This is a combined synopsis/solicitation for commercial products or commercial services prepared in accordance with FAR RFO part 12. This announcement constitutes the only solicitation. Offers are being requested and a separate written solicitation will not be issued. The solicitation number is 75F40126Q132585. This solicitation is issued as a Request for Quote (RFQ) for Preventive Maintenance and Repair Service Agreement for Emulate Zoe CM1 and CM2 culture modules.

This acquisition is not set-aside for small business concerns. This solicitation incorporates provisions and clauses by reference. The full text of provisions and clauses may be accessed electronically at https://www.acquisition.gov/far-overhaul.

The associated North American Industry Classification System (NAICS) Code is- 811210 - Electronic and Precision Equipment Repair and Maintenance; the applicable Small Business Size Standard is $34 million. This requirement is solicited as unrestricted full and open competition, any sized business may submit a quote.

Schedule of Items (all shipping and handling shall be included in the price)

Contract Line Item	Description	Quantity	Unit	Unit Price	Extended Price
1	Base Year: On-site Preventative maintenance service for CM2, serial numbers: ZOE-CM2-00237 ZOE-CM2 00235 as specified herein.	12	Months	$_____	$_____
2	Base Period: On-site Preventative maintenance service for CM1 serial numbers: ZOE-CM1 00142 ZOE-CM1-00141	6	Months	$_____	$_____

Statement of Work

Background

The U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), the Division of Applied Regulatory Science (DARS) in OCP/OTS/CDER is conducting a research program to evaluate the utility of a microphysiological system (MPS) in assessing the bronchopulmonary disposition of anti-infective drugs and predicting drug transfer into milk. MPS barrier models, such as lung alveolar and blood-milk barriers, provide a physiologically relevant in vitro platform that integrates key components—epithelial and endothelial cells, along with dynamic fluid flow—to better mimic the cellular microenvironment compared to traditional in vitro models. This research aims to assess the concordance between drug concentration profiles obtained from MPS experiments and clinical studies, offering alternative or complementary approaches to clinical research. Evaluating the lung alveolar model may provide

critical insights into drug penetration into alveolar epithelial lining fluid (ELF) and support regulatory decision-making in drug development. Similarly, assessing the blood-milk barrier model will determine its predictive accuracy by comparing outputs with available clinical data, including the InfantRisk Human Milk Biorepository (HMB), as well as nonclinical data from various studies. The findings from this study may contribute to the broader regulatory science framework by informing model validation, study design, and the integration of advanced in vitro models into nonclinical and clinical development programs. To ensure the continued success of this research program, proper maintenance of the Emulate machinery is essential to maintain data quality, equipment reliability, and operational continuity.

Objectives
The objective of the contract is to obtain a one-year maintenance contract including one-time preventative maintenance service and one year of coverage for Emulate machinery, specifically the Zoe CM1 and CM2 culture modules and related equipment, manufactured -by Emulate, Inc. (Boston, USA). This maintenance will provide the FDA with the necessary technology and resources to support research on MPS barrier models. The system will be used to advance scientific capabilities in evaluating bronchopulmonary drug disposition and predicting drug transfer into milk, consistent with the mission of the Center for Drug Evaluation and Research (CDER). The acquired maintenance for machinery and kits will facilitate studies aimed at assessing the utility of MPS barrier models as alternative or complementary approaches to clinical research, contributing to regulatory science and drug development.

Scope
FDA is seeking maintenance for our existing Emulate machinery, the Zoe CM modules and related equipment. Preventative maintenance, corrective/remedial maintenance repair service agreement on CM1 serial numbers: ZOE-CM1 00142 ZOE-CM1-00141 and CM2, serial numbers: ZOE-CM2-00237 ZOE-CM2 00235

Performance Requirements
-The contractor shall provide one (1) scheduled on-site planned preventive maintenance visit per year per instrument. The consumables required for PM visit shall be included in the contract. All costs for labor, travel, and parts required for preventative maintenance shall be included.
-The contractor shall provide unlimited on-site corrective maintenance and repairs where problems cannot be resolved remotely after 2 business days. All costs for labor, travel, and parts shall be included.
-The maintenance and repair activities shall be performed by the service engineers who are trained and certified by the manufacturer Emulate Inc., and the service provider should follow the Original Equipment Manufacturer (OEM) specifications, manuals, and service bulletins, using OEM-certified replacement parts, components, subassemblies, etc.
-The contractor shall include unlimited software and firmware updates during the entire coverage period(s).
-The contractor shall include unlimited technical support (via phone and email) on software and hardware related issues and trouble-shooting capabilities, Monday through Friday (excluding Federal Holidays).
- Access by the FDA COR and system operator personnel to the manufacturer's call center for technical assistance including software, which is staffed by senior engineers to provide a high level of expertise for troubleshooting the instrument.

-All maintenance and repair pricing must encompass costs for labor, travel, replacement parts, components, subassemblies, and any other necessary expenses related to the system.
- Deliverables: Service Records and Reports: Contractor shall provide a service record report in contractor's standard format after each PM or repair visit.
-Maintenance services must ensure proper functioning of equipment compatible with lung and blood-milk barriers' MPS chips for Emulate's Zoe Culture Module to enable continuous fluidic flow control.
- Maintenance coverage must include all compatible MPS chips and equipment, including: a. Ten Chip-S1 Basic Research Kits (BRK-S1-WER-24) with the Chip-S1 Stretchable Chip and accompanying Pod Portable Module. b. Seven Chip-R1 Basic Research Kits (BRK-R1-WER-24) with the Chip-R1 Non-Stretchable Chip and accompanying Pod Portable Module.
- Maintenance services must ensure proper calibration and functionality of all equipment components, including Steriflip filters and ER-1/ER-2 Chip Activation Reagent systems.
- Contractor shall provide updated technical documentation and step-by-step instructions for the use of Emulate consumable chips as part of maintenance services.
- Maintenance coverage must include equipment used with compound distribution kits for drug absorption studies.
- Contractor shall complete functional QC testing of all equipment during preventative maintenance service to ensure optimal performance and reliability.
The Contractor shall guarantee that all required maintenance services shall be performed to ensure equipment remains in optimal, usable and acceptable condition at the address as shown below.
-Vendor must notify recipient via email with service scheduling information when maintenance is planned.

Other

Government Points of Contact:
Attn: to be identified at time of award
Vendor will contact the Project Lead: to be identified at time of award by phone or email to schedule maintenance service.

Maintenance services must be coordinated with the Project Lead prior to scheduling. No services will be performed without prior authorization from the Project Lead.
Vendor must notify recipient via email with service scheduling information when maintenance is planned.

Government Furnished Equipment (GFE)/ Government Furnished Information (GFI)

- NA

Place of Performance
FDA White Oak Campus
US Food and Drug Administration
10903 New Hampshire Ave, WO 64 Rm 2083
Silver Spring, MD 20993

Period of Performance

Period of Performance:

Zoe-CM 1 7/1/2026 – 12/31/2026
Zoe-CM 2 7/1/2026 – 6/30/2027

Inspection and Acceptance Criteria
The Government will review all reporting requirement deliverables in accordance with specifications and standards identified in the statement of work or any directives issued by the COR. The contractor shall submit the reporting Requirements/Deliverables to the COR in accordance with the delivery schedule. The COR will perform inspection and acceptance of materials and services.

FOB Point Destination. All items shall include shipping and handling to the destination identified herein.

Holidays and Government Closures

Service/Delivery 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	Labor Day
Martin Luther King, Jr.'s Birthday	Columbus Day
Washington's Birthday	Veterans Day
Memorial Day	Thanksgiving Day
Juneteenth Day	Christmas Day
Independence Day	

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

Required:
52.212-4, Contract Terms and Conditions-Commercial Items (Deviation SEP 2025)
Applicable:
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 and 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)
52.222-19, Child Labor-Cooperation with Authorities and Remedies (Deviation) (RFO Sep 2025)
52.222-36, Equal Opportunity for Workers with Disabilities (Deviation) (RFO Sep 2025)
52.222-50, Combating Trafficking in Persons (Deviation) (RFO Sep 2025)
52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (Deviation) (RFO Sep 2025)
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, Buy American-Free Trade Agreements-Israeli Trade Act Alt II (DEVIATION) (RFO NOV 2025)
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)
52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Mar 2023)
52.233-3, Protest After Award (Deviation) (RFO Aug 2025)
52.233-4, Applicable Law for Breach of Contract Claim (Deviation) (RFO Aug 2025)
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)

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):
http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

HHSAR Clause 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) Submission instructions. 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) Alternate submission procedures. The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing.

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

(END OF CLAUSE)

HHSAR Clause 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.access-board.gov/ict/. Information about Section 508 is 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.
(End of clause)]

The supplies and/or services delivered hereunder shall be inspected and accepted at destination by the Contracting Officer's 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

a. Contracting Officer/Contract Administrator
Nick Sartain, Contracting Officer
Phone: 301-796-1988
Email: nick.sartain@fda.hhs.gov

b. COR –
The following COR will represent the Government for the purpose of this contract:
(To be completed at time of award)
Name:
Phone:
Email:

The COR 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 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

Payment terms Net 30 days after government acceptance. No advance payments will be made.

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.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 delivery 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

Contract Type: Commercial Item-Firm Fixed Price.

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/far-overhaul
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 (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 Alt II (DEVIATION) (RFO SEP 2025)

HHSAR Provisions

352.239-73[8] ~~Electronic~~ Information and [Communication] Technology Accessibility Notice (~~Dec 2015~~[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/accessibilitychecklists/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 https://section508.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.

(END OF PROVISION).

The provision at FAR 52.212-1 Instructions to Offerors-Commercial Items (Deviation) (RFO Aug 2025) The following addenda have been added to this provision:

Offerors are afforded the opportunity to inspect the existing instruments and site, at their own expense, prior to the date set for receipt of quotes by contacting the Contract Specialist/Contracting Officer identified herein to schedule an appointment. Failure to inspect the instruments/site will not relieve the successful offeror from fully meeting the requirements of the resulting contract at the price offered.

Technical Capability: Will be determined by review of information submitted by the offeror which must provide sufficient technical information necessary for the Government to conclusively determine that the offered products/services meet or exceed the technical requirements identified above. the vendor shall demonstrate that its proposed technical solution meets or exceeds the stated requirements. The Contractor shall have the technical understanding, skill, resources, and training to make all repairs and provide preventative maintenance and repair services. As part of the proposal the Contractor shall include sufficient technical information necessary for the Government to conclusively determine that the offered services meet or exceed the technical requirements identified above. Provide a written approach to satisfy all of the requirements herein. If not the OEM, provide demonstrated and verifiable prior experience providing the same or near-same repair and support activities for this OEM equipment—to include qualifications of field service engineers/technicians, a verifiable established supply chain with the OEM for specifications, manuals, bulletins, software and firmware updates, parts, components, subassemblies, reach-back technical support, etc. necessary to deliver the services herein. Approach may be supplemented with technical specifications, descriptive material, literature, brochures, publications, etc. which the offeror believes will further demonstrate their technical capability to deliver the required services within the timeframes listed above. Contractor quotes shall include details of the items covered under the service contract, any differing levels of the plan that are available, and the levels of service response that are available. Contractor shall provide estimated historical on-site response time from the initial call for service until a service technician was on-site for the brand name and model of instrument in this solicitation.

Any proprietary information shall be marked as such.

Past Performance: Information shall clearly demonstrate recent (within the last 3 years) and relevant prior experience information for the preventative maintenance, repair and technical support of the same or substantially similar services as that listed herein for the same brand name and model instrument, to include period of performance, description (how is this relevant to current requirement), your role and responsibilities as either prime or subcontractor, dollar value, client name, client address, client point of contact name, client point of contact phone number, and client point of contact email address. Respondents who do not provide a valid email address for the client POC or without a relevant record of past performance or for whom information on current or past performance is not available will not be evaluated favorably or unfavorably. Favorable past performance is considered higher than neutral past performance. The Government reserves the right to look to other sources of information (e.g., the Contractor Performance Assessment Reporting System (CPARS), etc.) to support past performance evaluations.

Price: The price(s) proposed must be detailed and shall represent the quoter's response to the schedule of supplies/services above. Quoters are also encouraged to submit a vendor quote with this document. Offerors 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 proposal however the Government reserves the right to obtain information for use in the evaluation from any and all sources including sources outside of the Government. The Government reserves the right to request additional information from a quoter at any time.

Service Contract Act Exemption

This solicitation is being issued under the premise that the offeror will certify that the combination of equipment maintenance/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 No.: WD 2015-4269 (Rev. 32) dated 5/13/2026 which is located at: https://sam.gov/wage-determination/2015-4269/32.

FAR 52.222-48 Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certifications (MAY 2014).

(a) The offeror shall 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 22.1003-4(c)(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 shall 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.

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

The provision at FAR 52.212-2 Evaluation-Commercial Items (Deviation) (RFO Aug 2025) . The specific evaluation criteria to be included in paragraph (a) of that provision are as follows:

The Government intends to award a contract resulting from this solicitation to the lowest priced technically acceptable responsible quoter/offeror whose quote, conforming to the solicitation, will be most advantageous to the Government, price and other factors considered. Quotes will be evaluated on their ability to meet the requirements provided herein.

Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors shall be used to evaluate offers:

- Technical Capability
- Past Performance
- Price

Technical capability and past performance, when combined, are more important than price. However, if the Government determines non-price factors to be essentially equal among competing offerors price becomes more important as a discriminating factor.

The Government reserves the right to request additional information or conduct discussions 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, price or other issues.

(b) *Options (if applicable)*. 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. The evaluation of options does not obligate the Government to exercise the option(s).

(c) Notice of award. A written notice of award or acceptance of an offer 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's determination of technical acceptability in no way relinquishes the Awardee's contractual obligation to ensure the quoted products meet the FDA's stated need.

Notice to Offerors:

- 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 this solicitation. Contracting officers will rely on representations from offers based on provisions in the solicitation. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM

One or more of the items under this acquisition is subject to Free Trade Agreements.

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.

All responsible sources may submit an offer, which if timely received, shall be considered. The offer must reference solicitation number 75F40126Q132585. The offers are due by email to nick.sartain@fda.hhs.gov on or before June 30, 2026 by 10:00 A.M. (Central Time in Jefferson, Arkansas).

For information regarding this solicitation, please contact Nick Sartain at (301) 796-1988 or email nick.sartain@fda.hhs.gov.