COMBINED SYNOPSIS/SOLICITATION FOR
Preventative Maintenance and Calibration for Q-Exactive Mass spectrometer and attached Ultimate 3000 HPLC
SOLICITATION NUMBER: FDA-24-1279657

i. This is a combined synopsis/solicitation for commercial services prepared in accordance with the Federal Acquisition Regulation (FAR) format in Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; quotes are being requested and a written solicitation will not be issued.

ii. The solicitation number is FDA-24-1279657. This solicitation is a request for quote (RFQ). Set Aside for Small Business.

iii. The solicitation documented and incorporated provisions and clauses in effect through the Federal Acquisition Circular (FAC) 2023-06, Effective 12/04/2023.

iv. The associated North American Industry Classification System (NAICS) Code is *334516 Analytical Laboratory Instrument Manufacturing* with a small business size standard of 1,000 employees.

v. The US Food & Drug Administration (FDA) intends to issue a Commercial Item Firm Fixed-Price purchase order that meets the following specifications below. Please submit all quotes with:
a) Pricing for all line items
Quotes that do not price all line items may be deemed *non-responsive*.
Period for Acceptance of Offers: The quoter agrees to hold the prices firm for 60 calendar days after quote due date.

	DESCRIPTION	QTY	DUE DATE
0001	PM & Calibration for Q-Exactive	1	immediately upon contract execution
0002	PM & Calibration for PM-U3000 HP LC (HPG)	1	immediately upon contract execution

vi. **Description**

STATEMENT OF WORK FOR
Preventative Maintenance and Calibration for Q-Exactive Mass spectrometer and attached Ultimate 3000 HPLC

BACKGROUND

A high-resolution liquid chromatography tandem mass spectrometer is a specialized instrument with wide ranging laboratory applications. The New York Laboratory-Medical Products (NYL-MP) has a high resolution Thermo Fisher Scientific Q-Exactive mass spectrometer and attached Ultimate 3000 high performance liquid chromatography instrument. The Q-Exactive mass spectrometer is primarily utilized for Health Fraud analysis which serves to identify undeclared enhancement and weight loss drugs in dietary supplements. The instruments specified above are subject to yearly to ensure optimal function of the instrumentation and seamless continuation of the Health Fraud program mission.

REQUIREMENTS:

The contractor shall meet the following requirements:

The Contractor shall provide one preventive maintenance inspection for each the Q-Exactive mass spectrometer and attached Ultimate 3000 HPLC.

- Contractor shall be inspect, calibrate, and perform all necessary adjustments at the time of visit on the instruments.
- Contractor shall completely check all units for parts that may need to be replaced, reassembled, adjusted, and the unit will be thoroughly tested.
- Preventative maintenance by the Contractor shall be made in accordance with model specific preventive maintenance checklists to assure maintenance in accordance with original factory specification.
- Contractor Shall complete the PM and shall provide the lab representative with a Preventive Maintenance Service Report upon completion of the preventive maintenance.
- Preventative maintenance inspections shall be done by certified Thermo Fisher Scientific field service engineers or authorized Thermo Fisher Scientific field service engineers.

ORDER ADMINISTRATION

PERIOD OF PERFORMANCE

The anticipated dates are: 09/17/2024 – 09/16/2025
The Period of Performance begins the date of contract award execution and continues for one year from the date of formal government acceptance.

Unless otherwise specified, the Contractor shall perform work Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:30 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day.

Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.
Government Holidays:

January (New Year's Day)	September (Labor Day)
January (Martin Luther King Day)	October (Columbus Day)
February (President's Day)	November (Veterans Day)
May (Memorial Day)	November (Thanksgiving Day)
June (Juneteenth)	December (Christmas Day)
July (Independence Day)	

SHIPPING LOCATION:
U.S. FDA New York Laboratory-Medical Products
158-15 Liberty Ave,
Jamaica NY 11433
Attn: POC to be identified at time of award

GOVERNMENT POINTS OF CONTACT
Contract Specialist
Elena Tatarov
U.S. Food and Drug Administration
Office of Acquisitions and Grants Services
Email: elena.tatarov@fda.hhs.gov

Contracting Officer's Representative (COR)
TBD – provided at time of award

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.

INVOICING INSTRUCTIONS

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

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov

c.

- **i.** The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
- **ii.** Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
- **iii.** The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
- **iv.** If your company is already registered to use IPP, you will not be required to re-register.
- **v.** If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(a) list of all invoices submitted to date under the subject award, including the following:
(1) invoice number, amount, & date submitted
(2) corresponding payment amount & date received
(b) total amount of all payments received to date under the subject contract or order
(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

vii. The provision at **52.212-1, Instructions to Offerors-Commercial Products and Commercial Services (SEP 2023)**, applies to this acquisition and with the following addenda:

PROPOSAL SUBMISSION FORMAT:
The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the Government to the expenditure of public funds in connection with the proposed acquisition.
The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of "macros". When submitting proposals via email, DO NOT include .exe,.mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine). If the offeror or applicant submits documents that contain macros, macro referenced files, and/or executable files, the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

viii. The provision at **52.212-2, Evaluation—Commercial Items (NOV 2021)**, is applicable to this requirement. The specific evaluation criteria to be included in paragraph (a) of that provision are as follows:

The Government will award a firm fixed priced contract resulting from this solicitation to the responsible quoter whose quote meets the requirements listed under this solicitation and is the lowest priced quote received in response to this solicitation. The quoter shall submit pricing in accordance with section v of this solicitation. Quotes that do not pricing for all line items may be deemed non-responsive.

Therefore, award will be made to quoter whose quote is determined to be *Lowest Price Technically Acceptable*. The Government intends to evaluate quotes and award an order without discussions. Quoters' initial quote should contain the Quoters' best terms from a price standpoint as well as demonstrate the ability to meet the solicitation requirements. If the contractor fails to demonstrate the solicitation requirements than it will be deemed technically unacceptable.

A written notice of award or acceptance of an offer mailed or otherwise furnished to the successful quoter within the time for acceptance specified in the offer, shall result in a binding contract without

further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

ix. The Provision at FAR **52.212-3, Offeror Representations and Certifications-Commercial Items (NOV 2023),** applies to this acquisition. The quoter shall complete only paragraph (b) of this provision if the quoter has completed the annual representations and certification electronically via the System for Award Management (SAM) website located at https://www.sam.gov/portal.

x. The clause at **52.212-4, Contract Terms and Conditions—Commercial Items (NOV 2023)**, applies to this acquisition with the addenda for invoicing instructions as stated in section "*Order Administration*".

xi. The clause at **52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (MAY 2024)**, applies to this acquisition.

(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 products and commercial services:
(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 Covered Entities (Dec 2023) (Section 1634 of Pub. L. 115-91).
(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Nov 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).
(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).
(5) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Mar 2023) (31 U.S.C. 3903 and 10 U.S.C. 3801).
(6) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).
(7) 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 products and commercial services:
[Contracting Officer check as appropriate.]
__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jun 2020), with Alternate I (Nov 2021)(41 U.S.C. 4704 and 10 U.S.C. 4655).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Nov 2021)(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) 52.203-17, Contractor Employee Whistleblower Rights (Nov 2023)(41 U.S.C. 4712); this clause does not apply to contracts of DoD, NASA, the Coast Guard, or applicable elements of the intelligence community—see FAR 3.900(a).
X (5) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020)(Pub. L. 109-282)(31 U.S.C. 6101 note).
__ (6) [Reserved].
__ (7) 52.204-14, Service Contract Reporting Requirements(Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016)(Pub. L. 111-117, section 743 of Div. C).
X (9) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).
__ (10) 52.204-28, Federal Acquisition Supply Chain Security Act Orders—Federal Supply Schedules, Governmentwide Acquisition Contracts, and Multi-Agency Contracts. (Dec 2023)(Pub. L. 115–390, title II).
__ (11)(i) 52.204-30, Federal Acquisition Supply Chain Security Act Orders—Prohibition. (Dec 2023)(Pub. L. 115–390, title II).
__ (ii) Alternate I (Dec 2023) of 52.204-30.
X (12) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Nov 2021)(31 U.S.C. 6101 note).
__ (13) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018)(41 U.S.C. 2313).
__ (14) [Reserved].
__ (15) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Oct 2022)(15 U.S.C. 657a).
X (16) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2022) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
__ (17) [Reserved]
__ (18)(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.
__ (19)(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.
__ (20) 52.219-8, Utilization of Small Business Concerns (Feb 2024) (15 U.S.C. 637(d)(2) and (3)).
__ (21)(i) 52.219-9, Small Business Subcontracting Plan (Sep 2023) (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 (Sep 2023) of 52.219-9.
__ (22)(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.
__ (23) 52.219-14, Limitations on Subcontracting (Oct 2022) (15 U.S.C. 637s).
__ (24) 52.219-16, Liquidated Damages—Subcontracting Plan (Sep 2021) (15 U.S.C. 637(d)(4)(F)(i)).
__ (25) 52.219-27, Notice of Set-Aside for, or Sole-Source Award to, Service-Disabled Veteran-Owned Small Business (SDVOSB) Concerns Eligible Under the SDVOSB Program (Feb 2024) (15 U.S.C. 657f).
X (26)(i) 52.219-28, Post Award Small Business Program Rerepresentation (Feb 2024) (15 U.S.C. 632(a)(2)).
__ (ii) Alternate I (Mar 2020) of 52.219-28.

__ (27) 52.219-29, Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Oct 2022) (15 U.S.C. 637(m)).
__ (28) 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 (Oct 2022) (15 U.S.C. 637(m)).
__ (29) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020) (15 U.S.C. 644(r)).
__ (30) 52.219-33, Nonmanufacturer Rule (Sep 2021) (15 U.S.C. 637(a)(17)).
X (31) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).
X (32) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (Feb 2024).
X (33) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
X (34)(i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).
__ (ii) Alternate I (Feb 1999) of 52.222-26.
X (35)(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 (36)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
__ (ii) Alternate I (Jul 2014) of 52.222-36.
X (37) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
X (38) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010)(E.O. 13496).
X (39)(i) 52.222-50, Combating Trafficking in Persons (Nov 2021) (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).
__ (40) 52.222-54, Employment Eligibility Verification (May 2022) (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial products or commercial services as prescribed in FAR 22.1803.)
__ (41)(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.)
__ (42) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (May 2024) (42 U.S.C. 7671, et seq.).
__ (43) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (May 2024) (42 U.S.C. 7671, et seq.).
__ (44) 52.223-20, Aerosols (May 2024)(42 U.S.C. 7671, et seq.).
__ (45) 52.223-21, Foams (May 2024) (42 U.S.C. 7671, et seq.).
__ (46) 52.223-23, Sustainable Products and Services (May 2024) (E.O. 14057, 7 U.S.C. 8102, 42 U.S.C. 6962, 42 U.S.C. 8259b, and 42 U.S.C. 7671l).
__ (47) (i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).
__ (ii) Alternate I (Jan 2017) of 52.224-3.
__ (48)(i) 52.225-1, Buy American-Supplies (Oct 2022) (41 U.S.C. chapter 83).
__ (ii) Alternate I (Oct 2022) of 52.225-1.
__ (49)(i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (NOV 2023) (19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, 19 U.S.C. chapter 29 (sections 4501-4732), Public Law 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 [Reserved].
__ (iii) Alternate II (Dec 2022) of 52.225-3.

__ (iv) Alternate III (Feb 2024) of 52.225-3.
__ (v) Alternate IV (Oct 2022) of 52.225-3.
X (50) 52.225-5, Trade Agreements (NOV 2023) (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. Subtitle A, Part V, Subpart G Note).
__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
X (55) 52.226-8, Encouraging Contractor Policies to Ban Text Messaging While Driving (May 2024) (E.O. 13513).
__ (56) 52.229-12, Tax on Certain Foreign Procurements (Feb 2021).
__ (57) 52.232-29, Terms for Financing of Purchases of Commercial Products and Commercial Services (Nov 2021) (41 U.S.C. 4505, 10 U.S.C. 3805).
__ (58) 52.232-30, Installment Payments for Commercial Products and Commercial Services (Nov 2021) (41 U.S.C. 4505, 10 U.S.C. 3805).
X (59) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018) (31 U.S.C. 3332).
__ (60) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
__ (61) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
__ (62) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
__ (63) 52.242-5, Payments to Small Business Subcontractors (Jan 2017)(15 U.S.C. 637(d)(13)).
__ (64)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Nov 2021)(46 U.S.C. 55305 and 10 U.S.C. 2631).
__ (ii) Alternate I (Apr 2003) of 52.247-64.
__ (iii) Alternate II (Nov 2021) 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 products and commercial services:
[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) (29 U.S.C.206 and 41 U.S.C. chapter 67).
X (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 for Contractor Workers Under Executive Order 14026 (Jan 2022).
__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2022) (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 products or commercial services. 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 (Nov 2021) (41 U.S.C. 3509).
(ii) 52.203-17, Contractor Employee Whistleblower Rights (Nov 2023) (41 U.S.C. 4712).
(iii) 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)).
(iv) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab Covered Entities (Dec 2023) (Section 1634 of Pub. L. 115-91).
(v) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Nov 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).
(vi) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).
(vii)
(A) 52.204–30, Federa Acquisition Supply Chain Security Act Orders—Prohibition. (Dec 2023)(Pub. L. 115–390, title II).
(B) Alternate I (Dec 2023) of 52.204–30.
(viii) 52.219-8, Utilization of Small Business Concerns (Feb 2024) (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.
(ix) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
(x) 52.222-26, Equal Opportunity (Sep 2015) (E.O.11246).
(xi) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
(xii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020)(29 U.S.C. 793).
(xiii) 52.222-37, Employment Reports on Veterans (Jun 2020)(38 U.S.C. 4212).
(xiv) 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.
(xv) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
(xvi)
(A) 52.222-50, Combating Trafficking in Persons (Nov 2021)(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).
(xvii) 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).
(xviii) 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).
(xix) 52.222-54, Employment Eligibility Verification (May 2022) (E.O. 12989).
(xx) 52.222-55, Minimum Wages for Contractor Workers Under Executive Order 14026 (Jan 2022).
(xxi) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2022) (E.O. 13706).
(xxii)
(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xxiii) 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. Subtitle A, Part V, Subpart G Note).
(xxiv) 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.
(xxv) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Mar 2023) (31 U.S.C. 3903 and 10 U.S.C. 3801). Flow down required in accordance with paragraph (c) of 52.232-40.
(xxvi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Nov 2021)(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 products and commercial services a minimal number of additional clauses necessary to satisfy its contractual obligations.
(End of clause)

xii. Additional contract requirement(s) or terms and conditions

FAR CLAUSES

<u>FAR 52.252-2 -- Clauses Incorporated by Reference. (FEB 1998)</u>

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/.

(End of Clause)

FAR CLAUSE NO.	DESCRIPTION	DATE
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.232-39	Unenforceability of Unauthorized Obligations.	JUN 2013

HHSAR CLAUSES

HHSAR CLAUSE NO.	DESCRIPTION	DATE
352.203-70	Anti-Lobbying	DEC 2015
352.208-70	Printing and Duplication	DEC 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	DEC 2015
352.227-70	Publications and Publicity	DEC 2015
352.231-70	Salary Rate Limitation	DEC 2015

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

(a) Definitions. As used in this clause-

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

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

HHSAR 352.239-74 Electronic and Information Technology 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)
- E207 Software (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 5 Software (Appendix C, Functional Performance Criteria and Technical 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.
- Accessibility checklists for various formats are available at the HHS site. Materials that are final items must be compliant with Section 508 at time of delivery, 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)

FAR/HHSAR PROVISIONS

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/.

(End of Clause)

FAR/HHSAR PROVISION NO.	DESCRIPTION	DATE
FAR 52.212-1	Instructions to Offerors—Commercial Products and Commercial Services.	NOV 2021
FAR 52.217-5	Evaluation of Options	JUL 1990
FAR 52.225-25	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications.	JUN 2020
HHSAR 352.239-73	Electronic and Information Technology Accessibility Notice	DEC 2015

xiii. All responsible sources may submit a quote, which if timely received, shall be considered. The quote and any questions shall reference solicitation number **FDA-24- 1279657**.

All quotes must be submitted via email to the point of contacts listed below on or before **August 26, 2024, 3:00 p.m. Eastern Time.**

It is the quoter's responsibility to monitor the internet site for the release of an amendment to the combined synopsis/solicitation (if any).

Quoters that fail to complete the required representations and certifications, or reject the terms and conditions of the solicitation, may be excluded from consideration.

xiv. **Point of Contacts**: Elena Tatarov, elena.tatarov@fda.hhs.gov