Combined Synopsis/Solicitation 75F40126Q133848

This is a combined synopsis/solicitation for commercial items prepared in accordance with the Federal Acquisition Regulation (FAR) RFO Part 12, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation request for proposals. The solicitation number is **75F40126Q133848**. This solicitation is issued as a Request for Quote (RFQ). For information regarding this solicitation, please contact Howard Nesmith by e-Mail at howard.nesmith@fda.hhs.gov.

The appropriate North American Industry Classification System (NAICS) Code is 811210 - Electronic and Precision Equipment Repair and Maintenance; with a Small Business Size standard $34.0 million. This requirement is competed unrestricted and made available to Full and Open competition, meaning any qualified vendor regardless of size status may submit a quote.

Statement of Need/Requirements:
The U.S. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) require a complete Benchtop Bioreactor System. This system will be used to investigate a novel class of complex Live Biotherapeutic Products that are generated from anaerobic fermentations from human stools.

Schedule of Items/Services:
Item #1
Benchtop Bioreactor System
To meet below Minimum Technical Requirements:

Quantity: 1

Manufacturer: _____

Model: _____

Item/Part Number: _____

Total Price: _____

Item #2 (Option Year #1)
Benchtop Bioreactor System Service Agreement
To meet below Minimum Post Warranty Service/Maintenance Requirements

Period of Performance: To Begin Upon Expiration of Instrument Warranty and Shall Continue for a Period of 1-Year

Annual Service/Maintenance Agreement Price: $_____

Item #3 (Option Year #2)

Benchtop Bioreactor System Service Agreement

Period of Performance: Upon Expiration of Previous Period of Performance and Shall Continue for a Period of 1-Year

Annual Service/Maintenance Agreement Price: $_____

Item #4 (Option Year #3)
Benchtop Bioreactor System Service Agreement

Period of Performance: Upon Expiration of Previous Period of Performance and Shall Continue for a Period of 1-Year

Annual Service/Maintenance Agreement Price: $_____

Item #5 (Option Year #4)
Benchtop Bioreactor System Service Agreement

Period of Performance: Upon Expiration of Previous Period of Performance and Shall Continue for a Period of 1-Year

Annual Service/Maintenance Agreement Price: $_____

GSA Contract Number: _____ *(If Applicable)*

Background:
The FDA/CBER is responsible for regulating these novel products. These products represent an intermediate between Fecal Microbiota Transplantation (FMT) products and more well defined Live Biotherapeutic Products (LBPs). Numerous regulatory questions surround the manufacturing of these products, including identification of critical quality attributes for product characterization, potential safety risks, and how manufacturing consistency can be achieved. Additionally, the bioreactor will be used for applications including generation of outer membrane vesicles and protein purifications for other studies in our laboratory and throughout our division when not in use for cultured stool studies.

Minimum Technical Requirements:
A complete benchtop bioreactor system(s) that allows for running four (4) x 1L bioreactors in parallel and is capable of sustaining and controlling high-density complex microbial cultures in a working volume of 500-1000mL. The system should be comprised of:

1. A control tower with the following features:
    a) An onboard touchscreen display or included computer/tablet with bioreactor control software that is easy to read and navigate.
        i. Software costs should be included with the system
        ii. Software should function entirely on the computer/tablet without the need for cloud storage or internet connection

   b) Continuous process monitoring and fully automated control of key process variables: temperature, dissolved oxygen, pH, foam, and biomass.
   c) A minimum of four (4) mass flow controllers (MFCs) for external gas supplies for air, oxygen, nitrogen and carbon dioxide per bioreactor.
   d) A minimum of four (4) onboard, variable-speed, bi-directional peristaltic pumps that can be assigned roles for pH, foam, and feed/level control via automated addition of acid, base, anti-foam, and Feed/Level for each bioreactor.
2. Four fermentation vessels, each with the following features:
   a) 0.3-1L working volume
   b) Sensors for continuous measurement of temperature, dissolved oxygen, pH, foam, Oxidation Reduction Potential (ORP), and biomass.
   c) Ports required for all necessary sensors and feed lines.
   d) Inoculation port
   e) Harvest pipe
   f) Vessel temperature control must be able to leverage both heating and cooling (e.g., water-jacketed vessel supplied by a recirculating chiller) and not rely on an external, fresh water source.
   g) A stir shaft equipped with Rushton-type, 6-blade impellers suitable for microbial culture.
   h) Ring sparger with either upward or downward flow
   i) Condenser with a flexible joint
   j) Stainless steel baffle insert
3. The system must have at least one onboard MFC to control sparge into each vessel.
4. A ring-type sparger should be used, and each vessel exhaust should be equipped with a condenser/exit gas cooler with flexible joint.
5. Units should be capable of both aerobic and anaerobic growth controlled automatically though injection of gases controlled independently for each vessel.
6. Temperature control unit(s) required for operation of the bioreactors should be included. These should allow both heating and cooling of the vessels independently.
7. The system should include all necessary probes, cables, housings, couplers and connections to measure the variables listed above.
8. Any other items that would fulfill the requirement for a complete bioreactor system that can be used upon set-up for the anaerobic cultivation of complex microbial communities.
9. An adequate supply of consumables for installation, setup, and initial operation, such as:
   a) Four (4) Autoclavable 250 mL storage bottles (per vessel) for liquid additions that consist of:
      i. Glass bottle.
      ii. Head piece (such as stainless steel) with two barbed hose connectors that will work with the required silicone pump tubing.
      iii. Screw cap with silicone gasket.
   b) Bottle rack or similar for substrate bottles
   c) Assorted blinding plugs
   d) O-rings, gaskets, grease, etc.

Training Requirements

1. Onsite installation and applications training for FDA staff at the White Oak facility that includes basic operation, routine maintenance, and how to operate the process control software.
2. Training should be performed by either qualified person(s) employed by the OEM or by individuals who have proof-of-training certification provided by the OEM that was acquired within one (1) year of the instrument delivery date.

Warranty Requirements

1. Warranty must cover all parts, labor, and service visits for at least one (1) year.
2. All replacements must be genuine OEM parts.
3. Warranty coverage shall commence on the date of acceptance.

Minimum Post Warranty Service/Maintenance Requirements:

- All maintenance and repair activities shall be performed by formally trained and certified Original Equipment Manufacturer (OEM) technicians/engineers.
- All repairs and PM services shall be performed following OEM specifications, manuals, and service bulletins, using OEM replacement parts, components, subassemblies, etc.
- All Corrective/Remedial Service(s) and Preventive Maintenance (PM) shall be inclusive of shipping, labor, travel, replacement parts, subassemblies, components, or modules necessary for repairs, etc.
- PM Service shall include at least one (1) on-site visit for routine instrument calibration/certification per year inclusive of all consumable parts required to complete the PM.
- Any part(s) that cannot be repaired on-site, shipping arrangements and material (e.g., boxes/crates) shall be provided without extra cost.
- Corrective/Remedial Repair visits shall be provided within 2-3 business days of call for service (for issues that can't be resolved remotely via phone or Internet).
- Service plan shall include direct access to OEM call center accessible by FDA Contracting Officer's Representative (COR), Technical Representative (TR) and/or System Operator Personnel for technical assistance which is staffed by technicians/engineers capable of providing high level troubleshooting expertise.
- Service plan shall include OEM technical developments, repair procedure bulletins, and unlimited software, firmware, and application updates.
- Technical support/assistance. (e.g., telephone-based, email-based, website-based, etc.) shall be provided Monday - Friday (excluding Federal Holidays) during normal business hours and shall begin on a solution to the problem within 8 business hours of contact for assistance.
- Deliverables: Service Records and Reports
  The Contractor shall, commensurate with the completion of each service call or preventative maintenance visit, provide the end-user of the equipment and the Contracting Officer with a copy of a field service report/ticket identifying the equipment name, manufacturer, model number, and serial number of the equipment being serviced/repaired and detailing the reason for the service call, a detailed description of the work performed, the test instruments or other equipment used to affect the repair or otherwis

e perform the service, the name(s) and contact information of the technician who performed the repair/service, and for information purposes, the on-site hours expended and parts/components replaced.

Place of Performance:
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
10903 New Hampshire Ave
Silver Spring, MD 20993

Service visits shall not be scheduled during Federal Holidays or Federal Closures as determined by Executive Orders or opm.gov. Federal Holidays are as follows:

New Year's Day
Martin Luther King, Jr.'s Birthday
Washington's Birthday
Memorial Day
Juneteenth
Independence Day
Labor Day
Columbus Day
Veterans Day
Thanksgiving Day
Christmas Day

Contract Type:
Firm-Fixed Price

Contract Clauses:
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/far-overhaul and https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

The clause at 52.212-4, Contract Terms and Conditions - Commercial Products and Commercial Services (Deviation SEP 2025) applies to this solicitation.
The following addenda apply:
52.203-17, Contractor Employee Whistleblower Rights (Nov 2023)
52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)
52.204-13, System for Award Management Maintenance (DEVIATION) (RFO AUG 2025)
52.209-6, Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, Proposed for Debarment, or Voluntarily Excluded (DEVIATION) (RFO NOV 2025
52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (DEVIATION) (RFO NOV 2025
52.219-4, Notice of Price Evaluation preference for HUBZone Small Business Concerns (DEVIATION) (RFO SEP 2025)
52.222-3, Convict Labor (DEVIATION) (RFO SEP 2025)
52.222-35, Equal Opportunity for Veterans (DEVIATION) (RFO SEP 2025)
52.222-36, Equal Opportunity for Workers with Disabilities (DEVIATION) (RFO SEP 2025)
52.222-37, Employment Reports on Veterans (DEVIATION) (RFO SEP 2025)
52.222-50, Combating Trafficking in Persons (DEVIATION) (RFO SEP 2025)

2026)
52.222-90, Addressing DEI Discrimination by Federal Contractors (DEVIATION) (RFO APR 2026)
52.223-23, Sustainable Products and Services (DEVIATION) (RFO SEP 2025)
52.225-3 Alt IV, Buy American-Free Trade Agreements-Israeli Trade Act (Nov 2023) Alternate IV (Oct 2022
52.225-5, Trade Agreements (Nov 2023)
52.226-8, Encouraging Contractor Policies to Ban Text Messaging While Driving (MAY 2024)
52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018)
52.232-36, Payment by Third Party (DEVIATION) (RFO SEP 2025)
52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Mar 2023)
52.233-3, Protest after Award (DEVIATION) (RFO SEP 2025)
52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004)
52.240-91, Security Prohibitions and Exclusions (DEVIATION) (RFO AUG 2025)
52.244-6, Subcontracts for Commercial Products and Commercial Services (DEVIATION) (RFO SEP 2025)

HHSAR Clauses
352.232-71 Electronic Submission of Payment Requests (APR 2026) (RFO DEVIATION)
(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 in FAR 32.905(b), and the applicable Payment clause included in this contract.
(b) Except as provided in paragraph (c) of this clause, the Contractor must 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.
(d) If alternate payment procedures are authorized, the Contractor must include a copy of the Contracting Officer's written authorization with each payment request.

352.239-79 Information [and Communication] Technology Accessibility. [Feb 2024]) [(DEVIATION)]

[(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all information and communication technology (ICT) supplies, products, platforms, information, documentation, and services support developed, acquired, maintained or delivered under this contract or order must comply with the Revised 508 Standards, which are located at 36 C.F.R. 1194.1 and Appendices A, B, and C, and are available at https://www.hhs.gov/web/section-508/index.html.

(b) Additional Section 508 accessibility standards applicable to this contract or order may be identified in the specification, statement of work, or performance work statement. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) In the event of a modification(s) to this contract or order, which adds new ICT supplies or services or revises the type of, or specifications for, supplies, products, platforms, information, documentation, or services support, the Contracting Officer shall require that the Contractor submit a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies or services conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(d) If this is an Indefinite-Delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies, products, platforms, information, documentation, or services support will define the specifications and accessibility standards for the order. In those cases, the Contractor shall be required to provide a completed HHS Section 508 Accessibility Conformance Checklist (see https://www.hhs.gov/web/section-508/accessibility-checklists/index.html) or an ACR (based on the VPAT see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies, products, platforms, information, documentation, or services support conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) The contractor shall identify to the Contracting Officer any perceived exception or exemption to Section 508 requirements.

Supplies and/or services delivered hereunder shall be inspected and accepted at destination by the Governments Contracting Officer Representative (COR) specified at award. If the supplies or services are acceptable, the COR shall promptly forward a report of inspection and acceptance to the paying office. If the supplies or services are not acceptable, the COR shall document the nonconforming items/services and immediately notify the Contracting Officer.

Contract Administration:

The COR as identified on any subsequent Contract in Box 6 a. on Form 347 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 Contracting Officer as identified on any subsequent Contract in Box 23 on Form 347 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 statement of work;

(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.

Payments:
No advance payment will be made under the resulting order/contract.
Payment Terms Net 30 Days After Government Acceptance of Supplies/Services.

INVOICE SUBMISSION
CONTRACTOR SHALL SUBMIT ALL INVOICES AS FOLLOWS:
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.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

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.

Notice Regarding the Use of Macros in Submitted Documents
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.

Solicitation Provisions:
This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. 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. Full text of any provision may be accessed electronically at this/these address(es): https://www.acquisition.gov/far-overhaul and https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html.

FAR Provisions:
52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation (Jan 2017)
52.204-7, System for Award Management—Registration 52.204-7 System for Award Management (DEVIATION) (RFO AUG 2025)
52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products (Feb 2021)
52.225-4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate (DEVIATION) (RFO SEP 2025)
52.240-90, Security Prohibitions and Exclusions Representations and Certifications 52.204-90 Offeror Identification (DEVIATION) (RFO AUG 2025)

HHSAR Provisions:
352.239-78 Information and [Communication] Technology Accessibility Notice (Feb 2024) [(Deviation)]

(a) Any offeror responding to this solicitation must comply with established HHS Information and Communication Technology (ICT) accessibility standards. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html.

(b) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-79 Information and Communication Technology Accessibility. In order to facilitate the Government's determination whether proposed ICT supplies, products, platforms, information, and documentation meet applicable Section 508 accessibility standards, offerors must submit an appropriate HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see https://www.itic.org/policy/accessibility/vpat), in accordance with the completion instructions. The purpose of the checklists and conformance reports are to assist HHS acquisition and program officials in determining whether proposed ICT supplies, products, platforms, information, and documentation conform to applicable Section 508 accessibility standards. Checklists and ACRs

evaluate—in detail—whether the ICT conforms to specific Section 508 accessibility standards and identifies remediation efforts needed to address conformance issues.

(c) If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, *i.e.*, after award of a contract or order, that supplies, products, platforms, information, documentation, or services support delivered do not conform to the described accessibility standards, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(d) In order to facilitate the Government's determination whether proposed ICT supplies meet applicable Section 508 accessibility standards, offerors must submit an Accessibility Conformance Report, in accordance with its completion instructions and tailored to the requirements in the solicitation. The purpose of the Report is to assist HHS acquisition and program officials in determining whether proposed ICT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document, in detail, whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available at https://Section508.gov/.

(e) In order to facilitate the Government's determination whether proposed ICT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the ICT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

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

(g) Items delivered as electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at http://508.hhs.gov/. Materials, other than items incidental to contract management, that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Contracting Officer's Representative.

The provision at FAR 52.212-1 Instructions to Offerors - Commercial Products and Commercial Services (DEVIATION)(RFO Aug 2025) applies to this solicitation. The following addenda apply:

Technical Acceptability - Offerors shall provide sufficient technical information necessary for the government to conclusively determine that the offered service/equipment/product meets all the technical requirements herein, to include descriptive material, literature, brochures and other information corresponding to each minimum technical requirement which demonstrates the capabilities of the offered system.

Price - The price(s) proposed must be detailed and shall represent the offeror's response to the schedule of supplies/services above.

Unique Entity Identifier (UEI):

To be considered for an award the offeror shall be registered and active in SAM (www.sam.gov) by the date and time set forth for receipt of quotes/proposals and shall include their SAM Unique Entity ID (UEI) with the quotation.

The Quoter 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 invoices to be applicable to the requirement
NOTE: Submission of the ACR is required for documentation purposes. In accordance with agency purchasing procedures, solutions which do not conform fully to the applicable 508 standards may still be purchased by FDA if the FDA Requiring Office obtains the appropriate approval. In order to obtain approval, the FDA must have an ACR from the vendor documenting the level of conformance of the items being purchased.

The Government is not responsible for locating or securing any information which is not identified in the quote; however, the Government reserves the right to obtain information for use in the evaluation from any sources including sources outside of the Government. The Government reserves the right to request additional information at any time.

Service Contract Act Exemption
This solicitation is being issued under the premise that the offeror will certify that the service it will propose to fulfill this requirement is exempt from the Service Contract Act per the conditions set forth in FAR 52.222-48 & FAR 22.1002-1(e)(1). If the Contractor certifies that the company is exempt under the terms and conditions of 52.222-48, then clause 52.222-51 will be applicable to the resulting order. In the event that a contractor does not make this certification, the traditional Service Contract Act clauses 52.222-41, and 52.222-43 shall be included in the resulting order award as Wage Determination #:**2015-5121**

52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Certification (DEVIATION) (RFO SEP 2025)
(a) The offeror must check the following certification:
Certification
The offeror □ does □ does not certify that-
(1) The items of equipment to be serviced under this contract are used regularly for other than Government purposes, and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontractor) in substantial quantities to the general public in the course of normal business operations;
(2) The services will be furnished at prices which are, or are based on, established catalog or market prices for the maintenance, calibration, or repair of equipment.
(i) An "established catalog price" is a price included in a catalog, price list, schedule, or other form that is regularly maintained by the manufacturer or the offeror, is either published or otherwise available for inspection by customers, and states prices at which sales currently, or were last, made to a significant number of buyers constituting the general public.

(ii) An "established market price" is a current price, established in the usual course of trade between buyers and sellers free to bargain, which can be substantiated from sources independent of the manufacturer or offeror; and

(3) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract are the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

(b) 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. If the offeror certifies to the conditions in paragraph (a) of this provision, and the Contracting Officer determines in accordance with FAR 22.1002-1(e)(3) that the Service Contract Labor Standards statute-

(1) Will not apply to this offeror, then the Service Contract Labor Standards clause in this solicitation will not be included in any resultant contract to this offeror; or

(2) Will apply to this offeror, then the clause at 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements, in this solicitation will not be included in any resultant contract awarded to this offeror, and the offeror may be provided an opportunity to submit a new offer on that basis.

(c) If the offeror does not certify to the conditions in paragraph (a) of this provision-

(1) The clause in this solicitation at 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements, will not be included in any resultant contract awarded to this offeror; and

(2) The offeror must notify the Contracting Officer as soon as possible, if the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation.

(d) The Contracting Officer may not make an award to the offeror, if the offeror fails to execute the certification in paragraph (a) of this provision or to contact the Contracting Officer as required in paragraph (c) of this provision. (End of provision)

Microsoft Suite Documents Containing Macros:

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of "macros". ***When submitting proposals via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine).*** If the offeror or applicant submits documents that contain macros**,** ***macro referenced files, and/or executable files*****,** the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission, and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offeror's or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

Buy American Act and Executive Order 14005

If applicable, respondent shall provide place (country) of product/service manufacture or performance and any other applicable information to enable review and analysis pertaining to the requirements under the Buy American Act and requirements relating to Executive Order 14005 Ensuring the Future is Made in All of America by All of America's Workers, in the event that a nonavailability waiver request submitted through the Made in America Office (MIAO) Digital

Waiver Portal is required. If the respondent does not provide a response for a line item, or if the respondent's SAM.gov online representation for FAR provision 52.225-4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate, is not completed or is unclear, the Government will presume that the item is made in America.

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

Period of Acceptance of Offers:
The offeror agrees to hold the prices in its quote firm through September 30, 2026.

The provision at 52.212-2 Evaluation—Commercial Products and Commercial Services (DEVIATION) (RFO AUG 2025) is applicable to this solicitation.

The Government intends to award a Firm-Fixed-Price Contract resulting from this Solicitation to the lowest price technically acceptable and responsible offeror. Offers will be evaluated on their ability to meet the requirements provided herein. The lowest priced offer will be evaluated first. If the lowest priced offeror is not technically acceptable, the next lowest priced offer will be evaluated and so on until a technically acceptable offer is determined.

The following subparagraph (a) factors apply:
(i) Technical Acceptability
(ii) Price

Technical Acceptability will be determined by review of information submitted by the offeror who shall provide sufficient descriptive material to demonstrate the proposed meet all requirements and by addressing each technical requirement as stated above for the Government to conclusively determine the proposed will satisfy its requirement.

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).

A written notice of award or acceptance of an offer will be transmitted via email 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 is not responsible for locating or securing any information, which is not identified in the quote and reserves the right to request additional information or conduct discussions at any time.

NOTICE

System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations. Examples include 52.222-25, Affirmative Action Compliance, and paragraph (d) of 52.212-3, Offeror Representations and Certifications — Commercial Products and Commercial Services. Contracting officers will not consider these representations when making award decisions or enforce requirements. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations, including 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation, and paragraph (t) of 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services. Agencies will not consider or use these representations. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

It is the offeror's responsibility to monitor sam.gov for the release of any information related to this acquisition, e.g., questions and answers, amendments, award notice, etc. Offerors that fail to complete the required representations and certifications or reject the terms and conditions of the solicitation may be excluded from consideration.

Respondents are responsible for submitting proposal/quote and any supporting documents before 1:00 PM Central Time - Local Prevailing Time in Jefferson, Arkansas on **08/17/2026**, by e-Mail to howard.nesmith@fda.hhs.gov and must reference solicitation number **75F40126Q133848.**