

75F40123Q00021

Request for Quotation: 75F40123Q00021_AMENDMENT ONE.

Posted Date: 12/20/2022

Response Date: December 23, 2022, 10:00 a.m. Eastern Standard Time.

Indicate company's SAM.gov Unique Entity ID on the quote. This requirement is being issued in conjunction with FAR 13 and additional information included in this notice. The incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2022-08.

THIS ANNOUNCEMENT CONSTITUTES THE ONLY SOLICITATION AND A SEPARATE SOLICITATION WILL NOT BE ISSUED. The solicitation number for this acquisition is 75F40123Q00021_P00001 AMENDMENT ONE and is being issued as a Request for Quote (RFQ). The NAICS Code for this solicitation is 811210. This requirement is full and open. This will be awarded as Firm-Fixed Price. Prospective Offerors are responsible for downloading the solicitation and any amendments from FDA eBid Board. The Government reserves the right to award an order without discussions if the Contracting Officer determines that the initial offer is providing the Best Value Lowest Price Technically Acceptable and discussions are not necessary.

The Government intends to issue an Purchase Order.

The U.S. Food and Drug Administration (FDA) requires the following:

*******BRAND NAME OR EQUAL*******

A. BACKGROUND AND OVERVIEW

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable,

consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

The Office of Science and Engineering Laboratories (OSEL) supports the CDRH's mission of protecting and promoting public health. The OSEL undertakes the highest quality science to provide their customers with the best methods, tools and expertise to:

- Ensure readiness for emerging and innovative medical technologies
- Develop appropriate evaluation strategies and testing standards
- Create accessible and understandable public health information and
- Deliver timely and accurate decisions for products across their life cycle

The Division of Biology, Chemistry, and Materials Science (DBCMS) participates in CDRH's mission of protecting and promoting public health by identifying and investigating issues related to the interaction between medical devices and the human body. The division accomplishes this through activities supporting the OSEL mission.

DBCMS focuses on device issues that involve:

- Analytical chemistry and electrochemistry
- Biocompatibility, toxicology, and biological risk assessment
- Biosensors and biomarkers
- Extractables, leachables, and chemical contamination
- Genomic and genetic technologies
- Immune and cellular responses
- Infection control, sterility, and biofilms
- Materials characterization, processing, and materials degradation
- Modeling of physiological processes
- Multicomponent mass transfer and reaction kinetics, and
- Nanotechnology.

A need is for the repair and maintenance of a chemical analysis instrument manufactured by Agilent Technologies called an Agilent 6540 B Quadrupole Time of Flight Mass Spectrometer (QTOF-MS). The QTOF-MS is a chemical analysis instrument used at CDRH. The instrument is located and operated in OSEL, DBCMS. This procurement request is for the service of the Mass Spectrometer and for immediate repairs required to return the instrument to factory recommended performance.

The Mass Spectrometer assists the CDRH mission by enabling research that improves analytical chemistry methods which will reduce the use of animals in biocompatibility testing and provide quantitative information to assess toxicological risk. Increased regulatory science research capabilities in analytical chemistry are needed at FDA to improve consensus standards, increase review efficiency and reduce its data burden.

Uninterrupted operation of the instrument to support the regulatory science research contributes to the improvement of regulatory science, a primary mission of OSEL. Maintaining this instrument is essential for conducting the research necessary to the modernization of biocompatibility testing, one of CDRH strategic priorities where chemical characterization and analysis is used to address several biocompatibility endpoints.

The defective Agilent 6540 B QTOF MS system once repaired is required for various regulatory projects and ongoing research projects, primarily for quantification of extractables and leachables from medical device extracts, and specific tasks designated in the Chemical Characterization Program Charter projects designated by DBCMS.

B. OBJECTIVES/PURPOSE

The repair and maintenance of the chemical analysis instrument manufactured by Agilent Technologies called an Agilent 6540 B Quadrupole Time of Flight Mass Spectrometer. This repair service is not a recurring requirement. The work must be performed by service engineers who are factory trained and certified in maintaining and repairing the instrument and its various components. Service and maintenance of this instrument must be performed by engineers that are specially trained to do this work and have access to the proprietary service manuals published by the manufacturer and specialized tools not generally available to end-users. The Mass Spectrometer is delicate, very complex, and many of its parts are not user serviceable.

The service provider needs to evaluate the current conditions of the instrument to diagnose any faults associated with the system, replace the defective turbo pump of the system with a new pump from the original manufacturer and establish the QTOF MS system performance to the OEM recommended performance levels.

C. SCOPE OF WORK

The Contractor shall provide repair and maintenance to the 6545 LC/Q-TOF Mass Spectrometer (Item #HHSF223201710146G) that includes the following system components to include parts, labor, travel, and all consumables:

- 1) 1260 Diode Array Detector: S/N DEAA307180
- 2) UHD Accurate Mass QTOF tracking module: S/N SG13488002
- 3) 1260 Nanoflow pump: S/N DEACM00331
- 4) 1260 High Performance Micro Autosampler: S/N DEACP00389
- 5) 1260 Infinity High Performance Degasser: S/N JPAAA03636
- 6) 1260 Standard Autosampler: S/N DEAAC27993

Immediate Response: The repair is for the defective Agilent Quadrupole Time of Flight Mass Spectrometer (QTOF MS) located in the DBCMS of OSEL. Failure to repair the instrument will result in the inability of OSEL to complete its research objectives. QTOF MS is one of the workhorses in the regulatory science research in the division. The increased regulatory science research using QTOF MS system is needed at FDA to improve standard practices in chemical characterization testing, increase review efficiency, and reduce industry burden. This instrument is also essential for conducting the research necessary to the modernization of biocompatibility testing, one of CDRH strategic priorities where chemical characterization and analysis is used to address several biocompatibility endpoints.

This instrument was installed in the laboratory in 2014 and has been under service contract until May 2022. Turbo pump of the instrument failed in August 2022 and the instrument. This procurement request is to repair the defective system and to ensure the FDA Conduct the research projects to fulfill the chemical characterization program charter requirements. The QTOF MS system performance needs to be restored to factory recommended performance levels. This is not a recurring requirement or recomplete for an expired contract.

C.1 See the service request summary below.

- a) Model Number: G6540B
- b) Model Description: UHD Accurate Mass QTOF tracking module
- c) Serial Number: SG13488002
- d) Service Request Problem Description: PRI ITEM Quote-turbo 2 not starting

C.2 The following services / part replacements will be required immediately:

- a) Repair (Priority trail charge)
- b) Additional Labor Charges
- c) New-Pfeiffer SplitFlow Pump, PMP03626F (Part Charge)
- d) TMH Power Assembly, 48V (Part Charge)
- e) Main/Lens Driver PCA Assy, Tested (Part Charge)
- f) Thermal compound White (Part Charge)

C.3 Repair services should include:

- a) Initial evaluation of the system performances to identify problem and the source of the problem. Trouble-shooting capabilities should be based on complete knowledge of the entire instrument system, immediate access to Agilent certified replacement parts, and immediate access to improvements and new procedures provided by the original vendor and manufacturer. On-Site repair activities shall be performed following the Original Equipment Manufacturer (OEM) specifications, manuals, and service bulletins, using OEM-certified replacement parts, components, subassemblies, etc.

- b) Replace the defective turbo pump with a new pump (Agilent Certified Parts required for repairs). After installation, ensure that the instrument vacuum is back to Original Equipment manufacturer(OEM) specifications and operational levels. Ensure removal of the replaced/defective parts, components according to safety guidelines.
- c) Ensure the system is performing to the factory recommended performances after the repair is completed. Need to perform full system tune and calibration after the repair and instrument performances should be comparable to the performance values obtained during the last preventative maintenance on the QTOF system conducted by the Agilent service engineer.
- d) The work is to be performed by as the service engineers who are factory trained and certified in maintaining and repairing the systems and its instrument components. They are specifically trained to do this and have access to the proprietary service manuals published by the manufacturer and customized tools that are reserved not available to the users. These systems are very complex, and most of the parts are not user serviceable.
- e) All labor, travel costs, and service parts, including consumable parts required for repair must be included. The Contractor shall provide on-site repair visit by a factory trained and certified engineer on site within 2-3 business days of the contract award. Contractor should take the defective components back for proper disposal/repair.
- f) On-Site repair activities shall be performed following the Original Equipment Manufacturer (OEM) specifications, manuals, and service bulletins, using OEM-certified replacement parts, components, subassemblies, etc.
- g) The Contractor shall provide written reports on repair via email in .pdf format and coordinated with the COR .

D. DELIVERY/ PERIOD OF PERFORMANCE/PLACE OF PERFORMANCE

D.1 Delivery

The item(s) are to be delivered to:

FDA/CDRH/OSEL/DCBMS

Attention: TBD

Research Chemist

10903 New Hampshire Ave

Building 64, Room 3079

Silver Spring, MD 20993

Phone: 301-796-2475

Email: TBD

D.2 Period of Performance:

Work shall be conducted Monday through Friday, excluding federal holidays. Unless otherwise directed, the Contractor shall adhere to working between the hours of 9 am – 4 pm Eastern Standard Time (EST), working no more than 40 hours per week. The on-site Contractor shall

maintain continuous service during the hours at the facility identified below. The service shall be delivered at (unless otherwise indicated).

D.3 Place of Performance:

U.S. Food and Drug Administration

CDRH/OSEL/DBCMS

Building 64, Room 3017

10903 New Hampshire Ave

Silver Spring, MD 20993

The Vendor shall work on-site at FDA. The work cannot be done remotely; work shall be done at the Government site where the equipment is currently located. Scheduling is to be coordinated through the technical point of contact on the Purchase Order.

D.2 Line Items and Pricing

The Contractor shall complete the pricing table below and provide the following deliverables:

Table 1 Line Item	Description	Unit Price	Unit Of Price	TOTAL
1	1 each Repair of The Contractor shall provide repair and maintenance to the 6545 LC/Q-TOF Mass Spectrometer (Item #HHSF223201710146G) that includes the following system components to	\$	Dollars	\$

Note: Provide a fixed price quote in accordance with the Statement of Work identified and the above template. The Contractor shall deliver on priority response, which is a 2 - 4 day response, FDA will be charged the lower standard rate for the "TRAIL charge" plus any additional labor required to repair the instrument. All parts, labor, travel, and consumables are firm-fixed price.

D.3 Section 508 Standard Compliance

Deliverables will conform to 36 CFR Part 1194.41, "Information, Documentation and Support," and 36 CFR Part 1194.24 "Video and Multimedia Products" which are of particular importance with regard to all written, graphical or broadcast, video materials or products produced for HHS (to include training). 36 CFR Part 1194.41 outlines the requirements supporting services for products accommodating the communication needs of end-users with disabilities. The deliverables will be provided in Microsoft Word and Adobe PDF formats and compatible with versions currently used at FDA.

C.A. Section 508

This language is applicable to Statements of Work (SOW) or Performance Work Statements (PWS) generated by the Department of Health and Human Services (HHS) that require a contractor or consultant to (1) produce content in any format that could be placed on a Department-owned or Department-funded Web site; or (2) write, create or produce any communications materials intended for public or internal use; to include reports, documents, charts, posters, presentations (such as Microsoft PowerPoint) or video material that could be placed on a Department-owned or Department-funded Web site.

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase electronic and information technologies (EIT) that meet specific accessibility standards. This law helps to ensure that federal employees with disabilities have access to, and use of, the information and data they need to do their jobs. Furthermore, this law ensures that members of the public with disabilities have the ability to access government information and services.

There are three regulations addressing the requirements detailed in Section 508. The Section 508 technical and functional standards are codified at 36 CFR Part 1194 and may be accessed through the Access Board's Web site at <http://www.access-board.gov>. The second regulation issued to implement Section 508 is the Federal Acquisition Regulation (FAR). FAR Part 39.2 requires that agency acquisitions of Electronic and Information Technology (EIT) comply with the Access Board's standards. The entire FAR is found at Chapter 1 of the Code of Federal Register (CFR) Title 48, located at <http://www.acquisition.gov>. The FAR rule implementing Section 508 can be found at <http://www.section508.gov>. The third applicable regulation is the HHS Acquisition Regulation (HHSAR).

Regardless of format, all Web content or communications materials produced for publication on or delivery via HHS Web sites - including text, audio or video - shall conform to applicable Section 508 standards to allow federal employees and members of the public with disabilities to access information that is comparable to information provided to persons without disabilities. All contractors (including subcontractors) or consultants responsible for preparing or posting content intended for use on an HHS-funded or HHS-managed Web site shall comply with applicable Section 508 accessibility standards, and where applicable, those set forth in the referenced policy or standards documents below. Remediation of any materials that do not comply with the applicable provisions of 36 CFR Part 1194 as set forth in the SOW or PWS, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.

The following Section 508 provisions apply to the content or communications material identified in this SOW or PWS:

Subpart B, 1194.21 - Software Applications and Operating Systems

Subpart C, 1194.31 - Functional Performance Criteria

Subpart D, 1194.41 - Information, Documentation, and Support

E. GENERAL INFORMATION

For all on-site maintenance, the Vendor's personnel are required to report to the security guards at the and who will contact the TPOC or the designated FDA employee. The Vendor's personnel must be always escorted by the TPOC or the designated FDA employee while working on-site under this order.

The Vendor shall perform all on-site maintenance service during the hours of 9:00 am to 5:00 pm ET, Monday through Friday, unless otherwise indicated by the TPOC.

F. GOVERNMENT HOLIDAYS

a. The Government hereby provides notification that Government personnel observe the listed days as holidays:

- | | |
|-----------------------------------|-----------------------|
| (1) New Year's Day | (7) Labor Day |
| (2) Martin Luther King's Birthday | (8) Columbus Day |
| (3) President's Day | (9) Veterans' Day |
| (4) Memorial Day | (10) Thanksgiving Day |
| (5) Juneteenth | (11) Christmas Day |
| (6) Independence Day | |

b. In addition to the days designated as holidays, the Government observes the following days:

- (1) Any other day designated by Federal Statute
- (2) Any other day designated by Executive Order
- (3) Any other day designated by the President's Proclamation

c. When any such day falls on a Saturday, the following Monday is observed. Except for designated around-the-clock or emergency operations, Contractor personnel will not be able to perform on-site under this contract with FDA on holidays set forth above. The Contractor will not charge any holiday as direct charge to the award.

d. It is understood and agreed between the Government and the Contractor that observance of such days by Government personnel shall not otherwise be a reason for an additional period of performance, or entitlement of compensation except as set forth within the award.

e. Nothing in this clause abrogates the rights and responsibilities of the parties relating to stop work provisions as cited in other sections of this contract.

F. EVALUATION AND AWARD:

FAR Evaluation—Commercial Products and Commercial Services (Nov 2021));

Lowest Priced, Technically Acceptable (LPTA)

G. INSTRUCTIONS TO OFFEROR FOR PROPOSAL SUBMISSION

FAR Instructions to Offerors—Commercial Products and Commercial Services (Nov 2021)

H. PROPOSAL SUBMISSION FORMAT:

*****Proposal shall be in 2 volumes: 1 Technical and 2 Price. The volumes shall be separate and complete. The volumes shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. No pricing information shall be provided in volume 1.*****

The total number of pages for the technical quote shall not exceed five (5) pages, using 1" margins, single spaced, font type Time New Roman, and a font size of 12.

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.

QUESTIONS DEADLINE: Interested offerors shall submit questions electronically to Patricia.Natividad@fda.hhs.gov no later than December 21, 2022, 10:00 a.m. Eastern Time. Please include the company name, FDA solicitation number, and "Question(s)" in the subject line.

QUOTES DUE: All quotes are due, electronically to Patricia.Natividad@FDA.HHS.GOV for the RFQ no later than, December 23, 2022, 10:00 a.m. Eastern Time.

PROVISIONS and CLAUSES:

FAR 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 will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): FAR clauses: <https://www.acquisition.gov/far/> and HHSAR clauses: <https://www.acquisition.gov/hhsar>

The following provisions and clauses apply:

FAR 52.211-6 Brand Name or Equal (AUG 1999);

FAR 52.212-3 Offeror Representations and Certifications-Commercial Items (Oct 2022);

FAR 52.212-4 Contract Terms and Conditions—Commercial Products and Commercial Services (Nov 2021)

FAR 52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services (Oct 2022)

(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 and Other Covered Entities (Nov 2021) (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) [52.233-3](#), 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 products and commercial services:

___ (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. 2402](#)).

___ (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.)

___ (4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).

___ (5) [Reserved].

___ (6) [52.204-14](#), Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).

___ (7) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).

___ (8) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Nov 2021) ([31 U.S.C. 6101 note](#)).

- __ (9) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) ([41 U.S.C. 2313](#)).
- __ (10) [Reserved].
- __ (11) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (OCT 2022) ([15 U.S.C. 657a](#)).
- __ (12) [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](#)).
- __ (13) [Reserved]
- X_ (14) (i) [52.219-6](#), Notice of Total Small Business Set-Aside (Nov 2020) ([15 U.S.C. 644](#)).
- __ (ii) Alternate I (MAR 2020) of [52.219-6](#).
- __ (15) (i) [52.219-7](#), Notice of Partial Small Business Set-Aside (Nov 2020) ([15 U.S.C. 644](#)).
- __ (ii) Alternate I (MAR 2020) of [52.219-7](#).
- __ (16) [52.219-8](#), Utilization of Small Business Concerns (OCT 2022) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).
- __ (17) (i) [52.219-9](#), Small Business Subcontracting Plan (OCT 2022) ([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 2021) of [52.219-9](#).
- _ (18) (i) [52.219-13](#), Notice of Set-Aside of Orders (MAR 2020) ([15 U.S.C. 644\(r\)](#)).
- __ (ii) Alternate I (MAR 2020) of [52.219-13](#).
- __ (19) [52.219-14](#), Limitations on Subcontracting (OCT 2022) ([15 U.S.C. 637s](#)).
- __ (20) [52.219-16](#), Liquidated Damages—Subcontracting Plan (SEP 2021) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
- __ (21) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (OCT 2022) ([15 U.S.C. 657f](#)).
- _X_ (22) (i) [52.219-28](#), Post Award Small Business Program Rerepresentation (OCT 2022) ([15 U.S.C. 632\(a\)\(2\)](#)).
- __ (ii) Alternate I (MAR 2020) of [52.219-28](#).
- __ (23) [52.219-29](#), Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (OCT 2022) ([15 U.S.C. 637\(m\)](#)).
- __ (24) [52.219-30](#), Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (OCT 2022) ([15 U.S.C. 637\(m\)](#)).
- __ (25) [52.219-32](#), Orders Issued Directly Under Small Business Reserves (MAR 2020) ([15 U.S.C. 644\(r\)](#)).
- __ (26) [52.219-33](#), Nonmanufacturer Rule (SEP 2021) ([15 U.S.C. 637\(a\)\(17\)](#)).
- _X_ (27) [52.222-3](#), Convict Labor (JUN 2003) (E.O.11755).
- _X_ (28) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (JAN 2022) (E.O.13126).
- _X_ (29) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).
- _X_ (30) (i) [52.222-26](#), Equal Opportunity (SEP 2016) (E.O.11246).
- __ (ii) Alternate I (FEB 1999) of [52.222-26](#).

- (31) (i) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

(ii) Alternate I (JUL 2014) of [52.222-35](#).
- (32) (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (JUN 2020) ([29 U.S.C. 793](#)).

(ii) Alternate I (JUL 2014) of [52.222-36](#).
- (33) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

(34) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).
- (35) (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).

(36) [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](#).)

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

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

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

(39) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

(40) (i) [52.223-13](#), Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

(ii) Alternate I (OCT 2015) of [52.223-13](#).

(41) (i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

(ii) Alternate I (Jun2014) of [52.223-14](#).

(42) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (MAY 2020) ([42 U.S.C. 8259b](#)).

(43) (i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

(ii) Alternate I (JUN 2014) of [52.223-16](#).

(44) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

(45) [52.223-20](#), Aerosols (JUN 2016) (E.O. 13693).

(46) [52.223-21](#), Foams (Jun2016) (E.O. 13693).

(47) (i) [52.224-3](#) Privacy Training (JAN 2017) (5 U.S.C. 552 a).

(ii) Alternate I (JAN 2017) of [52.224-3](#).

(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 (Oct 2022) ([41 U.S.C. chapter 83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

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

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

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

__ (v) Alternate IV (Oct 2022) of [52.225-3](#).

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

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

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

__ (53) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ([42 U.S.C. 5150](#)).

__ (54) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) ([42 U.S.C. 5150](#)).

__ (55) [52.229-12](#), Tax on Certain Foreign Procurements (FEB 2021).

__ (56) [52.232-29](#), Terms for Financing of Purchases of Commercial Products and Commercial Services (Nov 2021) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

__ (57) [52.232-30](#), Installment Payments for Commercial Products and Commercial Services (Nov 2021) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

X (58) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (OCT 2018) ([31 U.S.C. 3332](#)).

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

__ (60) [52.232-36](#), Payment by Third Party (MAY 2014) ([31 U.S.C. 3332](#)).

X (61) [52.239-1](#), Privacy or Security Safeguards (AUG 1996) ([5 U.S.C. 552a](#)).

__ (62) [52.242-5](#), Payments to Small Business Subcontractors (JAN 2017) ([15 U.S.C. 637\(d\)\(13\)](#)).

__ (63) (i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (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. chapter 67](#)).

___ (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (MAY 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

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

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

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

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

(7) [52.222-55](#), Minimum Wages 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) *CoXmptroller 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) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Nov 2021) (Section 1634 of Pub. L. 115-91).

(iv) [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).

(v) [52.219-8](#), Utilization of Small Business Concerns (OCT 2022) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702](#)(a) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

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

(vii) [52.222-26](#), Equal Opportunity (SEP 2015) (E.O.11246).

(viii) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

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

(x) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

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

(xii) [52.222-41](#), Service Contract Labor Standards (AUG 2018) ([41 U.S.C. chapter 67](#)).

(xiii) (A) [52.222-50](#), Combating Trafficking in Persons (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](#)).

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

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

(xvi) [52.222-54](#), Employment Eligibility Verification (MAY 2022) (E.O. 12989).

(xvii) [52.222-55](#), Minimum Wages for Contractor Workers Under Executive Order 14026 (JAN 2022).

(xviii) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (JAN 2022) (E.O. 13706).

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

(B) Alternate I (JAN 2017) of [52.224-3](#).

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

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

(xxii) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (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.

Parties responding to this solicitation may submit their offer in accordance with their standard commercial practices (e.g. on company letterhead, formal quote form, etc) but shall include the following information: 1) company's complete mailing and remittance addresses 2) discounts for prompt payment if applicable; 3) UEIN number; 4) Taxpayer ID number; 5) Catalog or Published Price Listing applicable to the service; 6) Offerors shall meet specifications as noted in the synopsis. Offerors shall include a completed copy of the provision at 52.212-3, Offeror Representations and Certifications/Commercial Items with their offer. Note: Contractor shall be registered and active in the System for Award Management (SAM) prior to the award of a contract. You may register by going to www.beta.sam.gov.

HHSAR Clauses and Provisions

HHSAR 352.211-3 Paperwork Reduction Act

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations

HHSAR 352.232-71 Electronic Submission of Payment Requests

(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.

FDA Clause

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

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).

<http://www.ipp.gov/vendors/index.htm>

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

<https://www.ipp.gov>

c. 1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.

2. Registration emails are sent via email from ipp.noreply@mail.ero.c.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

3. The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

4. If your company is already registered to use IPP, you will not be required to re-register.

5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

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

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

1. 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;

2. Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
 3. Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
 4. 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;
 5. Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
 6. Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
 7. 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

75F40123Q00021

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.