

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT1. Contract ID Code
Firm Fixed Price

Page 1 Of 11

2. Amendment/Modification No.

P00005

3. Effective Date

2021SEP14

4. Requisition/Purchase Req No.

SEE SCHEDULE

5. Project No. (If applicable)

6. Issued By

U.S. ACC, APG , NCD
 (b) (5)
 10 GENERAL GREEN AVE, BLDG 1
 NATICK, MA 01760-5011

Code

W58P05

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

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

Code 544P9

Facility Code

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)

SEE SECTION G (IF APPLICABLE)

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 6.302-2
- 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)

15B. Contractor/Officer

15C. Date Signed

16B. United States Of America

16C. Date Signed

(Signature of person authorized to sign)

By _____ /SIGNED/

(Signature of Contracting Officer)

2021SEP14

NSN 7540-01-152-8070

30-105-02

STANDARD FORM 30 (REV. 10-83)

PREVIOUS EDITIONS UNUSABLE

Prescribed by GSA FAR (48 CFR) 53.243

CONTINUATION SHEET**Reference No. of Document Being Continued**

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PIIN/SIIN

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MOD/AMD P00005

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION A - SUPPLEMENTAL INFORMATION

Buyer Name: (b) (6)
Buyer Office Symbol/Telephone Number: CCAP-CR/ (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: 2022JUL31

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

*** End of Narrative A0000 ***

The purpose of this modification is to:

- 1) Procure an additional 1,400,000 doses of antibody therapeutic (REGEN-COV) to treat COVID-19 in the general population.
- 2) Vendor Managed Inventory (VMI) and distribution activities shall continue for (b) (4), with a completion date of (b) (4). See Section B.
- 3) Update the contract expiration date from 11 January 2022 to 31 July 2022.
- 4) Update the Statement of Work to reflect new total contract deliverable quantities, delivery requirements, period of performance, and administrative language.
- 5) Add Attachment 0003, Contingencies and Operational Requirements.
- 6) See Section B and Section C for quantities and delivery schedule.
- 7) Increases obligation by \$2,940,000,000 from \$2,625,000,000 to \$5,565,000,000.00.

*** END OF NARRATIVE A0006 ***

CONTINUATION SHEET

Reference No. of Document Being Continued
 W15QKN-21-C-0014
 PIIN/SIIN MOD/AMD P00005

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT																														
0003AB	<p>Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.</p> <p style="text-align: center;">(End of narrative F001)</p> <p><u>REGEN-COV DOSES</u></p> <p>COMMODITY NAME: subCLIN 0003AB CLIN CONTRACT TYPE: Firm Fixed Price PRON: X21ZD485W1 PRON AMD: 01 ACRN: AE PSC: 6505</p> <p>Modification P00005 establishes CLIN 0003AB for a quantity of 476,190 doses for \$999,999,000. Binding Delivery Schedule is located below. The Goal Delivery Schedule can be found in Section C.2.</p> <p style="text-align: center;">(End of narrative B001)</p> <p><u>Packaging and Marking</u></p> <p><u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination</p> <p><u>Deliveries or Performance</u></p> <table border="0"> <tr> <td>DOC</td> <td>SUPPL</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><u>REL CD</u></td> <td><u>MILSTRIP</u></td> <td><u>ADDR</u></td> <td><u>SIG CD</u></td> <td><u>MARK FOR</u></td> <td><u>TP CD</u></td> </tr> <tr> <td>001</td> <td>W15BW91256ZD22</td> <td>W90ZQ2</td> <td>J</td> <td></td> <td>3</td> </tr> <tr> <td><u>DEL REL CD</u></td> <td><u>QUANTITY</u></td> <td><u>DEL DATE</u></td> <td></td> <td></td> <td></td> </tr> <tr> <td>001</td> <td>476,190</td> <td>31-JAN-2022</td> <td></td> <td></td> <td></td> </tr> </table> <p>FOB POINT: Destination</p> <p>SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54</p> <p>The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.</p> <p style="text-align: center;">(End of narrative F001)</p>	DOC	SUPPL					<u>REL CD</u>	<u>MILSTRIP</u>	<u>ADDR</u>	<u>SIG CD</u>	<u>MARK FOR</u>	<u>TP CD</u>	001	W15BW91256ZD22	W90ZQ2	J		3	<u>DEL REL CD</u>	<u>QUANTITY</u>	<u>DEL DATE</u>				001	476,190	31-JAN-2022				476190	EA	\$ 2,100.00000	\$ 999,999,000.00
DOC	SUPPL																																		
<u>REL CD</u>	<u>MILSTRIP</u>	<u>ADDR</u>	<u>SIG CD</u>	<u>MARK FOR</u>	<u>TP CD</u>																														
001	W15BW91256ZD22	W90ZQ2	J		3																														
<u>DEL REL CD</u>	<u>QUANTITY</u>	<u>DEL DATE</u>																																	
001	476,190	31-JAN-2022																																	

CONTINUATION SHEET

Reference No. of Document Being Continued
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 PIIN/SIIN MOD/AMD P00005

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AC	<p><u>REGEN-COV DOSES</u></p> <p>COMMODITY NAME: subCLIN 0003AC CLIN CONTRACT TYPE: Firm Fixed Price PRON: X21ZD486W1 PRON AMD: 01 ACRN: AF PSC: 6505</p> <p>Modification P00005 establishes CLIN 0003AC for a quantity of 447,620 doses for \$940,002,000. Binding Delivery Schedule is located below. The Goal Delivery Schedule can be found in Section C.2.</p> <p>(End of narrative B001)</p> <p><u>Packaging and Marking</u></p> <p><u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination</p> <p><u>Deliveries or Performance</u> DOC SUPPL <u>REL CD MILSTRIP ADDR SIG CD MARK FOR TP_CD</u> 001 W15BW91256ZD23 W90ZQ2 J 3 <u>DEL REL CD QUANTITY DEL DATE</u> 001 447,620 31-JAN-2022</p> <p>FOB POINT: Destination</p> <p>SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54</p> <p>The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.</p> <p>(End of narrative F001)</p>	447620	EA	\$ 2,100.00000	\$ 940,002,000.00
0004	<p><u>VENDOR MANAGED INVENTORY (VMI)</u></p> <p>COMMODITY NAME: VMI</p>	1	EA	\$ (b) (4)	\$ (b) (4)

CONTINUATION SHEET

Reference No. of Document Being Continued
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Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	<p>PSC: 6505 CLIN CONTRACT TYPE: Firm Fixed Price</p> <p>This CLIN applies to Vendor Managed Inventory (VMI) that shall continue for [REDACTED] (b) (4) [REDACTED].</p> <p>(End of narrative B001)</p> <p><u>Packaging and Marking</u></p> <p><u>Inspection and Acceptance</u> INSPECTION: Destination ACCEPTANCE: Destination</p> <p><u>Deliveries or Performance</u> DOC SUPPL REL_CD MILSTRIP ADDR SIG_CD MARK FOR TP_CD 001 3 DEL_REL_CD QUANTITY DEL_DATE 001 1 (b) (4)</p> <p>FOB POINT: Destination</p> <p>SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54</p>				

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

exclusive of a pediatric dose authorization, then for purposes of all deliveries and purchases of product under this contract following such approval or authorization, a dose would be such lower dose. The Product may be delivered in a co-formulated presentation or in a presentation consisting of each antibody in separate vials, provided the formulation is consistent with the FDA approval or authorization. For clarity, any product delivered in a presentation (including any dose pack) containing greater than the then-current dose of the product, shall be purchased based on the number of doses contained in such presentation, provided the FDA has authorized or approved multiple doses to be prepared from the presentation. For example, if, at the time of delivery of product, the lowest volume approved or authorized dose of the product for therapeutic use is 1.2 grams of the product (600 mg of casirivimab and 600 mg of imdevimab) and the product is delivered in a presentation consisting of 2.4 grams (1.2 grams of casirivimab and 1.2 grams of imdevimab) and the FDA has authorized or approved the preparation of multiple doses from such presentation, then such delivery shall be counted as 2 doses delivered for purposes of this contract.

EUA Wind-Down. If a BLA is issued during the term of this Contract for REGEN-COV, contractor shall ensure that any doses subsequently provided to the Government under this Contract are appropriately labeled under the terms of the EUA (before expiration) or the BLA and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the BLA.

C.3 Requirements:

C.3.1 Distribution: The contractor shall distribute the product to Government designated sites as directed by the Government, EUA authorized or BLA approved finished drug product in vials in accordance with the products storage and handling requirements in the EUA (and, if granted, the BLA as applicable), 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 and on behalf of the Government. The Government will be solely responsible for all allocation determinations related to drug product sold hereunder, 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 (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, (b) (4), the Government (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 (or any other ordering process mutually agreed by such entities). Storage and distribution activities shall be supported under this agreement through the end of the period of performance. The Government will make every effort to ensure appropriate delivery and 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 noncommercial 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 (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 (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

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

- 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 from date of award through [REDACTED] (b) (4).

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 Vendor-Managed Inventory (VMI), and the Governments corresponding acceptance of such drug product, as described in this paragraph. 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 Governments acceptance of drug product will be [REDACTED] (b) (4) the Governments written acceptance of such drug product or, [REDACTED] (b) (4) provide written notice of acceptance or rejection of such drug product, within [REDACTED] (b) (4). 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] (b) (4) 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, except as provided in Special Contract Requirements Paragraph 4., Donation of Excess Product, which remains in effect.

C.9 Government Technical Point of Contact:

[REDACTED] (b) (6)
HHS BARDA
[REDACTED] (b) (6)
[REDACTED]

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Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION G - CONTRACT ADMINISTRATION DATA

LINE	PRON/ AMS CD/ MIPR/ GFEBBS ATA	OBLG STAT	JO NO/ ACCT ASSIGN	ACRN	PRIOR AMOUNT	INCREASE/ DECREASE	CUMULATIVE AMOUNT
0003AA	X21ZD484W1	1	S.0074658.7.4.1.1.1	AD \$	0.00 \$	999,999,000.00 \$	999,999,000.00
0003AB	X21ZD485W1	1	S.0074658.7.4.1.1.2	AE \$	0.00 \$	999,999,000.00 \$	999,999,000.00
0003AC	X21ZD486W1	1	S.0074658.7.4.1.1.3	AF \$	0.00 \$	940,002,000.00 \$	940,002,000.00
NET CHANGE						\$ 2,940,000,000.00	

ACRN	ACCOUNTING CLASSIFICATION	INCREASE/ DECREASE
AD	021 202120222040 A5XAH 643627E79RG04 2550 L074890014 S.0074658.7.4.1.1	021001 \$ 999,999,000.00
AE	021 202120222040 A5XAH 643627E79RG04 2550 L074890022 S.0074658.7.4.1.2	021001 \$ 999,999,000.00
AF	021 202120222040 A5XAH 643627E79RG04 2550 L074890199 S.0074658.7.4.1.3	021001 \$ 940,002,000.00
NET CHANGE		\$ 2,940,000,000.00

	PRIOR AMOUNT OF AWARD	INCREASE/DECREASE AMOUNT	CUMULATIVE OBLIG AMT
NET CHANGE FOR AWARD:	\$ 2,625,000,000.00	\$ 2,940,000,000.00	\$ 5,565,000,000.00

LINE	ACRN	EDI/SFIS ACCOUNTING CLASSIFICATION	
0003AA	AD	021 202120222040 A5XAH 643627E79RG04 2550 L074890014 S.0074658.7.4.1.1	021001
0003AB	AE	021 202120222040 A5XAH 643627E79RG04 2550 L074890022 S.0074658.7.4.1.2	021001
0003AC	AF	021 202120222040 A5XAH 643627E79RG04 2550 L074890199 S.0074658.7.4.1.3	021001

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Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION J - LIST OF ATTACHMENTS

<u>List of</u> <u>Addenda</u>	<u>Title</u>	<u>Date</u>	<u>Number</u> <u>of Pages</u>	<u>Transmitted By</u>
Attachment 0003	CONTINGENCIES AND OPERATIONAL REQUIREMENTS	13-SEP-2021	002	EMAIL

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ATT/EXH ID Attachment 0003
PAGE 1

Contingencies and Operational Requirements

Goal Delivery Schedule*

- Approximately (b) (4) doses delivered in (b) (4)
- Approximately (b) (4) doses delivered in (b) (4)
- Approximately (b) (4) doses delivered in (b) (4)
- Approximately (b) (4) doses delivered in (b) (4)

* The delivery schedule is non-binding and for illustrative purposes only and it is subject to the following contingencies and operational requirements:

A. FDA action on submissions currently under review:

(b) (4)

B. Additional Regulatory Actions:

(b) (4)

C. Operational Requirements:

(b) (4)

(b) (4)

