SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30

1. REQUISITION NUMBER	PAGE 1 OF 48
0011720874	

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
W58P0522C0001	17-Nov-2021			

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER (No Collect Calls)	8. OFFER DUE DATE/LOCAL TIME

9. ISSUED BY CODE W58P05

ACC-APG - COVID RESPONSE - W58P05
6472 INTEGRITY COURT (BUILDING 4401)
ABERDEEN PROVING GROUND MD 21005-3013

TEL:
FAX:

10. THIS ACQUISITION IS

- [X] UNRESTRICTED OR [ ] SET ASIDE: ____ % FOR:
- [ ] SMALL BUSINESS
- [ ] WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
- [ ] HUBZONE SMALL BUSINESS
- [ ] EDWOSB
- NAICS: 325412
- [ ] SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
- [ ] 8(A)
- SIZE STANDARD: 1,250

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING / 14. METHOD OF SOLICITATION
[X] SEE SCHEDULE	Net 30 Days	[ ]	[ ] RFQ [ ] IFB [ ] RFP

15. DELIVER TO CODE

SEE SCHEDULE

16. ADMINISTERED BY CODE S3309A

DCMA GARDEN CITY
207 NEW YORK AVENUE
STATEN ISLAND NY 10305-5013

17a. CONTRACTOR/ OFFEROR CODE 86491 FACILITY CODE 86491

PFIZER INC.
PFIZER
235 E 42ND ST
NEW YORK NY 10017-5703

TELEPHONE NO.

18a. PAYMENT WILL BE MADE BY CODE HQ0337

DFAS-COLUMBUS CENTER
NORTH ENTITLEMENT OPERATIONS
P O BOX 182266
COLUMBUS OH 43218-2266

[ ] 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a. UNLESS BLOCK BELOW IS CHECKED [ ] SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	SEE SCHEDULE				

25. ACCOUNTING AND APPROPRIATION DATA

See Schedule

26. TOTAL AWARD AMOUNT (For Govt. Use Only)

(b) (4) [redacted]

[ ] 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1. 52.212-4. FAR 52.212-3. 52.212-5 ARE ATTACHED. ADDENDA [ ] ARE [ ] ARE NOT ATTACHED

[X] 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA [X] ARE [ ] ARE NOT ATTACHED

[X] 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

[ ] 29. AWARD OF CONTRACT: REF. OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR	31a. UNITED ST OFFICER)		
(b) (6) [redacted]	(b) (6) [redacted]		
30b. (TY	30c. DATE SIGNED 2021-11-17	31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT) (b) (6) [redacted] TEL: EMAIL:	31c. DATE SIGNED 17NOV2021

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA – FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	SEE SCHEDULE				

32a. QUANTITY IN COLUMN 21 HAS BEEN

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

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
	32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER ☐ PARTIAL ☐ FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT ☐ COMPLETE ☐ PARTIAL ☐ FINAL	37. CHECK NUMBER

38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY *(Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT *(Location)*	
		42c. DATE REC'D *(YY/MM/DD)*	42d. TOTAL CONTAINERS

Section SF 1449 - CONTINUATION SHEET

EXECUTIVE SUMMARY

1. Background: In December of 2019, an outbreak of COVID-19 was reported in Wuhan City, Hubei Province, China. The World Health Organization (WHO) states that COVID-19 is the infectious disease caused by the most recently discovered coronavirus. The WHO declared the global COVID-19 outbreak a pandemic on 11 March 2020, stating it is a "public health crisis." On 31 January 2020, the U.S. Department of Health and Human Services (HHS) Secretary declared a public health emergency (PHE) for the U.S. to aid the nation's health care community in responding to COVID-19. On 13 March 2020, the President of the United States of America declared COVID-19 an emergency IAW 42 U.S.C. 5122 (the Robert T. Stafford Disaster Relief and Emergency Assistance Act) which allows for Special Emergency Procurement Authority IAW 41 U.S.C.1903. On 18 March 2020, the President invoked this authority in accordance with the Defense Production Act and later authorized the Operation Warp Speed (OWS) Mission (now referred to as "Countermeasures Acceleration Group" (CAG)).

Under the President's CAG Mission, Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), HHS, and Biomedical Advanced Research and Development Authority (BARDA) are leading a whole of nation effort with the primary goal to execute and maintain a well-defined portfolio of COVID-19 medical countermeasure candidates to maximize the probability of having safe and effective diagnostics, therapeutics and vaccines, as fast as possible, for mass distribution.

In an effort to obtain innovative therapeutics for the treatment of COVID-19, the Government posted Medical Countermeasures (MCM) Commercial Solutions Opening (CSO), Solicitation Number W911QY-20-S-C001, Area of Interest (AoI) number A005 for an Oral Antiviral Therapeutic Treatment on the Government Point of Entry website, SAM.gov. on 25 June 2021. Pfizer Incorporated responded to this CSO with their Oral Protease Inhibitor drug PF-07321332 for the treatment of SARS-CoV-2. After review, the treatment was accepted by the Government. Therefore, in furtherance of the United States Government's goal, the Government will procure 10M treatment courses of Pfizer's oral antiviral therapeutic treatment.

2. This action has a Firm Fixed Price value of $5,295,000,000.00 At this time, CLIN 0001 is funded in the amount of $5,295,000,000.00.

3. The Representations and Certifications made by Pfizer in the System for Award Management (SAM) are hereby incorporated into this contract by reference.

4. The Pfizer Small Business Subcontracting Plan, effective January 1, 2021 to December 31, 2021, is hereby incorporated into the contract (see Attachment 0001)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		(b) (4)	Each	(b) (4)	(b) (4)

Oral Protease Inhibitor PF-07321332
FFP
The contractor shall produce, store, and distribute 10,000,000 five (5) day treatment courses of the oral protease inhibitor compound (oral antiviral treatment), PF-07321332 IAW the Statement of Work (SOW), Product Release Schedule & Delivery Information (Section G) and CDRLs (Exhibit A) on this contract. A unit is defined as one full five (5) day treatment course.

The Contractor shall distribute the product as directed by the U.S. Government (USG) with the contractor insuring against any supply loss from time of title transfer at origin through to end destination (located within the United States, including its territories and possessions) with replacement product transferred to the USG. Transfer of product to USG and distribution will not occur unless, on the date of transfer, there is an approved New Drug Application or active Emergency Use Authorization for the product authorizing use of the drug to treat COVID-19 as described in the SOW.
FOB: Destination
PSC CD: 6505

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AA (b) (4)
CIN: GFEBS001172087400001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AB (b) (4)
CIN: GFEBS001172087400002

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000103					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AC (b) (4)
CIN: GFEBS001172087400003

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000104					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AD (b) (4)
CIN: GFEBS001172087400004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000105					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AE (b) (4)
CIN: GFEBS001172087400005

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000106					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AF (b) (4)
CIN: GFEBS001172087400006

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000107					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AG (b) (4)
CIN: GFEBS001172087400007

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000108					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AH (b) (4)
CIN: GFEBS001172087400008

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000109					$0.00

FFP
PURCHASE REQUEST NUMBER: 0011720874

NET AMT $0.00

ACRN AJ (b) (4)
CIN: GFEBS001172087400009

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		1	Job		NSP

Technical Data/Deliverables
FFP
The contractor shall deliver Technical Data IAW Contract Data Requirements List (CDRL) IAW deliverables, Exhibit A
FOB: Origin (Shipping Point)
PROJECT: COVID-19 CAG
PSC CD: 6505

NET AMT

STATEMENT OF WORK

Proprietary and Confidential Business Information Exempt from Disclosure Under FOIA Exemption Four

STATEMENT OF WORK
ORAL ANTIVIRAL THERAPEUTIC TREATMENT

C.1.1. GENERAL

C.1.2. Objective

The Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRN) in coordination with the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) seeks to acquire treatment courses of critical therapeutics for the COVID-19 response. The JPEO will coordinate the activities as awarded under these contracts.

C.1.3. Background

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

U.S.C. § 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Under the U.S. Government's (USG) COVID-19 Response mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 medical countermeasure (MCM) candidates to maximize availability of safe and effective vaccines, therapeutics and diagnostics as fast as possible for mass distribution. As such, BARDA has a specific need to procure orally administered, direct-acting antiviral therapeutic treatment.

C.1.4. Scope of Work

The USG seeks delivery of an orally administered, direct-acting antiviral therapeutic authorized or approved by the Food and Drug Administration (FDA) to treat high risk outpatients with a reduction of hospitalization and/or mortality endpoint, all outpatients with a symptom alleviation endpoint, and/or post- and pre-exposed populations demonstrating a reduction in symptomatic COVID-19. The therapeutic shall have completed all testing and manufacturing to support delivery of the established quantities, within the timelines established under this contract.

Alternative endpoints may be considered if they are accepted by the FDA. Emergency Use Authorization (EUA) shall be obtained no later than end of Quarter 1 of Calendar Year 2022 (Q1 CY2022) and/or New Drug Application (NDA) approval no later than end of Q3 CY2022 subject to technical, clinical and manufacturing success and FDA authorization/approval.

C.2. TASKS

C.2.1 Task 1 - Product Development Source Material and Manufacturing Plan. The Contractor shall provide a Product Development Source Material and Manufacturing Plan within 30 days of award to fulfill the USG order. The Manufacturing Plan shall include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product(s), an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the USG. If multiple indications are under consideration, a timeline and quantity of drug for each indication should be provided.

C.2.2 Task 2 – Manufacture. The Contractor shall manufacture the therapeutic product(s) using an established manufacturing process for active pharmaceutical ingredient, bulk drug product and pack/labelled final drug product, with a ramp-up capacity plan that provides enough doses to meet the desired number of treatment courses. The Contractor shall manufacture according to Current Good Manufacturing Practice (cGMP) commensurate with the conditions submitted and authorized by the FDA through the Emergency Use Authorization application.

C.2.3 Task 3 – Storage. The Contractor shall store the packaged drug product under cGMP conditions until EUA and/or FDA approval. Following EUA or FDA approval, the product shall be stored for a period of up to six months after initial acceptance by the USG. Timing for this acceptance will be as outlined in the contract. The Contractor shall not be obligated to rotate stock at any time during the six-month storage period. The USG acknowledges and

agrees that for product stored by the Contractor at USG's request, USG shall not be entitled to a refund for product based on actual shelf life remaining upon delivery to the end destination.

C.2.4 Task 4 – Distribution. The Contractor, through its distributor (or distributors as the USG may permit) shall distribute product quantities to locations as directed by the USG consistent with the terms of this SOW. Contractor shall use a single distribution company to distribute product with the Contractor insuring against any supply loss from time of title transfer at origin through to end destination, i.e. pharmacies, located within the United States (including its territories and possessions). During performance of this contract, the Contractor may request Government approval to add additional distribution companies. Said approval shall be at the sole discretion of the Government. Transfer of product to USG and distribution shall not occur unless, on the date of transfer, there is an active EUA or FDA approval for the product authorizing use of the drug to treat COVID-19 for the agreed upon indication.
The single distributor must meet the following requirements as specified and agreed upon in the Distribution Plan and Memorandum of Understanding:

a. Product shall be shipped within 24 hours from initial receipt of order.
b. Shipments shall be monitored for the duration of transit and all information regarding shipments and orders shall be provided to the USG.
c. Provide notification to USG in the event of a delay of shipment.
d. Provide package recovery when shipments are required to be returned due to unavailability of delivery.
e. The distributor must be able to interface with the USG Ordering Portal, Health Partner Ordering Portal (HPOP).

The Contractor shall provide the following data deliverables in accordance with the CDRLs outlined in Attachment I, Antiviral Deliverables Table:
CDRL A007 Supply Chain and Distribution Tracking
CDRL A008 Distribution Plan
CDRL A009 Distribution Memorandum of Understanding

C.2.5 Task 5 - Material Transfer Agreement (MTA).
Within 10 days of USG providing Contractor with a draft National Institute of Allergy and Infectious Diseases (NIAID) Non-Clinical Evaluation Agreement between Contractor and the USG (the "**MTA**"), which is substantially similar to the draft previously provided to Contractor, the Parties will execute the MTA, provided that both Parties have engaged in a good faith negotiation, to include the following material terms:

(i) At the USG's request, the Parties would execute no more than ten (10) HHS Division of Microbiology and Infectious Diseases (DMID) Service Request Forms for:

    (a) the evaluation of PF-07321332 as a single agent in a SARS-CoV2 live virus variant assay (each an "**In Vitro SRF**"), wherein the assay will be performed at one or more currently authorized USG supported test sites, will include remdesivir as a positive control as well as other blinded test articles selected from clinical candidates of interest to the USG and related analogs thereof, and, if Vero cells (or other cells with strong efflux pumps) are used, the experiment(s) will be conducted in the presence of an efflux inhibitor provided by Contractor, provided that (a) if the test site differs

from NIAID-IRF and the assay protocol no. VR-05-04 entitled Single Drug Screen Assay – 384 well plate which was provided to Contractor, prior to executing the In Vitro SRF, USG would provide Contractor with at least thirty (30) days to provide input on the design of the live virus variant testing assay and to, at Contractor's sole discretion and pursuant to Sections 6.3, 6.4, and 6.6 of the MTA, allow Contractor to negotiate with the USG supported test site(s) with regards to a license to any Contractor Subject Inventions (as defined in the MTA) which are not Class 1 Subject Inventions (as defined in the MTA) and (b) each In Vitro SRF would not obligate Contractor to provide more than 10 mg powder (or an equivalent solubilized stock) of PF-07321332; and/or

(b) for the evaluation of PF-07321332 as a single agent in a mouse model against SARS-CoV-2 variants that are capable of establishing infection in wildtype mice ("**In Vivo SRF**"), wherein the assay would be performed at one or more currently authorized USG-supported test sites, and will use an appropriate positive control as well as other blinded test articles selected from clinical candidates of interest to the USG and related analogs thereof, provided that (a) prior to executing the In Vivo SRF, (1) USG would share the details of the planned in vivo studies with Contractor and (2) USG would provide Contractor with at least thirty (30) days to provide input on the study design and to, at Contractor's sole discretion and pursuant to Sections 6.3, 6.4 and 6.6 of the MTA, allow Contractor to negotiate with the USG supported test site(s) with regards to a license to any Contractor Subject Inventions which are not Class 1 Subject Inventions, and (b) the In Vivo SRF would not obligate Contractor to provide more than 10 g of PF-07321332.

(ii) The USG shall agree, and shall cause its Contractors to agree, to comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication of results involving unblinded products arising from the MTA, including International Committee of Medical Journal Editors standards regarding authorship and contributions.

(iii) Absent Contractor's advance written consent, which consent would be in Contractor's sole discretion, the USG shall agree, and shall cause each Contractor to agree, it will not use PF-07321332 as a control in any assays, use PF-07321332 in any drug development-related activities, nor test PF-07321332 in combination with other therapeutics or potential therapeutics.

To the extent there is a conflict between the terms of this section C.2.5 and the MTA, the terms of the MTA shall govern work to be performed under the MTA.

C.2.6. Task 6 - Informational Material. To the extent consistent with the terms of any EUA as well as applicable legal, regulatory or compliance requirements or guidance, including but not limited to requirements or guidance under the Food, Drug and Cosmetic Act, the Contractor shall develop learning material to assist in administration and increase uptake of their drug to the public including but not limited to pamphlets, infomercials, websites, etc. Contractor will make a reasonable effort to share core draft educational materials with the USG (BARDA)

during the creation process. The USG may provide comments on Educational Materials to Contractor within 3 business days for Contractor's consideration.

C.2.7 Task 7 - Program Management Activities. The Contractor shall manufacture in compliance with FDA cGMP commensurate with the conditions submitted and authorized by FDA through the Emergency Use Authorization application. The Contractor shall be responsible for management of all activities, including but not limited to managing subcontractors to meet the goals of the contract, holding routine meetings with USG, and completion of meeting minutes.

C.3.0 **DELIVERABLES**

C.3.1. The Contractor shall provide the information deliverables to the USG, in accordance with theContract Data Requirement List (CDRL), Section J, Exhibit A.

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
000102	N/A	N/A	N/A	N/A
000103	N/A	N/A	N/A	N/A
000104	N/A	N/A	N/A	N/A
000105	N/A	N/A	N/A	N/A
000106	N/A	N/A	N/A	N/A
000107	N/A	N/A	N/A	N/A
000108	N/A	N/A	N/A	N/A
000109	N/A	N/A	N/A	N/A
0002	Origin	Government	Origin	Government

CONTRACT ADMINISTRATION
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.

G.1 (b) (6) [redacted]

[redacted]

ACC Joint COVID-19 Response Division

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

(b) (6)

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

(b) (6)

G.4 PLACES OF PERFORMANCE

Pfizer Headquarters
235 East 42nd Street
New York, NY 10038

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 or office of the PCO 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.

PRODUCT RELEASE SCHEDULE

Contractor shall make quantities of the Final Drug Product that are suitable for release available for Government inspection in accordance with the table below:

Product Release Schedule											
	Dec	Jan	Feb	Mar	April	May	June	Jul	Aug	Sep	Total
Units*	50,000	100,000	150,000	400,000	500,000	600,000	750,000	1,200,000	3,000,000	3,250,000	10,000,000

*As used herein, a "unit" is defined as one treatment course.

All treatment courses must have an active FDA authorization or approval at time of delivery. If the FDA has not yet authorized or approved the product at the time of scheduled product release in any month per the table above, the Contractor shall retain the product until the FDA authorizes or approves the product, and Contractor shall then release all doses due to the Government in the month in which the FDA authorization or approval is granted. Delayed release in any particular month shall not result in an adjustment to the remainder of the release schedule. The Contractor will make its best effort to accelerate the above release schedule, and accelerated release deliveries will be at no additional cost to the Government.

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	31-DEC-2021	50,000	N/A FOB: Destination	
0001	31-JAN-2022	100,000	N/A FOB: Destination	
0001	28-FEB-2022	150,000	N/A FOB: Destination	
0001	31-MAR-2022	400,000	N/A FOB: Destination	
0001	30-APR-2022	500,000	N/A FOB: Destination	
0001	31-MAY-2022	600,000	N/A FOB: Destination	
0001	30-JUN-2022	750,000	N/A FOB: Destination	
0001	31-JUL-2022	1,200,000	N/A FOB: Destination	
0001	31-AUG-2022	3,000,000	N/A FOB: Destination	
0001	30-SEP-2022	3,250,000	N/A FOB: Destination	
000101	N/A	N/A	N/A	N/A
000102	N/A	N/A	N/A	N/A
000103	N/A	N/A	N/A	N/A
000104	N/A	N/A	N/A	N/A
000105	N/A	N/A	N/A	N/A
000106	N/A	N/A	N/A	N/A
000107	N/A	N/A	N/A	N/A
000108	N/A	N/A	N/A	N/A

000109	N/A	N/A	N/A	N/A
0002	N/A	N/A	N/A	N/A

ACCOUNTING AND APPROPRIATION DATA

AA: 0212021202220400000664643260 S.0074658.7.4.4.1 6100.0152021001
COST CODE: A5XAH
AMOUNT: (b) (4)

AB: 0212021202220400000664643260 S.0074658.7.4.4.3 6100.0152021001
COST CODE: A5XAH
AMOUNT (b) (4)

AC: 0212021202220400000664643260 S.0074658.7.4.4.4 6100.0152021001
COST CODE: A5XAH
AMOUNT: (b) (4)

AD: 0212021202220400000664643260 S.0074658.7.4.4.5 6100.0152021001
COST CODE: A5XAH
AMOUNT: (b) (4)

AE: 0212021202220400000664643260 S.0074658.7.4.4.6 6100.0152021001
COST CODE: A5XAH
AMOUNT: (b) (4)

AF: 0212021202220400000664643260 S.0074658.7.4.4.7 6100.0152021001
COST CODE: A5XAH
AMOUNT: (b) (4)

AG: 0212021202220400000664643260 S.0074658.7.4.4.8 6100.0152021001
COST CODE: A5XAH
AMOUNT (b) (4)

AH: 0212021202220400000664643260 S.0074658.7.4.4.9 6100.0152021001
COST CODE: A5XAH
AMOUNT: (b) (4)

AJ: 0212021202220400000664643260 S.0074658.7.4.4.10 6100.0152021001
COST CODE: A5XAH
AMOUNT (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001172087400001	(b) (4)
AB	000102	GFEBS001172087400002	(b) (4)
AC	000103	GFEBS001172087400003	(b) (4)
AD	000104	GFEBS001172087400004	(b) (4)
AE	000105	GFEBS001172087400005	(b) (4)
AF	000106	GFEBS001172087400006	(b) (4)
AG	000107	GFEBS001172087400007	(b) (4)
AH	000108	GFEBS001172087400008	(b) (4)
AJ	000109	GFEBS001172087400009	(b) (4)

CLAUSES INCORPORATED BY REFERENCE

52.203-3	Gratuities	APR 1984
52.203-6 Alt I	Restrictions On Subcontractor Sales To The Government (JUN 2020) -- Alternate I	OCT 1995
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
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.	OCT 2020
52.212-4	Contract Terms and Conditions--Commercial Items	OCT 2018
52.219-9	Small Business Subcontracting Plan	JUN 2020
52.222-50	Combating Trafficking in Persons	OCT 2020
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.242-13	Bankruptcy	JUL 1995
52.245-1	Government Property	SEP 2021
52.245-9	Use And Charges	APR 2012
52.246-2	Inspection Of Supplies--Fixed Price	AUG 1996
52.246-16	Responsibility For Supplies	APR 1984
52.247-34	F.O.B. Destination	NOV 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7006	Billing Instructions	OCT 2005
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019
252.204-7015	Notice of Authorized Disclosure of Information for Litigation Support	MAY 2016
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Country that is a State Sponsor of Terrorism	MAY 2019
252.211-7007	Reporting of Government-Furnished Property	AUG 2012
252.225-7012	Preference For Certain Domestic Commodities	DEC 2017
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7015	Technical Data--Commercial Items	FEB 2014
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 2016
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018
252.232-7010	Levies on Contract Payments	DEC 2006
252.232-7017	Accelerating Payments to Small Business Subcontractors--Prohibition on Fees and Consideration	APR 2020
252.243-7002	Requests for Equitable Adjustment	DEC 2012
252.244-7000	Subcontracts for Commercial Items	JAN 2021
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished Property	APR 2012

252.245-7002	Reporting Loss of Government Property	JAN 2021
252.245-7003	Contractor Property Management System Administration	APR 2012
252.245-7004	Reporting, Reutilization, and Disposal	DEC 2017
252.247-7023	Transportation of Supplies by Sea	FEB 2019
WAWF	Army Electronic Invoicing	FEB 2006

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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 (JUL 2021)

(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).

x (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 (NOV 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 (NOV 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)).

____ (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 (NOV 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).

X (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).

____ (ii) Alternate I (FEB 1999) of 52.222-26.

X (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.

X (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.

X (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 (OCT 2020) (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.

X (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 (JAN 2021) (41 U.S.C. chapter 83).

____ (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (JAN 2021) (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 (JAN 2021) of 52.225-3.

____ (iii) Alternate II (JAN 2021) of 52.225-3.

____ (iv) Alternate III (JAN 2021) 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 (FEB 2021) (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 (FEB 2021).

____ (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. 55305 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 (NOV 2020) (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 (OCT 2020) (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 (NOV 2020) (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. 55305 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)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (NOV 2020)

(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)

252.204-7018 PROHIBITION ON THE ACQUISITION OF COVERED DEFENSE TELECOMMUNICATIONS EQUIPMENT OR SERVICES (JAN 2021)

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

Covered defense 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) Telecommunications services provided by such entities or using such equipment; or

(3) Telecommunications equipment or services produced or provided by an entity that the Secretary of Defense reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Covered foreign country means--

(1) The People's Republic of China; or

(2) The Russian Federation.

Covered missions means--

(1) The nuclear deterrence mission of DoD, including with respect to nuclear command, control, and communications, integrated tactical warning and attack assessment, and continuity of Government; or

(2) The homeland defense mission of DoD, including with respect to ballistic missile defense.

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).

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

(b) Prohibition. In accordance with section 1656 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115-91), the contractor shall not provide to the Government any equipment, system, or service to carry out covered missions that uses covered defense telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless the covered defense telecommunication equipment or services are covered by a waiver described in Defense Federal Acquisition Regulation Supplement 204.2104.

(c) Procedures. The Contractor shall review the list of excluded parties in the System for Award Management (SAM) at https://www.sam.gov for entities that are excluded when providing any equipment, system, or service, to carry out covered missions, that uses covered defense telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless a waiver is granted.

(d) Reporting.

(1) In the event the Contractor identifies covered defense 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, the Contractor shall report at https://dibnet.dod.mil the information in paragraph (d)(2) of this clause.

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

(i) Within 3 business days from the date of such identification or notification: The contract number; the order number(s), if applicable; supplier name; 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 30 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 a covered defense 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), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

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

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

(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.

(ii) For fixed price line items—

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

Invoice (Contractor Only)

(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.

Invoice as 2-in-1

(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.

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

(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*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W58P05
Admin DoDAAC**	W58P05
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

(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.

(b) (6)

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

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 clause)

CAG SPECIAL CLAUSES (SEC. H)
TERMS AND CONDITIONS
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 a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the Contracting Officer which the Contracting Officer will provide in accordance with Countermeasures Acceleration Group (CAG) 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 Government or third-party 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 delivery timing or sites, 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 relating to delivery timing or sites 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 for the following activities: (1) to comply with any law, rule, regulation, court ruling or similar order; (2) 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 (3) provision 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 Section H except to the extent that a disclosure is otherwise prohibited by law.

The Government will provide Contractor with a written notice prior to releasing, in response to a Freedom of Information Act (FOIA) request, any document submitted by Contractor to Government. During this period, Contractor shall have the right to notify Government which documents, if any, contain trade secrets of Contractor, or its collaboration partners (or other information legally withholdable from release under FOIA).

H.2 Publication and Publicity

The contractor shall not release any press releases, or any other publications, which address delivery of product under this contract, without prior 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 proposed publication which contains delivery, timing or government sites to the COR for security review prior to publication. The contractor shall also inform the COR when and how the abstract article or other publication was published, and furnish a copy of the final product.

(b) Neither Contractor nor the Government shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Contract, the transactions contemplated by it, or the relationship between Contractor and the Government hereunder, without the prior written consent of the other, such consent not to be unreasonably withheld or delayed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction.

(c) Notwithstanding the foregoing, Contractor retains the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its COVID-19 development program, without the Government's consent or involvement, if said publication or release of information contains no information regarding any Government activity.

(d) Unless authorized in writing by the Contracting Officer, the contractor shall not display any Government logo or seal including Operating Division or Staff Division logos on any publications.

(e) 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

(a) 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.

(b) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the contract "Disputes" clause (FAR 52.233-1).

(c) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor and the Government will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(d) The Receiving Party shall not directly or indirectly, divulge or reveal to any person or entity any Confidential Information of another Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this Contract. Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government or Contractor, shall be shared strictly on a need to know basis for the purposes of this Contract and is subject to the restrictions of this provision. In addition to the above, Confidential Information may be subject to the protections of the Trade Secrets Act as well as any other remedies available under this Contract or the law.

(e) Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this contract; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; (v) was approved for public release by prior written permission of the Disclosing Party; or (vi) required by law or regulation to be disclosed, provided, however, that the Receiving Party has provided written notice to the disclosing party promptly so as to enable such disclosing party to seek a protective order or otherwise prevent disclosure of such information. For clarity, Contractor shall have the right to disclose Contractor's Confidential Information to any third parties as necessary to perform this contract.

(f) 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 clause, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

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

(h) The provisions of paragraph (H.3.d) of this clause shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

(i) The obligation of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

H.4 Reserved

H.5 Regulatory Compliance

(a) The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR Parts 210 and 211. Production shall occur using cGMP manufacturing process, fully compliant with 21 CFR Parts 210 and 211, for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides doses sufficient to meet Contractor's obligations under this Agreement.

(b) 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, including any waivers or exceptions.

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), as amended (together, the "Prep Act Declaration"):

(a) 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;

(b) 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

(c) Contractor is a "Covered Person" per 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 PREP Act Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractor's 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 is 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 Contractor prior to use and, if the parties disagree on such use, the dispute will be resolved according to the contract "Disputes Clause" (FAR 52.233-1).

H.7 Most Favored Nation Clause

(a) If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase (i) the same or a lesser volume of Product than the U.S. Government commits to purchase (ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.

(b) 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 lower priced courses are first supplied or delivered to the applicable Covered Nation (the "Amended Pricing Effective Date"), the U.S. Government will receive that lower price for Product for which Contractor has not invoiced the U.S. Government following that Amended Pricing Effective Date.

(c) 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 Contractor product.

(d) For purposes of this section, "Covered Nation" shall mean a nation that is a member of the Group of Seven (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States) plus Switzerland and "Product" shall the mean 5-day treatment courses of Contractor's COVID-19 oral antiviral treatment (i.e., PF-07321332) that is the subject of this contract.

(e) The USG shall not be entitled to the price of Product purchased by a Covered Nation for purposes of donation or resale by the Covered Nation to non-governmental organizations, intergovernmental organizations, or "lower-income" or "lower middle-income countries" as those terms are defined by the World Bank as of the date of the effective date of agreement between Contractor and the Covered Nation.

(f) For clarity, if Contractor enters into an agreement with more than one nation, a multinational organization, or a multilateral organization, and a Covered Nation receives Product under such an agreement or benefits from the price under such an agreement, the Parties agree that the relevant volume for purposes of H.7.(a)(i) shall be the total Product volume specified in such agreement and not the Product volume any one Covered Nation receives.

H.8 Reserved

H.9 Acceptance, Invoicing, Payment, and Risk of Loss

Contractor will provide Release Documentation to the COR for review. The COR will review and, when appropriate and in a timely manner and no more than 2 business days after submission, will notify Contractor of the Government's acceptance, on a lot-by-lot basis. Upon acceptance by the Government and delivery to the Contractor designated storage facility, title to accepted treatment courses will pass to the Government. Contractor will invoice the Government on a monthly basis for accepted treatment courses, and the Government shall make payment in accordance with FAR 52.212-4(i).

Regardless of where acceptance occurs, risk of loss of, or damage to, supplies shall remain with the contractor until delivery of Final Drug Product (FDP) to USG's designated end destination, as set forth in H.10. In the event of loss of, or damage to, accepted product prior to delivery to USG's end destination, the Government shall accept replacement product as its sole remedy. All end destinations shall be located in the United States, its territories or possessions.

"Release Documentation" shall mean lot documentation limited to sample label, Safety Data Sheet, Certificate of Compliance and Certificate of Analysis.

H.10 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 end destination. In these circumstances, the Government will accept FDP at the contractor facility (Origin), as specified in H.9. The contractor however, shall continue to be responsible for secure delivery of the therapeutic to the USG designated end destination.

H.11 Intellectual Property Rights

Contractor represents that, to its knowledge, the rights held by or granted to the Contractor, including rights in pending patent applications, if granted, will be sufficient to enable the Contractor to perform its obligations under the contract. Notwithstanding the foregoing, if the Contractor later determines that additional rights are needed or

desirable to perform its obligations under this contract, Contractor will make reasonable efforts to obtain any such rights, including all intellectual property licenses. Nothing in this clause or any other term of this Agreement constitutes express or implied Government authorization and consent for Contractor or its subcontractor(s) to utilize, manufacture or practice inventions covered by valid United States or foreign patents to which Contractor or its subcontractor(s) does not have rights in the performance of work under this Agreement.

H.12 No Government Funding

The awardee represents that it has not received U.S. Government funding for the awardee's research and/or development of its oral antiviral compound, PF-07321332, for the potential treatment of SARS-CoV-2 Coronavirus.

H.13 Termination

The Government may terminate this contract for cause in accordance with FAR 52.212-4 (m). If the Government contemplates a termination for cause, the contracting officer shall give the contractor written notice specifying the failure and providing a period of 30 days (or longer period as necessary) in which to cure the failure. Upon expiration of the 30 days (or longer period), the contracting officer may issue a notice of termination for default unless it is determined that the failure to perform has been cured. Notwithstanding FAR 52.212-4(l), the Government will not exercise its unilateral right to Terminate for Convenience during the performance of work supported by this contract.

Termination for Product Discontinuation. In the event that (a) Contractor notifies the Government that, as a result of emerging safety or efficacy data, Contractor is ceasing efforts to develop its oral protease inhibitor compound, PF-07321332, (b) Contractor does not receive an EUA for the use of PF-07321332 to treat COVID-19 by the end of Q1 2022, or (c) Contractor receives U.S. regulatory approval or authorization, but such approval or authorization is subsequently withdrawn and, after a reasonable amount of time, the parties determine that the authorization will not be restored or approval will not be granted, the Government may notify Contractor of its intent to terminate this Contract, and the Parties will agree to effect a no-cost settlement to end performance of this Agreement within thirty (30) days of such notice. From and after the effective date of any such termination, Contractor shall have no further obligation to deliver PF-07321332, and the Government shall have no further obligation to accept PF-07321332 for delivery.

The Government acknowledges that as of the effective date of this contract, Contractor's compound, PF-07321332, is in clinical development and remains subject to clinical, technical, manufacturing and regulatory success, among other risks.

H.14 Buy Back

In the event that the EUA or NDA for PF-07321332 is revoked due to safety or efficacy concerns that were not apparent at the time of contract award, except for a EUA or NDA revocation related to decreased efficacy of PF-07321332 on COVID-19 variants, the Contractor, at the Government's request, agrees to buy back from the Government all treatment courses accepted by the Government under this contract that have a remaining shelf life and have yet to be distributed to third parties for administration or to administration sites. Courses that are bought back under this provision will be destroyed. Contractor shall notify the contracting officer immediately upon notification of revocation of the EUA. Contractor shall repurchase the courses within (30) days of the notice at the same price as purchased by the Government unless otherwise agreed.

H.15 Donation of Excess Product

A. In the event the Government determines that doses of PF-07321332 funded under the contract are no longer needed by the Government, the Government may donate, either directly or through a non-governmental organization or intergovernmental organization, remaining doses to any "lower-income" or "lower middle-income countries", as those terms are defined by the World Bank as of the date of donation ("Donee Nation"), that: (1) (a) has an active marketing approval in place for use of PF-07321332 at the time of donation or, (b) if no marketing approval is in place, has an active regulatory authorization and (2) has entered into an indemnification/limitation of liability agreement with Contractor that covers donated doses.

B. The Government shall notify Contractor prior to any planned donation to a Donee Nation. Contractor agrees to work with the Government in good faith to ensure all applicable regulatory submissions, import/export permits, and other requirements for donation are completed in advance of shipment to the extent that donation is authorized under Paragraph A above. Nothing in this Paragraph shall require the Contractor to seek regulatory approval in any particular country.

C. Contractor will be responsible for shipment of PF-07321332 to the receiving Donee Nation; provided, however, Contractor shall have no obligation to repackage or relabel the courses already purchased by the USG for delivery to the U.S.market and provided further that Contractor shall only be responsible for shipment of the courses of PF-07321332 to one reasonable location within the receiving Donee Nation, or as otherwise agreed between the Parties. Contractor shall be responsible for the cost of standard shipping; expedited shipping will be paid for by the U.S. Government. The minimum quantity to be shipped by Contractor is one shipper. Upon execution of this contract, one shipper contains 100 treatment courses,

D. The parties acknowledge that Article H.6 regarding PREP Act coverage does not apply to the provision of any doses under this paragraph to a Donee Nation. The USG makes no representations as to PREP Act coverage thereto.

H.16 Special License Agreement

Pursuant to DFARS 252.227-7015, incorporated into this contract, this Special License Agreement hereby grants Limited Rights (as defined by DFARS 252.227-7013(a) incorporated herein) including the right to use, modify or reproduce Technical Data (as defined by DFARS 252.227-7013(a)(15) incorporated herein) within the Government for non-manufacturing purposes as provided for in DFARS 252.227-7015(c) in all Technical Data comprising the deliverables identified in contract Attachment [deliverables table] Data Rights, except the Deliverable identified as A020 (Educational Materials), for which the data rights are granted as specifically stated therein.

This agreement does not alter any rights that the U.S. Government may have previously obtained under other agreements with third parties. Section B CLIN 0001 is full compensation to the Contractor for all of the deliverables and rights granted by this contract inclusive of all contract clauses.

The Contractor shall mark all deliverables referred to above as required under DFARS 252.227-7013(f)(4). The contractor hereby warrants that it has secured all rights necessary to grant the U.S. Government the rights as recited above.

H.17 Subject Inventions Not Expected

The Government acknowledges that it is not funding research, development or chemistry manufacturing and controls (CMC)/process development under this contract. As such, neither the Contractor nor the Government expect that conception or reduction to practice of any Subject Inventions will result from performance under this contract. Accordingly, as between the Contractor and the Government, any and all inventions conceived or first reduced to practice in the performance of this contract shall be owned by Contractor.

H.18 Limitation of Liability

In addition to the protections afforded under the PREP Act discussed above, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items. Notwithstanding the foregoing, in the event Contractor is found liable for any damages under this contract, such damages shall be limited to the amount of payments Contractor has received from the Government hereunder.

H.19 Excusable Delays

The parties recognize that the global pandemic caused by COVID-19 has had a significant impact on the availability of certain suppliers and other resources necessary to produce certain pharmaceutical and related products.

Accordingly, notwithstanding any provision in this contract to the contrary, Contractor shall not be liable for default if nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence, as contemplated in FAR 52.212-4(f). For avoidance of doubt, occurrences beyond the reasonable control of the Contractor and without its fault or negligence also include supply chain disruptions arising from or related to the COVID-19 pandemic and the availability of materials for performance of this contract.

In the event of an excusable delay caused by a supply chain disruption arising from or related to the COVID-19 pandemic and the availability of materials for performance of this contract, Contractor shall follow the procedures at FAR 52.212-4(f). The Government acknowledges and agrees that Contractor's efforts to manufacture and deliver on the timeline set forth in this contract are aspirational in nature and subject to significant risks and uncertainties.

Accordingly, notwithstanding any provision to the contrary herein, the Contractor will be granted reasonable delay in performance if it is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence.

H. 20 EUA Wind Down

EUA Wind-Down. If a NDA is approved during the term of this Contract for PF-07321332, Contractor shall ensure that any treatment course subsequently provided to the Government under this Contract, after a reasonable amount of time in which to runoff existing inventory, are appropriately labeled and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the NDA. This plan will be approved by the FDA.

ADDENDA

Inspection and Acceptance Section Clause Addenda
For the purposes of this contract, FAR 52.246-2 and FAR 52.246-16 are superseded in their entirety by H.9 Acceptance, Invoicing, Payment, and Risk of Loss.

Addenda to DFARS 252.204-7003
This contract does not include the acquisition of "government personnel work product" per DFARS 252.204-7003.

DFARS Clause 252.227-7037 does not apply to any of the CDRLs in the Data Deliverables Table. To the extent there is other technical data furnished under this contract, Pfizer shall comply with DFARS Clause 252.227-7037.

LIST OF ATTACHMENTS & EXHIBITS

	Number	Transmitted

List of Addenda	Title	Date	of Pages	by
Exhibit A	CDRLs/Deliverable Table	28 OCT 2021	21	EMAIL
Attachment 0001	Pfizer Subcontracting Plan	1 JUN 2021	13	EMAIL

EXHIBIT A
EXEMPT FROM DISCLOSURE UNDER FOIA EXEMPTION FOUR

EXHIBIT A, ANTIVIRAL DELIVERABLES TABLE

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
A001	Post Award Teleconference	The contractor shall complete an initial teleconference after contract award 1. Outline activities for the next 30 days	•Within one week of contract award •Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one •COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days •Contractor provides meeting minutes to COR within **5** business days after the meeting •COR reviews, comments and approves minutes within 10 business days of receipt	Limited
A002	Every 2 Weeks Program Progress Meeting (PPM)	The Contractor shall participate in teleconferences every 2 weeks after contract award with BARDA to discuss the performance on the contract. Contractor shall provide a mutually agreed upon standard status report and progress update covering: • Clinical Development (e.g. enrollment numbers and high-level results from the proof-of-concept, interim and full analyses) • Key FDA engagements (e.g. Type A,B,C, meetings, approvals, major notifications, inspections, findings 483s, EIR etc.). Contractor retains right to redact from any FDA communications information unrelated to the Product • Manufacturing / Distribution (schedule adherence, delivery updates, USG inventory position, audits) • Contract deliverables updates	•First meeting within a month of contract award, pending concurrence by the contracting officer •Contractor shall provide itinerary and additions to standing agenda at least 2 business days in advance •COR edits/approves and instructs contractor to distribute agenda 1 day in advance •Contractor provides meeting minutes and all standard agreed update slides and data presented to COR within **5** business days after the meeting •COR reviews, comments, and approves minutes within 5 business days of receipt • Contractor shall notify BARDA of upcoming FDA meetings (Type A,B,C) at the every 2 weeks meeting •The Contractor shall forward FDA-issued final minutes of any meeting with the FDA to BARDA within 5 calendar days of receipt	Limited
A003	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	•No agenda will be required for the meeting •No meeting minutes are required	Limited

[1] As used in this table, Limited Rights has the meaning defined by DFARS 252.227-7013(a).

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
		(via teleconference or email). Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery Daily check-ins may occur on weekdays, excluding federal holidays. Upon agreement of both parties, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	•Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day	
A004	Monthly & Annual Technical Progress Reports/Annual Meeting	A consolidated submission of all slides and data presented at the biweekly telecoms will serve as the monthly report. The report only consists of a summary of quantity of product delivered, when and location of the delivery.	•Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see CDRL A009). The COR and CO will review the monthly reports with the Contractor and provide feedback within 10 business days of receipt. •Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits	Limited
A005	Draft and Final Deliverables Progress Report	A Draft and Final Deliverables Progress Report containing a summation of the deliverables performed over the entire Contract. This report shall be in sufficient detail to describe the progress achieved and completion of agreed upon deliverables. Report should contain original schedule and attained schedule during the Contract. Descriptions and rationale for SOW items that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft." The final report should be submitted and marked as FINAL. This report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where.	•The Draft Deliverables/Progress Report shall be submitted 75 calendar days before the end of the PoP and the Final Deliverables Progress Report on or before the end of the PoP •COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report	Limited
A006	Product Source Material and	The Contractor shall update Product Source Material and Contractor	•Contractor will update Product Source Material Report	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
	Manufacturing Reports and Projections	Locations Report submitted during Project Coordination Team (PCT) meetings 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 The Contractor will provide completed manufacturing reports and manufacturing treatment course tracking projections/actuals This deliverable only applies to material manufactured for this Contract and which the Government has agreed to purchase. The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, an overall manufacturing point of contact, and work performed per location, to include sub-contractors	○ Within 30 days of substantive changes are made to sources and/or materials • Contractor will update the treatment course tracking projections every two weeks Updates will be provided at each PPM. • Contractor shall provide update within 48 hours if treatment course delivery schedule is impacted by more than 15% from agreed baseline schedule. • The Government may request a daily check in meeting to discuss concerns and recommend corrective actions	
A007	Supply Chain and Distribution Tracking	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 anticipated delivery schedule using a tracking template subject to Contractor's approval. Contractor will relay final drug product information as it is released to the BARDA/ASPR. This information will be returned to BARDA, the contractor and the distributor. The distributor will use that information to ship therapeutics to pharmacies.	Provide the following information in order to coordinate the movement and delivery of antiviral product from manufacturing locations to a single distributor and pharmacies • Provide a Point of Contact information (name, title, phone, email) for manufacturing / supply chain matters • Provide therapeutic labeling, packaging and distribution information within 12 hours of it becoming available. At a minimum, include the following, and as applicable: • Primary Packaging Information • Number of doses per primary pack • 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	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
			• 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 • Include the following DSCSA data elements, TI, TH and TS in packing lists. • Include the contract 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 electronic/scanned copies of all bulk shipment related documents to the COR for three-way matching on the day shipment occurs.	
A008	Distribution Plan	This plan shall be developed in accordance with the Statement of Work and in collaboration with the Government and will describe the process to distribute EUA-or NDA-approved product to pharmacies, 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. Contractor's PF-07321332 is exempt in the US from serialization at this time due to the ongoing Public Health Emergency (PHE) Contractor continues to build/invest in serialization readiness on our packaging lines for PF-07321332. Contractor plans to begin serializing PF-07321332 at the unit of sale once NDA approved and the product is no longer included in the PHE.	Initial Plan and any amendments will be delivered electronically to the COR and CO within 60 days of award unless otherwise agreed by the Parties. The Government shall approve the Distribution Plan before distribution can commence.	Limited
A009	Distribution Memo of Understanding	This document is an understanding between ASPR, contractor, and the	Initial MOU and any amendments will be delivered electronically to the COR and CO within 45 days of	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
		distributor to set forth the terms for each party to work together.	award or as otherwise agreed by the parties.	
A010	Manufacturing Development Plan	This plan shall describe the manufacturing process for the product in a level of detail and format that is mutually acceptable to the Government and Contractor 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 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 contract award to the CO and COR	Limited
A011	Quality Management Plan	This shall describe the Quality Management Plan for the product in a level of detail and format that is mutually acceptable to the Government and Contractor. Plan may include but is not limited to the manufacturing 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	Plan will be delivered electronically within 30 days of contract award to the CO and COR.	Limited
A012	Release Documentation for treatment courses to be Delivered	Contractor will deliver Certificate of Analysis and Certificate of Compliance for doses to be delivered	Documentation shall be provided at least 14 days prior to delivery	Limited

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A013	Security Plan	No CUI will be exchanged between the parties in relation to this contract. Develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the obligations under this contract. The Government acknowledges that this program will reflect Contractor's established security procedures in place with respect to its facilities and information security, which are at least as protective as would be customary for a global company. Contractor will use commercially reasonable efforts to implement any further procedures/precautions reasonably requested by the Government with respect to Statement of Work, at Contractor's sole discretion and as long as such implementation would not adversely impact Contractor's ordinary operation of its facilities and systems in connection with its other business and products. This plan shall establish security practices and procedures that demonstrate how the Awardee will meet and adhere to the security program, and shall be delivered to the Government within thirty (30) calendar days of award or as otherwise agreed by the parties. The Contractor shall also use commercially reasonable efforts to ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and Contractor's security plans.	• The Government will review in detail and submit comments within ten (10) business days to the CO and COR 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 (30) calendar days after receipt of the comments. • The Security Plan shall include a timeline for compliance of all the required security measures reasonably requested by the Government. 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.	Limited
A014	Supply Chain Resiliency Plan	A comprehensive Supply Chain Resiliency Program, or Contractor Equivalent, that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods. A critical component is defined as any material that is essential to the	Delivery of plan is within 60 calendar days of award	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
		product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment. Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized. The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications. b) For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities. c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the Agreement delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries. The Contractor shall articulate in the plan, the methodology for inventory control, production		

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		planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. a) Production rates and lead times shall be understood and communicated to the Contracting Officer or the Contracting 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 Contracting Officer and the Contracting Officer's Representative 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 CO issues the request. The contractor may arrange for additional time if deemed necessary, and agreed to by the CO. The Government will have Limited Rights in any documents provided under this subsection.		
A015	BARDA Audit	Contractor shall accommodate for cause site visits related to manufacturing of US supply by BARDA upon 30 days written notice and during normal business hours. 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 This deliverable only applies to material manufactured for this	•If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 20 business days of the audit •COR and CO will review the report and provide a response to the Contractor with 10 business days Once corrective action is completed, the Contractor will provide a final report to BARDA	Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
		Contract project, and for which the Government has agreed to purchase.		
A016	QA Audits	BARDA reserves the right to participate in for cause QA audits by Contractor related to manufacturing performed by the sub-contractors if BARDA participation is acceptable to the Contractor and the subcontractor. 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 non-conformance to FDA regulations for GMP 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	•Contractor shall notify CO and COR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors •Contractor shall provide the COR and CO with the Executive Summary and subsequent response corrective/actions if applicable within 10 business days of completion. COR and CO will review the report and provide a response to the Contractor with 10 business days	Limited
A017	Master Delivery Schedule and Delivery Deviation Notification	The contractor shall provide a Master Delivery Schedule including a list of critical milestones that must be met to ensure on time delivery. The Master Delivery Schedule must provide baselines for achieving critical milestones. The Master Delivery Schedule may be limited to those milestones associated with delivery of the product. Contractor may provide pre-existing documentation of critical milestones. Contractor shall use diligent efforts to notify the Government within 48 hours of any event, risk, formal or informal FDA communication, or other issue that would be reasonably expected to materially change the anticipated delivery schedule by one week or more.	•The Master Delivery Schedule is due within 30 business days of contract award •The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set •In the event of Delivery Schedule slippage, Contractor shall provide high level details to return to original delivery schedule, or as close to agreed schedule as possible within 5 days of establishing slippage will be realized •An Incident Report will be provided within 5 days for incidents that present liability to the project	Limited
A018	FDA Correspondence and Submissions	FDA Interactions and Inspections Documentation. Contractor shall provide the Government within 72 hours of receipt any FDA Form 483, Establishment Inspection Report (EIR), regulatory authorization or approval-related letter and/or warning or untitled letter that is reasonably likely to materially impede production or the ability to meet supply deadlines under the		Limited

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates	Data Rights[1]
		contract, including status of Emergency Use Authorization and/or NDA approval .		
A019	Press Releases	Each party agrees to accurately and factually represent the work conducted under this contract in all press releases	Each party shall ensure that the other party, (the CO, in the case of Government), has received and approved release directly related to this contract not less than 5 business days prior to the issuance of the press release unless agreed to by the COR. • 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	Limited
A020	Educational Materials	Contractor will develop learning material to assist in administration and increase appropriate uptake of their drug to the public including but not limited to pamphlets, infomercials, websites, etc., subject to FDA guidance, regulation, and/or review.	Contractor shall provide a digital copy of any Materials within five (5) business days of their date of first use during the Post-Authorization Period. "Materials" are publicly-disseminated communications intended to help inform either HCPs or consumers on the availability and appropriate use of the product, including communication of authorized labeling. For the avoidance of doubt, "Materials" do not include unbranded disease awareness campaigns, or medical product-related scientific-exchange that is otherwise exempt from FDA regulation. "Post-Authorization Period" means the period of time following the receipt of an authorization from the FDA under an EUA and prior to receipt of an approval of an NDA from the FDA, or until such time the Agreement expires or is terminated if such date is earlier than the receipt of NDA approval	The Government has rights to use, reproduce, display, release or disclose final, unmodified, FDA-approved educational materials and to have or authorize others to do so.