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| Request for Quotation (RFQ) | |
| RFQ Number: 75F40123Q116663-A00001 | |
| RFQ Title: Technical Expert Services: Technical Expertise in Predictive Toxicology for Drug-induced liver injury (DILI) | |
| Original RFQ Issue Date: 01/27/2023 | Original RFQ Close Date: 02/06/2023, 12:00 pm Central Time |
| RFQ Amendment A00001 Date: 02/10/2023 | Amended RFQ Close date: 02/16/2023, 2pm Central time |
| Shipping Address: US Food and Drug Administration National Center for Toxicological Research (NCTR) 3900 NCTR Rd Jefferson AR 72079 | Individual Receiving Shipment: To be provided at award |

The purpose of Amendment A00001 is to extend the closing date for submission of quotes through 02/16/2023, no later than 2pm Central time.

This Request for Quote (RFQ) document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2023-01 effective December 30, 2022.

The associated North American Industry Classification System (NAICS) code for this acquisition is 541690 – Other Scientific and Technical Consulting Services; the applicable Small Business Size Standard is \$19 million. This requirement is solicited as a full and open acquisition; any sized business may submit a proposal.

Schedule of Supplies or Services and Prices/Costs, Contract Line Items (CLINs)

Pricing shall be an all-inclusive price which includes travel, plus everything the contractor will require to perform the work stated herein.

Line Item 1 – Base Year: Technical Expertise in Predictive Toxicology for Drug-induced liver injury (DILI).

QTY: 12 months

Price: \$ _____

Line Item 2 – Option Year 1: Technical Expertise in Predictive Toxicology for Drug-induced liver injury (DILI) as per the specifications included herein.

QTY: 12 months

Price: \$ _____

Total Price (Base + 1 Option Year): \$ _____

GSA Contract Number (if applicable): _____

Contract Type: Commercial Service – Firm Fixed Price

Description of Contract Requirements/Statement of Work (SOW)

The Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR), Division of Bioinformatics and Biostatistics (DBB) requires input of an expert with medical practice experience for Drug-induced liver injury (DILI) who should also have research experience with postmarket surveillance databases. It is critical for the performance of the integrative analysis model to be validated with an independent data source, preferably based on patient data. NCTR researchers plan to use the data from postmarket surveillance databases (e.g., FDA Adverse Event Reporting System (FAERS) and WHO VigiBase) to evaluate the correlation between model predictions (generated by DILIBay or other machine learning approaches) and postmarket DILI reporting frequencies. This requires the input of an expert with medical practice experience for DILI who should also have research experience with postmarket surveillance databases. The expert will help to ensure that the results obtained from the analysis are medically relevant and properly validated with real-world data.

Drug-induced liver injury (DILI) is the leading cause of drug withdraws as well as abandonment of otherwise promising drug candidates in the research process. A promising approach for addressing this problem is to utilize high throughput in vitro assays and in silico predictions to generate a detailed profile for DILI potential for each drug candidate. Researchers at the Division of Bioinformatics and Biostatistics (DBB) at the National Center for Toxicological Research (NCTR) are developing an integrative analysis approach of high throughput assays to evaluate the risk of DILI with additional validations using postmarket surveillance data. This approach includes a Bayesian graphical model, DILIBay, as well as machine learning techniques such as random forest and neural networks. It will provide regulatory scientists with an inference engine to conveniently evaluate many diverse in vitro assays in a statistically consistent manner. The development of this model involves advanced statistical modeling and programming, evaluating molecular biomarkers of liver toxicity, incorporating adverse outcome pathways related to liver, and validations using real-world data from postmarket surveillance.

For the purposes of this RFP, the specialized consultant shall be identified as “key personnel.” **HHSAR Clause 352.237-75 Key Personnel** (DEC 2015) applies to this acquisition.

Objective

Working in close coordination with researchers in DBB at NCTR in Jefferson, Arkansas, the contractor shall assist in the formulation of the approach to validate model predictions with data from postmarket surveillance, advise the DBB staff in the relevance of available data regarding the medical problems of interest, evaluate the quality and completeness of the data and suggest the inclusion/exclusion of specific cases, advise on the appropriate methods of writing papers and protocols, and provide support in the generation of manuscripts and other documentation. This will require communication with the DBB staff via e-mail, phone calls and Zoom or Teams meetings to make recommendations as appropriate. At least one visit to the NCTR campus will be scheduled with the Technical Point of Contact (TPOC)/Contracting Officer’s Representative (COR) per year. This is further detailed in Tasks and Deliverables and Milestones. Work shall be no more than 80 hours per year.

Performance/Tasks

1. At the suggestion of the TPOC/COR, the contractor will evaluate relevant literature, case reports, modeling approaches, and prediction results. The contractor will provide evaluations, suggestions, and interpretations to the NCTR team either verbally or in writing.
2. Additionally, the contractor will review draft manuscripts related to liver toxicity and data mining with postmarket surveillance data, provide recommendations for revisions to prepare for publication (following the standard practice in the scientific community for conducting manuscript writing), and assist in the development of research protocols to further the research.

The outlined work above can be conducted at the contractor's facility. The contractor will communicate with the COR/TPOC via e-mail, phone calls and Zoom or Teams meetings to make recommendations as appropriate.

3. The contractor will visit NCTR campus at least once to communicate findings, discuss the plan for research activities, and provide training for junior researchers. The visit will span at least two (2) business days and include a seminar presentation.
 - a. The contractor shall perform needed literature assessment and access resources for presentation, etc., therefore, shall furnish equipment needed to access these resources (i.e., personal laptop).
 - b. NCTR shall provide access to guest Wi-Fi and projection equipment if needed for presentations.

Minimum Position Requirements and Qualifications

1. Shall demonstrate in-depth knowledge of current issues in the field of liver toxicity with at least ten years' experience in this field.
2. Shall demonstrate in-depth knowledge of postmarket surveillance databases.
3. Shall demonstrate knowledge of data mining, modeling, and multidisciplinary research.
4. Shall have experience in mentoring graduate students and junior researchers.
5. Shall have verifiable records of publications in cited scientific journals and publications with at least five publications related to the subject matter (liver toxicity and postmarket surveillance) as the primary author.
6. Shall have experience in practicing medicine in gastroenterology.
7. Shall have PhD and MD, minimum 15-20 years' experience.

Deliverables/Milestones:

| Item | Deliverable | Description | Due Date |
|------|--------------------------------|--|---|
| 1 | Literature and Document review | <p>Contractor will evaluate relevant literature, case reports, modeling approaches, and prediction results. The contractor will provide evaluations, suggestions, and interpretations to the NCTR team either verbally or in writing.</p> <p>Contractor will review draft manuscripts related to liver toxicity and data mining with postmarket surveillance data, provide recommendations for revisions to prepare for publication (shall follow the standard practice in the scientific community for conducting the manuscript writing), and assist in the development of research protocols to further the research.</p> | Throughout Period of Performance |
| 2 | Visit NCTR | The contractor will visit NCTR campus at least once to communicate findings, discuss the plan for research activities, and provide training for junior researchers. The visit will span at least two business days and include a seminar presentation. The contractor shall furnish equipment needed to perform needed literature assessments and access resources for presentations, etc. (i.e., personal laptop). NCTR shall provide access to guest Wi-Fi and projection equipment if needed for presentations. | One two-day visit during each Period of Performance |
| 3 | Summary Report | Report shall contain a detailed summary of work performed for/during site visits, protocol/manuscripts reviewed, meetings attended, seminars/trainings provided, and any other notable activities during the billing period. Report shall include hours expended during the reporting period and the cumulative amount for the period of performance. | At time of invoicing |

All deliverables shall be developed using Microsoft Office products that are compatible with the versions currently utilized by the FDA (i.e., MS 2016) and are 508 compliant. Reports shall be provided by e-mail with each invoice from the Contractor.

The Contractor shall deliver all products to the Technical Point of Contact/Contracting Officer's Representative (TPOC/COR). The TPOC/COR or other technical staff will notify the Contractor of deliverable acceptance regarding overall compliance with the guideline's requirements of the task. Reports shall also be submitted to the Contract Specialist/Contracting Officer.

The Contractor shall ensure the accuracy and completeness of all deliverables in accordance with referenced policy, regulations, laws, and directives. Reports and presentations shall be concise and clearly written; errors, misleading or unclear statements, incomplete or irrelevant information, and/or excessive rhetoric, repetition, or excessive length if a page limit is imposed, shall be considered deficiencies and will be subject to correction by the contractor at no additional cost to the

Government. Unless specified otherwise, the TPOC/COR will review and approve all deliverables.

Unless specified otherwise, the Contractor shall provide a copy of each deliverable listed in DELIVERABLES section to the TPOC/COR for review. The Government will review the deliverable and suggest any changes. If changes are required, unless specified otherwise, the Contractor shall resubmit the revised deliverable to the TPOC/COR five (5) business days after receiving the Government's input, unless otherwise agreed to in advance.

Deliverable products shall be reviewed, validated, and tested as appropriate to ensure that they meet applicable/specified standards, policy, business requirements, and quality measures. In the event of the rejection of any deliverable, the Contractor shall be notified in writing by the TPOC/COR, giving the specific reason(s) for rejection. The Contractor shall have ten (10) business days to respond to the rejected deliverable and return it to the TPOC/COR.

Section 508:

- Electronic content must be accessible to HHS acceptance criteria. [Accessibility checklists for various formats](#) are available at the HHS site. Materials that are final items must be compliant with Section 508 at time of delivery, except upon approval of the Contracting Officer or Representative.

Deliveries, Acceptance, and Performance

Period(s) of Performance. Base plus one (1) Option Year with anticipated period of performance dates estimated as:

Base Year: 04/03/2023 – 04/02/2024

Option Year 1: 04/03/2024 – 04/02/2025

Place of Performance

Research work may be performed at the contractor's place of business. However, as stated above, the contractor will be required to travel to NCTR to communicate findings, discuss the plan for research activities, and provide training for junior researchers, as well as to present a seminar. Travel costs shall be included in the quote.

US FDA /National Center for Toxicological Research (NCTR)

3900 NCTR Rd.

Jefferson AR 72079

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

During site visits the contractor shall perform needed literature assessments and access resources for presentations, etc., therefore, the contractor shall furnish equipment needed to access these resources (i.e., personal laptop). NCTR shall provide access to guest Wi-Fi and projection equipment if needed for presentations.

Security and Privacy

The Contractor shall be responsible for determining that the individuals provided to perform under this contract will not have an adverse effect on the efficiency, effectiveness, and integrity of the FDA, and will uphold the scope of work.

Due to the possible sensitive nature of the information discussed, contractor personnel shall be required to sign a Commitment to Protect Non-Public Information form 3398, which will be included as an attachment to any resultant contract.

The Contractor must assure the protection of the information and data it receives in performance of this contract from unauthorized use or disclosure and must avoid actions that would cause a reasonable person to question the impartiality of the Contractor, its employees, or the Government in the performance of this immediate contract and potential participation in future actions. The data provided shall not be used or disclosed outside of this contract without prior approval from the TPOC/COR. The Contractor is prohibited from any use of the data. The data is solely owned by the FDA.

Acceptance

The supplies and/or services delivered hereunder shall be inspected and accepted at destination by the TPOC/COR specified at award. If the supplies or services are acceptable, the TPOC/COR shall promptly forward a report of inspection and acceptance to the paying office. If the supplies or services are not acceptable, the TPOC/COR shall document the nonconforming items/services and immediately notify the contracting officer.

Payments

Net 30 days after government acceptance of a proper invoice. Payments will not be made more frequently than monthly in arrears. Advance payments will not be made.

Contract Clauses:

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):

<https://www.acquisition.gov/browse/index/far> and

<https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

52.212-4 Contract Terms and Conditions-Commercial Items (Dec 2022) applies to this acquisition. The following addenda apply:

FAR Clauses

52.204-13 System for Award Management and Maintenance (Oct 2018)

52.204-18 Commercial and Government Entity Code Maintenance (Aug 2020)

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within any time of contract expiration; provided that the Government gives the Contractor a preliminary written notice of its

intent to extend any time before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years. (End of clause)

52.222-49 Service Contract Labor Standards-Place of Performance Unknown (May 2014)

For the purposes of this clause the blank(s) is/are completed as follows:

“(a)...none.”; “within 10 days of the issuance of this solicitation.”

52.232-18 Availability of Funds (Apr 1984)

HHSAR Clauses

352.232-71 Electronic Submission of Payment Requests (Feb 2022)

(a) Definitions. As used in this clause-

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

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

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

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

(END OF CLAUSE)

352.239-74 Electronic and Information Technology Accessibility (Dec 2015)

Paragraph (c). The Section 508 standards applicable to this contract are:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- Electronic content must be accessible to HHS acceptance criteria.

- [Accessibility checklists for various formats](#) are available at the HHS site. Materials that are final items must be compliant with Section 508 at time of delivery, except upon approval of the Contracting Officer or Representative.
- E206 Hardware (Appendix A, Application and Scoping Requirements)
- E207 Software (Appendix A, Application and Scoping Requirements)
- Chapter 4 Hardware (Appendix C, Functional Performance Criteria and Technical Requirements)
- Chapter 5 Software, (Appendix C, Functional Performance Criteria and Technical Requirements)

The supplies and/or services delivered hereunder shall be inspected and accepted at destination by the Technical Point of Contact (TPOC) specified at award. If the supplies or services are acceptable, the TPOC shall promptly forward a report of inspection and acceptance to the paying office. If the supplies or services are not acceptable, the TPOC shall document the nonconforming items/services and immediately notify the contracting officer.

Contract Administration

Contracting Officer

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the contract; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The contact information for the Contracting Officer is:

Name: Suzanne Martella

Email: suzanne.martella@fda.hhs.gov

Phone: (870) 543-7540

Technical Point of Contact (TPOC)/Contracting Officer's Representative (COR)

The TPOC is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The following Technical Point of Contact (TPOC)/COR will represent the Government for this contract (*to be provided upon contract award*):

Name:

Email:

Phone:

Invoice Submission

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.
 - Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;

- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
 - Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
 - Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
 - Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
 - Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
 - Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.
- f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
- (a) list of all invoices submitted to date under the subject award, including the following:
 - (1) invoice number, amount, & date submitted
 - (2) corresponding payment amount & date received
 - (b) total amount of all payments received to date under the subject contract or order
 - (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
- g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
- h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.
- i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.
- j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.
- k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-

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

Be advised that FDA does not accept documents which contain the use of macros. ***When submitting documents via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine).*** Document submissions required throughout the award period(s) shall not have macro enabled functionality and any document delivered having that functionality will be deemed delinquent, if not corrected prior to the due date.

52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Products and Commercial Services (Dec 2022) (Deviation 2017-02, Jun 2017) (Deviation, APR 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 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 (Jul 2018) (Section 1634 of Pub. L. 115-91).
- (3) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (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: [*Contracting Officer check as appropriate.*]

- (1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (June 2020), with *Alternate I* (Nov 2021) ([41 U.S.C. 4704](#) and [10 U.S.C. 4655](#)).
- (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Nov 2021) ([41 U.S.C. 3509](#))).
- (3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- (4) [52.203-17](#), Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights (April 2014) (41 U.S.C. 4712) relating to whistleblower protections).
- (5) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).

- (6) [Reserved].
- (7) [52.204-14](#), Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (8) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- (9) [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](#)).
- (10) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) ([41 U.S.C. 2313](#)).
- (11) [Reserved].
- (12) (i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Sep 2021) ([15 U.S.C. 657a](#)).
- (ii) Alternate I (Mar 2020) of [52.219-3](#).
- (13)(i) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Sep 2021) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).
- (ii) Alternate I (Mar 2020) of [52.219-4](#).
- (14) [Reserved]
- (15) (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](#).
- (16) (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](#).
- (17) [52.219-8](#), Utilization of Small Business Concerns (Oct 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).
- (18) (i) [52.219-9](#), Small Business Subcontracting Plan (NOV 2021) ([15 U.S.C. 637\(d\)\(4\)](#)).
- (ii) Alternate I (Nov 2016) of [52.219-9](#).
- (iii) Alternate II (Nov 2016) of [52.219-9](#).
- (iv) Alternate III (Jun 2020) of [52.219-9](#).
- (v) Alternate IV (Jun 2020) of [52.219-9](#).
- (19)(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](#).
- (20) [52.219-14](#), Limitations on Subcontracting (Sep 2021) ([15 U.S.C. 637\(a\)\(14\)](#)).
- (21) [52.219-16](#), Liquidated Damages-Subcontracting Plan (Jan 1999) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
- (22) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Sep 2021) ([15 U.S.C. 657f](#)).
- X (23) (i) [52.219-28](#), Post Award Small Business Program Rerepresentation (Sep 2021) ([15 U.S.C. 632\(a\)\(2\)](#)).
- (ii) Alternate I (MAR 2020) of [52.219-28](#).
- (24) [52.219-29](#), Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Sep 2021) ([15 U.S.C. 637\(m\)](#)).
- (25) [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 (Sep 2021) ([15 U.S.C. 637\(m\)](#)).
- (26) [52.219-32](#), Orders Issued Directly Under Small Business Reserves (Mar 2020) ([15 U.S.C. 644\(r\)](#)).
- (27) [52.219-33](#), Nonmanufacturer Rule (Sep 2021) ([15U.S.C. 637\(a\)\(17\)](#)).
- X (28) [52.222-3](#), Convict Labor (Jun 2003) (E.O.11755).
- X (29) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (Dec 2022) (E.O.13126).

- X (30) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
- X (31)(i) [52.222-26](#), Equal Opportunity (Sep 2016) (E.O.11246).
- (ii) Alternate I (Feb 1999) of [52.222-26](#).
- (32)(i) [52.222-35](#), Equal Opportunity for Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- (ii) Alternate I (Jul 2014) of [52.222-35](#).
- X (33)(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](#).
- (34) [52.222-37](#), Employment Reports on Veterans (Jun 2020) ([38 U.S.C. 4212](#)).
- (35) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- X (36)(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).
- (37) [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 and commercial services as prescribed in FAR [22.1803](#).)
- (38)(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.)
- (39) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- (40) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- (41)(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](#).
- (42)(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](#).
- (43) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (May 2020) ([42 U.S.C. 8259b](#)).
- (44)(i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of [52.223-16](#).
- X (45) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
- (46) [52.223-20](#), Aerosols (Jun 2016) (E.O. 13693).
- (47) [52.223-21](#), Foams (Jun2016) (E.O. 13693).
- (48) (i) [52.224-3](#) Privacy Training (Jan 2017) (5 U.S.C. 552 a).
- (ii) Alternate I (Jan 2017) of [52.224-3](#).
- X (49) [52.225-1](#), Buy American-Supplies (Nov 2021) ([41 U.S.C. chapter 83](#)).
- (50) (i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (Dec 2022) ([19 U.S.C. 3301 note](#), [19 U.S.C. 2112 note](#), [19 U.S.C. 3805 note](#), [19 U.S.C. 4001 note](#), 19 U.S.C. chapter 29 (sections 4501-4732), Public Law 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
- (ii) Alternate I [Reserved]
- (iii) Alternate II (Dec 2022) of [52.225-3](#).

- (iv) Alternate III (Jan 2021) of [52.225-3](#).
 - (51) [52.225-5](#), Trade Agreements (Dec 2022) ([19 U.S.C. 2501](#), *et seq.*, [19 U.S.C. 3301](#) note).
 - X (52) [52.225-13](#), Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
 - (53) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).
 - (54) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ([42 U.S.C. 5150](#)).
 - (55) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) ([42 U.S.C. 5150](#)).
 - (56) [52.229-12](#), Tax on Certain Foreign Procurements (Jun 2020).
 - (57) [52.232-29](#), Terms for Financing of Purchases of Commercial Products and Commercial Services (Nov 2021) ([41 U.S.C. 4505](#), [10 U.S.C. 3805](#)).
 - (58) [52.232-30](#), Installment Payments for Commercial Products and Commercial Services (Nov 2021) ([41 U.S.C. 4505](#), [10 U.S.C. 3805](#)).
 - X (59) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (Oct 2018) ([31 U.S.C. 3332](#)).
 - (60) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).
 - (61) [52.232-36](#), Payment by Third Party (May 2014) ([31 U.S.C. 3332](#)).
 - X (62) [52.232-40](#), Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)(DEVIATION APR 2020)([31 U.S.C. 3903](#) and [10 U.S.C. 2307](#)).
 - (63) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).
 - (64) [52.242-5](#), Payments to Small Business Subcontractors (Jan 2017) ([15 U.S.C. 637\(d\)\(13\)](#)).
 - (65)(i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Nov 2021) ([46 U.S.C. Appx. 1241\(b\)](#) 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) ([29 U.S.C.206](#) and [41 U.S.C. chapter 67](#)).
 - (5) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
 - (6) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
 - (7) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Jan 2022).
 - (8) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2022) (E.O. 13706).

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

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

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

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

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

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial products and 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 2018) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

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

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

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

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

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

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

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

- (xiii)(A) [52.222-50](#), Combating Trafficking in Persons (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 (May2014) ([41U.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 Under Executive Order 13658 (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. Subtitle A, Part V, Subpart G 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. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the Contractor may include in its subcontracts for commercial products and commercial services a minimal number of additional clauses necessary to satisfy its contractual obligations.
- (End of clause)

Solicitation Provisions

52.252-1 Solicitation Provisions Incorporated by Reference (FEB 1998)

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

FAR Provisions

52.204-7 System for Award Management (Oct 2018)

52.204-16 Commercial and Government Entity Code Reporting (Aug 2020)

52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Nov 2021) (fill-in appropriate boxes below):

(d) *Representation. The Offeror represents that—*

(1) It will, will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The

Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that—

It does, does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds "does" in paragraph (d)(2) of this section.

HHSAR Provisions

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

Shall meet the level of conformance of the delivered service/items to the 508 standards identified in HHSAR Clause 352.239-74(c) herein

Instructions to Offerors

The provision at FAR 52.212-1 Instructions to Offerors - Commercial Products and Commercial Services (Nov 2021) applies to this solicitation. The following addenda apply:

It is the offeror's responsibility to monitor the Government Point of Entry (GPE) (sam.gov) for information relevant to this solicitation, e.g., questions and answers, amendments, etc. An official authorized to bind the Offeror must sign the terms and conditions of the offer. Offerors that fail to complete the required representations and certifications or reject the terms and conditions of the solicitation may be excluded from consideration.

Paragraph (b)(4). **Technical Approach/Capability:** Offeror must provide sufficient information for the Government to conclusively determine that the offered service meets or exceeds the requirements identified herein. The quote shall demonstrate that the offeror provides a sound, compliant approach to performing the work described in the Statement of Work, including describing the Offeror's understanding of the tasks and how the Offeror intends to satisfy the scientific and technical requirements.

Provide a written narrative (no more than 20 numbered pages [CV does not count in the page count]) aligned with each minimum performance requirement and each deliverable to describe the technical approach that will be used to satisfy all the requirements listed in the "Tasks" section of this solicitation. Identify personnel key to the success of the proposed approach, which at a minimum shall include a Technical Expert in Predictive Toxicology for Drug-induced liver injury (DILI). Discuss their roles and responsibilities as well as their experience in performing same or near-same services and provide resumes/curriculum vitae for each.

Offer shall provide qualifications of proposed Key Personnel and demonstrate that the proposed Key Personnel have the requisite experience and qualifications to meet the requirements outlined herein. Offeror shall provide evidence of related education, knowledge and experience for proposed key personnel in the activities in the statement of work, to include a resumé and/or Curriculum Vitae and letter of commitment from potential candidate.

The Offeror shall submit a written Accessibility Conformance Report (ACR) for each item not in compliance with 508 standards identified in clause **352.239-74**, describing how the item(s) will fully

address the accessibility requirements outlined in the solicitation; and a description of the evaluation methods the offeror will use to validate for conformance to the Revised 508 Standards. The ACR should be based on the Voluntary Product Accessibility Template Version 2.0 (MS Word) provided by the Industry Technology Industry Council (ITIC). For this requirement we anticipate only deliverables/reports and invoices to be applicable to the requirement.

Paragraph (b)(10). **Past Performance:** Provide the below information for contracts ongoing or completed during the last three (3) years (“recent”), that are the same or similar in nature to this solicitation (“relevant”). Contracts may include those entered into with the federal Government, agencies of state and local government, and commercial customers. Include the following information for each reference:

- Description of service
- Period of Performance
- Location
- Total Contract Value
- Prime or Subcontractor (provide name of Prime if subcontractor)
- Names of the personnel who performed the Predictive Toxicology for Drug Induced Liver Injury (DILI) and identify whether they were an employee, consultant, etc.
- Total amount and percentage of work performed by the contractor (or subcontractor if so indicated above)
- Name of Contracting Agency/Organization
- Contracting Officer/Client’s name and verified telephone number and email address
- Contract number
- COR/TPOC’s name and verified telephone number and email address
- Identify other Predictive Toxicology for Drug Induced Liver Injury (DILI) work that may have been performed during the same period

The Government reserves the right to obtain information for use in the evaluation from any and all sources including sources outside of the Government.

Price: Offeror shall complete the pricing table provided in the paragraph entitled: **Schedule of Supplies or Services/Costs, Contract Line Items (CLINs)**, above. The Government intends to make an award based on the initial proposals. If further questions are required, the Contracting Officer may contact the offeror. ***Include the firm’s Unique Entity ID (UEI) number with Offer.***

The price proposed shall represent the offeror’s response to the schedule of supplies/services above.

Proprietary and/or confidential information shall be clearly marked.

The government is not responsible for locating or securing any information which is not identified in the proposal; however, the Government reserves the right to obtain information for use in the evaluation from all sources including sources outside of the Government.

Microsoft Suite Documents Containing Macros

The offeror or applicant shall submit all electronic documents created by Microsoft Office suite products without the use of “macros”. If the offeror or applicant submits documents that contain macros the Government will not be able to view or open such documents and the submission will be

considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure that all electronic documents submitted do not contain or otherwise use macros.

NOTE: This solicitation is issued under the premise that the offeror's Key Personnel fulfilling the role of Technical Expert in Predictive Toxicology for Drug-induced liver injury (DILI) is exempt from the Service Contract Act as they are considered a Professional employee per [\(29 CFR 541\)](#).

Per FAR 22.1102, a *Professional employee*, means any person meeting the definition of "employee employed in a bona fide . . . professional capacity" given in [\(29 CFR 541\)](#). The term embraces members of those professions having a recognized status based upon acquiring professional knowledge through prolonged study. Examples of these professions include accountancy, actuarial computation, architecture, dentistry, engineering, law, medicine, nursing, pharmacy, the sciences (such as biology, chemistry, and physics, and teaching). To be a professional employee, a person must not only be a professional but must be involved essentially in discharging professional duties.

The contractor shall check the following certification:

CERTIFICATION

The offeror does does not certify that-

The employee is considered a "*professional employee*" as per the definition above and is: (1) Compensated on a salary or fee basis pursuant to [§ 541.600](#) at a rate of not less than \$684 per week (or \$455 per week if employed in the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, or the U.S. Virgin Islands by employers other than the Federal government, or \$380 per week if employed in American Samoa by employers other than the Federal government), exclusive of board, lodging or other facilities; and; and (2) Whose primary duty is the performance of work: (i) Requiring knowledge of an advanced type in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction; or (ii) Requiring invention, imagination, originality or talent in a recognized field of artistic or creative endeavor. [\(29 CFR 541\)](#)

In the event that a Contractor does not make this certification, the traditional Service Contract Act clause 52.222-41 shall be included in the resulting order award as well as the applicable Wage Determination No. will be inserted (see FAR Clause 52.222-49).

Evaluation Criteria

The provision at 52.212-2 Evaluation-Commercial Products and Commercial Services (Nov 2021) is applicable to this solicitation. The provision is tailored to include evaluation factors.

The Government intends to award a contract resulting from this solicitation to the responsible Offeror whose offer is the most advantageous to the Government, price and other factors considered. The Government will make award to the Offeror whose proposal represents the best value to the Government as determined by using tradeoffs among the technical, past performance, and price evaluation factors. Offerors are placed on notice that any proposals which are not minimally responsive to all the technical factors cited herein will be deemed reflective of an inherent lack of

technical competence and may be grounds for the rejection of the proposal(s). Offerors shall ensure that any relevant prior experience to be considered is documented within the proposal. The following factors shall be used to evaluate offers:

- Technical Approach/ Capability
- Past Performance
- Price

Technical Capability (i.e., how well the proposed approach will meet or exceed the Government's requirements) and past performance (i.e., when (recent-within last 3 years), what (relevant), and how well), are relatively equal, but when combined are significantly more important than price when determining the best overall value to the Government, though price remains a significant consideration.

Offerors are advised that the Government intends to evaluate proposals and make award without discussions.

Past Performance

The lack of a past performance record may result in an unknown performance risk assessment (neutral). Positive past performance is considered higher than unknown/ neutral past performance.

(b) *Options*. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(c) A written notice of award or acceptance of an offer mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

The Government reserves the right to request additional information at any time. Once the Government determines the offeror that is the best-suited (i.e., the apparent successful offeror), the Government reserves the right to communicate with only that offeror to address any remaining issues, if necessary, and finalize a contract with that offeror. These issues may include technical, past performance and price.

The Provision at FAR 52.212-3, Offeror Representations and Certifications-Commercial Products and Commercial Services (Dec 2022), applies to this acquisition.

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

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

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

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

Forced or indentured child labor means all work or service—

- (1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or
- (2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

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

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

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

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

- (1) PSC 5510, Lumber and Related Basic Wood Materials;
- (2) Product or Service Group (PSG) 87, Agricultural Supplies;
- (3) PSG 88, Live Animals;
- (4) PSG 89, Subsistence;
- (5) PSC 9410, Crude Grades of Plant Materials;
- (6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;
- (7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;
- (8) PSC 9610, Ores;
- (9) PSC 9620, Minerals, Natural and Synthetic; and
- (10) PSC 9630, Additive Metal Materials.

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

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

Reasonable inquiry has the meaning provided in the clause [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

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

defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

- (1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;
- (2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;
- (3) Consist of providing goods or services to marginalized populations of Sudan;
- (4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;
- (5) Consist of providing goods or services that are used only to promote health or education; or
- (6) Have been voluntarily suspended. "Sensitive technology"—

Sensitive technology—

- (1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—
 - (i) To restrict the free flow of unbiased information in Iran; or
 - (ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and
- (2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

Service-disabled veteran-owned small business concern—

- (1) Means a small business concern—
 - (i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and
 - (ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.
- (2) Service-disabled veteran means a veteran, as defined in [38 U.S.C. 101\(2\)](#), with a disability that is service connected, as defined in [38 U.S.C. 101\(16\)](#).

Small business concern—

- (1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and size standards in this solicitation.
- (2) *Affiliates*, as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties' control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

Small disadvantaged business concern, consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

- (1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—
 - (i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and
 - (ii) Each individual claiming economic disadvantage has a net worth not exceeding \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and
- (2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

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

- (1) Directly by a parent corporation; or
- (2) Through another subsidiary of a parent corporation

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

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

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

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

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

- (1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and
- (2) Whose management and daily business operations are controlled by one or more women.

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

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

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

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

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

(c) Offerors must complete the following representations when the resulting contract is for supplies to be delivered or services to be performed in the United States or its outlying areas, or when the contracting officer has applied part 19 in accordance with 19.000(b)(1)(ii). Check all that apply.

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

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

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

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

(5) *Women-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it is, is not a women-owned small business concern.

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

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

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

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

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

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

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

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

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

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

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

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

of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order 11246-

(1) Previous contracts and compliance. The offeror represents that-

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

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

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

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

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

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

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

(i) The Offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product.

(ii) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(iii) The terms "domestic end product," "end product," "foreign end product," and "United States" are defined in the clause of this solicitation entitled "Buy American-Supplies."

(2) Foreign End Products:

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

[List as necessary]

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

(g)(1) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate*. (Applies only if the clause at FAR [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (g)(1)(iii) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product," "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "Israeli end product," and "United States" are defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act."

(ii) The Offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act."

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

[List as necessary]

(iii) The Offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled "Buy American-Free Trade Agreements-Israeli Trade Act." The Offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

Other Foreign End Products:

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |
| _____ | _____ |

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |

[List as necessary]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR [part 25](#).

(2) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate II.* If Alternate II to the clause at FAR [52.225-3](#) is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Israeli end products as defined in the clause of this solicitation entitled “Buy American-Free Trade Agreements-Israeli Trade Act”:

Israeli End Products:

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

[List as necessary]

(3) *Buy American-Free Trade Agreements-Israeli Trade Act Certificate, Alternate III.* If Alternate III to the clause at [52.225-3](#) is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled “Buy American-Free Trade Agreements-Israeli Trade Act”:

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |
| _____ | _____ |

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |

[List as necessary]

(4) *Trade Agreements Certificate*. (Applies only if the clause at FAR [52.225-5](#), Trade Agreements, is included in this solicitation.)

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

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

Other End Products:

| Line Item No. | Country of Origin |
|---------------|-------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

[List as necessary]

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

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

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

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

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

(4) Have, have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds the threshold at [9.104-5\(a\)\(2\)](#) for which the liability remains unsatisfied.

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

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

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

(ii) *Examples.*

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

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

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

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

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

(1) *Listed end products.*

| Listed End Product | Listed Countries of Origin |
|--------------------|----------------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

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

- (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.
- (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.
- (j) *Place of manufacture.* (Does not apply unless the solicitation is predominantly for the acquisition of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly-
- (1) In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or
- (2) Outside the United States.
- (k) *Certificates regarding exemptions from the application of the Service Contract Labor Standards* (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services.) [*The contracting officer is to check a box to indicate if paragraph (k)(1) or (k)(2) applies.*]
- (1) Maintenance, calibration, or repair of certain equipment as described in FAR [22.1003-4\(c\)\(1\)](#). The offeror does does not certify that-
- (i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;
- (ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR [22.1003-4\(c\)\(2\)\(ii\)](#)) for the maintenance, calibration, or repair of such equipment; and
- (iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.
- (2) Certain services as described in FAR [22.1003-4\(d\)\(1\)](#). The offeror does does not certify that-
- (i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;
- (ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR [22.1003-4\(d\)\(2\)\(iii\)](#));
- (iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and
- (iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.
- (3) If paragraph (k)(1) or (k)(2) of this clause applies-
- (i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

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

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

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

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

(3) *Taxpayer Identification Number (TIN)*.

TIN: _____.

TIN has been applied for.

TIN is not required because:

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

Offeror is an agency or instrumentality of a foreign government;

Offeror is an agency or instrumentality of the Federal Government.

(4) *Type of organization*.

Sole proprietorship;

Partnership;

Corporate entity (not tax-exempt);

Corporate entity (tax-exempt);

Government entity (Federal, State, or local);

Foreign government;

International organization per 26 CFR1.6049-4;

Other _____.

(5) *Common parent*.

Offeror is not owned or controlled by a common parent;

Name and TIN of common parent:

Name _____.

TIN _____.

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

(n) Prohibition on Contracting with Inverted Domestic Corporations.

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

(2) *Representation*. The Offeror represents that—

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

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

(o) Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.

(1) The offeror shall e-mail questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

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

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

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

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

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

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

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

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

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

(2) If the Offeror indicates "has" in paragraph (p)(1) of this provision, enter the following information:
Immediate owner CAGE code: _____.

Immediate owner legal name: _____.

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

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

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

Highest-level owner CAGE code: _____.

Highest-level owner legal name: _____.

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

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

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

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

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

(2) The Offeror represents that—

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

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

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

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

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

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

Predecessor legal name: _____.

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

(s) [Reserved].

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

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

(2) Representation. [Offeror to check applicable block(s) in paragraph (t)(2)(i) and (ii)].

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

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

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

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

(u) (1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees

or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

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

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

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

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

(2) The Offeror represents that—

(i) It does, does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(ii) After conducting a reasonable inquiry for purposes of this representation, that it does, does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

(End of Provision)

Defense Priorities and Allocation System (DPAS)

The Defense Priorities and Allocations System (DPAS) and assigned rating are not applicable to this solicitation notice.

Submission of Offers

All responsible sources may submit an offer, which if timely received, shall be considered. The proposal must reference solicitation number 75F40123R116663. Proposals are due by email only to Suzanne Martella at suzanne.martella@fda.hhs.gov on or before the date and time indicated on page 1 of this solicitation.