

FDA-RFQ-75F40120Q00011
Thermo Nanospray Source for Fusion
BRAND NAME OR EQUAL

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Solicitation Number:	75F40120Q00011
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NAICS Code:	334516, Analytical Laboratory Instrument Manufacturing, Small Size Standard 1,000 Employees

PART 1 – Description

The U.S. Food & Drug Administration (FDA) Office of Pharmaceutical Quality (OPQ), Office of Testing and Research (OTR), Division of Pharmaceutical Analysis (DPA), requires the purchase of a Nanospray source for the current Thermo Orbitrap Fusion system. This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in Federal Acquisition Regulation (FAR) Subpart 12.6, as supplemented with additional information included in this notice.. This announcement constitutes the only solicitation; quotes are being requested, and a separate written solicitation will not be issued.

This solicitation is a Request for Quote (RFQ) using FAR parts 12 and 13 procedures. The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2020-04 January 15, 2020. The North American Industry Classification System (NAICS) code for the proposed acquisition is 334516 Analytical Laboratory Instrument Manufacturing, small business size standard 1000 employees.

This requirement is for a **Thermo Scientific EASY-Spray Source Kit (NG), Catalog number: ES082- BRAND NAME OR EQUAL**

PART 2 – Supplies or Services and Prices/Costs

2.1 Contract Type

Purchase Order Type: Firm-Fixed Price

2.2 Base

CLIN	Service and Supply Description	Quantity	Unit Price	Firm-Fixed Price
0001	Thermo Scientific EASY-Spray Source Kit (NG), Catalog number: ES082 BRAND NAME OR EQUAL	1		
0002	Delivery, and Service Contract Coverage for 90 Days.	1		
	Total Firm Fixed Price*			

***The firm-fixed-prices are inclusive of all costs, such as shipping, parts, installation, labor, travel, and any other warranty and service maintenance costs. Payment is only authorized**

for the respective firm-fixed prices upon successful completion of the respective CLINs, including delivery and acceptance of all deliverables, as determined by the FDA Contracting Officer's Representative (COR), and upon submission of a proper invoice. Proper invoice submissions includes following the invoice instructions below.

PART 3 – Description/Specifications

3.1 STATEMENT OF WORK: Purchase of a Nanospray source for the current Thermo Orbitrap Fusion system in FDA/CDER/OPQ/OTR laboratory in St. Louis

Background/Statement of Need

Nano LC-MS plays an important role in protein therapeutics analysis using mass spectrometry. This is particularly relevant for determining low abundant proteins/peptides in limited samples. Protein therapeutics, especially therapeutic monoclonal antibodies (mAb), has become a primary focus for the pharmaceutical industry worldwide. There are several projects in FDA/CDER/OPQ/OTR LABORATORY conducting the characterization of protein therapeutics by mass spectrometry.

Given the compatibility with preserving the native like structure of biological macromolecules, nano-electrospray ionization (nESI) has become the de-facto source for structural proteomics studies by mass spectrometry (MS). By acquiring the Thermo Nanospray source we would be able to exploit this technology to perform LC/MS based proteomics studies with better repeatability and sensitivity. This is becoming an increasingly important feature in the study of biotherapeutics, as well as in the determination of host cell proteins in monoclonal antibodies (mAb's) and for sensitive glycosylation analysis.

To enhance the application of the High-Resolution MS at the FDA/CDER/OPQ/OTR LABORATORY, the Nanospray source enables more sensitive and robust Nanoflow liquid chromatography (NanoLC) studies to be performed, by coupling directly to existing THERMO_ULTIMATE3000_RSLCNANO Nano LC and Orbitrap Fusion Mass Spectrometer systems.

The nanospray source must be compatible with the currently available Thermo Orbitrap Fusion mass spectrometer, Thermo Scientific™ UltiMate™ 3000 RSLCnano system, Xcalibur software and Chromeleon software. To improve the repeatability the spray, repeatable accurate installation of nanospray source is also required. Thermo EASY-Spray Source is the only commercially available nanospray source that meets all the requirements. Compared to the Nanospray Flex Series Ion Source, EASY-Spray Source provides more stable sprays, and a number of key advantages including column temperature control, easy to use, longer column life time, easy to adjust the spray position.

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Objective

The Thermo Nanospray source will be used to extend the capability of the FDA/CDER/OPQ/OTR LABORATORY to perform nanoLC/MS proteomics studies, and further enable NanoLC based approaches not currently available at the FDA/CDER/OPQ/OTR LABORATORY.

Scope

Enhance the capability of the FDA/CDER/OPQ/OTR LABORATORY to perform structural proteomics, and NanoLC based studies.

Deliverable table

Deliverable	Description	Quantity/Media	Date Completed
1	Thermo EASY-Spray Source Kit (NG), Catalog number: ES082	1	90 days after contract approval.

Government-Furnished Property, Material, Equipment, or Information (GFP, GFM, GFE, or GFI)

Government furnished property includes the THERMO_ULTIMATE3000_RSLCNANO NanoLC and Orbitrap Fusion Mass Spectrometer system that the new hardware will be attached to. Equipment (e.g. hand tools) required for installation is expected to be provided upon delivery of instrumentation (end product). Additional solvent consumables, LC-MS grade water and acetonitrile, required for general use of the end product will be supplied by the FDA/CDER/OPQ/OTR LABORATORY.

Required Specifications/Salient Characteristics

Parameters	Descriptions
Hardware	Must be compatible with the currently available Thermo Orbitrap Fusion mass spectrometer, and the Thermo Scientific™ UltiMate™ 3000 RSLCnano system
Software	Must be compatible with the currently available Orbitrap Tribrid MS Series Instrument Control Software, Xcalibur software and Chromeleon

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	software
Spray Voltage	Must covers 1200 – 2500 V
Flow Rate	Must covers 50nL/min to 3000nL/min
Column Heater	Must have temperature control for heating nano columns at 30-60C
Nano Column	Must be compatible with nano column length up to 500mm.
Backpressures	At least 1000 bar
Other	<ul style="list-style-type: none"> • Must include camera and monitor for viewing the spray. • Adjustable and easy position the emitter position. • Warranty should cover all parts after shipment for at least 90 days.

Special requirement

N/A

Part 4 –Performance and Deliverables

4.1 Period of performance

The period of performance (POP) begins the date of contract award execution and continues for 90 days beginning on the day of formal government acceptance. This is a standard procurement for a commercial product item. Period of performance will be the standard delivery after placement of the order, plus warranty for 90 days.

4.2 Delivery, Installation, Training, and Support: 52.247-34 F.O.B. Destination

Delivery period of 90 days upon completion of the contract approval is expected for all hardware. No onsite installation or consulting required.

The vendor is responsible for delivery of the instrument and all components specified above to:

Delivery Location:

U.S. Food and Drug Administration
 FDA/CDER/OPQ/OTR
 Division of Pharmaceutical Analysis

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Attention: To-Be-Determined (TBD)
645 S. Newstead Avenue St. Louis, MO 63110

The vendor shall cover all costs associated with the following:

- Crating and shipping shall be included in this proposal to the delivery address
- On-site installation, hardware, software, and applications training shall be provided at the FDA site. All appropriate training manuals and literature shall be supplied electronically.
- Technical support shall be provided through common avenues: phone, web, fax, during standard business hour

4.3 Place of Performance and Work Hours

The delivery of the items and or services must occur during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM, excluding holidays.

4.4 Packing, Marking and Shipping

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

4.5 Inspection and Acceptance

The Contractor shall comply with all inspection and acceptance criteria in accordance with FAR 52.246-2, Inspection of Supplies- Fixed-Price (Aug 1996). Upon request, the Contracting Officer will make the full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

www.acquisition.gov/far/index.html

The Contracting Officer Representative (COR) will perform inspection and acceptance of equipment, installation and services to be provided. The COR, To-Be-Determined (TBD), is the authorized representative of the Contracting Officer.

PART 5 –Contract Administration

5.1 Representative's

The Contracting Officer Representative (COR) will perform inspection and acceptance of equipment and services to be provided.

For this PART, To-Be-Determined (TBD) is the authorized representative of the Contracting Officer.

The COR is responsible for the following as required by this order: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical

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evaluations; (4) performing technical inspections and acceptances; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the *only person with authority to act as an agent of the Government under this order*. Only the Contracting Officer has authority to: direct or negotiate any changes in the order, including modifying or extending the period of performance, changing the delivery schedule, authorizing reimbursement to the Contractor for any costs incurred during the performance of this order, or otherwise change any terms and conditions of this order.

**The contact information for the Contracting Officer's Representative is the following:
To-Be-Determined (TBD)**

The contact information for the Contracting Officer is the following:

Richard (Rob) Robinson
U.S. Food and Drug Administration
Office of Acquisitions and Grants Services
4041 Powder Mill Road
Beltsville, MD 20705
Richard.Robinson@fda.hhs.gov

The contact information for the Contract Specialist is the following:

Wallace Cruz
U.S. Food and Drug Administration
Office of Acquisitions and Grants Services
4041 Powder Mill Road
Beltsville, MD 20705
Wallace.Cruz@fda.hhs.gov

5.2 FDA Three-Way Match Invoicing Procedures

FDA Three-Way Match Invoicing Procedures

A. The contractor shall submit all invoices to:

U.S. FOOD AND DRUG ADMINISTRATION
Attn: Vendor Payments
Division of Payment Services
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002
301-827-3742
FDAVendorPaymentsTeam@fda.hhs.gov

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*** Acceptable methods of delivery include: E-mail (preferred) and Standard Mail. Provide a copy marked courtesy to the COR or Technical Point of Contact (TPOC). The COR/TPOC is TBD.

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:

- (i) Name and address of the contractor;
- (ii) Invoice date and invoice number;
- (iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);
- (iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:
 - (a) period of performance for which costs are claimed;
 - (b) itemized travel costs, including origin and destination;
 - (c) any other supporting information necessary to clarify questionable expenditures;
 - (d) the contractor shall include the award item number for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed;
 - (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;
 - (vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);
 - (vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment);
 - (viii) Name, title, and phone number of person to notify in event of defective invoice;
 - (ix) Taxpayer Identification Number (TIN);
 - (x) banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT);
 - (xi) Name and telephone number of the FDA Contracting Officer Representative (COR) or other Program Center/Office point of contact, as referenced on the award;
 - (xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
 - (a) list of all invoices submitted to date under the subject award, including the following:
 - (1) invoice number, amount, & date submitted
 - (2) corresponding payment amount & date received
 - (b) total amount of all payments received to date under the subject contract or order
 - (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance;
 - (xiii) Any other information or documentation required by the award.

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C. An electronic invoice is acceptable if submitted in Adobe Acrobat (PDF) format. All items listed in (i) through (xiii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.

D. Questions regarding invoice payments should be directed to the Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

PART 6 – Contract clauses

6.1 FAR Clauses

FAR Clauses Incorporated by Reference:

52.252-2 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 shall make their full text available. Also, the full text of a clause may be accessed electronically at:

www.acquisition.gov/far/index.html

52.202-1 Definitions (November 2013)

52.203-5 Covenant Against Contingent Fees (May 2014)

52.203-6 Restrictions on Subcontractor Sales to the Government (Sep 2006)

52.203-6 Alternative I

52.203-7 Anti-Kickback Procedures (May 2014)

52.204-19 Incorporation by Reference of Representations and Certifications (Dec 2014)

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2019).

52.212-4 Contract Terms and Conditions-Commercial Items (Oct 2018)

52.222-50 Combating Trafficking in Persons (Jan 2019).

52.233-4 Applicable Law for Breach of Contract Claim (Oct 2004)

52.223-18 Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011).

52.225-13 Restrictions on Certain Foreign Purchases (Jun 2008).

52.232-39 Unenforceability of Unauthorized Obligations (Jun 2013).

52.233-3 Protest after Award (Aug 1996).

52.233-3_Alternate I

52.233-4 Applicable Law for Breach of Contract Claim (Oct 2004).

52.246-2 Inspection of Supplies- Fixed-Price (Aug 1996)

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FAR Clauses in Full Text:

52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Oct 2019)

(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 2019) (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:

[52.203-13](#), Contractor Code of Business Ethics and Conduct (Oct 2015) ([41 U.S.C. 3509](#))).

[52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2018) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).

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[52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) ([31 U.S.C. 6101 note](#)).

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

- (i) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).

[52.222-3](#), Convict Labor (June 2003) (E.O.11755).

[52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (Oct 2019) (E.O.13126).

[52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).

- (i) [52.222-26](#), Equal Opportunity (Sept 2016) (E.O.11246).

- (i) [52.222-35](#), Equal Opportunity for Veterans (Oct 2015) ([38 U.S.C. 4212](#)).

- (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jul 2014) ([29 U.S.C.793](#)).

[52.222-37](#), Employment Reports on Veterans (Feb 2016) ([38 U.S.C. 4212](#)).

- (i) [52.222-50](#), Combating Trafficking in Persons (Jan 2019) ([22 U.S.C. chapter 78](#) and E.O. 13627).

[52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011) (E.O. 13513).

[52.225-1](#), Buy American-Supplies (May 2014) ([41 U.S.C. chapter 83](#)).

- (i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) ([41 U.S.C. chapter 83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).

- (ii) Alternate I (May 2014) of [52.225-3](#).

[52.225-13](#), Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

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52.232-33, Payment by Electronic Funds Transfer-System for Award Management
(Oct 2018) (31 U.S.C. 3332).

(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:

N/A

(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, 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 (Oct 2015) (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

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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 2019) (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 \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.
- (vi) [52.222-17](#), Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause [52.222-17](#).
- (vii) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
- (viii) [52.222-26](#), Equal Opportunity (Sept 2015) (E.O.11246).
- (ix) [52.222-35](#), Equal Opportunity for Veterans (Oct 2015) ([38 U.S.C.4212](#)).
- (x) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jul 2014) ([29 U.S.C.793](#)).
- (xi) [52.222-37](#), Employment Reports on Veterans (Feb 2016) ([38 U.S.C.4212](#)).
- (xii) [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](#).
- (xiii) [52.222-41](#), Service Contract Labor Standards (Aug 2018) ([41 U.S.C. chapter 67](#)).
- (xiv) (A) [52.222-50](#), Combating Trafficking in Persons (Jan 2019) ([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).
- (xv) [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](#)).

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- (xvi) [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](#)).
- (xvii) [52.222-54](#), Employment Eligibility Verification (Oct 2015) (E.O. 12989).
- (xviii) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2015).
- (xix) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xx) (A) [52.224-3](#), Privacy Training (Jan 2017) ([5 U.S.C. 552a](#)).
- (B) Alternate I (Jan 2017) of [52.224-3](#).
- (xxi) [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](#)).
- (xxii) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (May 2014) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).
- (xxiii) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx.1241\(b\)](#) and [10 U.S.C.2631](#)). 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)

6.2 HHSAR Clauses Incorporated by Reference

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: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html#352.223-70>.

352.211-3, PAPERWORK REDUCTION ACT (DEC 2015)

352.203-70, ANTI-LOBBYING (DEC 2015)

352.215-70, LATE PROPOSALS AND REVISIONS (DEC 2015)

352.222-70, CONTRACTOR COOPERATION IN EQUAL EMPLOYMENT OPPORTUNITY INVESTIGATIONS (DEC 2015)

PART 7 – Solicitation Provisions

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Solicitation Provisions Incorporated by Reference:

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):

www.acquisition.gov/far/index.html

FAR 52.204-7, System for Award Management (Oct 2018)

FAR 52.204-16, Commercial and Government Entity Code Reporting (Jul 2016)

FAR 52.204-22, Alternative Line Item Proposal (Jan 2017)

FAR 52.204-26, Covered Telecommunications Equipment or Services--Representation

FAR 52.212-1, Instructions to Offerors- Commercial Items (Oct 2018)

FAR 52.212-3, Offeror Representations and Certifications- Commercial Items (Oct 2018)

FAR 52.222-22, Previous Contracts and Compliance Reports (Feb 1999)

FAR 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals-
Representation (Dec 2016)

FAR 52.225-18, Place of Manufacture (Aug 2018)

FAR 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or
Transactions Relating to Iran-Representation and Certifications (Aug 2018)

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

(End of provisions)

Solicitation Provisions in Full Text:

52.211-6 Brand Name or Equal.

As prescribed in 11.107(a), insert the following provision:

Brand Name or Equal (Aug 1999)

1. (a) If an item in this solicitation is identified as “brand name or equal,” the purchase description reflects the characteristics and level of quality that will satisfy the Government’s needs. The salient physical, functional, or performance characteristics that “equal” products must meet are specified in the solicitation.

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2. (b) To be considered for award, offers of “equal” products, including “equal” products of the brand name manufacturer, must-
 - a. (1) Meet the salient physical, functional, or performance characteristic specified in this solicitation;
 - b. (2) Clearly identify the item by-
 - i. (i) Brand name, if any; and
 - ii. (ii) Make or model number;
 - c. (3) Include descriptive literature such as illustrations, drawings, or a clear reference to previously furnished descriptive data or information available to the Contracting Officer; and
 - d. (4) Clearly describe any modifications the offeror plans to make in a product to make it conform to the solicitation requirements. Mark any descriptive material to clearly show the modifications.
3. (c) The Contracting Officer will evaluate “equal” products on the basis of information furnished by the offeror or identified in the offer and reasonably available to the Contracting Officer. The Contracting Officer is not responsible for locating or obtaining any information not identified in the offer.
4. (d) Unless the offeror clearly indicates in its offer that the product being offered is an “equal” product, the offeror shall provide the brand name product referenced in the solicitation.

(End of provision)

52.212-3 Offeror Representations and Certifications-Commercial Items (Oct 2018)

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 (u) of this provision.

(a) *Definitions.* As used in this provision—

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“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.

“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.

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“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”—
 - (1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—
 - i. (i) To restrict the free flow of unbiased information in Iran; or
 - ii. (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

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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 veterans or, 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 with 13 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 at 13 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 CFR 124.104(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.

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“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. “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. “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. “Women-owned business concern” means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women. “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 least 51 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.

“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.

(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

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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 applicable to the NAICS code 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 (u) 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 13CFR124.1002.

(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.

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(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.

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(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 50percent 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 Order 11246-

(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.

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(e) *Certification Regarding Payments to Influence Federal Transactions (31 U.S.C. 1352)*. (<http://uscode.house.gov/browse.xhtml;jsessionid=114A3287C7B3359E597506A31FC855B3>). (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
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Line Item No.	Country of Origin
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[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
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Line Item No.	Country of Origin
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[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.”

Line Item No.	Country of Origin
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Other Foreign End Products:

[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”:

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Canadian or Israeli End Products:

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

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(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.

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(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).]

Listed End Product

Listed Countries of Origin

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Listed End Product	Listed Countries of Origin
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(1) *Listed end products.*

(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.

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(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

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(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.

(1) *Taxpayer Identification Number (TIN)* ([26 U.S.C. 6109](#)). (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*.

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- Sole proprietorship;
- Partnership;
- Corporate entity (not tax-exempt);
- Corporate entity (tax-exempt);
- Government entity (Federal, State, or local);
- Foreign government;
- International organization per 26CFR1.6049-4;
- Other _____.

(5) *Common parent.*

- Offeror is not owned or controlled by a common parent;
- Name and TIN of common parent:

(i) Name _____.

(ii) 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-

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(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 \$3,500 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)

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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

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(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.

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(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).

PART 8 – Instructions to Offerors

FAR 52.212-1 INSTRUCTIONS TO OFFERORS – COMMERCIAL ITEMS (OCT 2018) is incorporated by reference (https://www.acquisition.gov/content/52212-1-instructions-offerors-commercial-items#i52_212-1). Addenda are attached below.

Quoters shall include in the quote:

- ✓ a point of contact (name, telephone number, and email address),
- ✓ proposed firm-fixed-prices estimated delivery date,
- ✓ business size and type (e.g. small, 8(a) small businesses, veteran-owned small businesses, woman-owned small businesses, etc.),

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- ✓ Dun and Bradstreet (DUNS) number,
 - ✓ country of manufacturing of equipment, and
 - ✓ certification that all company information listed in the System for Award Management (SAM) database is complete, accurate, and current.
- Quoters shall ensure the solicitation number is visible in the header of the email transmission of their quote.
 - Quoters shall provide specifications and/or characteristics for the equipment with the quote.
 - Quoters shall complete the pricing tables for the base period equipment.

**Faxed quotes will not be accepted.
Quotes must be valid through March 31, 2020.**

RESPONSE DATE

RFQ Due Date: All quotes and revisions shall be submitted via FDA BidBoard at or before 4:00 PM Eastern Time on 27 February 2020

PART 9 – Evaluation Factors for Award

Award shall be made to the bidder with the Lowest Priced Technically Acceptable (LPTA) offer.

In order to be considered technically acceptable:

- The Government will evaluate the extent to which the quote demonstrates the ability to meet the requirements as noted in Part 3 and 4 of this RFQ, to include the ability to provide all items meeting the required specifications/salient characteristics, delivery, installation, and warranty requirements

Price

- The government will evaluate the price of each item described in PART 2 as well as the total overall price to determine it is fair and reasonable and in accordance with the quoters' GSA pricing (with consideration of any applicable discounts offered).