1. The purpose of this modification is to change/correct the Inspect By DoDAAC from S3605A/BARDA to W911QY/BARDA in WAWF clause 252.232-7006.						
2. This change is necessary to allow the contractor to invoice properly in WAWF.						
3. The total contract value and all other terms and conditions remain unchanged.						
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-Nov-2020
				(Signature of Contracting Officer)		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

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:

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

COMBO

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(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.

N/A

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(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**	W911QY
Inspect By DoDAAC	W911QY/BARDA
Ship To Code	7BM13 – Amerisource Bergen Corporation

(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 S	PAGE OF PAGES 1 3
2 AMENDMENT/MODIFICATION NO P00003	3 EFFECTIVE DATE 19-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) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LILLY AND COMPANY (b) (6) 1 LILLY CORPORATE CTR INDIANAPOLIS IN 46285			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016	
CODE 75602			X 10B. DATED (SEE ITEM 13) 27-Oct-2020	
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)				
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: 45 CFR part 101, Health Resources and Priorities Allocations System (HRPAS)				
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) 21546 OBLIGATION AMOUNT: \$0.00 See Block 14 continuation page.				
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) (b) (6) / CONTRACTING OFFICER	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR (b) (6)		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6)	
(Signature of person authorized to sign)			(Signature of Contracting Officer)	
			16C. DATE SIGNED 20-Nov-2020	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

The purpose of this modification is to:

1. Add a Health Resources Priorities and Allocations System (HRPAS) priority rating of DO-HR to this contract:

This is a DO rated contract for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR Part 101). If the contractor needs to utilize industrial resources to fulfill this rated order for a health resource, it is authorized pursuant to 45 CFR §101.36(b) to place the same priority rating and program identification symbol for health resources on its orders for industrial resources with its suppliers.

2. Add a Defense Priorities and Allocation System (DPAS) priority rating of DO-C9 to this contract to act as the equivalent to the HRPAS priority rating of DO-HR.

3. Add FAR 52.211-15, Defense Priority and Allocation Requirements

This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Contractor shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

The total funded amount and total contract price remain unchanged.

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-C9 has been added.

SECTION I - CONTRACT CLAUSES

The following have been added by full text:

52.211-15 DEFENSE PRIORITY AND ALLOCATION REQUIREMENTS (APR 2008)

This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Contractor shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

(End of clause)

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	32	26 October 2020
Attachment 0001	Security Requirements	6	11 October 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE	PAGE OF PAGES
				S	1 3
2. AMENDMENT/MODIFICATION NO. P00004	3. EFFECTIVE DATE 25-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) See Item 6		CODE	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LULLY AND COMPANY (b) (6) 1 LULLY CORPORATE CTR INDIANAPOLIS IN 46286			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X	10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016	
			X	10B. DATED (SEE ITEM 13) 27-Oct-2020	
CODE 75602	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).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
X D. OTHER (Specify type of modification and authority) FAR 52.232-22					
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: jpapa21576 MODIFICATION OBLIGATION AMOUNT: \$437,500,000.00 1. The purpose of this modification is to add incremental funding in the amount of \$437,500,000.00 via SubCL N 0001 03. 2. This change was requested by the requiring activity in order to meet mission goals 3. As a result of this modification, the total funded amount for this contract was increased by \$437,500,000.00. The total value and all other terms and conditions remain unchanged.					
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) / CONTRACTING OFFICER		
			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)		16C. DATE SIGNED 25-Nov-2020
			(Signature of Contracting Officer)		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000103 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000103	ACRN AB @ \$437,500,000.00 FFP PR #0011579643 for 350,000 doses to be delivered NLT 31 December 2020 per bilateral agreement by KO & contractor on 24 Nov 2020. PURCHASE REQUEST NUMBER: 0011579643				\$0.00
				NET AMT	\$0.00
	ACRN AB CIN: GFEB001157964300001				\$437,500,000.00

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000103:

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

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 \$437,500,000.00 from \$375,000,000.00 to \$812,500,000.00.

SUBCLIN 000103:

Funding on SUBCLIN 000103 is initiated as follows:

ACRN: AB

CIN: GFEB001157964300001

Acctng Data: 0212021202220400000665654255

S.0074658.5.30

6100.9000021001

Increase: \$437,500,000.00

Total: \$437,500,000.00

Cost Code: A5XAH

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES	
			S	1	3
2 AMENDMENT/MODIFICATION NO P00005	3 EFFECTIVE DATE 02-Dec-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) See Item 6		CODE	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LULLY AND COMPANY (b) (6) 1 LULLY CORPORATE CTR INDIANAPOLIS IN 46285			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X 10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016		
			X 10B. DATED (SEE ITEM 13) 27-Oct-2020		
CODE 75602	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).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
X D. OTHER (Specify type of modification and authority) FAR 52.232-22					
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: jpapa21578 MODIFICATION OBLIGATION AMOUNT: \$375,000,000.00					
1. The purpose of this modification is to add incremental funding in the amount of \$375,000,000.00 via SubCLIN 0001 04.					
2. This change was requested by the requiring activity in order to meet mission goals					
3. As a result of this modification, the total funded amount for this contract was increased by \$375,000,000.00 from \$812,500,000.00 to \$1,187,500,000.00. The total value and all other terms and conditions remain unchanged.					
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) / CONTRACTING OFFICER		
			TEL: (b) (6) (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)		02-Dec-2020	
		(Signature of Contracting Officer)			

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000104 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000104	ACRN AC @ \$375,000,000.00 FFP PR #0011580971 for 300,000 doses to be delivered NLT 31 January 2021 per bilateral agreement by KO & contractor on 24 Nov 2020. PURCHASE REQUEST NUMBER: 0011580971				\$0.00
				NET AMT	\$0.00
	ACRN AC CIN: GFEB001158097100001				(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000104:

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

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 \$375,000,000.00 from \$812,500,000.00 to \$1,187,500,000.00.

SUBCLIN 000104:

Funding on SUBCLIN 000104 is initiated as follows:

ACRN: AC

CIN: GFEB001158097100001

Acctng Data: 0212021202220400000665654255

S.0074658.5.34

6100.9000021001

Increase: \$375,000,000.00

Total: \$375,000,000.00

Cost Code: A5XAH

(End of Summary of Changes)

W911QY-21-C-0016
Attachment 0001
OWS Security Requirements

Date: 26 October 2020

of pages: 6

Security Requirements

Access and General Protection/Security Policy and Procedures

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

Security Plan

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

- a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan	
Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	<ul style="list-style-type: none">• organization chart and responsibilities• written security risk assessment for site• threat levels with identification matrix (High, Medium, or Low)

	<ul style="list-style-type: none"> • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	<ul style="list-style-type: none"> • policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	<ul style="list-style-type: none"> • internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	<ul style="list-style-type: none"> • identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> • intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan	

Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment	
Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security	
Description:	
Closed Circuit Television (CCTV) Monitoring	<ul style="list-style-type: none"> a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	<ul style="list-style-type: none"> a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	<ul style="list-style-type: none"> a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	<ul style="list-style-type: none"> a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access

	<ul style="list-style-type: none"> i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	<ul style="list-style-type: none"> a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	<ul style="list-style-type: none"> a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations	
Description:	
Information Sharing	<ul style="list-style-type: none"> a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	<ul style="list-style-type: none"> a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security	
Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	<ul style="list-style-type: none"> a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security	
Description:	

Physical Document Control	<ul style="list-style-type: none"> a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e., shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity	
Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	<ul style="list-style-type: none"> a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	<ul style="list-style-type: none"> a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	<ul style="list-style-type: none"> a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	<ul style="list-style-type: none"> a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	<ul style="list-style-type: none"> a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.

Media and Information Protection	<ul style="list-style-type: none"> a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	<ul style="list-style-type: none"> a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. Transportation Security	
Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	<ul style="list-style-type: none"> a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	<ul style="list-style-type: none"> a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	<ul style="list-style-type: none"> a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. <ul style="list-style-type: none"> • Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements	
Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	
Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	

W911QY-21-C-0016
Exhibit A
Contract Data Requirements List
CDRLs

Date: 26 October 2020 #
of pages: 32

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
---------------------------------------	--	-------------------------------

1. DATA ITEM NO. A002	2. TITLE OF DATA ITEM Kickoff Meeting Agenda and Minutes	3. SUBTITLE
---------------------------------	--	--------------------

4. AUTHORITY (Data Acquisition Document No.) DI-ADMN-81505	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
--	-------------------------------------	-------------------------------------

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION			
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS The Awardee shall complete a Kickoff meeting after agreement award • Within a month of agreement award, pending concurrence by the agreements officer • Awardee shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting • AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 3 business days • Awardee provides meeting minutes to AOR within 3 business days after the meeting • AOR reviews, comments, and approves minutes within 10 business days	BARDA	1			
	JPEO CBRND	1			
	15. TOTAL →		2	0	0

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
----------------------------------	----------------	----------------------------------	----------------

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
--	------------------------	---

D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
---------------------------------------	--	-------------------------------

1. DATA ITEM NO. A009	2. TITLE OF DATA ITEM Draft Technical Progress Report	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION			
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

<p>16. REMARKS</p> <p>A draft Final Technical Progress Report containing a summation of the work performed over the entire Agreement. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft'</p> <ul style="list-style-type: none"> • The Draft Technical Progress Report shall be submitted 60 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP • AOR will provide feedback on draft report within 15 calendar days of receipt, which the Awardee shall consider incorporating into the Final Report 	BARDA	1		
	JPEO CBRND	1		
	15. TOTAL →		2	0

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
----------------------------------	----------------	----------------------------------	----------------

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM <input type="checkbox"/> OTHER <input type="checkbox"/>
--	------------------------	---

D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
---------------------------------------	--	-------------------------------

1. DATA ITEM NO. A011	2. TITLE OF DATA ITEM Product Development Source Material and Manufacturing Reports	3. SUBTITLE
---------------------------------	---	--------------------

4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

16. REMARKS The contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites. The contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use. • Awardee will submit Product Development Source Material Report o Within month of Agreement award o Within 30 days of substantive changes are made to sources and/or materials o Or on the 6th month contract anniversary. • Contractor will update the Dose Tracking Template weekly during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, contractor must address all concerns raised by BARDA in writing • Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company.	BARDA	1			
	JPEO CBRND	1			
15. TOTAL		2	0	0	

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
--	------------------------	---

D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
---------------------------------------	--	-------------------------------

1. DATA ITEM NO. A012	2. TITLE OF DATA ITEM Contractor Locations	3. SUBTITLE
---------------------------------	--	--------------------

4. AUTHORITY (Data Acquisition Document No.) contractor format acceptable	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
---	-------------------------------------	-------------------------------------

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-awardees. Contractor will submit Work Locations Report: • Within 5 business days of Agreement award • Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO	BARDA	1			
	JPEO CBRND	1			
	15. TOTAL →		2	0	0

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
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1. DATA ITEM NO. A014	2. TITLE OF DATA ITEM Supply Chain and Distribution Tracking	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the enclosed dose tracking templates (see above). Awardee will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the awardee and distributor. Distributors will use that information to ship therapeutics in bulk to sites of administration/end user. Provide the following information in order to coordinate the movement and delivery of antibody from manufacturing locations sites of administration/end user : • Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage and distribution locations: • Head of Manufacturing • Production Planning • Logistics • Distribution • Labeling • Provide therapeutic labeling, packaging and distribution information as soon as it becomes available. At a minimum, include the following: • Primary Container Information • Number of doses per primary container • Unit of Sale (carton, box, package, other) • Quantity per Unit of Sale • National Drug Code (NDC) or NDC-like code under EUA • Unit of Sale dimensions (H,W, L) • Unit of Sale weight • Intermediate Package • Intermediate Package dimensions • Intermediate Package weight • Quantity Unit of Sale per pallet • Storage Requirements • Stability Information • Obtain concurrence on planned shipment protocols prior to transport • If therapeutic will require ultra-cold storage temperatures at the designated distribution centers, products should be packaged in 10-dose units to facilitate pick/pack process and reduce exposure of workers to ultra-cold temperatures. • Include the following DSCSA data elements, TI, TH and TS in packing lists. • Include the Agreement number on the packing list for all shipments • Include a copy of the MSDS (with QR code) in the packing list envelope with each shipment. • Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. Send electronic/scanned copies of all bulk shipment related documents to the AOR for three-way matching on the day shipment occurs.	BARDA	1			
	JPEO CBRND	1			
	15. TOTAL	2	0	0	

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
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1. DATA ITEM NO. A016	2. TITLE OF DATA ITEM Manufacturing Development Plan	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION			
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS This plan shall describe("describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks.") • Plan will be delivered electronically within 30 days of Agreement award to the AO and AOR	BARDA	1			
	JPEO CBRND	1			
15. TOTAL		2	0	0	

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
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1. DATA ITEM NO. A019	2. TITLE OF DATA ITEM Release documentation for doses to be delivered	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) contractor format acceptable	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final Reg Repro

16. REMARKS Certificate of Analysis Certificate of Compliance • as soon as practicable, prior to delivery	BARDA	1			
	JPEO CBRND	1			
15. TOTAL →	2	0	0	0	

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP <input checked="" type="checkbox"/> TM _____ OTHER _____
D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly

16. REMARKS (Continued)

Agreements Officer or the Agreements Officer's Representative as necessary.

b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

- I. Critical Material
- II. Vendor
- III. Supplier, Manufacturing / Distribution Location
- IV. Supplier Lead Time
- V. Shelf Life
- VI. Transportation / Shipping restrictions

The AO and AOR reserve the right to request un-redacted copies of technical documents provided in response to this subsection, during the period of performance, for distribution within the Government.

Documents shall be provided within ten (10) days after AO issues the request. The contractor may arrange for additional time if deemed necessary, and agreed to by the AO. The Government will have Limited Rights in any documents provided under this subsection.

- Delivery of plan is within 30 calendar days of award

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>Regulatory documents</u>
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
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1. DATA ITEM NO. A027	2. TITLE OF DATA ITEM FDA Submissions	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

16. REMARKS The contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final" • Contractor shall submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission or within a shorter timeframe upon Awardee request and approval from the AOR • BARDA will provide feedback to contractor within 10 business days of receipt or within a shorter timeframe upon Awardee request and approval from the AOR. • The contractor must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission • Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of submission	BARDA	1		
	JPEO CBRND	1		
	15. TOTAL →		2	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>Regulatory documents</u>
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
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1. DATA ITEM NO. A029	2. TITLE OF DATA ITEM Provision of Public Law 115-92 Sponsor Authorization Letter	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION			
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter in the Contractor's format that will be delivered to the designated OWS POC(s). • Within 30 days of award	BARDA	1			
	JPEO CBRND	1			
15. TOTAL →	2	0	0	0	

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0001	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>Regulatory documents</u>
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D. SYSTEM/ITEM Therapeutics	E. CONTRACT/PR NO. W911QY21C0016	F. CONTRACTOR Lilly
---------------------------------------	--	-------------------------------

1. DATA ITEM NO. A030	2. TITLE OF DATA ITEM Press Releases	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) contractor format acceptable	5. CONTRACT REFERENCE SOW	6. REQUIRING OFFICE BARDA
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY see remarks	12. DATE OF FIRST SUBMISSION see remarks	14. DISTRIBUTION			
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see remarks	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases • Contractor shall ensure that the AO has received and approved an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release • If corrective action is required, the contractor agrees to accurately and factually represent the work conducted under this contract in all press releases • Any final press releases shall be submitted to BARDA no later than one (1) calendar day prior to its release	BARDA	1			
	JPEO CBRND	1			
	15. TOTAL →		2	0	0

G. PREPARED BY (b) (6)	H. DATE	I. APPROVED BY (b) (6)	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A.** Self-explanatory.
- Item B.** Self-explanatory.
- Item C.** Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.
- Item D.** Enter name of system/item being acquired that data will support.
- Item E.** Self-explanatory (to be filled in after contract award).
- Item F.** Self-explanatory (to be filled in after contract award).
- Item G.** Signature of preparer of CDRL.
- Item H.** Date CDRL was prepared.
- Item I.** Signature of CDRL approval authority.
- Item J.** Date CDRL was approved.
- Item 1.** See DoD FAR Supplement Subpart 4.71 for proper numbering.
- Item 2.** Enter title as it appears on data acquisition document cited in Item 4.
- Item 3.** Enter subtitle of data item for further definition of data item (optional entry).
- Item 4.** Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.
- Item 5.** Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).
- Item 6.** Enter technical office responsible for ensuring adequacy of the data item.
- Item 7.** Specify requirement for inspection/acceptance of the data item by the Government.
- Item 8.** Specify requirement for approval of a draft before preparation of the final data item.
- Item 9.** For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).
- Item 10.** Specify number of times data items are to be delivered.
- Item 11.** Specify as-of date of data item, when applicable.
- Item 12.** Specify when first submittal is required.
- Item 13.** Specify when subsequent submittals are required, when applicable.
- Item 14.** Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.
- Item 15.** Enter total number of draft/final copies to be delivered.
- Item 16.** Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.

FOR THE CONTRACTOR

Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.

a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the production or development for the Government of that item of data. These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES	
2. AMENDMENT/MODIFICATION NO. P00006			S	1 6	
3. EFFECTIVE DATE 22-Dec-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) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LILLY AND COMPANY (b) (6) 1 LILLY CORPORATE CTR INDIANAPOLIS IN 46285			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X	10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016	
			X	10B. DATED (SEE ITEM 13) 27-Oct-2020	
CODE 75602		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)					
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).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
X D. OTHER (Specify type of modification and authority) 10 U.S.C. 2304(c)(2)/FAR 6.302-2					
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) MODIFICATION OBLIGATION AMOUNT: (b) (4)					
1. The purpose of this modification is to update the minimum quantity from 300,000 to 950,000 and maximum quantity from 950,000 to 3,000,000, and to update Section C.1 from a maximum of 950,000 to 3,000,000.					
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 of this contract was increased by (b) (4) from (b) (4) to (b) (4)					
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) (b) (6)		
15B. CONTRACTOR/OFFEROR (b) (6)			TEL: (b) (6) EMAIL: (b) (6)		
15C. DATE SIGNED 12-22-20		16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 22 Dec 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) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

The contractor shall produce and deliver 300,000 vials of the monoclonal antibody (mAb) therapeutic, LY-CoV555 at a fixed unit price of (b) (4) per vial for a total price of (b) (4). The contractor may deliver up to an additional 650,000 vials of LY-CoV555 at the fixed unit price per vial of (b) (4) upon bilateral agreement on the quantity with the government. Any additional doses will be acquired in increments of 10,000 vials. The not to exceed (NTE) price of this CLIN represents the fixed unit price at the maximum quantity of 950,000 vials. This is a fixed unit price contract. This cost reimbursement structure is only a mechanism which allows for invoicing of variable quantities delivered IAW Lilly's allocation model. This CLIN shall be executed IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract

To:

The contractor shall produce and deliver 950,000 vials of the monoclonal antibody (mAb) therapeutic, LY-CoV555 at a fixed unit price of (b) (4) per vial for a total price of (b) (4). The contractor may deliver up to an additional 2,050,000 vials of LY-CoV555 at the fixed unit price per vial of (b) (4) upon bilateral agreement on the quantity with the government. Any additional doses will be acquired in increments of 10,000 vials. The not to exceed (NTE) price of this CLIN represents the fixed unit price at the maximum quantity of 3,000,000 vials. This is a fixed unit price contract. This cost reimbursement structure is only a mechanism which allows for invoicing of variable quantities delivered IAW Lilly's allocation model. This CLIN shall be executed IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract

The estimated/max cost has increased by (b) (4) from (b) (4) to (b) (4)

The pricing detail quantity has increased by (b) (4) from (b) (4) to (b) (4)

The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4)

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

Statement of Work

C.1 EXECUTIVE SUMMARY (Scope of Project):

Manufacturing shall occur using cGMP validated manufacturing processes for bulk drug substance and fill and finished drug product. The specific objective is the acquisition of a minimum of 300,000 treatment courses (defined as 0.7g/dose/vial) for a targeted US population for delivery during the first two months after EUA or Contract Award date, whichever is later, with the possibility to acquire additional doses up to a maximum of 3,000,000. Any additional quantities above the minimum are dependent upon available supply to USG as determined by Lilly and need for additional product as determined by USG. The contractor shall also provide storage and distribution.

The product to be produced and delivered include the monoclonal antibody (mAb) therapeutic, LY-CoV555 (a monotherapy), subject to EUA approval.

C.2 TASKS

Task 1: The contractor shall establish a quality agreement (CDRL A018) with the US Government on requirements for the US Government to accept packaged drug product as a completed deliverable. Quality agreement must be negotiated within the first 30 days of award and prior to Government acceptance of drug product. The drug will not transfer to US Government unless there is an active EUA for the product.

Task 2: The contractor shall provide a Product Development Source Material and Manufacturing Plan within 30 days of award to fulfill the US Government order. The manufacturing plan should include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the US Government.

Task 3: The contractor shall manufacture the therapeutic product(s) using an established manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity plan that provides enough doses to meet the desired number of treatment courses.

Task 4: Storage. The contractor shall store the packaged drug product under cGMP conditions until the U.S. Government has directed the allocation of the product.

Task 5: Distribution. The contractor shall distribute the product as directed by the U.S. Government (USG) through the contractor's commercial distribution network with the contractor insuring against any supply loss from time of title transfer at origin through to end destination (site of administration) with replacement product transferred to the US government. Transfer of product to USG and distribution will not occur unless there is an active EUA or FDA approval/licensure for the product. Once the minimum dose requirement is met, the contractor shall communicate to USG in writing to the KO every month how many additional doses, if any, are available for acquisition along with the input data and other documentation used to run the global allocation model to allow review of how the available dose number was derived. Additional doses will only transfer to USG if Lilly has supply available and if USG determines need.

Task 6: Program Management Activities: The contractor shall establish the capacity in compliance with Food and Drug Administration (FDA) current good manufacturing practices (cGMP) regulations, and Biosafety Level standards if applicable. The contractor shall be responsible for management of all activities, including but not limited to, subcontractors to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the contractor shall provide a monthly report that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

The contractor shall provide minutes and reports in accordance with the following deliverables and the Contract Data Requirements List (CDRL), Section J, Exhibit A.

Post Award Teleconference. The contractor shall complete an initial teleconference after contract award in accordance with CDRL A001. The goal of this teleconference is to outline activities for the next 30 days and

discuss agenda items for the post-award Kickoff Meeting (CDRL A002).

Kickoff Meeting. The Contractor shall complete a Kickoff meeting after contract award in accordance with CDRL A002. This will occur within a month of contract award, pending concurrence by the contracting officer.

Every 2 weeks Teleconference. The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract in accordance with CDRL A003. Meeting frequency can be increased with agreement between both parties as needed during the course of the Project.

Quarterly Meetings. At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in either Washington D.C or at work sites of the Contractor or subcontractors in accordance with CDRL A004.

FDA Meeting Minutes and other communications with FDA. All formal and informal communications with the FDA should be provided to BARDA in accordance with CDRL A005. Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.

Daily check in with project staff for COVID-19 Contract. Contractor shall participate in a daily check-in update if necessary with the Project Managers and additional project staff as needed (via teleconference or email) in accordance with CDRL A006. Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery,

Monthly Progress Reports. A consolidated submission of all slides and data presented at the biweekly telecons will serve as the monthly report in accordance with CDRL A007. The report only consists of a summary of quantity of product delivered, when and location of the delivery.

Milestone Reports. Milestone reports shall be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW) and Integrated Master Schedule (IMS). As applicable, an Executive Summary highlighting the progress, issues and relevant manufacturing activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages. This should be submitted in accordance with CDRL A008.

Draft and Final Technical Progress Report. A draft Final Technical Progress Report containing a summation of the work performed over the entire Contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' in accordance with CDRL A009. The final report should be submitted in accordance with CDRL A010. This report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where.

Product Development Source Material and Manufacturing Reports. The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites in accordance with CDRL A011. The contract will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar.

Contractor Locations. The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors in accordance with CDRL A012.

Pandemic Management Plan. A pandemic facility and/or operational management plan including change

procedures from normal to pandemic operations. Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency in accordance with CDRL A013.

Supply Chain and Distribution Tracking. Distribution Concept of Operations. BARDA, and MCM Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using a dose tracking templates. Contractor will relay final drug product information as it is being released to the BARDA/ASPR for allocation and ordering by state public health departments. This information will be returned to BARDA, the contractor and distributor. Distributors will use that information to ship therapeutics in bulk to sites of administration/end user. This will be done in accordance with CDRL A014.

Distribution Plan. This plan shall describe the Contractor's process to allocate (the global allocation model) and distribute EUA-or BLA-approved product to point of care facilities, necessary to meet the Government's need for administration. The plan shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response. This will be done in accordance with CDRL A015.

Manufacturing Development Plan. This plan shall describe describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks." This will be done in accordance with CDRL A016.

Quality Management Plan. Plan may include, but is not limited to the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation. This will done in accordance with CDRL A017.

Quality Agreement. Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place in accordance with CDRL A018.

Release documentation for doses to be delivered. In accordance with CDRL A019 contractor will deliver Certificate of Analysis and Certificate of Compliance as soon as practicable, prior to delivery.

Manufacturing and Distribution Records. In accordance with CDRL A020 contractor will timely deliver the following records for drug substance and drug product for USG review and comment: (1) Certificate of Analysis; (2) Certificate of Conformance/Compliance; and (3) a sample label and carton from production run.

Security Plan. In accordance with CDRL A021 the contractor will deliver a security plan within 30 days of award.

Supply Chain Resiliency Plan. In accordance with CDRL A022 the contractor will deliver a supply chain resiliency plan within 30 days of award.

Manufacturing Data Requirements. In accordance with CDRL A023 the contractor will deliver

manufacturing data requirements within 30 days of award.

BARDA Audit. Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA in accordance with CDRL A024.

FDA Inspections. In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and KO with copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector in accordance with CDRL A025.

QA Audits. BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action in accordance with CDRL A026.

FDA Submissions. The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final." This will be done in accordance with CDRL A027.

EUA Filing. The Contractor shall provide a copy of any request for EUA submitted to the FDA in accordance with CDRL A028.

Provision of Public Law 115-92 Sponsor Authorization Letter. The Contractor shall submit Public Law 115-92 Sponsor Authorization Letter in the Contractor's format that will be delivered to the designated OWS POC(s). This will be done in accordance with CDRL A029.

Press Releases. Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases in accordance with CDRL A030.

C.3 SECURITY

The contractor shall comply with all Operation Warp Speed Security requirements in Section J Attachment 0001, OWS Security Requirements.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE	PAGE OF PAGES	
				S	1	3
2 AMENDMENT/MODIFICATION NO P00007	3 EFFECTIVE DATE 26-Jan-2021	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) See Item 6		CODE		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ L LLY AND COMPANY [REDACTED] 1 L LLY CORPORATE CTR INDIANAPOLIS IN 46285				9A. AMENDMENT OF SOLICITATION NO.		
				9B. DATED (SEE ITEM 11)		
				X 10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016		
				X 10B. DATED (SEE ITEM 13) 27-Oct-2020		
CODE 75602	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).						
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:						
X D. OTHER (Specify type of modification and authority) FAR 52.232-22						
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: [REDACTED] MODIFICATION OBLIGATION AMOUNT: [REDACTED]						
1. The purpose of this modification is to add incremental funding in the amount of [REDACTED] via [REDACTED]						
2. This change was requested by the requiring activity in order to meet mission goals						
3. As a result of this modification, the total funded amount for this contract was increased by [REDACTED] from [REDACTED] to [REDACTED]. The total value and all other terms and conditions remain unchanged.						
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)		
				[REDACTED] / CONTRACTING OFFICER		
				TEL: [REDACTED] EMAIL: [REDACTED]		
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
(Signature of person authorized to sign)				BY [REDACTED]		26-Jan-2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000105 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000105	(b) (4) FFP PR (b) (4) for 500,000 doses to be delivered NLT 31 March 2021 per bilateral agreement by KO & contractor on 15 Jan 2021. PURCHASE REQUEST NUMBER: (b) (4)				(b) (4)
				NET AMT	(b) (4)
	(b) (4) (b) (4)				(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000105:

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

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) to (b) (4).

SUBCLIN 000105:

Funding on SUBCLIN 000105 is initiated as follows:

(b) (4)
(b) (4)

(b) (4) [Redacted]

[Redacted]

[Redacted]

(b) (4) [Redacted]

Total: (b) (4) [Redacted]

Cost Code: (b) (4) [Redacted]

(End of Summary of Changes)