		ORDE	R FOR SU	PPLIES OR SER\	/ICES					PAGE	JF PAGE	-5
IMPORTANT:	Mark all packages	and papers with conti	ract and/or or	der numbers.						1		23
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3. ORDER NO.		4 F	REQUISITION/F	EFERENCE NO.								
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ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

PAGE NO

IMPORTANT: Mark all packages and papers with contract and/or order numbers. DATE OF ORDER CONTRACT NO. ORDER NO. HHSF223201810005B 75F40122F19210 04/04/2022 QUANTITY UNIT ITEM NO. SUPPLIES/SERVICES UNIT AMOUNT QUANTITY ACCEPTED ORDERED PRICE (d) (a) (f) (b) (c) (e) (g) BPA Call against BPA No. HHSF223201810005B for Professional and Technical services Base Period: \$567,058.74 Optional Labor CLIN Base Period: \$202,161.60 Option Period I: \$1,701,176.22 Optional Labor CLIN Option Period I: \$606,484.80 Option Period II: \$1,162,394.04 Optional Labor CLIN Option Period II: \$414,431.28 Option Period III: \$1,124,691.96 Optional Labor CLIN Option Period III: \$400,953.84 Total Labor Cost: \$4,555,320.96 Total Optional Labor CLINs: \$1,624,031.52 Total: \$6,179,352.48 COR: Michael Fischer CO: James Whitt CS: James Samuels Contract Type: Labor Hour This order is issued in accordance with contractor s duote dated March 7, 2022. Admin Office: DHHS/FDA/OAGS/DAO ATTN: James Samuels 4041 Powder Mill Road Beltsville MD 20705 Period of Performance: 04/04/2022 to 07/03/2022 Funding for BPA Call 75F40122F19210, 567,058.74 1 Litigation Support Services FOIA against BPA No. HHSF223201810005B. Base Period: April 4, 2022 through July 3, 2022 Consultant III @ Rate of \$89.17 Consultant IV @ Rate of \$123.29 Management Analyst II @ Rate of \$59.31 Management Analyst III @ Rate of \$76.83 Project Manager III @ Rate of \$122.28 Program Manager III @ Rate of \$132.31 Delivery: 30 Days After Award Accounting Info: 2022.6998002.25147.C2202133100A024 Appr. Yr.|: 2022 CAN: 6998002 Object Class: Continued ...

\$567,058.74

ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

PAGE NO

3

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER CONTRACT NO.

HHSF223201810005B 04/04/2022

ORDER NO.

75F40122F19210

ITEM NO.	SUPPLIES/SERVICES	QUANTITY		PRICE	AMOUNT	QUANTITY ACCEPTED
(a)	(b)	(c)	(d)	(e)	(f)	(g)
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2	Optional Labor CLIN (Base Period)				0.00	
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3	Funding for BPA Call 75F40122F19210, Litigation Support Services FOIA against BPA No. HHSF223201810005B.				0.00	
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	Amount: \$1,701,176.22(Option Line Item)					
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4	Optional Labor CLIN (Option Period I)				0.00	
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TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

PAGE NO

4

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER CO 04/04/2022 H.

CONTRACT NO.

HHSF223201810005B

ORDER NO.

75F40122F19210

### Punding for SPA Call 75F40122F19210,	ITEM NO.	SUPPLIES/SERVICES	QUANTITY	LINIT	UNIT	AMOUNT		QUANTITY
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ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

PAGE NO

DATE OF ORDER CONTRACT NO. ORDER NO. HHSF223201810005B 75F40122F19210 04/04/2022 ITEM NO. SUPPLIES/SERVICES QUANTITY UNIT UNIT AMOUNT QUANTITY ORDERED ACCEPTED PRICE (d) (a) (f) (b) (c) (e) (g) Delivery: 30 Days After Award Accounting Info: 6998002.25147.00000000.00 CAN: 6998002 Object Class: 25147 Funded: \$0.00 Period of Performance: 10/04/2023 to 04/03/2024 0.00 Optional Labor CLIN (Option Period III) 8 Consultant III @ Rate of \$89.17 Management Analyst III @ Rate of \$76.83 Amount: \$400,953.84(Option Line Item) Accounting Info: 2010.6998002.25147.00000000.00 Appr. Yr.: 2010 CAN 6998002 Object Class: 25147 Funded: \$0.00 Period of Performance: 10/04/2023 to 04/03/2024 The total amount of award: \$6,179,352.48. The obligation for this award is shown in box 17(i). TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) \$0.00

Statement of Work

Litigation Support Services- Freedom of Information Act (FOIA)
Food and Drug Administration (FDA)
Office of Career Outreach and Development (OCOD)
The Division of Disclosure and Oversight Management (DDOM)

1.0 INTRODUCTION:

1.1 Background

The Freedom of Information Act, commonly known as the FOIA, was enacted by Congress in 1966 to give the American public greater access to the federal government's records. The Electronic Freedom of Information Act Amendments of 1996 expanded the scope of the FOIA to encompass electronic records and required the creation of "electronic reading rooms" to make records more easily and widely available to the public. The Division of Disclosure and Oversight Management (DDOM) within the Center for Biologics Research and Review (CBER), at the FDA, is CBER's liaison for inquiries from Congress, the General Accountability Office (GAO), and the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG). Further, DDOM manages the disclosure of all documents to the public and congress, in response to court orders and requests from foreign counterparts. DDOM also handles all Freedom of Information Act (FOIA) requests and related litigation for the Center.

This is a request for services to assist in the disclosure review of records related to the various types of records sharing managed by DDOM and, records to be produced per court order for a pending FOIA litigation. The influx of regular work has been steadily increasing, and the division recently became involved in a FOIA litigation, in which the court has ordered the FDA to produce 55,000 pages of records every 30 days until production of all records has been completed. The estimated page count of records is about 500,000 (pages not inclusive of data files (SAS) which are unable to be paginated)((40 rows equals 1 page, thusly, the data files to convert is about 700,000 pages). Contractors are needed to meet the demanding and unprecedented court ordered production of records and to assist in other activities associated with disclosure assignments of the DDOM.

1.2 Objectives

The objective of this Order is to procure FOIA support services to assist DDOM with disclosure review and records sharing functions of the FDA in accordance with FOIA, HHS, and FDA regulations.

2.0 REQUIREMENTS:

The Contractor shall provide at least fifteen (15) qualified personnel to provide FOIA support services. The scope of the services includes but is not limited:

• Providing FOIA services to address an approximate volume of at least **55,000 pages every 30 days and at least 500,000 in total** (pages not inclusive of data files (SAS) which are unable to be paginated (40 rows equals 1 page, thusly, the data files to convert is about 700,000 pages)

- Drafting FOIA related correspondence.
- Coordinating searches for responsive documents.
- Applying appropriate FOIA exemptions to non-disclosable information within responsive documents.
- Preparing records for release, including the redaction of materials to be withheld, and duplicating materials, as necessary.
- 2.1 <u>Tasks</u>: The Contractor shall provide FOIA support services as outlined in the following tasks:

2.1.1 Disclosure Review:

- Review, evaluate, and analyze routine disclosure requests and recommend clearance of CBER's disclosure activities.
- Ensure disclosure analysis requests are accurate, satisfactory, completed in a timely manner, and contain only information which is considered disclosable as provided under the FOIA, the Privacy Act, and the FDA's implementing regulations.
- Review documents for disclosure and recommend appropriate action.
- Keep abreast of all changes to the statutes and regulations to ensure CBER's compliance.
- Maintain awareness of current developments in CBER to correctly review and analyze records for disclosure.
- Apply understanding of scientific principles, content and context related to drug and biological products to make consistent disclosure determinations on CBER related records. (*This task will only be required for Contractors that are responsible for reviewing documents with a scientific content*).
- Prepare an index of produced documents to include document details and descriptions of any withheld portions of the documents including exemption code(s).

2.1.2 Redaction of Records:

- The contractor shall redact records in accordance with the requirements of the 1966 Freedom of information Act, the 2007 OPEN Gov't Act, and the E-Gov Act.
- Utilize Adobe 10 to redact and prepare records for production, including boxing exempt material, applying redactions, sanitizing the records, and applying Bates numbering if applicable.
- Ensure released materials do not contain information exempted under the applicable statutes.

2.1.3 <u>Communication/ Reporting:</u>

- Keep division management informed of the nature of all sensitive requests.
- Discuss all issues with the project manager, contracting officer representative and/or technical point of contact to obtain approval for the response and other related actions.
- The contractor will be required to provide weekly progress reports.
- The Contractor shall attend a kick-off meeting and provide a post-award conference summary.

3.0 DELIVERABLES:

The Contractor shall submit all deliverables pursuant to the direction of the contracting officer representative (COR). The Contractor shall ensure accuracy, functionality, completeness, professional quality, and overall compliance with government guidelines/requirements of the deliverables at the time documents are submitted for final clearance. The Contractor shall submit a weekly status report, entitled "Weekly Progress Report," to FDA. The "Weekly Progress Report" shall include the status of each component, as listed below.

The "Weekly Progress Report" must list activities and accomplishments for the week, work products in progress, activities planned to begin the following month, and activities planned to begin the following month.

- Hours expended during the reporting period by individual(s).
- Cumulative hours expended through the reporting period by labor category.
- Summary of work accomplished during the reporting period and progress of work assigned.
- Problem areas; and
- Schedule of activities planned and estimated hours for the next reporting period and remaining hours to complete activities

Section	Deliverables	Due Date
2.1.3	Kick-Off Meeting- Post Award Summary Conference Summary	Due no later than one (1) week after award.
2.0	FOIA Support Services (Disclosure Review, Redaction, and Communication/Reporting Services)	Ongoing
2.1.2	Progress Reports	Weekly

Be advised that FDA does not accept documents which contain the use of macros. When submitting documents via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e., email blocks, quarantine). Document submissions required throughout the award period(s) shall not have macro enabled functionality and any document delivered having that functionality will be deemed delinquent, if not corrected prior to the due date.

4.0 INSPECTION AND ACCEPTANCE:

All work under this order is subject to inspection and final acceptance by the COR. The contractor shall ensure that the deliverables meet the following standards:

• Accuracy: Work products shall be at least ninety percent (90%) accurate in presentation, technical content, and adherence to accepted elements of style

- Technical Soundness: Work products, especially digital work products, shall exhibit no technical flaws.
- Clarity: Work products shall be clear and concise.
- Consistency to Requirements: All work products must satisfy the requirements of the statement of work.
- Timeliness: Work products shall be submitted by the due date specified in this statement of work or submitted in accordance with a later scheduled date determined by the Government.
- File Editing: All text and diagrammatic files shall be editable by the Government.
- Format: Work products shall be submitted electronically and, in the format, mutually agreed upon prior to submission.

All services delivered to the COR will be deemed to have been accepted 30 calendar days after date of delivery. If written approval or disapproval has not been given within such period. The COR's approval or revision to the services delivered shall be within the general scope of work stated in this order.

5.0 PERIOD OF PERFORMANCE:

Base Year: April 4, 2022 – July 3, 2022 Option One: July 4, 2022 – April 3, 2023

Option Period Two: April 4, 2023 – October 3, 2023 Option Period Three: October 4, 2023 – April 3, 2024

6.0 PLACE OF PERFORMANCE:

Work shall be performed Monday through Friday during normal hours of operation. Due to the pandemic, the FDA has temporarily implemented a maximum flexibility telework policy. While the telework policy is effective, Contractors are authorized to work remotely. Contractors working remotely shall follow the FDA's telework policies and procedures and ensure that the work area is secure. When the return-to-work program is implemented, The Contractor shall be able to perform work on the Government sites within the Washington DC Metro Area at the following location:

FDA/CBER 10903 New Hampshire Avenue Building 71 Silver Spring, MD 20993-0002

The contractor will only be paid for the hours of services delivered.

Telework will be allowed at the discretion of the COR. Contractors teleworking will be required to send an email stating their start time and end time as well as a description of what was worked on while teleworking.

Exceptions to this schedule include:

• Recognized Federal Holidays – The Contractor is not required to provide service on the

- Federal holidays or on days designated as Federal holidays for the Washington D.C. area.
- Inclement Weather- The individual is not required to provide on-site service on days when the Federal Government is closed due to inclement weather. The individual is required to follow, at a minimum, other directives Issued by the Office of Personnel Management or such other official for late arrivals due to inclement weather. In the event the Federal Government is closed by order of the President of the United States or the Office of Personnel Management for any reason, or the Agency, the Center or the building is closed for administrative or safety reasons, the individual will follow directives issued by the COR or contracting officer concerning reporting for work.

7.0 PRICING

PERFORMANCE PERIOD: April 4,	2022 – July 3, 2022 (BA Site (Govt. or	ASE PERIOD) 3 MO	Est. Number of	Ev	tended Price		
Labor Category	Contractor	Hourly Rate	Hours		urs x Bill Rate)		
Consultant III	Contractor	\$ 89.17	1,440.00	\$	128,404.80		
Consultant III*	Contractor	\$ 89.17	480.00	\$	42,801.60		
Consultant IV	Contractor	\$ 123.29	480.00	\$	59,179.20		
Management Analyst II	Contractor	\$ 59.31	1,440.00	\$	85,406.40		
Management Analyst II*	Contractor	\$ 59.31	480.00	\$	28,468.80		
Management Analyst III	Contractor	\$ 76.83	2,400.00	\$	184,392.00		
Management Analyst III*	Contractor	\$ 76.83	480.00	\$	36,878.40		
Project Manager III	Contractor	\$ 122.28	6.00	\$	733.68		
Program Manager III	Contractor	\$ 132.31	6.00	\$	793.86		
Total Labor (Base Period) :				\$	567,058.74		
OPTIONAL LABOR CLIN (Base Pe	riod) :						
Consultant III	Contractor	\$ 89.17	1,440.00	\$	128,404.80		
Management Analyst III	Contractor	\$ 76.83	960.00	\$	73,756.80		
OPTIONAL LABOR CLIN (Base Pe	riod) :			\$	202,161.60		
TOTAL LABOR + OPTIONAL LABO	OR CLIN (Base Period)	:		\$	769,220.34		
* Work is anticipated to be performed by Subcontractor							
Work is anticipated to be performed							
PERFORMANCE PERIOD: July 4, 2		PTION PERIOD I) 9	MONTHS				
PERFORMANCE PERIOD: July 4, 2	2022 – April 3, 2023 <mark>(OF</mark> Site (Govt. or	<u> </u>	Est. Number of		tended Price		
PERFORMANCE PERIOD: July 4, 2 Labor Category	2022 – April 3, 2023 (OF Site (Govt. or Contractor	Hourly Rate	Est. Number of Hours	(Ho	urs x Bill Rate)		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III	Site (Govt. or Contractor	Hourly Rate \$ 89.17	Est. Number of Hours 4,320.00	(Hou	385,214.40		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III*	2022 – April 3, 2023 (OF Site (Govt. or Contractor	Hourly Rate \$ 89.17 \$ 89.17	Est. Number of Hours 4,320.00 1,440.00	(Hot	385,214.40 128,404.80		
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PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III* Consultant IV Management Analyst II	Site (Govt. or Contractor Contractor Contractor	## Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00	\$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III* Consultant IV Management Analyst II Management Analyst II*	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor	## Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 59.31	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00	\$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III* Consultant IV Management Analyst II Management Analyst III* Management Analyst III	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00	\$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III* Consultant IV Management Analyst II Management Analyst III* Management Analyst III Management Analyst III Management Analyst III	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00	\$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III* Consultant IV Management Analyst II Management Analyst III* Management Analyst III Management Analyst III Management Analyst III Project Manager III	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83 \$ 122.28	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00	\$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant IV Management Analyst II Management Analyst III Management Analyst III Management Analyst IIII Project Manager III Program Manager III	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04 2,381.58		
PERFORMANCE PERIOD: July 4, 2 Labor Category Consultant III Consultant III* Consultant IV Management Analyst II Management Analyst III* Management Analyst IIII Management Analyst IIII Project Manager III Program Manager III Total Labor (Option Period I):	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83 \$ 122.28	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00 18.00	\$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04		
Consultant III Consultant III Consultant III Consultant IV Management Analyst II Management Analyst III Management Analyst III Management Analyst IIII Project Manager III Program Manager III Total Labor (Option Period I): OPTIONAL LABOR CLIN (OPTION	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83 \$ 122.28 \$ 132.31	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00 18.00 18.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04 2,381.58 1,701,176.22		
Consultant III Consultant III Consultant III Consultant IV Management Analyst II Management Analyst III Management Analyst III Management Analyst IIII Project Manager III Program Manager III Total Labor (Option Period I): OPTIONAL LABOR CLIN (OPTION Consultant III	Site (Govt. or Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83 \$ 122.28 \$ 132.31	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00 18.00 4,320.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04 2,381.58 1,701,176.22		
Labor Category Consultant III Consultant III* Consultant IV Management Analyst II Management Analyst III Management Analyst III Management Analyst IIII Project Manager III Program Manager III Total Labor (Option Period I): OPTIONAL LABOR CLIN (OPTION Consultant III Management Analyst III	Site (Govt. or Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83 \$ 122.28 \$ 132.31	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00 18.00 18.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04 2,381.58 1,701,176.22		
Consultant III Consultant III Consultant III Consultant IV Management Analyst II Management Analyst III Management Analyst III Management Analyst IIII Project Manager III Program Manager III Total Labor (Option Period I): OPTIONAL LABOR CLIN (OPTION Consultant III	Site (Govt. or Contractor	Hourly Rate \$ 89.17 \$ 89.17 \$ 123.29 \$ 59.31 \$ 76.83 \$ 76.83 \$ 122.28 \$ 132.31	Est. Number of Hours 4,320.00 1,440.00 1,440.00 4,320.00 1,440.00 7,200.00 1,440.00 18.00 4,320.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	385,214.40 128,404.80 177,537.60 256,219.20 85,406.40 553,176.00 110,635.20 2,201.04 2,381.58 1,701,176.22		

PERFORMANCE PERIOD: April 4, 2023 – October 3, 2023 (OPTION PERIOD II) 6 MONTHS							
Labor Category	Contractor		Rate	Est. Number of Hours		Extended Price (Hours x Bill Rate)	
Consultant III	Contractor	\$	39.17	2,952.00	\$	263,229.84	
Consultant III*	Contractor	\$	39.17	984.00	\$	87,743.28	
Consultant IV	Contractor	\$ 12	23.29	984.00	\$	121,317.36	
Management Analyst II	Contractor	\$	59.31	2,952.00	\$	175,083.12	
Management Analyst II*	Contractor	\$	59.31	984.00	\$	58,361.04	
Management Analyst III	Contractor	\$	76.83	4,920.00	\$	378,003.60	
Management Analyst III*	Contractor	\$	76.83	984.00	\$	75,600.72	
Project Manager III	Contractor	\$ 12	22.28	12.00	\$	1,467.36	
Program Manager III	Contractor	\$ 13	32.31	12.00	\$	1,587.72	
Total Labor (Option Period I) :					\$	1,162,394.04	
OPTIONAL LABOR CLIN (OPTION PEI	RIOD II)						
Consultant III	Contractor	\$	89.17	2,952.00	\$	263,229.84	
Management Analyst III	Contractor	\$	76.83	1,968.00	\$	151,201.44	
OPTIONAL LABOR CLIN (Option Perio	od II) :				\$	414,431.28	
TOTAL LABOR + OPTIONAL LABOR (CLIN (Option Period	II) :			\$	1,576,825.32	
* Work is anticipated to be performed by				· 	_		
PERFORMANCE PERIOD: October 4,			<u>PERIOD II</u>				
Labor Category	Site (Govt. o Contractor		ourly Rate	Est. Number of Hours	Extended Price (Hours x Bill Rate)		
Consultant III	Contractor	\$	89.17	2,856.00	\$	254,669.52	
Consultant III*	Contractor	\$	89.17	050.00	_	04.000.04	
				952.00	\$	84,889.84	
Consultant IV	Contractor	\$	123.29		\$	84,889.84 117,372.08	
Consultant IV Management Analyst II	Contractor Contractor	\$		952.00		<u> </u>	
			123.29	952.00	\$	117,372.08	
Management Analyst II	Contractor	\$	123.29 59.31	952.00 2,856.00 952.00	\$	117,372.08 169,389.36	
Management Analyst II Management Analyst II*	Contractor Contractor	\$	123.29 59.31 59.31	952.00 2,856.00 952.00 4,760.00	\$ \$ \$	117,372.08 169,389.36 56,463.12	
Management Analyst II* Management Analyst III Management Analyst III	Contractor Contractor Contractor	\$ \$ \$	123.29 59.31 59.31 76.83	952.00 2,856.00 952.00 4,760.00 952.00	\$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80	
Management Analyst II Management Analyst II* Management Analyst III Management Analyst III*	Contractor Contractor Contractor Contractor	\$ \$ \$	123.29 59.31 59.31 76.83 76.83	952.00 2,856.00 952.00 4,760.00 952.00	\$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16	
Management Analyst II Management Analyst II* Management Analyst III Management Analyst III* Project Manager III	Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28	952.00 2,856.00 952.00 4,760.00 952.00 12.00	\$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36	
Management Analyst II Management Analyst II* Management Analyst III Management Analyst III* Project Manager III Program Manager III	Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28	952.00 2,856.00 952.00 4,760.00 952.00 12.00	\$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72	
Management Analyst II Management Analyst II* Management Analyst III Management Analyst III* Project Manager III Program Manager III Total Labor (Option Period III):	Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28	952.00 2,856.00 952.00 4,760.00 952.00 12.00	\$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72	
Management Analyst II Management Analyst III* Management Analyst III Management Analyst III* Project Manager III Program Manager III Total Labor (Option Period III): OPTIONAL LABOR CLIN (OPTION PE	Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28 132.31	952.00 2,856.00 952.00 4,760.00 952.00 12.00 12.00	\$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72 1,124,691.96	
Management Analyst II Management Analyst II* Management Analyst III Management Analyst III* Project Manager III Program Manager III Total Labor (Option Period III): OPTIONAL LABOR CLIN (OPTION PE	Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28 132.31	952.00 2,856.00 952.00 4,760.00 952.00 12.00 12.00	\$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72 1,124,691.96	
Management Analyst II Management Analyst III* Management Analyst III Management Analyst III* Project Manager III Program Manager III Total Labor (Option Period III): OPTIONAL LABOR CLIN (OPTION PE Consultant III Management Analyst III OPTIONAL LABOR CLIN (Option Period III) TOTAL LABOR + OPTIONAL LABOR (III)	Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28 132.31	952.00 2,856.00 952.00 4,760.00 952.00 12.00 12.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72 1,124,691.96 254,669.52 146,284.32	
Management Analyst II Management Analyst III* Management Analyst III Management Analyst IIII* Project Manager III Program Manager III Total Labor (Option Period III): OPTIONAL LABOR CLIN (OPTION PECONSULTANT III Management Analyst III OPTIONAL LABOR CLIN (Option Period III): TOTAL LABOR + OPTIONAL LABOR CLIN (Option Period III): *Work is anticipated to be performed by	Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28 132.31	952.00 2,856.00 952.00 4,760.00 952.00 12.00 12.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72 1,124,691.96 254,669.52 146,284.32 400,953.84 1,525,645.80	
Management Analyst II* Management Analyst III* Management Analyst III Management Analyst III* Project Manager III Program Manager III Total Labor (Option Period III): OPTIONAL LABOR CLIN (OPTION PE Consultant III Management Analyst III OPTIONAL LABOR CLIN (Option Period III): * Work is anticipated to be performed by Total LABOR (Base + All Options)	Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor	\$ \$ \$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28 132.31	952.00 2,856.00 952.00 4,760.00 952.00 12.00 12.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72 1,124,691.96 254,669.52 146,284.32 400,953.84 1,525,645.80 4,555,320.96	
Management Analyst II Management Analyst III* Management Analyst III Management Analyst III* Project Manager III Program Manager III Total Labor (Option Period III): OPTIONAL LABOR CLIN (OPTION PE Consultant III Management Analyst III OPTIONAL LABOR CLIN (Option Period III): TOTAL LABOR + OPTIONAL LABOR (III) * Work is anticipated to be performed by	Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Contractor Options)	\$ \$ \$ \$ \$ \$	123.29 59.31 59.31 76.83 76.83 122.28 132.31	952.00 2,856.00 952.00 4,760.00 952.00 12.00 12.00	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	117,372.08 169,389.36 56,463.12 365,710.80 73,142.16 1,467.36 1,587.72 1,124,691.96 254,669.52 146,284.32 400,953.84 1,525,645.80	

8.0 GOVERNMENT FURNISHED EQUIPMENT (GFE)/GOVERNMENT FURNISHED INFORMATION:

The Government will provide each Contractor staff with a laptop, monitor, and Personal Identity Verification (PIV) badge. The Contractor shall maintain an inventory of all FDA accountable property and ensure the return of the property upon completion of all work required under the order. Further, Contractor assigned to this order shall provide verification of completion of all mandatory FDA training, including Annual Security Awareness Training if assigned an FDA

laptop that allows for FDA network access.

All property, data and information provided by the Government in the performance of this order remains the property of the Government and shall be surrendered to the Government upon completion or termination of this requirement. Likewise, all deliverables generated under this requirement remain the property of the Government.

The Government shall retain all rights and privileges, including those of patent and copy, to all Government-furnished data and materials. The Contractor shall neither retain nor reproduce for private or commercial use any data or other materials furnished under this contract. The Contractor agrees not to assert any rights at common law or in equity or establish any claim to statutory copyright in such data.

These rights are not exclusive and are beyond any other rights and remedies to which the Government is otherwise entitled elsewhere in this contract.

9.0 POSITION REQUIREMENTS:

The Contractor shall ensure that all Contractor support personnel are adequately trained, possess the requisite experience, and are otherwise fully qualified to provide the required services and the high level of support required by this Task Order. The FDA considers the Contractor's selection of the individuals to work on this Task Order as critical to the success of OCOD's mission. Personnel must have demonstrable experience in the work areas described herein, and the project must be fully staffed at the Task Order effective date.

During the first ninety (90) days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer within 15 calendar days after the occurrence of any of these events and provide the information required by paragraph (c) below. After the initial 90-day period, the Contractor shall submit the information required by paragraph (c) to the Contracting Officer at least 15 days prior to making any permanent substitutions.

The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes, and any additional information requested by the Contracting Officer. Proposed substitutes must have comparable qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within fifteen (15) calendar days after receipt of all required information of the decision on substitutions.

9.1 <u>Preferred Qualifications: The following qualifications are preferred:</u>

9.1.1Consultant V:

- BS or MS in biological science or related field. At least one (1) year of experience in biopharmaceutical manufacturing, quality analytics, biotechnology research and development or other area relevant research program.
- Familiarity with and knowledge of FOIA statutory requirements
- Experience recognizing and segregating various types of nondisclosable information contained within a wide range of agency

records.

- Experience applying FOIA exemption codes to responsive records Ability to prepare legally defensible proposals to withhold and/or deny agency records in whole or in part for submission to agency offices for final review.
- 9.1.2Management Analyst III:
 - Familiarity with and knowledge of FOIA statutory requirements
 - Experience with performing disclosure review.

10.0 SECURITY AND PRIVACY:

The Contractor shall determine that the individuals provided to perform these tasks will not have an adverse effect on the efficiency, effectiveness, and integrity of the FDA, and will uphold the scope of work.

The Contractor shall be expected to have all necessary credential(s) processed prior to beginning work. All contractor personnel must have FDA Security clearance before providing services. All necessary administrative paperwork to hire non-FDA employees must have sufficient time to be processed in the FDA systems. The process normally takes four weeks, and the contractor shall allocate sufficient time for the new hire to be processed in the FDA system prior to the commencement of work.

A. <u>Baseline Security Requirements</u>

- 1) Applicability. The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
- 2) Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
- a. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.
- 3) Safeguarding Information and Information Systems. In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:
- a. Protect government information and information systems to ensure:
- Confidentiality, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information.
- Integrity, which means guarding against improper information modification or

destruction, and ensuring information non-repudiation and authenticity; and

- Availability, which means ensuring timely and reliable access to and use of information.
- b. Provide security for any Contractor systems, and information contained therein, connected to an FDA network, or operated by the Contractor on behalf of FDA regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party. This includes notifying the FDA Systems Management Center (SMC) within one (1) hour of discovery/detection in the event of an information security incident.
- c. Adopt and implement the policies, procedures, controls, and standards required by the HHS/FDA Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the FDA Information Security Program security requirements, outlined in the FDA Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing your ISSO.
- d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.
- 4) Information Security Categorization. In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendix C, and based on information provided by the ISSO or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	[] Low [X] Moderate []
High Integrity:	[] Low [X] Moderate []
High	
Availability:	[X] Low [] Moderate [] High
Overall Risk L	evel:[] Low [X] Moderate [] High
	mation provided by the Privacy Office, system/data owner, or other privacy it has been determined that this solicitation/contract involves:
L INI. DII	TWI W DII
[] No PII	[A] Yes PII
Personally Ider	ntifiable Information (PII). Per the OMB Circular A-130, "PII is information

Personally Identifiable Information (PII). Per the OMB Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [] Low [X] Moderate [] High

5) Controlled Unclassified Information (CUI). CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls,

excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa). As implemented the term "handling" refers to "...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, reusing, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

- a. marked appropriately.
- b. disclosed to authorized personnel on a Need-To-Know basis.
- c. protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and
- d. returned to FDA control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization and the FDA IS2P Appendix T: Sanitization of Computer-Related Storage Media.
- 6) Protection of Sensitive Information. For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.

Confidentiality and Nondisclosure of Information. Any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS/FDA sanction policies and/or governed by the following laws and regulations:

- a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records).
- b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
- c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).
- 7) Internet Protocol Version 6 (IPv6). All procurements using Internet Protocol shall

comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).

- 8) Government Websites. All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.
- 9) Contract Documentation. The Contractor shall use FDA-provided templates, policies, forms, and other agency documents to comply with contract deliverables as appropriate.
- 10) Standard for Encryption. The Contractor (and/or any subcontractor) shall:
- a. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
- b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
- c. All devices (i.e.: desktops, laptops, mobile devices, etc.) that store, transmit, or process non-public FDA information should utilize FDA-provided or FDA information security authorized devices that meet HHS and FDA-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
- d. Verify that the encryption solutions in use are compliant with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.
- e. Use the Key Management system on the HHS Personal Identification Verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys (PIV card) shall be provided to the COR upon request and at the conclusion of the contract. Upon completion of contract, contractor ensures that COR can access and read any encrypted data.
- 11) Contractor Non-Disclosure Agreement (NDA). Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the FDA non-disclosure agreement (3398 Form), as applicable. A copy of each signed and witnessed NDA

shall be submitted to the CO and/or COR prior to performing any work under this acquisition.

12) Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) – The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee

with conducting a PTA for the information system and/or information handled under this contract to determine whether a full PIA needs to be completed.

- a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist procuring activity representative, program office and the FDA SOP or designee with completing a PIA for the system or information after completion of the PTA and in accordance with HHS and FDA policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002. The PTA/PIA must be completed and approved prior to active use and/or collection or processing of PII and is a prerequisite to agency issuance of an authorization to operate (ATO).
- b. The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee in reviewing and updating the PIA at least every three years throughout the Enterprise Performance Life Cycle (EPLC) /information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

B. Training

- 1) Mandatory Training for All Contractor Staff. All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable FDA Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete FDA Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS and FDA training policies.
- 2) Role-based Training. All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS and FDA policy and FDA Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Standard Operating Procedures (SOP).
- 3) Training Records. The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

C. Rules of Behavior

- 1) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior.
- 2) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior (ROB) before accessing HHS and FDA data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual FDA Information Security Awareness Training. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines.

D. <u>Incident Response</u>

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/FDA SMC /Incident Response Team (IRT) teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies." The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by FISMA as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for another than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII."

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

- 1) Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
- 2) NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so, instructed by the Contracting Officer or representative, the Contractor shall send FDA approved notifications to affected individuals as directed by FDA's SOP.
- 3) Report all suspected and confirmed information security and privacy incidents and breaches to the FDA Systems Management Center, COR, CO, and other stakeholders, (Recommend adding the FDA Senior Official for Privacy with contact information and either defining or deleting "other stakeholders.") including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour of discovery/detection, and

consistent with the applicable FDA and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contact information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

a. cooperates and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach.

- b. not include any sensitive information in the subject or body of any reporting e-mail; and
- c. encrypts sensitive information in attachments to email, media, etc.
- 4) Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information and HHS and FDA incident response policies when handling PII breaches.
- Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation demand.

E. <u>Position Sensitivity Designations</u>

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract: [See the FDA Security Article, entitled Contractor Personnel Security Clearance Standards and Residency Requirements for the Position Risk Designation Tier(s) (i.e., 1, 2, and/or 4") that apply to this award.]

F. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

Roster. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster and any revisions to the roster because of staffing changes shall be submitted to the COR and/or CO per the COR or CO's direction. Any revisions to the roster because of staffing changes shall be submitted within a timeline as directed by the COR and/or CO. The COR will notify the

Privacy Act

This order is subject to the Privacy Act of 1974, because the requirements in this order provides for the design, development, or operation of a system of records about individuals.

The System of Records Notice (SORN) that is applicable to this task order is: 09-90-0058
 Tracking Records and Case Files for FOIA and Privacy Act Requests and Appeals.

- The design, development, or operation work the Contractor is to perform is: The contracted support services personnel will have access to FOIA requests which are subject to the Privacy Act of 1974.
- The disposition to be made of the Privacy Act records upon completion of this order performance is: Records are retained and disposed of in accordance with General Records Schedule (GRS) 4.2 "Information Access and Protection Records" (superseding GRS 14 "Information Services Records"), which prescribes retention periods ranging from approximately two (2) years to six (6) years after final agency action or adjudication by a court, date of closure, or last entry.

11.0 SECTION 508:

The Section 508 accessibility standards applicable to this contract are:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats is available at http://508.hhs.gov/, or from the Section 508 Coordinator listed at https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)

12.0 Contract Type:

This is a Labor-Hour type Order.

13.0 Contract Administration Data:

Michael Fischer, COR, michael.fischer@fda.hhs.gov

James Whitt, Contracting Officer, james.whitt@fda.hhs.gov

James Samuels, Contracting Specialist, james.samuels@fda.hhs.gov

Reference for FAR Clauses: https://www.acquisition.gov/browse/index/far

FAR Clauses by Reference:

52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018)

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)

Clauses by Full Text:

HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2022)

(a) Definitions. As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

- (b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
- (c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
- (d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

- a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm
- b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov

- 1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 5 business days of the contract award for new contracts or date of modification for existing contracts.
- 2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
- 3. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
- 4. If your company is already registered to use IPP, you will not be required to re-register.
- 5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.
 - d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).
 - e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.
- Direct Labor include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)-show rate, base and total amount;
- Consultants (if applicable) include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.
 - f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
 - (a) list of all invoices submitted to date under the subject award, including the following:

- (1) invoice number, amount, & date submitted
- (2) corresponding payment amount & date received
- (b) total amount of all payments received to date under the subject contract or order
- (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
- g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
- h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.
- i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.
- j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.
- k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

LIST OF ATTACHMENTS

- Attachment 1- Statement of Work
- Attachment 2 Federal Acquisition Regulation (FAR) Class Deviation 18-01, Whistleblower Protection for Contractor Employees
- Attachment 3- HHS FAR Class Deviation 2020-02
- Attachment 4- CAAC Letter 2020-05 FAR text 2020-014 United States-Mexico-Canada Agreement

ATTACHMENT 3

Department of Health and Human Service (HHS)
Federal Acquisition Regulation (FAR) Class Deviation 18-01
Whistleblower Protection for Contractor Employees

Solicitation and Contract Addendum for Non-Commercial Items/Services that Exceed the Simplified Acquisition Threshold

Background: The FAR currently provides that when the 4-year pilot program under 41 U.S.C. 4712 expires, the previous whistleblower coverage is back in effect. However, the Civilian Agency Acquisition Council (CAAC) issued CAAC Letter 2017-02, dated July 5, 2017, to further implement 41 U.S.C. 4712 (as amended by Public Law 114-261) to make permanent the 4-year pilot program and clarifies the use of certain Whistleblower Protection clauses. In turn, the HHS Deputy Assistant Secretary for Office of Grants and Acquisition Policy and Accountability/Senior Procurement Executive issued HHS FAR Class Deviation 18-01, dated February 8, 2018, to implement CAAC guidance and Enhance Whistleblower Protection for Contractor Employees.

Pursuant to the above-stated authorities, the underlying solicitation/contract hereby incorporates the following Terms and Conditions:

PART 3-IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

* * * * *

Subpart 3.9-whistleblower Protections for Contractor Employees 3.900 Scope of subpart.

This subpart implements various statutory whistleblower programs. This subpart does not implement 10 U.S.C. 2409, which is applicable only to DoD, NASA, and the Coast Guard.

41 U.S.C. 4705 (in effect before July 1, 2013). Sections 3.901 through 3 .906 of this subpart implemented 41 U.S.C. 4705, applicable to civilian agencies other than NASA and the Coast Guard.

41 U.S.C. 4712 (in effect on and after July 1, 2013). Section 3.908 of this subpart implements the pilot program, applicable to civilian agencies other than NASA and the Coast Guard, except as provided in paragraph (d) of this section.

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), implemented in 3.909, applicable to all agencies.

Contracts funded by the American Recovery and Reinvestment Act. Section 3.907 of this subpart implements section 1553 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5), and applies to all contracts funded in whole or in part by that Act.

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52.203-17 Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights. (APR 2014)

- (a) This contract and employees working on this contract will be subject to the whistleblower rights and remedies in the pilot program on Contractor employee whistleblower protections established at 41 U.S.C. 4712 by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and FAR 3.908
- (b) The Contractor shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under 41 U.S.C. 4712, as described in section 3.908 of the Federal Acquisition Regulation.
- (c) The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts over the simplified acquisition threshold. (End of clause)

Attachment 4 HHS FAR Class Deviation 2020-02

FAR Deviation Text Baseline is FAC 2020-05, published in the Federal Register on February 27, 2020.

Deviations are shown by [bracketed bold additions] and strikeouts.

FAR text unchanged shown as asterisks *** or *****

PART 12—ACQUISITION OF COMMERCIAL ITEMS

* * * * *

Subpart 12.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Items

* * * * *

12.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(d) ***

(12) Insert the clause at 52.232-40, Providing Accelerated Payments to Small Business Subcontractors, as prescribed in 32.009-2.

* * * * *

PART 32—CONTRACT FINANCING

* * * *

32.009 Providing accelerated payments to small business [contractors and to prime contractors that subcontract with a small business concern]subcontractors.

32.009-1 General.

- [(a) Pursuant to 31 U.S.C. 3903(a) and 10 U.S.C. 2307(a), agencies shall provide accelerated payments, to the fullest extent permitted by law, with a goal of 15 days after receipt of a proper invoice and all other required documentation, if a specific payment date is not established by contract, to—
- 1) Small business contractors, and
- 2) Prime contractors that subcontract with a small business concern, if the prime contractor agrees to make payments to the small business subcontractor in accordance with the accelerated payment date, to the maximum extent practicable, without any further consideration from or fees charged to the subcontractor.]Pursuant to the policy provided by OMB Memorandum M-12-16, Providing Prompt Payment to Small Business Subcontractors (and as extended by OMB Memoranda M-13-15 and M-14-10, both titled Extension of Policy to Provide Accelerated Payment to Small Business Subcontractors), agencies shall take measures to ensure that prime contractors pay small business subcontractors on an accelerated timetable to the maximum extent practicable, and upon receipt of accelerated payments from the Government. This

acceleration does not provide any new rights under the Prompt Payment Act and does not affect the application of the Prompt Payment Act late payment interest provisions.

[(b)] This acceleration does not provide any new rights under the Prompt Payment Act and does not affect the application of the Prompt Payment Act late payment interest provisions.

32.009-2 Contract clause.

Insert clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors, in all solicitations and contracts.

* * * * *

SUBPART 32.9—PROMPT PAYMENT

* * * * *

32.903 Responsibilities.

- (a) * * *
- (5) May authorize the use of the accelerated payment methods specified at 5 CFR 1315.5 **[(but see 32.009-1(a))]**.

* * * * *

32.906 Making payments.

- (a) * * *
- (2) That the use of accelerated payment methods are necessary (see 32.903(a)(5)) [(but see 32.009-1(a))].

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

* * * * *

Subpart 52.2—Text of Provisions and Clauses

* * * * *

52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

As prescribed in 12.301(b)(4), insert the following clause:

CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEM (MAR 2020)[(DEVIATION APR 2020)]

* * * * *

(b) * * *

(60) [52.232-40, Providing Accelerated Payments to Small Business Subcontractors (DEC 2013)(DEVIATION APR 2020)(31 U.S.C. 3903 and 10 U.S.C. 2307).
(61)] 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).
([62] 61) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).
([63]62)(i) 52.247-64, Preference for Privately Owned U.S Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
(ii) Alternate I (Apr 2003) of 52.247-64.
(iii) Alternate II (Feb 2006) of 52.247-64.
* * * *
52.213-4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items).
As prescribed in 13.302-5(d), insert the following clause:
TERMS AND CONDITIONS—SIMPLIFIED ACQUISITIONS (OTHER THAN COMMERCIAL ITEMS (JAN 2020)[(DEVIATION APR 2020)]
(a)***

(a)**^{*}

(2)***

(vi) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (DEC 2013)[(DEVIATION APR 2020)(31 U.S.C. 3903 and 10 U.S.C. 2307)].

(viii) 52.244-6, Subcontracts for Commercial Items (AUG 2019)[(DEVIATION APR 2020)].

52.232-40 Providing Accelerated Payments to Small Business Subcontractors.

As prescribed in 32.009-2, insert the following clause:

PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (DEC 2013)[(DEVIATION APR 2020)]

(a)[(1) In accordance with 31 U.S.C. 3903 and 10 U.S.C. 2307, u], Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract [in accordance with the accelerated payment date established], to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, [with a goal of 15 days] after receipt of a proper invoice and all other required documentation from the small business subcontractor [if a specific payment date is not established by contract.

- (2) The Contractor agrees to make such payments to its small business subcontractors without any further consideration from or fees charged to the subcontractor].
- (b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.
- (c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of clause)

* * * * *

52.244-6 Subcontracts for Commercial Items.

As prescribed in 44.403, insert the following clause:

SUBCONTRACTS FOR COMMERCIAL ITEMS (AUG 2019)[(DEVIATION APR 2020)]

* * * * *

(c)(1) * * *

(xix) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (DEC 2013)**[(DEVIATION APR 2020)]**, if flow down is required in accordance with paragraph (c) of FAR

clause 52.232-40.

* * * * *

Attachment 5 CAAC Letter 2020-05 FAR text 2020-014 United States-Mexico-Canada Agreement

Baseline is FAC 2020-06

Additions shown by: [bolded]. Deletions shown by: struck.

June 22, 2020

PART 4-ADMINISTRATIVE AND INFORMATION MATTERS

* * * * *

SUBPART 4.12-REPRESENTATIONS AND CERTIFICATIONS

* * * * *

4.1202 Solicitation provision and contract clause.

(a) Insert the provision at 52.204-8, Annual Representations and Certifications, in solicitations, except for commercial item solicitations issued under FAR part 12. The contracting officer shall check the applicable provisions at 52.204-8(c)(2). Use the provision with its Alternate I in solicitations issued after October 1, 2022, that will result in a multiple-award contract with more than one North American Industry Classification System code assigned (see 19.102(b)). When the provision at 52.204-7, System for Award Management, is included in the solicitation, do not separately include the following representations and certifications:

* * * * *

(28) 52.225-4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate (Basic, Alternates $\frac{1}{1}$ and III).

* * * * *

PART 13 - SIMPLIFIED ACQUISITION PROCEDURES

* * * * *

Subpart 13.3 - Simplified Acquisition Methods

* * * * *

13.302-5 Clauses.

* * * * *

(d) * * *

(3) (i) When an acquisition for supplies for use within the United States cannot be set aside for small business concerns and trade agreements apply (see subpart 25.4), substitute the clause at FAR 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act, used with Alternate I or Alternate II, if appropriate, instead of the clause at FAR 52.225-1, Buy American-Supplies.

* * * * *

PART 18-EMERGENCY ACQUISITIONS

* * * * *

SUBPART 18.1-AVAILABLE ACQUISITION FLEXIBILITIES

* * * * *

18.120 [[Reserved]] Use of patented technology under the North American Free Trade Agreement.

Requirement to obtain authorization prior to use ogf patented technology may be waived in circumstances of extreme urgency or national emergency. (See 27.204-1.)

* * * * *

PART 22 - APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS
* * * * *

SUBPART 22.15-PROHIBITION OF ACQUISITION OF PRODUCTS PRODUCED BY FORCED OR INDENTURED CHILD LABOR

* * * * *

22.1503 Procedures for acquiring end products on the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor.

* * * * *

(b) The requirements of this subpart that result from the appearance of any end product on the List do not apply to a solicitation or contract if the identified country of origin on the List is—

- (1) Canada, and the anticipated value of the acquisition is \$25,000 or more (see subpart 25.4);
- $\frac{(2)}{1}$ Israel, and the anticipated value of the acquisition is \$50,000 or more (see 25.406);
- (3[2]) Mexico, and the anticipated value of the acquisition is \$83,099 or more (see subpart 25.4); or
- (4[3]) Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, [Canada,] Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Korea, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or the United Kingdom and the anticipated value of the acquisition is \$182,000 or more (see 25.402(b)).

* * * * *

22.1505 Solicitation provision and contract clause.

(a) * * * For solicitations estimated to equal or exceed \$25,000[\$50,000], the contracting officer must exclude from the List in the solicitation end products from any countries identified at 22.1503(b), in accordance with the specified thresholds.

* * * * *

PART 25-FOREIGN ACQUISITION

* * * * *

25.003 Definitions.

As used in this part-

* * * * *

"Designated country" means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan (known in the World Trade Organization as

"the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu" (Chinese Taipei)), Ukraine, or United Kingdom);

(2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);

* * * * *

"Free Trade Agreement country" means Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore.

* * * * *

SUBPART 25.4—Trade Agreements

* * * * *

25.400 Scope of subpart.

- (a) This subpart provides policies and procedures applicable to acquisitions that are covered by—
- (1) The World Trade Organization Government Procurement Agreement (WTO GPA), as approved by Congress in the Uruguay Round Agreements Act (Pub. L. 103-465);
- (2) Free Trade Agreements (FTA), consisting of-
- (i) NAFTA (the North American Free Trade Agreement, as approved by Congress in the North American Free Trade Agreement
 Implementation Act of 1993 (Pub. L. 103-182) (19 U.S.C. 3301 note)) [USMCA (United States-Mexico-Canada Agreement, as approved by Congress in the United States-Mexico-Canada Agreement
 Implementation Act (Government Procurement Agreement applicable only to United States and Mexico) (Pub. L. 116-113) (19 U.S.C. chapter 29 (sections 4501-4732))];

* * * * *

25.401 Exceptions.

* * * * *

(b) In the World Trade Organization Government Procurement Agreement (WTO GPA) and each FTA, there is a U.S. schedule that lists services that are excluded from that agreement in acquisitions by the United States. Acquisitions of the following

services are excluded from coverage by the U.S. schedule of the WTO GPA or an FTA as indicated in this table:

	The service (Federal Service Codes from the Federal Procurement Data System Product/Service Code Manual are indicated in parentheses for some services.)	WTO GPA AND KOREA		Singapore	Australia and Morocco FTA
(1)	All services purchased in support of military services overseas.		X	X	X
1 '	(i) Automatic data processing (ADP) telecommunications and transmission services (D304), except enhanced (i.e., valueadded) telecommunications services.		X		
	(ii) ADP teleprocessing and timesharing services (D305), telecommunications network management services (D316), automated news services, data services or other information services (D317), and other ADP and telecommunications services (D399)	X	X		
	(iii) Basic	*	*	X	X

	telecommunications network services (i.e., voice telephone services, packet- switched data transmission services, circuit-switched data transmission services, telex services, facsimile services, and private leased circuit services, but not information services, as defined in 47 U.S.C. 153(24))				
(3)	Dredging	Х	X	X	X
	(i) Operation and management contracts of certain Government or privately owned facilities used for Government purposes, including Federally Funded Research and Development Centers	X		X	
	(ii) Operation of all Department of Defense, Department of Energy, or the National Aeronautics and Space Administration facilities; and all Government-owned research and development facilities or Government-owned environmental laboratories	* *	X	* *	X

	Research and development	X	X	X	X
	Transportation services (including launching services, but not including travel agent services)	X	X	X	X
(7)	Utility services	Х	X	X	X
	Maintenance, repair, modification, rebuilding and installation of equipment related to ships (J019)		X		X
(9)	Nonnuclear ship repair (J998)		X		X

^{*}Note 1. Acquisitions of the services listed at (2)(iii) of this table are a subset of the excluded services at (2)(i) and (ii), and are therefore not covered under the WTO GPA.

25.402 General.

* * * * *

(b) The value of the acquisition is a determining factor in the applicability of trade agreements. Most of these dollar thresholds are subject to revision by the U.S. Trade Representative approximately every 2 years. The various thresholds are summarized as follows:

Table 1 to Paragraph (b)

Trade agreement	1 1 2	Service contract	Construction contract (equal to or exceeding)
-----------------	-------	---------------------	---

^{**}NoTE 2. Acquisitions of the services listed at (4)(ii) of this table are a subset of the excluded services at (4)(i), and are therefore not covered under the WTO GPA.

	exceeding)	exceeding)	
WTO GPA	\$182,000	\$182,000	\$7,008,000
FTAs:			
Australia FTA	83,099	83,099	7,008,000
Bahrain FTA	182,000	182,000	10,802,884
CAFTA-DR (Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua)	83,099	83,099	7,008,000
Chile FTA	83,099	83,099	7,008,000
Colombia FTA	83,099	83,099	7,008,000
Korea FTA	100,000	100,000	7,008,000
Morocco FTA	182,000	182,000	7,008,000
NAFTA [USMCA]:			
-Canada	25,000	83,099	10,802,884
-Mexico	83,099	83,099	10,802,884
Oman FTA	182,000	182,000	10,802,884
Panama FTA	182,000	182,000	7,008,000
Peru FTA	182,000	182,000	7,008,000
Singapore FTA	83,099	83,099	7,008,000
Israeli Trade Act	50,000		

Subpart 25.11 - Solicitation Provisions and Contract Clauses

25.1101 Acquisition of supplies.

The following provisions and clauses apply to the acquisition of supplies and the acquisition of services involving the furnishing of supplies.

* * * * *

- (b)(1)(i) Insert the clause at 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act, in solicitations and contracts if—
- (A) The acquisition is for supplies, or for services involving the furnishing of supplies, for use within the United States, and the acquisition value is \$25,000 [\$50,000] or more, but is less than \$182,000;

* * * * * *

- (ii) If the acquisition value is \$25,000 or more but is less than \$50,000, use the clause with its Alternate I.
- ($i\pm i$) If the acquisition value is \$50,000 or more but is less than \$83,099, use the clause with its *Alternate II*.
- (i \forall ii]) If the acquisition value is \$83,099 or more but is less than \$100,000, use the clause with its Alternate III.
- (2) (i) Insert the provision at 52.225-4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate, in solicitations containing the clause at 52.225-3.
- (ii) If the acquisition value is \$25,000 or more but is less than \$50,000, use the provision with its Alternate I.
- (ii \pm) If the acquisition value is \$50,000 or more but is less than \$83,099, use the provision with its *Alternate II*.
- (i \forall [ii]) If the acquisition value is \$83,099 or more, but is less than \$100,000, use the provision with its Alternate III.

* * * * *

PART 27-PATENTS, DATA, AND COPYRIGHTS

* * * * *

SUBPART 27.2-PATENTS AND COPRIGHTS

- 27.204 Patented technology under trade agreements.
- 27.204-1 Use of patented technology under the North American Free Trade Agreement[United States-Mexico-Canada Agreement].
- (a) The requirements of this section apply to the use of technology covered by a valid patent when the patent holder is from a country that is a party to the North American Free Trade Agreement (NAFTA).
- (b) Article 1709(10) of NAFTA generally requires a user of technology covered by a valid patent to make a reasonable effort to obtain authorization prior to use of the patented technology. However, NAFTA provides that this requirement for authorization may be waived in situations of national emergency or other circumstances of extreme urgency, or for public noncommercial use.
- (c) Section 6 of Executive Order 12889, "Implementation of the North American Free Trade Act," of December 27, 1993, waives the requirement to obtain advance authorization for an invention used or manufactured by or for the Federal Government. However, the patent owner shall be notified in advance whenever the agency or its contractor knows or has reasonable grounds to know, without making a patent search, that an invention described in and covered by a valid U.S. patent is or will be used or manufactured without a license. In cases of national emergency or other circumstances of extreme urgency, this notification need not be made in advance, but shall be made as soon as reasonably practicable.
- (d) The contracting officer, in consultation with the office having cognizance of patent matters, shall ensure compliance with the notice requirements of NAFTA Article 1709(10) and Executive Order 12889. A contract award should not be suspended pending notification to the patent owner.
- (e) Section 6(c) of Executive Order 12889 provides that the notice to the patent owner does not constitute an admission of infringement of a valid privately-owned patent.
- (f) When addressing issues regarding compensation for the use of patented technology, Government personnel should be advised that NAFTA uses the term "adequate remuneration." Executive Order 12889 equates "remuneration" to "reasonable and entire compensation" as used in 28 U.S.C. 1498, the statute that gives

jurisdiction to the U.S. Court of Federal Claims to hear patent and copyright cases involving infringement by the Government.

(g) When questions arise regarding the notice requirements or other matters relating to this section [with regard to use of patented technology under the USMCA], the contracting officer should consult with legal counsel.

27.204-2 Use of patented technology under the General Agreement on Tariffs and Trade (GATT).

Article 31 of Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights, to GATT (Uruguay Round) addresses situations where the law of a member country allows for use of a patent without authorization, including use by the Government.

* * * * *

PART 52-SOLICITATION PROVISIONS AND CONTRACT CLAUSES

* * * * *

SUBPART 52.2-TEXTS OF PROVISIONS AND CLAUSES

* * * * *

52.204-8 Annual Representations and Certifications.

As prescribed in 4.1202(a), insert the following provision: ANNUAL REPRESENTATIONS AND CERTIFICATIONS (MAR 2020 [DATE])

* * * * *

(c)(1)***

(xxi) 52.225-4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate. (Basic, Alternates $\frac{1}{7}$ II $_{7}$ and III.) This provision applies to solicitations containing the clause at 52.225-3.

- (A) If the acquisition value is less than \$25,000[50,000], the basic provision applies.
- (B) If the acquisition value is \$25,000 or more but is less than \$50,000, the provision with its Alternate I applies.
- [(B)] $\frac{(C)}{(C)}$ If the acquisition value is \$50,000 or more but is less than \$83,099, the provision with its Alternate II applies.
- [(C)] $\frac{\text{(D)}}{\text{(D)}}$ If the acquisition value is \$83,099 or more but is less than \$100,000, the provision with its Alternate III applies.

52.212-3 Offeror Representations and Certifications—Commercial Items.

As prescribed in 12.301(b)(2), insert the following provision:

Offeror Representations and Certifications—Commercial Items ($\frac{\text{JUN 2020}}{\text{DATE}}$)

* * * * *

- (g) (1) Buy American—Free Trade Agreements—Israeli Trade Act Certificate. (Applies only if the clause at FAR 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act, is included in this solicitation.)
- (i) The offeror certifies that each end product, except those listed in paragraph (g) (1) (ii) or (g) (1) (iii) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product," "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country," and "United States" are defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act."
- (ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act"

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.	Country of Origin

[List as necessary]

(iii) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g) (1) (ii) of this provision) as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act." The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of "domestic end product."

Other Foreign End Products

Line Item No.		Country of Origin	
[List as necessary]			

- (iv) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.
- (2) Buy American—Free Trade Agreements—Israeli Trade Act
 Certificate, Alternate I. If Alternate I to the clause at FAR
 52.225-3 is included in this solicitation, substitute the
 following paragraph (g) (l) (ii) for paragraph (g) (l) (ii) of the
 basic provision:
- (g) (1) (ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Canadian End Products:

Line Item No.

(List as necessary)

(3)—Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate II. If Alternate II to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g) (1) (ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Canadian or Israeli End Products:

Line Item No.	Country of Origin
[List as necessary]	

- (4[3]) Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate III. If Alternate III to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:
- (g) (1) (ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.		Country of Origin
[List as necessary]		

(5[4]) Trade Agreements Certificate. (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

* * * * *

52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

As prescribed in 12.301(b)(4), insert the following clause:

CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (JUN 2020 [DATE])

* * * * *

(b) * * *

 $\underline{\hspace{0.5cm}}$ (28) 52.222-19, Child Labor-Cooperation with Authorities and Remedies ($\underline{\hspace{0.5cm}}$ ($\underline{\hspace{0.5cm}}$ DATE]) (E.O. 13126).

* * *

- ____ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (MAY 2014 JUL 2020) (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, [19 U.S.C. chapter 29 (sections 4501-4732),] Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
- __ (ii) Alternate I (MAY 2014) of 52.225-3.
- (iii) Alternate II (MAY 2014[DATE]) of 52.225-3.

- $(i[ii] \forall)$ Alternate III (MAY 2014) of 52.225-3.
- ___ (50) 52.225-5, Trade Agreements (OCT 2019[**DATE**]) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

52.222-19 Child Labor-Cooperation with Authorities and Remedies.

As prescribed in 22.1505(b), insert the following clause:

CHILD LABOR—COOPERATION WITH AUTHORITIES AND REMEDIES (JAN 2020[DATE])

- (a) Applicability. This clause does not apply to the extent that the Contractor is supplying end products mined, produced, or manufactured in—
- (1) Canada, and the anticipated value of the acquisition is \$25,000 or more;
- $\frac{(2)}{(2)}$ Israel, and the anticipated value of the acquisition is \$50,000 or more;
- (3[2]) Mexico, and the anticipated value of the acquisition is \$83,099 or more; or
- (4[3]) Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, [Canada,] Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Korea, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or the United Kingdom and the anticipated value of the acquisition is \$182,000 or more.

* * * * *

52.225-3 Buy American-Free Trade Agreements-Israeli Trade Act.

As prescribed in 25.1101(b)(1)(i), insert the following clause:

Buy American—Free Trade Agreements—Israeli Trade Act (MAY 2014 [DATE])

(a) Definitions. As used in this clause-

* * * * *

"Free Trade Agreement country" means Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador,

Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore.

* * * * *

Alternate I [[Reserved]] (MAY 2014). As prescribed in 25.1101(b)(1)(ii), add the following definition to paragraph (a) of the basic clause, and substitute the following paragraph (c) for paragraph (c) of the basic clause:

"Canadian end product" means an article that-

- (1) Is wholly the growth, product, or manufacture of Canada; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Canada into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.
- (c) Delivery of end products. 41 U.S.C. chapter 83 provides a preference for domestic end products for supplies acquired for use in the United States. In accordance with 41 U.S.C. 1907, the component test of the Buy American statute is waived for an end product that is a COTS item (See 12.505(a)(1)). In addition, the Contracting Officer has determined that NAFTA applies to this acquisition. Unless otherwise specified, NAFTA applies to all items in the Schedule. The Contractor shall deliver under this contract only domestic end products except to the extent that, in its offer, it specified delivery of foreign end products in the provision entitled "Buy American-Free Trade Agreements—Israeli Trade Act Certificate." If the Contractor specified in its offer that the Contractor would supply a Canadian end product, then the Contractor shall supply a Canadian end product or, at the Contractor's option, a domestic end product.

Alternate II (MAY 2014[DATE]). As prescribed in 25.1101(b)(1)(ii $\frac{1}{2}$), add the following definition to paragraph (a) of the basic clause, and substitute the following paragraph (c) for paragraph (c) of the basic clause:

"Canadian end product" an article that-

- (1) Is wholly the growth, product, or manufacture of Canada; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in Canada into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.
- (c) Delivery of end products. 41 U.S.C. chapter 83 provides a preference for domestic end products for supplies acquired for use in the United States. In accordance with 41 U.S.C. 1907, the component test of the Buy American statute is waived for an end product that is a COTS item (See 12.505(a)(1)). In addition, the Contracting Officer has determined that NAFTA and the Israeli Trade Act apply[ies] to this acquisition. Unless otherwise specified, these[this] trade agreements apply[ies] to all items in the Schedule. The Contractor shall deliver under this contract only domestic end products except to the extent that, in its offer, it specified delivery of foreign end products in the provision entitled "Buy American-Free Trade Agreements-Israeli Trade Act." If the Contractor specified in its offer that the Contractor would supply a Canadian end product or an Israeli end product, then the Contractor shall supply a Canadian end product, an Israeli end product or, at the Contractor's option, a domestic end product.

Alternate III (May 2014). As prescribed in 25.1101(b)(1)[(iii)](iv), delete the definition of "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product" and add in its place the following definition of "Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end product" in paragraph (a) of the basic clause; and substitute the following paragraph (c) for paragraph (c) of the basic clause:

* * * * *

52.225-4 Buy American—Free Trade Agreement—Israeli Trade Act Certificate.

As prescribed in 25.1101(b)(2)(i), insert the following provision:

Buy American-Free Trade Agreements-Israeli Trade Act Certificate (MAY 2014)

- (a) The offeror certifies that each end product, except those listed in paragraph (b) or (c) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product," "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "Israeli end product," and "United States" are defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act."
- (b) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

FREE TRADE AGREEMENT COUNTRY END PRODUCTS (OTHER THAN BAHRAINIAN, MOROCCAN, OMANI, PANAMANIAN, OR PERUVIAN END PRODUCTS) OR ISRAELI END PRODUCTS:

Line Item No.		Country of Origin	
[List as necessary]			

(c) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (b) of this provision) as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act." The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of "domestic end product."

Other Foreign End Products:

Line Item No.		Country of Origin	
[List as necessary]			

(d) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation.

(End of provision)

Alternate I [[Reserved]] (MAY 2014). As prescribed in 25.1101(b)(2)(ii), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act-Balance of Payments Program":

Canadian End Products:

Line Item No.

(List as necessary)

Alternate II (MAY 2014[DATE]). As prescribed in 25.1101(b)(2)[(ii)](iii), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act—Balance of Payments Program":

Canadian or Israeli End Products

Line Item No.	Country of Origin

[List as necessary]		

Alternate III (MAY 2014). As prescribed in 25.1101(b)(2)[(iii)](iv), substitute the following paragraph (b) for paragraph (b) of the basic provision:

* * * * *

52.225-5 Trade Agreements.

As prescribed in 25.1101(c)(1), insert the following clause:

TRADE AGREEMENTS (OCT 2019 [DATE])

(a) Definitions. As used in this clause.

Caribbean Basin country end product-

- (1) Means an article that-
- (i)(A) Is wholly the growth, product, or manufacture of a Caribbean Basin country; or
- (B) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a Caribbean Basin country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed; and
- (ii) Is not excluded from duty-free treatment for Caribbean countries under 19 U.S.C. 2703(b).
- (A) For this reason, the following articles are not Caribbean Basin country end products:
- (1) Tuna, prepared or preserved in any manner in airtight containers;
 - (2) Petroleum, or any product derived from petroleum;
- (3) Watches and watch parts (including cases, bracelets, and straps) of whatever type including, but not limited to, mechanical, quartz digital, or quartz analog, if such watches or watch parts contain any material that is the product of any

country to which the Harmonized Tariff Schedule of the United States (HTSUS) column 2 rates of duty apply (i.e., Afghanistan, Cuba, Laos, North Korea, and Vietnam); and

- (4) Certain of the following: textiles and apparel articles; footwear, handbags, luggage, flat goods, work gloves, and leather wearing apparel; or handloomed, handmade, and folklore articles;
- (B) Access to the HTSUS to determine duty-free status of articles of these types is available at https://usitc.gov/tata/hts/index.htm. In particular, see the following:
- (1) General Note 3(c), Products Eligible for Special Tariff treatment.
- (2) General Note 17, Products of Countries Designated as Beneficiary Countries under the United States-Caribbean Basin Trade Partnership Act of 2000.
- (3) Section XXII, Chapter 98, Subchapter II, Articles Exported and Returned, Advanced or Improved Abroad, U.S. Note 7(b).
- (4) Section XXII, Chapter 98, Subchapter XX, Goods Eligible for Special Tariff Benefits under the United States-Caribbean Basin Trade Partnership Act; and
- (2) Refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the acquisition, includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

Designated country means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan (known in the World Trade Organization as "the Separate Customs Territory of Taiwan,

Penghu, Kinmen and Matsu (Chinese Taipei)"), Ukraine, or United Kingdom);

- (2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);
- (3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia); or
- (4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

Designated country end product means a WTO GPA country end product, an FTA country end product, a least developed country end product, or a Caribbean Basin country end product.

End product means those articles, materials, and supplies to be acquired under the contract for public use.

Free Trade Agreement country end product means an article that-

- (1) Is wholly the growth, product, or manufacture of a Free Trade Agreement (FTA) country; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in an FTA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services)

incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

Least developed country end product means an article that-

- (1) Is wholly the growth, product, or manufacture of a least developed country; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a least developed country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product, includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

United States means the 50 States, the District of Columbia, and outlying areas.

U.S.-made end product means an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.,

WTO GPA country end product means an article that-

- (1) Is wholly the growth, product, or manufacture of a WTO GPA country; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services, (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

(b) Delivery of end products. The Contracting Officer has determined that the WTO GPA and FTAs apply to this acquisition. Unless otherwise specified, these trade agreements apply to all items in the Schedule. The Contractor shall deliver under this contract only U.S.-made or designated country end products except to the extent that, in its offer, it specified delivery of other end products in the provision entitled "Trade Agreements Certificate."

(End of clause)

* * * * *

52.225-11 Buy American—Construction Materials Under Trade Agreements.

As prescribed in 25.1102(c), insert the following clause:

Buy American—Construction Materials Under Trade Agreements (OCT 2019[DATE])

(a) Definitions. As used in this clause-

* * * * *

"Designated country" means any of the following countries:

- (1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or United Kingdom);
- (2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);

* * * * *

Alternate I (MAY 2014[DATE]). As prescribed in 25.1102(c)(3), add the following definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) of the basic clause, and substitute the following paragraphs (b)(1) and (b)(2) for paragraphs (b)(1) and (b)(2) of the basic clause:

"Bahrainian, Mexican, or Omani construction material" means a construction material that—

- (1) Is wholly the growth, product, or manufacture of Bahrain, Mexico, or Oman; or
- (2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in Bahrain, Mexico, or Oman into a new and different construction material distinct from the materials from which it was transformed.
- (b) Construction materials. (1) This clause implements 41 U.S.C. chapter 83, Buy American, by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the component test of the Buy American statute is waived for construction material that is a COTS item. (See FAR 12.505(a)(2)). In addition, the Contracting Officer has determined that the WTO GPA and all the Free Trade Agreements except the Bahrain FTA, NAFTA[United States-Mexico-Canada Agreement], and the Oman FTA apply to the this acquisition. Therefore, the Buy American statute restrictions are waived for designated country construction materials other than Bahrainian, Mexican, or Omani construction materials.

* * * * *

52.225-23 Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials Under Trade Agreements.

As prescribed in 25.1102(e), insert the following clause:

REQUIRED USE OF AMERICAN IRON, STEEL, AND MANUFACTURED GOODS—BUY AMERICAN STATUTE—CONSTRUCTION MATERIALS UNDER TRADE AGREEMENTS (OCT 2019 [DATE])

(a) Definitions. As used in this clause-

* * * * *

"Designated country" means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic

- of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or United Kingdom);
- (2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);

"Recovery Act designated country" means any of the following countries:

- (1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or United Kingdom);
- (2) A Free Trade Agreement country (FTA) (Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore); or