Questions and Answers and Updated RFQ

Question 1.

Reference: Section 4.2

Question: Per section 4.2, the testing facility "shall hold CLIA, CAP, ISO 9001, and cGMP accreditations".

We have CLIA and CAP accreditations, but not ISO 9001. Does that disqualify us? Also, can you clarify what type of accreditation is required for cGMP? We offer certain types of sequence characterization at cGMP level, but are not aware of any certificates issued for cGMP, of the type that are issued by CLIA and CAP.

Answer: RFQ Section 4.2 has been updated to indicate that Facility shall hold CLIA and CAP accreditations. ISO 9001 and cGMP are removed from requirements.

Request for Quote (RFQ)
Food and Drug Administration (FDA)
For
Sanger and whole genome sequencing for FDA/CVM in support of a study

1. Background

The exact nucleotide sequences targeted for gene editing are required for the most efficient outcomes. Because publicly available reference sequences cannot account for cell line specific genetic variation, we require Sanger sequencing of the genomic regions we intend to target. Upon completion of targeted gene editing, we require whole genome sequencing of our samples in order to perform analyses to determine the unintended alterations that occurred, both at the intended target site and elsewhere in the animal genome. This acquisition is for Sanger and whole genome sequencing services; FDA/CVM does not have the equipment to perform this work in-house in a cost-effective manner.

2. Objectives

The objective of this acquisition is for a contractor to perform Sanger and whole genome sequencing for FDA/CVM in support of a study. Sanger sequencing is to provide an accurate, targeted nucleotide sequence that is less than 1500bp long. These sequencing results will be used to design guide RNAs for targeted CRISPR/Cas9 genome editing and to design the homology arms of targeting vectors to mediate homology dependent repair (HDR) mediated genomic edits.

The objective of the whole genome sequencing is to provide accurate sequencing of edited pig genomes, which are approximately 2.7 Gb long. This will allow us to determine the changes to the genome that resulted from the CRISPR/Cas9 mediated editing events.

3. Scope

As a result of this contract, CVM/OR/DAVR expects to receive the sequence of short regions of the pig genome and plasmids. CVM/OR/DAVR also expects to receive a 30x whole genome sequence of submitted pig cell samples.

4. Requirements

There are two overarching requirements of this contract. The first is to perform Sanger sequencing and the second is to perform whole genome sequencing.

4.1 For Sanger sequencing, the contractor shall meet the following requirements at a minimum:

- Shall perform 250 Sanger sequencing reactions
- Shall receive samples from CVM in batches of between 10 and 30 samples per shipment, with a minimum of 9 shipments and a maximum of 25 shipments
- Shall be able to sequence bacterial clones, purified plasmids, and purified PCR products
- Shall provide standard forward and reverse primers, including T7, T3, M13, and SP6
- For samples with sequence lengths over 1kb, the attainable Sanger sequencing result shall be at least 500 bp
- Shall pick up samples by courier from the FDA White Oak Campus or shall accept shipped samples from a standard carrier such as UPS or FedEx.
- Shall be located within the continental United States, unless free shipping is offered
- Shall repeat runs that are poor quality, with the repeat runs not counting against the 250 sequencing reactions. Poor run quality shall be determined by sequence stretches >5bp with ambiguous base calls greater than 60bp from the sequencing start and end sites. If the region is highly repetitive or has high GC content (>70%), a failed run will be accepted following 1 repeat.

Task Number	Work Milestones	Turnaround Time

4.1	Sanger Sequence submitted DNA samples and return base calls and chromatograms	3 business days/sample

For Task 4.1 of the above table, the turn around time is from sample receipt at the contractor's facility. If courier pick up is offered, the sample should be picked up the same business day if the sample is deposited by 12pm EST or picked up next business day if the sample is deposited after 12pm EST.

4.2 For whole Genome sequencing, the contractor shall meet the following requirements at a minimum:

- CVM/OR will provide all cell samples and the contractor shall supply all reagents necessary for all steps taking place at the contractor's facility.
- Shall extract DNA from 16 pig cell line samples.
- DNA shall be double stranded and non-degraded with a DNA integrity number, as measured by an Agilent Bioanalyzer or equivalent, of >7.0 and a A260/280 >/= 1.7.
- Library prep kit shall be able to use as little as 100ng of DNA input.
- Shall generate 16 sequencing libraries using the extracted gDNA and a kit compatible with the pig genome.
- Upon sequencing libraries passing quality control, 80% of the reads shall have a Q score above 30. If not, contractor shall assume costs to repeat any sequencing runs.
- Shall sequence the 16 generated libraries on an Illumina platform using 150 bp paired end reads to a depth sequencing coverage of at least 30X, with each sample yielding approximately 85 Gb raw throughput.
- Shall supply the costs and any specialized materials to ship the samples from 8401 Muirkirk Rd, Laurel, MD 20708 to the contracted sequencing facility.
- Shall receive the samples in a maximum of two shipments, with the shipment sizes being either 16 samples at once or 12 samples and then 4 samples.
- Shall send shipment information within 3 business days of notification that samples are ready to ship.
- Facility shall hold CLIA and ~~,~~ CAP~~, ISO 9001, and cGMP~~ accreditations.
- The whole genome sequencing samples shall be shipped with an easily trackable, overnight carrier on dry ice. These samples will be shipped such that they will arrive Tuesday, Wednesday, or Thursday, unless the sequencing facility is open on Saturdays, in which case, samples will be shipped to arrive Tuesday, Wednesday, Thursday, or Friday.
- Shall transfer all raw sequencing data to CVM/OR or CVM/ONADE via precisionFDA (https://precision.fda.gov/) to a folder that will be communicated after the contract is awarded.

Task Number	Work Milestones	Turnaround Time
4.2.1	Isolate gDNA from mammalian cell sample	1 week
4.2.2	Prepare sequencing libraries of samples for whole genome sequencing	1 week
4.2.3	Run quality control on sample libraries	1 week
4.2.4	Sequence sample libraries	8 weeks
4.2.5	Determine sequence quality	1 week
4.2.6	Deliver raw sequencing reads (fastq files)	1 week

For Task 4.2.1 of the above table, the turnaround time begins upon sample receipt. For tasks 4.2.2 to 4.2.6 of the above table, the task turnaround time begins upon completion of the prior task. For example, if task 4.2.2 is completed in 3 days (Day 3), task 4.2.3 should be completed in a week starting from Day 4.

5. Deliverables

5.1 For Sanger sequencing, the contractor shall deliver the sequence base calls and chromatogram electronically, either via email to COR at TBD or through an FDA accessible company website, no more than 3 business days following sample receipt, unless the sequence quality is unacceptable. To qualify to be an acceptable quality, greater than 80% of the base calls greater than 20 base pairs from the sequencing start and end site must be callable, with less than 5% "N" base calls

5.2 For Whole Genome Sequencing, the contractor shall provide the followings:
1) shall upload the full untrimmed raw read files in the format of fastq for the 16 samples to the FDA hosted high performance computing platform - precisionFDA (https://precision.fda.gov/).
2) shall provide information about how the data was generated (DNA extraction method, library preparation method, sequencing method, quality control method, instrument run parameters, base calling).
3) shall deliver the raw reads within 12 weeks of sample receipt, unless the original samples do not pass quality control. In order to pass the quality control, greater than 80% of the reads have a Q score above 30.

6. Place of Performance
The contract will be performed at the Contractor's facility.

7. Place of Performance
The period of performance will be a 12-month period.

8. Insepction and Acceptance
All items specified in this Requirements Statement to be delivered under this order are subject to final inspection and acceptance by an authorized representative for the Government. The authorized representative of the Government is the Government's COR, who is responsible for inspection and acceptance of all services, materials, or supplies to be provided by the Contractor.

The COR will coordinate with FDA's bioinformatician, who runs the raw data through an analysis pipeline and verifies the sample quality. The COR will provide written notification of acceptance or rejection within 10 days of receipt. The Contractor shall correct any deficiencies within thirty (30) days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this time frame, the Contractor shall immediately notify the COR of the reason for the delay and provide a proposed corrective action plan within ten (10) business days.

9. Contract Type
The contract type of this order is firm-fixed price (FFP).

10. Government Points of Contacts
Contract Specialist (CS)
Min Jie Zeng
Office of Acquisitions and Grants Services
Food and Drug Administration
Minjie.Zeng@fda.hhs.gov

Contracting Officer (CO):
TBD

Contract Officer Representative (COR):
TBD

Technical Point of Contact (TPOC):

TBD

11. Contracting Officer Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.
The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

12. Security Requirement

A. Baseline Security Requirements

1) **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes the following:

a. 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.

2) **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 in order 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.

3) **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 Categorie*s, 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:	[X] Low [ ] Moderate [ ] High
Integrity:	[ ] Low [X] Moderate [ ] High

Availability: [X] Low [ ] Moderate [ ] High
Overall Risk Level: [ ] Low [X] Moderate [ ] High

Based on information provided by the Privacy Office, system/data owner, or other privacy representative, it has been determined that this solicitation/contract involves:

[X] No PII [ ] Yes PII

4) **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, re- using, 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*.

5) **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).

6) **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.

B. Incident Response

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 an other 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, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

a. cooperate 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. encrypt 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.

5) 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.

C. Contract Initiation and Expiration

1) **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with FDA OAGS SMGs to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization and FDA IS2P Appendix T: *Sanitization of Computer-Related Storage Media*

2) **Contractor Responsibilities Upon Physical Completion of the Contract**. The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or FDA policies.

D. Records Management and Retention

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/FDA policies and shall not dispose of any records unless authorized by HHS/*FDA*.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/FDA policies.

13. Confidentiality and Nondisclosure of Information

Any information provided to the contractor 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 or entity 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 shall be under the supervision of the Contractor. Each Contractor employee 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 can be used only for that purpose and to the extent authorized herein. The information shall not be disclosed to any other entity without prior FDA approval.

Contractor Non-Disclosure Agreement (NDA). Each Contractor employee having access to non-public government information under this contract shall complete the FDA non-disclosure agreement (3398 Form) (see Attachment 1), as applicable. Contractor must submit FDA form 3398 Prior to samples being sent and/or contractor employee performing work on the contract. Contractor will have up to 20 calendar days to return FDA form 3398 to the FDA. Upon receipt of samples, the contractor shall perform the required proteomics analysis which shall be delivered within 30 calendar days from receipt of the government provided human plasma samples. All data will be provided to FDA in a Microsoft Excel spreadsheet via email or an internet site for downloading. The service company does not own the data (i.e., intellectual property). FDA is the owner of the data.

Sanitization of Government Files and Information. As part of contract closeout and at expiration of the contract, the Contractorshall provide all required documentation to the COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization and FDA IS2P Appendix T: Sanitization of Computer-Related Storage Media

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).

14. FAR/HHSAR Clauses
FAR 52.252-4, Clauses Incorporated by Reference (Feb 1998)

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

FAR 52.227-14, Rights in Data-General (May 2014)
FAR 52.232-39: Unenforceability of Unauthorized Obligations (Jun 2013)
FAR 52.232-40: Providing Accelerated Payment to Small Business Subcontractors (Dec 2013)

FAR 52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (Jul 2021)

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

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

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

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

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

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

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

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

[Contracting Officer check as appropriate.]

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

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

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

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

__ (5) [Reserved].

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

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

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

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

__ (10) [Reserved].

__ (11)

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

__ (ii) Alternate I (Mar 2020) of 52.219-3.

__ (12)

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

__ (ii) Alternate I (Mar 2020) of 52.219-4.

__ (13) [Reserved]

__ (14)

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

__ (ii) Alternate I (Mar 2020) of 52.219-6.

__ (15)

(i) 52.219-7, Notice of Partial Small Business Set-Aside (Nov 2020) (15 U.S.C. 644).

__ (ii) Alternate I (Mar 2020) of 52.219-7.

__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).

__ (17)

(i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).

__ (ii) Alternate I (Nov 2016) of 52.219-9.

__ (iii) Alternate II (Nov 2016) of 52.219-9.

__ (iv) Alternate III (Jun 2020) of 52.219-9.

__ (v) Alternate IV (Jun 2020) of 52.219-9

__ (18)

(i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).

__ (ii) Alternate I (Mar 2020) of 52.219-13.

__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).

__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).

_X_ (22)

(i) 52.219-28, Post Award Small Business Program Rerepresentation (Nov 2020) (15 U.S.C. 632(a)(2)).

__ (ii) Alternate I (MAR 2020) of 52.219-28.

__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020) (15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

_X_ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

_X_ (28) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (Jan2020) (E.O.13126).

_X_ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

_X_ (30)

(i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).

__ (ii) Alternate I (Feb 1999) of 52.222-26.

_X_ (31)

(i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

__ (ii) Alternate I (Jul 2014) of 52.222-35.

_X_ (32)

(i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

__ (ii) Alternate I (Jul 2014) of 52.222-36.

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

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

_X_ (35)

(i) 52.222-50, Combating Trafficking in Persons (Oct 2020) (22 U.S.C. chapter 78 and E.O. 13627).

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

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

__ (37)

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

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

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

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

__ (40)

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

__ (ii) Alternate I (Oct 2015) of 52.223-13.

__ (41)

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

__ (ii) Alternate I (Jun2014) of 52.223-14.

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

__ (43)

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

__ (ii) Alternate I (Jun 2014) of 52.223-16.

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

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47)

(i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).

__ (ii) Alternate I (Jan 2017) of 52.224-3.

_X_ (48) 52.225-1, Buy American-Supplies (Jan2021) (41 U.S.C. chapter 83).

__ (49)

(i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (Jan 2021)(41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

__ (ii) Alternate I (Jan 2021) of 52.225-3.

__ (iii) Alternate II (Jan 2021) of 52.225-3.

__ (iv) Alternate III (Jan 2021) of 52.225-3.

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

_X_ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Feb 2021) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

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

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (Feb 2021) .

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

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

_X_ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

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

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

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

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

__ (63)

(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. 55305 and 10 U.S.C. 2631).

__ (ii) Alternate I (Apr 2003) of 52.247-64.

__ (iii) Alternate II (Feb 2006) of 52.247-64.

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

[Contracting Officer check as appropriate.]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

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

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

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

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

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

__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020).

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

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

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

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

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

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

(e)

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

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

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

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

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

(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(vii) 52.222-26, Equal Opportunity (Sep 2015) (E.O.11246).

(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).

(xiii)

(A) 52.222-50, Combating Trafficking in Persons (Oct 2020) (22 U.S.C. chapter 78 and E.O 13627).

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

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).

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

(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020).

(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix)

(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(B) Alternate I (Jan 2017) of 52.224-3.

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

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. 55305 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

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

(End of clause)

This contract incorporates one or more HHSAR clauses by reference, with the same force and effect as if they were given in full text. The full text of the HHSAR clauses may be accessed electronically at this address:

http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html.

HHSAR 352.222-70, Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)

HHSAR 352.227-14 Rights in Data—Exceptional Circumstances (SEPT 2014)

HHSAR 352.239-74: Information and Communication Technology (ICT) Accessibility (DEC 2015)
(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) 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)
- 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)
- 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 are available at https://www.hhs.gov/web/section-508/making-files-accessible/index.html, 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.

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

15. Provision

FAR 52.252-1, Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

HTTPS://WWW.ACQUISITION.GOV/

FAR 52.203-18: Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements—Representation (Jan 2017)
FAR 52.204-24: Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Oct 2020)
FAR 52.204-26: Covered Telecommunications Equipment or Services-Representation (Oct 2020)

FAR 52.212-3 Offeror Representations and Certifications-Commercial Items (Feb 2021)
The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual

representations and certification electronically in the System for Award Management (SAM) accessed through https://www.sam.gov. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (v)) of this provision.

(a) Definitions. As used in this provision—

"Covered telecommunications equipment or services" has the meaning provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business eligible under the WOSB Program.

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

Inverted domestic corporation, means a foreign incorporated entity that meets the definition of an inverted domestic corporation under 6 U.S.C. 395(b), applied in accordance with the rules and definitions of 6 U.S.C. 395(c).

Manufactured end product means any end product in product and service codes (PSCs) 1000-9999, except—

(1) PSC 5510, Lumber and Related Basic Wood Materials;

(2) Product or Service Group (PSG) 87, Agricultural Supplies;

(3) PSG 88, Live Animals;

(4) PSG 89, Subsistence;

(5) PSC 9410, Crude Grades of Plant Materials;

(6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;

(7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;

(8) PSC 9610, Ores;

(9) PSC 9620, Minerals, Natural and Synthetic; and

(10) PSC 9630, Additive Metal Materials.

Place of manufacture means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

Restricted business operations means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

(1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;

(2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended.“Sensitive technology”—

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3)of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

Service-disabled veteran-owned small business concern—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veteransor, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service connected, as defined in 38 U.S.C. 101(16).

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.

Small disadvantaged business concern, consistent with13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13.CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Subsidiary means an entity in which more than 50 percent of the entity is owned—

(1) Directly by a parent corporation; or

(2) Through another subsidiary of a parent corporation

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term “successor” does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

Veteran-owned small business concern means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance

with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

Women-owned small business concern means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(b)
(1) Annual Representations and Certifications. Any changes provided by the Offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications in SAM

(2) The offeror has completed the annual representations and certifications electronically in SAM accessed through http://www.sam.gov. After reviewing SAM information, the Offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications-Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard(s) applicable to the NAICS code(s) referenced for this solicitation), at the time this offer is submitted and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs _____.

[Offeror to identify the applicable paragraphs at (c) through (v) of this provision that the offeror has completed for the purposes of this solicitation only, if any.

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted electronically on SAM.]

(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply.

(1) Small business concern. The offeror represents as part of its offer that it □ is, □ is not a small business concern.

(2) Veteran-owned small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it □ is, □ is not a veteran-owned small business concern.

(3) Service-disabled veteran-owned small business concern. [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.] The offeror represents as part of its offer that it □ is, □ is not a service-disabled veteran-owned small business concern.

(4) Small disadvantaged business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, that it □ is, □ is not a small disadvantaged business concern as defined in 13 CFR124.1002.

(5) Women-owned small business concern. [Complete only if the offeror represented itself as a

small business concern in paragraph (c)(1) of this provision.] The offeror represents that it □ is, □ is not a women-owned small business concern.

(6) WOSB concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(5) of this provision.] The offeror represents that-

(i) It □ is, □ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(6)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(7) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a WOSB concern eligible under the WOSB Program in (c)(6) of this provision.] The offeror represents that-

(i) It □ is, □ is not an EDWOSB concern, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(7)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

Note: Complete paragraphs (c)(8) and (c)(9) only if this solicitation is expected to exceed the simplified acquisition threshold.

(8) Women-owned business concern (other than small business concern). [Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it □ is a women-owned business concern.

(9) Tie bid priority for labor surplus area concerns. If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:_____

(10) HUBZone small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, as part of its offer, that–

(i) It □ is, □ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It □ is, □ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order11246-
(1) Previous contracts and compliance. The offeror represents that-

(i) It □ has, □ has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It □ has, □ has not filed all required compliance reports.

(2) Affirmative Action Compliance. The offeror represents that-

(i) It □ has developed and has on file, □ has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or

(ii) It □ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) Certification Regarding Payments to Influence Federal Transactions (31 http://uscode.house.gov/ U.S.C. 1352). (Applies only if the contract is expected to exceed $150,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(f) Buy American Certificate. (Applies only if the clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American-Supplies, is included in this solicitation.)

(1) The offeror certifies that each end product, except those listed in paragraph (f)(2) 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 offeror shall list as 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.” The terms “commercially available off-the-shelf (COTS) item” “component,” “domestic end product,” “end product,” “foreign end product,” and “United States” are defined in the clause of this solicitation entitled “Buy American-Supplies.”

(2) Foreign End Products:

Line Item No.

Country of Origin

_____

_____

_____

_____

_____

_____

[List as necessary]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR part 25.

(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 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.”

(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)(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 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) Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate III. If Alternate III to the clause at 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) Trade Agreements Certificate. (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(5)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

Line Item No.

Country of Origin

_____

_____

_____

_____

_____

_____

[List as necessary]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) Certification Regarding Responsibility Matters (Executive Order 12689). (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals–

(1) □ Are, □ are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) □ Have, □ have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(3) □ Are, □ are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses enumerated in paragraph (h)(2) of this clause; and

(4) □ Have, □ have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,500 for which the liability remains unsatisfied.

(i) Taxes are considered delinquent if both of the following criteria apply:

(A) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(B) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(ii) Examples.
(A) The taxpayer has received a statutory notice of deficiency, under I.R.C. §6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability

until the taxpayer has exercised all judicial appeal rights.

(B) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. §6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(C) The taxpayer has entered into an installment agreement pursuant to I.R.C. §6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(D) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. §362 (the Bankruptcy Code).

(i) Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126). [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b).]

(1) Listed end products.

Listed End Product

Listed Countries of Origin

_____

_____

_____

_____

(2) Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]

(i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

(ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j) Place of manufacture. (Does not apply unless the solicitation is predominantly for the acquisition

of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly-

(1) □ In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or

(2) □ Outside the United States.

(k) Certificates regarding exemptions from the application of the Service Contract Labor Standards (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services.) [The contracting officer is to check a box to indicate if paragraph (k)(1) or (k)(2) applies.]

(1) Maintenance, calibration, or repair of certain equipment as described in FAR 22.1003-4(c)(1). The offeror □ does □ does not certify that–

(i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR 22.1003-4(c)(2)(ii)) for the maintenance, calibration, or repair of such equipment; and

(iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

(2) Certain services as described in FAR 22.1003-4(d)(1). The offeror □ does □ does not certify that-

(i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR 22.1003-4(d)(2)(iii));

(iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and

(iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.

(3) If paragraph (k)(1) or (k)(2) of this clause applies–

(i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

(ii) The Contracting Officer may not make an award to the offeror if the offeror fails to execute the certification in paragraph (k)(1) or (k)(2) of this clause or to contact the Contracting Officer as required in paragraph (k)(3)(i) of this clause.

(l) Taxpayer Identification Number (TIN) (26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to the SAM to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (l)(3) through (l)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) Taxpayer Identification Number (TIN).

TIN: _____.

TIN has been applied for.

TIN is not required because:

Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

Offeror is an agency or instrumentality of a foreign government;

Offeror is an agency or instrumentality of the Federal Government.

(4) Type of organization.

Sole proprietorship;

Partnership;

Corporate entity (not tax-exempt);

Corporate entity (tax-exempt);

Government entity (Federal, State, or local);

Foreign government;

International organization per 26 CFR1.6049-4;

Other _____.

(5) Common parent.

Offeror is not owned or controlled by a common parent;

Name and TIN of common parent:

Name _____.

TIN _____.

(m) Restricted business operations in Sudan. By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(n) Prohibition on Contracting with Inverted Domestic Corporations.
(1) Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of an inverted domestic corporation, unless the exception at 9.108-2(b) applies or the requirement is waived in accordance with the procedures at 9.108-4.

(2) Representation. The Offeror represents that–

(i) It □ is, □ is not an inverted domestic corporation; and

(ii) It □ is, □ is not a subsidiary of an inverted domestic corporation.

(o) Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.
(1) The offeror shall e-mail questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(2) Representation and Certifications. Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror-

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds the threshold at FAR 25.703-2(a)(2) with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (et seq.) (see OFAC's Specially Designated Nationals and Blocked Persons List at https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx).

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if-

(i) This solicitation includes a trade agreements certification (e.g., 52.212-3(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country

end products.

(p) Ownership or Control of Offeror. (Applies in all solicitations when there is a requirement to be registered in SAM or a requirement to have a unique entity identifier in the solicitation).

(1) The Offeror represents that it □ has or □ does not have an immediate owner. If the Offeror has more than one immediate owner (such as a joint venture), then the Offeror shall respond to paragraph (2) and if applicable, paragraph (3) of this provision for each participant in the joint venture.

(2) If the Offeror indicates "has" in paragraph (p)(1) of this provision, enter the following information:

Immediate owner CAGE code: _____.

Immediate owner legal name: _____.

(Do not use a "doing business as" name)

Is the immediate owner owned or controlled by another entity: □ Yes or □ No.

(3) If the Offeror indicates "yes" in paragraph (p)(2) of this provision, indicating that the immediate owner is owned or controlled by another entity, then enter the following information:

Highest-level owner CAGE code: _____.

Highest-level owner legal name: _____.

(Do not use a "doing business as" name)

(q) Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law.

(1) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, The Government will not enter into a contract with any corporation that–

(i) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(ii) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(2) The Offeror represents that–

(i) It is □ is not □ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the

tax liability; and

(ii) It is □ is not □ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(r) Predecessor of Offeror. (Applies in all solicitations that include the provision at 52.204-16, Commercial and Government Entity Code Reporting.)

(1) The Offeror represents that it □ is or □ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(2) If the Offeror has indicated "is" in paragraph (r)(1) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: (or mark "Unknown").

Predecessor legal name: ____.

(Do not use a "doing business as" name).

(s) [Reserved].

(t) Public Disclosure of Greenhouse Gas Emissions and Reduction Goals. Applies in all solicitations that require offerors to register in SAM (12.301(d)(1)).

(1) This representation shall be completed if the Offeror received $7.5 million or more in contract awards in the prior Federal fiscal year. The representation is optional if the Offeror received less than $7.5 million in Federal contract awards in the prior Federal fiscal year.

(2) Representation. [Offeror to check applicable block(s) in paragraph (t)(2)(i) and (ii)].
(i) The Offeror (itself or through its immediate owner or highest-level owner) □ does, □ does not publicly disclose greenhouse gas emissions, i.e., makes available on a publicly accessible website the results of a greenhouse gas inventory, performed in accordance with an accounting standard with publicly available and consistently applied criteria, such as the Greenhouse Gas Protocol Corporate Standard.

(ii) The Offeror (itself or through its immediate owner or highest-level owner) □ does, □ does not publicly disclose a quantitative greenhouse gas emissions reduction goal, i.e., make available on a publicly accessible website a target to reduce absolute emissions or emissions intensity by a specific quantity or percentage.

(iii) A publicly accessible website includes the Offeror's own website or a recognized, third-party greenhouse gas emissions reporting program.

(3) If the Offeror checked "does" in paragraphs (t)(2)(i) or (t)(2)(ii) of this provision, respectively, the Offeror shall provide the publicly accessible website(s) where greenhouse gas emissions and/or reduction goals are reported:_____.

(u)
(1) In accordance with 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), Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with an entity that requires employees or

subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(2) The prohibition in paragraph (u)(1) of this provision does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(3) Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(v) Covered Telecommunications Equipment or Services-Representation. Section 889(a)(1)(A) of Public Law 115-232.

(1) The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(2) The Offeror represents that it □ does, □ does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(End of Provision)

HHSAR 352.239-73, Electronic Information and Technology Accessibility Notice (Dec 2015)

16. Instructions to Qutors

a. This is a combined/synopsis solicitation issued under FAR Part 12 and 13.5 procedures. This is an restricted procurement, setting aside for small business concern. The NAICS code is 621511. Small Business Size Standard is $35 Million.

b. Quoters shall certify their quotes to be valid for at least 30 days.

c. Quoters shall submit a quote for all requirements listed in this RFQ. Partial quotes will not be considered. Incomplete pricing or pricing with omissions may not be considered for award.

d. Quoters shall submit all assumptions in their quotation.

e. Quoters are advised that additional terms and conditions submitted with their quotation that is in conflict of the terms and conditions of this solicitation may be deems as technically unacceptable and may not be considered for award. All additional terms and conditions must be submitted with its quotation.

f. Quoters providing quotations must clearly state the overall cost to the Government.

g. Quoters shall ensure that their initial submission represents their best pricing and that all

information is provided to determine technical acceptability. The Government will not research items to determine compatibility; all information regarding compatibility must be contained within the quotation.

h. Quotes shall confirm in writing that all the requirements of this RFQ, especially those listed on Section 4 and 5, will be met.

i. Please submit questions to Min Jie (Terry) Zeng via email at minjie.zeng@fda.hhs.gov by September 1, 2021, 4PM Eastern Time.

j. Please submit quotes to Min Jie (Terry) Zeng via email at minjie.zeng@fda.hhs.gov by September 6, 2021, 4PM Eastern Time.

17. Evaluation Method

The Government will award a contract resulting from this solicitation to the responsible quoter as a fixed-price contract on the lowest price technically acceptable (LPTA) evaluation method. Award will be made on the basis of the lowest evaluated price meeting or exceeding the requirements of the solicitation, which specified in Section 4.0 Requirements and 5.0 Deliverables. The Quoter's initial quotation shall contain the Quoter's best terms from a price standpoint. Failure to demonstrate meeting any of the requirements will result in a rating of technically unacceptable and will not be considered for award.

The following factors shall be used to evaluate quotes:

- Total price.
- Technical features meeting/exceeding requirements stated in Section 4.0 Requirements and 5.0 Deliverables.
- Statement indicates that deliverables are meeting Section 508 compliance requirements.

END OF SOLICITATION