

Statement of Work (SOW)

Heavy isotope labeling analysis in UNIFI

UNIFI Small Molecule License

Version Date: 4/29/2020

1. Background

The FDA seeks to purchase a license to enable UNIFI small molecule analysis on the FDA's purchased and owned UNIFI workstation to allow for heavy isotope labeling analysis of tracked C₁₃-labeled metabolites such as amino acids. The FDA also requires training to properly use the new UNIFI small molecule option.

2. Objective

The objective is to obtain a license to enable UNIFI small molecule analysis on the FDA's purchased and owned UNIFI workstation to allow for heavy isotope labeling analysis of tracked C₁₃-labeled metabolites such as amino acids. The FDA also requires training to properly use the new UNIFI small molecule option.

3. Product Description

The FDA requires a software license and installation of UNIFI small molecule option on the purchased and owned UNIFI workstation. As the FDA already has UNIFI installed on a Waters workstation in the lab, this purchase is necessary to unlock the small molecule workflow so the FDA can analyze heavy-isotope labeled small molecules.

4. Salient Characteristics

The following Technical Specifications must be met:

Installation and Total Assurance Plan for UNIFI Small Molecule License:

- a. Data processing software specifically designed for the processing of metabolite data: The Waters Metabolite Identification Application Solution with UNIFI provides biotransformation scientists with the most comprehensive analytical tools for identifying and characterizing metabolites. This application solution brings unparalleled ease and efficiency to routine Met ID processes. As a consequence, scientists can rapidly derive results from complex data sets, and focus their time and skill on efforts that fuel and accelerate the discovery and development process.
- b. The flexibility of the UNIFI™ Software architecture provides users with the ability to:
 - Define and build their own software experience for analysis and processing in drug metabolism studies.
 - Capture, manage, and share information in a way never before possible, leading to greater scientific understanding of metabolic processes in the discovery and development of new drugs. Obtain metabolic stability information, soft spot localization, or definitive metabolite identification.
 - Convert raw digital input into information that actual forms the basis of decision-making.
 - Fully integrate UPLC®/MS acquisition and data management with data analysis tools

Public notice of a proposed contract action less than \$25,000

5. Inspection and Acceptance

The COR will perform inspection and acceptance of all products and services. The performance criteria for these products shall be timely delivery and closure of all activities and deliverables listed above and within the established Period of Performance.

All invoices shall be submitted for review within 30 calendar days of the end of the period of performance.

6. Place of Performance

Agarabi Bioprocessing Lab
10903 New Hampshire Avenue, Silver Spring, MD 20993
Building 52/72 Room 2232

The UNIFI Workstation is installed in the Agarabi Bioprocessing Lab (currently room 2232) and the small molecule license must be installed on this computer in the Agarabi Bioprocessing Lab. Training will take place in the Agarabi Bioprocessing Lab.

7. Period of Performance

The period of performance for this award will be year is (1) year from the date of the award for software license and support services.

8. Order Type

The order type is Firm-Fixed-Price.

9. Authorized Contractor

The Contractor shall be the software Original Software Manufacturer (OEM) or an authorized reseller/servicing agent of the software OEM.

The Contractor shall notify the Contract Specialist / Contracting Officer immediately if this requirement is registered by a reseller with the OEM.

10. Security

It is not anticipated that the contractor will be exposed to sensitive Agency information or data. But the contractor agrees that the contract personnel will not divulge or release information or data developed or obtained in connection with performance of this contract, unless made public by FDA or upon written approval by the COR.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

11. Order of Precedence

The Contractor shall follow the terms and conditions of this order. Should the Contractor include any additional terms and conditions resulting in conflicts between this document and the Contractor's document, the Order of Precedence shall be as specified in FAR Clause 52.212-4. Any indemnification and governing law language in the Contractor's terms and conditions shall be invalid and shall be stricken and removed from the order. Any additional terms and conditions shall not be prohibited by applicable laws

Public notice of a proposed contract action less than \$25,000

and regulations. Any additional terms and conditions identified with a web link and/or incorporated by reference shall be stricken and removed from the order. The Contractor shall provide all terms and conditions with their quotations as attachments, appendixes, etc.

In the event of any inconsistencies between any licensing agreement incorporated into this order as an attachment and the FAR and HHSAR Clauses incorporated into this order, the FAR or HHSAR Clauses shall take precedence.

12. Three Way Invoicing:

To be included at time of award.

13. Reporting Requirement/Delivery Schedule

Deliverables and schedule will be coordinated by the Contracting Officer's Representative (COR).

14. Points of Contact

Contracting Officer (CO):

Michele Andrews

Phone: 240-402-7522

Email: michele.andrews@fda.hhs.gov

Contract Specialist (CS):

Bradley Hill

Phone: 240-402-7522

Email: michele.andrews@fda.hhs.gov

Contracting Officer's Representative (COR):

To be determined at time of award.

15. 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 purchase order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Vendor 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 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,

Public notice of a proposed contract action less than \$25,000

terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the Vendor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the purchase order.

16. Section 508 Standard Compliance

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase information and communication technologies (ICT) 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 information and communication technology (ICT) 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 - must 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 must 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, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.

Unless an agency exception to this requirement exists, the Contractor must conform to applicable Section 508 standards and must apply best practices associated with Section 508 compliance during the application design, development, and testing phases. The Contractor shall utilize FDA approved tools to verify the compliance with the Section 508 standards and ensure the delivery of the fully compliant products.

The following Section 508 standards apply to this Statement of Requirements:

- 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)
- 302 - Functional Performance Criteria (Appendix C, Application and Scoping Requirements)
- E207 Software (Appendix A, Application and Scoping Requirements)
- E208 Documentation and Support Services
- Chapter 5 Software to include all WCAG 2.0 A and AA standards (Appendix C, Functional Performance Criteria and Technical Requirements)
- Chapter 6: Documentation and Support Services

**Language to be included in Instructions to Quoters

Public notice of a proposed contract action less than \$25,000

If “or equal”, or alternative items are proposed, the vendor shall provide product specifications for those items proposed. All products proposed (whether brand name listed or, or equal items proposed) must satisfy the salient functional characteristics/functional requirements set forth in the Scope of Work section below. If a vendor proposes an, or equal product, the vendor must provide an example where the or equal solution was successfully deployed in an environment with the below constraints and that the or equal solution integrated seamlessly into that environment. In addition, any or equal product proposed must integrate seamlessly with our previously installed Waters UNIFI software and Waters UNIFI workstation. Any vendor proposing an or equal product must provide an example where the or equal product integrated seamlessly.

17. Authorized Reseller / Servicing Agent / Original Equipment Manufacturer (OEM)

The Contractor shall be the Original Equipment Manufacturer (OEM) or an authorized reseller/servicing agent of the Original Equipment Manufacturer (OEM). The Quoter shall notify the Contract Specialist / Contracting Officer immediately if this requirement is registered by a reseller with the OEM.

18. FAR/HHSAR CLAUSES AND PROVISIONS

FAR CLAUSES:

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

52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders Commercial Items (Mar 2020)

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

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)

(section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

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

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

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

[Contracting Officer check as appropriate.]

___ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

___ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509)).

___ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010)

Public notice of a proposed contract action less than \$25,000

(Section 1553 of Pub. L. 111-5). (Applies to contracts

funded by the American Recovery and Reinvestment Act of 2009.)

XX (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2016) (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).

XX (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note).

__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

__ (10) [Reserved].

__ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).

__ (ii) Alternate I (Nov 2011) of 52.219-3.

XX (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

__ (ii) Alternate I (Jan 2011) of 52.219-4.

__ (13) [Reserved]

XX (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644).

__ (ii) Alternate I (Nov 2011).

__ (iii) Alternate II (Nov 2011).

__ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

__ (ii) Alternate I (Oct 1995) of 52.219-7.

__ (iii) Alternate II (Mar 2004) of 52.219-7.

__ (16) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)).

__ (17)(i) 52.219-9, Small Business Subcontracting Plan (Jan 2017) (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 (Nov 2016) of 52.219-9.

__ (v) Alternate IV (Nov 2016) of 52.219-9.

XX (18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).

__ (19) 52.219-14, Limitations on Subcontracting (Jan 2017) (15 U.S.C. 637(a)(14)).

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

__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657 f).

Public notice of a proposed contract action less than \$25,000

- XX (22) 52.219-28, Post Award Small Business Program Representation (Jul 2013) (15 U.S.C. 632(a)(2)).
- (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (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 (Dec 2015) (15 U.S.C. 637(m)).
- XX (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- XX (26) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Jan 2018) (E.O. 13126).
- XX (27) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- XX (28) 52.222-26, Equal Opportunity (Sept 2006) (E.O. 11246).
- (29) 52.222-35, Equal Opportunity for Veterans (Oct 2015)(38 U.S.C. 4212).
- XX (30) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
- (31) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).
- (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- XX (33)(i) 52.222-50, Combating Trafficking in Persons (Mar 2015) (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).
- (34) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- (35)(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.)
- (36) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- (37) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- (38)(i) 52.223-13, Acquisition of EPEAT -Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Oct 2015) o 52.223-13.
- (39)(i) 52.223-14, Acquisition of EPEAT -Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-14.
- (40) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
- (41)(i) 52.223-16, Acquisition of EPEAT-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).

Public notice of a proposed contract action less than \$25,000

- ___ (ii) Alternate I (Jun 2014) of 52.223-16.
- __XX_ (42) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011) (E.O. 13513).
- ___ (43) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
- ___ (44) 52.223-21, Foams (Jun 2016) (E.O. 13693).
- ___ (45)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).
- ___ (ii) Alternate I (JAN 2017) of 52.224-3.
- __XX_ (46) 52.225-1, Buy American Supplies (May 2014) (41 U.S.C. chapter 83).
- ___ (47)(i) 52.225-3, Buy American Free Trade Agreements Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
- ___ (ii) Alternate I (May 2014) of 52.225-3.
- ___ (iii) Alternate II (May 2014) of 52.225-3.
- ___ (iv) Alternate III (May 2014) of 52.225-3.
- ___ (48) 52.225-5, Trade Agreements (Oct 2016) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- __XX_ (49) 52.225-13, Restrictions on Certain Foreign Purchases (June 2008) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- ___ (50) 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).
- ___ (51) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
- ___ (52) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
- ___ (53) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- ___ (54) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- __XX_ (55) 52.232-33, Payment by Electronic Funds Transfer System for Award Management (Jul 2013) (31 U.S.C. 3332).
- ___ (56) 52.232-34, Payment by Electronic Funds Transfer Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
- __XX_ (57) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
- ___ (58) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- ___ (59) 52.242-5, Payments to Small Business Subcontractors (Jan 2017)(15 U.S.C. 637(d)(12)).
- ___ (60)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
- ___ (ii) Alternate I (Apr 2003) of 52.247-64.

Public notice of a proposed contract action less than \$25,000

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

[Contracting Officer check as appropriate.]

__ (1) 52.222-17, Nondisplacement of Qualified Workers (May 2014)(E.O. 13495).

XX (2) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).

XX (3) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

XX (4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (5) 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).

__ (6) 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).

__ (7) 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).

XX (8) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

XX (9) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

__ (10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792).

__ (11) 52.237-11, Accepting and Dispensing of \$1 Coin (Sept 2008) (31 U.S.C. 5112(p)(1)).

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

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

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract.

If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

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

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a

Public notice of a proposed contract action less than \$25,000

subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause

- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).
- (ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (iii) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (iv) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.
- (v) 52.222-21, Prohibition of Segregated Facilities (Apr 2015)
- (vi) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).
- (vii) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).
- (viii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
- (ix) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212)
- (x) 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.
- (xi) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).
- (xii) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O 13627). Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O 13627).
- (xiii) 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).
- (xiv) 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).
- (xv) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
- (xvi) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
- (xvii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xviii)(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
- (B) Alternate I (Jan 2017) of 52.224-3.
- (xix) 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).
- (xx) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xxi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

Public notice of a proposed contract action less than \$25,000

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

(End of clause)

FAR 52.252-2: Clauses Incorporated by Reference (Feb 1998)

This purchase order 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 address:

<https://www.acquisition.gov/far/current/html/FARTOCP52.html#wp372482>

(End of Clause)

FAR 52.203-19: Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements (Jan 2017)

(a) The Contractor shall not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(b) The Contractor shall notify current employees and subcontractors that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this clause, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this clause, are no longer in effect.

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

(d) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the Contractor is not in compliance with the provisions of this clause.

(e) The Contractor shall include the substance of this clause, including this paragraph (e), in subcontracts under such contracts.

(End of Clause)

FAR 52.232-39: Unenforceability of Unauthorized Obligations (June 2013)

FAR 52.232-40: Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

HHSAR CLAUSES:

The below Health and Human Services Acquisition Regulation (HHSAR) Clauses apply.

Public notice of a proposed contract action less than \$25,000

HHSAR Clauses can be viewed in full text at: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

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

HHSAR 352.224-71 Confidential Information (Dec 2015)

HHSAR 352.239-74 Electronic Information and Technology Accessibility

(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:

- 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)
- E302 - Functional Performance Criteria (Appendix C, Application and Scoping Requirements)
- E207 Software (Appendix A, Application and Scoping Requirements)
- E208 Documentation and Support Services
- Chapter 5 Software to include all WCAG 2.0 A and AA standards (Appendix C, Functional Performance Criteria and Technical Requirements)
- Chapter 6: Documentation and Support Services

(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,

Public notice of a proposed contract action less than \$25,000

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)

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 address:

<https://www.acquisition.gov/far/current/html/FARTOCP52.html#wp372482>

FAR 52.204-26 Covered Telecommunications Equipment or Services-Representation (Dec 2019)

FAR 52.211-6 Brand Name or Equal (Aug 1999)

FAR 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements—Representation (January 2017)

(a) Definition. As used in this provision--

“Internal confidentiality agreement or statement”, “subcontract”, and “subcontractor”, are defined in the clause at 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

(b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

Public notice of a proposed contract action less than \$25,000

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

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

(End of provision)

The below Health and Human Services Acquisition Regulation (HHSAR) Provisions apply.

HHSAR Provisions can be viewed in full text at: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

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

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS website <http://www.hhs.gov/web/508>.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in

Public notice of a proposed contract action less than \$25,000

determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

19. Instructions to Offerors

- Quoters shall submit a quote for all requirements listed in this Notice using the Deliverables Table in Section 5 or something substantially similar. Partial quotes will not be considered. Incomplete pricing or pricing with omissions may not be considered for award.
- Quoters shall submit all assumptions in their quotation.
- Quoters are advised that additional terms and conditions submitted with their quotation that is in conflict of the terms and conditions of this solicitation may be deemed as technically unacceptable and may not be considered for award. All additional terms and conditions must be submitted with its quotation.
- Quoters shall submit all applicable terms and conditions in full text as attachments, appendix, or exhibits.
- 508 Compliance- Quoters shall submit all applicable terms and conditions in full text as attachments, appendix, or exhibits. Quoters shall submit Product Accessibility Templates (PAT) in full text with their quotations. The PAT template can be found with the following link:
<http://www.hhs.gov/web/section-508/contracting/technology-products/vpath-instructions/index.html#>
- All Quoters providing quotations must clearly state the overall cost to the Government.
- This is a Brand Name or Equal RFQ. Quote's providing "equal" products shall comply with FAR Clause 52.211-6 Brand Name or Equal.
- Or Equal to Quoters shall map their quotation to the information specified in the requirements section. Quoters are advised that should their quotation be in conflict with or does not clearly reflect the specified requirement of this solicitation, their quotation may be deemed as technically unacceptable and may not be considered for award.
- The Government reserves the right to award without dialogue. The Government does not intend to have dialogue to allow revision of the quotation. But the Government reserves the right to dialogue with Quoters should the Government determined it is necessary for quotation revisions prior to award.
- Quoters should ensure that their initial submission represents their best pricing and that all information is provided to determine technical acceptability. The Government will not research items to determine compatibility; all information regarding compatibility must be contained within the quotation.
- Questions about this public notice must be submitted to Bradley Hill by email at Bradley.Hill@fda.hhs.gov no later than 12:00 Noon Eastern Time (ET) on May 18, 2020. Phone calls will not be accepted.
- Quotes must be submitted to Bradley.Hill@fda.hhs.gov no later than 12:00 Noon Eastern Time (ET), on May 20, 2020. Phone calls will not be accepted.

Quotes shall clearly be marked as response to: RFQ#1226940

Public notice of a proposed contract action less than \$25,000

20. Award Basis

The FDA will evaluate quotes received in response to this Public Notice on a lowest price-technically-acceptable basis. A technically acceptable quote is one that offers to provide the FDA with the goods and services specified in this Statement of Work - or functionally equivalent goods that meets all the salient characteristics and requirements of this SOW – within the specified delivery schedule.

The Contracting Officer will evaluate “equal” products in accordance with FAR Clause 52.211-6 Brand Name or Equal.

Failure to demonstrate meeting the requirements of this notice will result in a rating of technically unacceptable and will not be considered for award.