AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. Contract ID Code	Page	Of
Firm Fixed Price	1	6

2. Amendment/Modification No.	3. Effective Date	4. Requisition/Purchase Req No.	5. Project No. (If applicable)
P00004	2021JUL26	SEE SCHEDULE	

6. Issued By Code W58P05

U.S. ACC, APG , NCD
(b) (6)
10 GENERAL GREEN AVE, BLDG 1
NATICK, MA 01760-5011

EMAIL: (b) (6)

7. Administered By (If other than Item 6) Code

8. Name And Address Of Contractor (No., Street, City, County, State and Zip Code)

REGENERON PHARMACEUTICALS, INC.
777 OLD SAW MILL RIVER RD
TARRYTOWN, NY 10591-6717

Code 544P9 Facility Code

☐ **9A. Amendment Of Solicitation No.**

9B. Dated (See Item 11)

☒ **10A. Modification Of Contract/Order No.**

W15QKN-21-C-0014

10B. Dated (See Item 13)

2021JAN12

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers

☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing items 8 and 15, and returning _____ copies of the amendments: (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)

NO CHANGE TO OBLIGATION DATA

13. THIS ITEM ONLY APPLIES TO MODIFICATIONS OF CONTRACTS/ORDERS
It Modifies The Contract/Order No. As Described In Item 14.

☐ **A. This Change Order is Issued Pursuant To: 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 data, etc.) Set Forth In Item 14, Pursuant To The Authority of FAR 43.103(b).**

☒ **C. This Supplemental Agreement Is Entered Into Pursuant To Authority Of:** FAR 52.243-1

☐ **D. Other (Specify type of modification and authority)**

E. IMPORTANT: Contractor ☐ **is not,** ☒ **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.)

SEE SECOND PAGE FOR DESCRIPTION

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)	
15B. Contractor/Offeror	**15C. Date Signed**	**16B. United States Of America**	**16C. Date Signed**
_____ (Signature of person authorized to sign)		By /SIGNED/ (Signature of Contracting Officer)	2021JUL26

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION A - SUPPLEMENTAL INFORMATION

Buyer Name: (b) (6)
Buyer Office Symbol/Telephone Number: CCAP/(b) (6)
Type of Contract 1: Firm Fixed Price
Kind of Contract: Other
Kind of Modification: G
Type of Business: Large Business Performing in U.S.
Surveillance Criticality Designator: A
Weapon System: No Identified Army Weapons Systems
Contract Expiration Date: 2022JAN11

Paying Office: HQ0490
DFAS-INDY VP GFEBS
8899 E. 56TH STREET
INDIANAPOLIS IN 46249-3800

*** End of Narrative A0000 ***

The purpose of this modification is to:

1) Revise CLIN 0001AC delivery date from (b) (4) to (b) (4). This change is for administrative purposes only as delivery was complete on or before (b) (4).

2) Add the following sentences to paragraph C.3.1: "The Government will make every effort to ensure appropriate utilization of Government purchased product based on clinical need. Prior to the anticipated time of FDA approval of a Biologics License Application (BLA) for REGEN-COV, the parties will plan and coordinate to ensure efficient and effective distribution of commercial and non-commercial product."

3) Revise paragraph C.8 to state, "Authorized or Approved Uses: Product sold to the Government may be distributed for use in any indication approved or authorized by the FDA."

All other terms and conditions of this contract remain in full force and effect.

*** END OF NARRATIVE A0005 ***

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS				
0001AC	COVID-19 THERAPEUTIC (REGN10987 AND REGN1093	(b) (4)	EA	$ 2,100.00000	$ (b) (4)

COMMODITY NAME: COVID THERAPEUTIC
CLIN CONTRACT TYPE:
Firm Fixed Price
PRON: CB1RD41544 PRON AMD: 04 ACRN: AC
PSC: 6505

Packaging and Marking

Inspection and Acceptance
INSPECTION: Destination ACCEPTANCE: Destination

Deliveries or Performance

DOC REL CD	MILSTRIP	SUPPL ADDR	SIG CD	MARK FOR	TP CD
001	W56XNH10011003	W90ZQ2	J		3

DEL REL CD	QUANTITY	DEL DATE
001	(b) (4)	(b) (4)

FOB POINT: Destination

SHIP TO:
(W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B
HQ JPEO
5101 HOADLEY ROAD
ABERDEEN PROVING GROUND,MD,21010-54

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

Production of Regeneron Therapeutic in Support of National Emergency Response to Coronavirus 2019 (COVID-19)

C.1 Scope: The Department of Defense (DoD) and Department of Health and Human Services (DHHS), in support of Operation Warp Speed (OWS) and national emergency response to the Coronavirus Disease 2019 (COVID-19), requires the production of Regeneron therapeutic cocktail REGN10987 and REGN10933 (casirivimab and imdevimab) on a commercial item basis, up to 1,250,000 doses to treat members of the DoD and the general population infected with the SARS CoV-2 Virus.

C.1.1 Background: The DHHS continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States. DHHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China, and which has now spread worldwide, including in the United States. The virus has been named SARS-CoV-2 and the disease it causes has been named Coronavirus Disease 2019 (abbreviated COVID-19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a Public Health Emergency (PHE) for the United States to aid the nations healthcare community in responding to COVID-19. On March 11, WHO publicly characterized COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a national emergency.

In July 2020, the DoD awarded an Other Transaction Agreement under the authority of 10 USC 2371b to Regeneron to manufacture and sell drug product to the Government, and to distribute such drug product for the Government in the U.S. These manufacturing production activities included manufacturing at-scale, filling and finishing, and storage and shipping of REGN10987 and REGN10933 as a therapeutic cocktail to treat COVID-19 infected patients. On November 21, 2020, Regeneron announced that the antibody cocktail casirivimab and imdevimab administered together, has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

As part of DHHS preparedness and response activities, DHHS seeks to purchase up to 1,250,000 doses of the EUA authorized (or Biologics License Application (BLA) approved) casirivimab and imdevimab therapeutic, enough to treat much of the targeted US population currently or projected to be infected over the coming months.

C.2 Objectives and Quantity: The contractor shall produce up to 1,250,000 doses of therapeutic, and the Government will purchase all such doses available in Vendor-Managed Inventory (VMI) by the applicable date set forth below:

No Later Than (NLT) June 30, 2021. The Government will consider extending the time for delivery to NLT September 30, 2021, if the contractor is unable to complete delivery to VMI by June 30, 2021, after making a good faith effort to do so. However, prior to any extension to the delivery schedule, the contractor shall coordinate with the Government to determine an appropriate path forward, aligning with Government needs. The contractor shall comply with the procedures of FAR 52.212-4(f), Excusable Delays.

C.3 Requirements:

C.3.1 Therapeutic: The contractor shall distribute the product to Government designated sites as directed by the Government, EUA authorized finished drug product in vials in accordance with the products storage and handling requirements in the EUA, including temperature controls. This shall include storage and distribution activities. Regeneron will engage one or more third party service providers (each a Distributor) to perform storage and distribution activities for drug product at the direction of the Government. The Government will be solely responsible for all allocation determinations related to drug product, including allocation to end users and communication of such allocation determinations to the Distributor. Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government or distributed, as applicable, solely within the United States (including its territories and possessions). The contractor shall [redacted (b) (4)], until the product is distributed to the end user (e.g., the hospital, infusion center or other end-user). To the extent that Regeneron is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory or in distribution and in the possession of the Distributor, [redacted (b) (4)], the Government [redacted (b) (4)] of such property. The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, Assistant Secretary for Preparedness and Response (ASPR), and AmerisourceBergen. Storage and distribution activities under the EUA shall be supported under this agreement through the end of the period of performance. The Government will make every effort to ensure appropriate utilization of Government purchased product based on clinical need. Prior to the anticipated time of FDA approval of a Biologics License Application (BLA) for REGEN-COV, the parties will plan and coordinate to ensure efficient and effective distribution of commercial and non-commercial product.

C.3.2 Product Development Manufacturing Reports and Projections: Regeneron will provide manufacturing reports and manufacturing dose tracking projections/actuals, in the format and having the content mutually agreed upon by the Government and Regeneron. Regeneron will update the reports [redacted (b) (4)] during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared), with the first deliverable submission within [redacted (b) (4)] of award. For clarity, the reports described in this section apply to Formulated Drug Substance and Drug Product prior to delivery and acceptance

by the Government. Tracking reports for product following delivery and acceptance, shall be set forth in the Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen.

C.4 Reporting: The contractor shall provide the following reports/deliverables in accordance with Exhibit A:

CDRL #	Title
A001	Post Award Teleconference Minutes
A002	Kickoff Meeting Agenda and Minutes
A003	Teleconference Minutes
A004	Quarterly Meetings
A005	FDA Meeting Minutes
A006	Daily Check-in with Project Staff for COVID-19 Agreement
A007	Monthly Progress Reports
A008	Milestone Reports
A009	Draft Technical Progress Report
A010	Final Technical Progress Report
A011	Product Development Source Material and Manufacturing Report
A012	Contractor Locations
A013	Pandemic Management Plan
A014	Supply Chain and Distribution Tracking
A015	Distribution Plan
A016	Manufacturing Development Plan
A017	Quality Management Plan
A018	Quality Agreement
A019	Release Documentation for Doses to be Delivered
A020	Manufacturing and Distribution Records
A021	Security Plan
A022	Supply Chain Resiliency Plan
A023	Manufacturing Data Requirements
A024	BARDA Audit
A025	FDA Inspections
A026	QA Audits
A027	FDA Submissions
A028	EUA Filing
A029	Provision of Public Law 115-92 SPONSOR Authorization Letter
A030	Press Releases

C.5 Period of Performance: The period of performance for this contract is twelve (12) months.

C.6 Inspection/Acceptance:

C.6.1 Inspection: The Technical Point of Contact (TPOC) is a duly authorized representative of the Government, and is responsible for the inspection and/or acceptance of all items/activities to be delivered and/or completed under this contract. The parties acknowledge that acceptance may depend on the compliance with FDA regulations at 21 CFR 600-680 regarding the BLA, current Good Manufacturing Practice (cGMP) regulations at 21 CFR 210, 211, and other FDA regulations.

C.6.2 Acceptance: Title to drug product will pass to the Government upon delivery of such drug product to VMI, and the Governments corresponding written acceptance of such drug product. The Government shall accept product that conforms to contract requirements based on a Certificate of Analysis (COA) and any other quality documentation required to be provided by Regeneron, as set forth in the Quality Agreement ("Required Documents"), and the parties shall perform their obligations relating to product delivery set forth in the applicable Quality Agreement for the product. The Government's acceptance of drug product will be [redacted] provide written notice of acceptance or rejection within [redacted] Any visibly damaged product will be rejected immediately. The contractor will transfer product from VMI to the Distributor for distribution directed by the Government; provided that, product shall not be provided to the Distributor until it is accepted by the Government. The contractor shall provide a shipment temperature tracking report within [redacted] of contractors receipt of such report from its storage vendor, or otherwise in accordance with the applicable Quality Agreement. Any product subject to a temperature excursion outside of acceptable tolerances, shall be rejected. Any rejected product shall be returned to the contractor or otherwise disposed of according to contractor instructions. The Government will not be obligated to pay for rejected vials, nor will rejected vials count toward the delivery requirement. The contractor shall establish a notification mechanism for delivery sites to contact the Government regarding rejected vials.

C.7 Packaging and Marking: The contractor shall label product according to FDA guidance/instructions. Packaging shall be in shipping containers according to the contractors standard commercial practice.

C.8 Authorized and Approved Uses: Product sold to the Government may be distributed for use in any indication approved or authorized by

the FDA.

Public Disclosures: Notwithstanding any other provision in this contract, the contractor may publicly release any information related to this contract without prior approval to the extent necessary to satisfy or address regulatory requirements, contractual obligations to third parties, and the public interest in data about the safety or efficacy of the product.

Public Readiness and Emergency Preparedness (PREP) Act: The Government will ensure that no product purchased under this contract is used outside the United States (including its territories or possessions) or in a way that is not protected from liability by a declaration issued under the PREP Act that is active at the time of use.

C.9 Government Technical Point of Contact:

(b) (6)
HHS BARDA
(b) (6)
(b) (6)

*** END OF NARRATIVE C0001 ***