COMBINED SYNOPSIS/SOLICITATION

1. GENERAL INFORMATION

This is a combined synopsis/solicitation for commercial products or commercial services prepared in accordance with part 12. This announcement constitutes the only solicitation. Offers are being requested and a separate written solicitation will not be issued.

Solicitation number 75F40126Q00397 is issued as a Request for Quotation (RFQ) for nineteen (19) new hotplates with stirrers and associated clamping accessories for the FDA New York Human and Animal Food Laboratory (NYHAFL). The equipment will support analysis of regulatory samples using official AOAC, BAM, and EAM methods. All equipment shall be new and unused, meet the minimum requirements in Attachment 1 - Statement of Work, be delivered within thirty (30) calendar days after award, and include a minimum twenty-four (24) month warranty as specified in the Statement of Work.

This acquisition is not set aside for small business concerns.

Set-Aside: None (Unrestricted)

NAICS Code: 334516 - Analytical Laboratory Instrument Manufacturing Small Business Size Standard: 1,000 employees

This solicitation incorporates provisions and clauses by reference. The full text of provisions and clauses may be accessed electronically at: https://acquisition.gov/ | https://acquisition.gov/far-overhaul | https://acquisition.gov/hhsar

All responsible sources may submit a quotation, which will be considered by the agency.

2. DELIVERY AND PERFORMANCE

Place of Delivery / Place of Performance: U.S. Food and Drug Administration, New York Laboratory, 158-15 Liberty Avenue, Jamaica, NY 11433

FOB Point: Destination

Inspection and Acceptance: Inspection and acceptance shall be performed at the delivery location in accordance with the terms of clause 52.212-4.

Period of Performance

Supplies: Delivery Timeframe + Warranty

Delivery shall be completed within thirty (30) calendar days after award. The delivered equipment shall include a minimum twenty-four (24) month warranty beginning on the date of Government acceptance, in accordance with the Statement of Work.

3. CONTRACT LINE ITEMS (CLINs)

CLIN	Description	Qty	Unit	Unit Price	Total Price
0001	Hotplates with stirrers and clamping accessories includes a 24-month warranty	19	EA		

4. POINTS OF CONTACT

Contracting Officer:

Name: Iris Johnson
Email: Iris.Johnson1@fda.hhs.gov
Office: (301) 796-3353

5. CONTRACT CLAUSES

5A. Clauses Incorporated by Reference

Appl.	Clause/Prov. No.	Title	Date
REQ	**52.212-4**	Terms and Conditions—Commercial Products and Commercial Services	Nov 2025
X	**52.204-13**	System for Award Management—Maintenance	Nov 2025
X	**52.204-91**	Contractor Identification	Nov 2025
X	**52.209-10**	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2025
X	**52.222-3**	Convict Labor	Nov 2025
X	**52.222-19**	Child Labor—Cooperation with Authorities and Remedies	Nov 2025
X	**52.222-50**	Combating Trafficking in Persons (or with Alt I)	Nov 2025
REQ	**52.222-90**	Addressing DEI Discrimination by Federal Contractors	Apr 2026
X	**52.232-33**	Payment by Electronic Funds Transfer—System for Award Management	Oct 2018
X	**52.232-40**	Providing Accelerated Payments to Small Business Subcontractors	Mar 2023
X	**52.233-3**	Protest After Award	Nov 2025

Appl.	Clause/Prov. No.	Title	Date
X	**52.233-4**	Applicable Law for Breach of Contract Claim	Nov 2025
X	**52.244-6**	Subcontracts for Commercial Products and Commercial Services	Nov 2025
X	**52.225-1**	Buy American—Supplies (or with Alt I)	Nov 2025
REQ	**HHSAR 352.232-71**	Electronic Submission of Payment Requests	Apr 2026

5B. Clauses Incorporated by Full Text

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://acquisition.gov

https://acquisition.gov/far-overhaul

https://acquisition.gov/hhsar

(End of clause)

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

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm

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

c.

1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal

Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
2. Registration emails are sent via email from ipp.noreply@mail.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.

1. Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
2. Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
3. Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
4. Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
5. Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
6. Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
7. Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(1) list of all invoices submitted to date under the subject award, including the following:
(i.) invoice number, amount, & date submitted
(ii.) corresponding payment amount & date received
(2) total amount of all payments received to date under the subject contract or order
(3) 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.

(End of clause)

6. SPECIFICATIONS

The Contractor shall furnish and deliver nineteen (19) new hotplates with stirrers and clamping accessories in accordance with Attachment 1 - Statement of Work. All items shall meet the minimum technical requirements, delivery requirements, documentation requirements, and warranty requirements stated in the Statement of Work.

A. SOLICITATION PROVISIONS

A1. Provisions Incorporated by Reference

Appl.	Clause/Prov. No.	Title	Date
REQ	**52.204-7**	System for Award Management—Registration	Nov 2025
REQ	**52.212-1**	Instructions to Offerors—Commercial Products and Commercial Services	Nov 2025
X	**52.212-2**	Evaluation—Commercial Products and Commercial Services (if applicable)	Nov 2025
X	**52.225-2**	Buy American Certificate	Oct 2022

Basis for Award

Lowest Price Technically Acceptable (LPTA): Award will be made to the responsible offeror submitting the lowest-priced quotation that is determined technically acceptable. Technical acceptability will be evaluated on a pass/fail basis against the minimum requirements in Attachment 1 - Statement of Work. A quotation that does not meet all minimum requirements will be technically unacceptable. Price will be evaluated for reasonableness.

B. OFFER SUBMISSION

Questions Due: Questions due by Thursday August 27, 2026, 10:30 AM ET.

Quotations Due: Thursday September 03, 2026, 2:30 PM ET.

Submission Method: Email to the Contracting officer Iris Johnson, Iris.Johnson1@fda.hhs.gov.

Preferred File Format: Searchable PDF. Excel may be used for pricing if desired.

Page Limit: N/A.

Quoters Shall Submit:

- Technical quotation identifying the manufacturer and model/part number offered. Manufacturer product literature or a commercial datasheet is sufficient to demonstrate compliance; a separate compliance matrix is not required.
- Firm-fixed unit price and total price for CLIN 0001, including delivery and all required accessories.
- Warranty terms confirming at least twenty-four (24) months of coverage as required by the Statement of Work.
- Unique Entity Identifier (UEI) and confirmation of active SAM.gov registration.

- Delivery lead time confirming delivery within thirty (30) calendar days after award.
- Country of origin for the offered end product(s), as required by the Buy American provisions and clauses included in this RFQ.

Points of Contact

Contracting Officer, Iris Johnson, Iris.Johnson1@fda.hhs.gov.

C. ADDITIONAL INFORMATION

Amendments:

Any amendments to this RFQ will be posted to the FDA eBid Board and/or provided by email to solicited vendor(s), as applicable. Vendors are responsible for reviewing any amendment issued before submitting a quotation.

Attachments (if applicable):

Attachment 1 - Statement of Work: Hotplates with Stirrers and Clamping Accessories.

STATEMENT OF WORK (SOW)

Procurement of a Pulsed Field Ablation (PFA) System for Non-Clinical Research Use

1. Background

The U.S. Food and Drug Administration (FDA) requires a clinical Pulsed Field Ablation (PFA) system for use in a non-clinical research environment. The system will support FDA research activities related to cardiac ablation technologies. The PFA system must be FDA-approved or cleared for clinical use in the United States and capable of operating in a research laboratory setting.

2. Objective

The objective of this acquisition is to obtain a complete, off-the-shelf PFA system that enables FDA researchers to conduct non-clinical research involving cardiac ablation technologies. The system shall include the generator, compatible catheters, required accessories and cables, documentation, training, warranty coverage, and technical support necessary for safe and effective operation.

3. Scope

The Contractor shall furnish and deliver one (1) complete PFA system, including a PFA generator, five (5) compatible clinical PFA catheters, and all accessories, cables, connectors, software, licenses, and other components required for the system to operate in the Government's non-clinical research environment. The Contractor shall also provide product documentation, training, warranty coverage, and technical support as specified in this SOW.

The Contractor shall identify in its quotation any external equipment, third-party hardware, software, subscriptions, licenses, disposables, or facility requirements that are necessary for full operation but are not included in the quoted price.

4. Minimum Technical Requirements

4.1 Regulatory Compliance

4.1.1 The proposed PFA system shall be FDA-approved or cleared for clinical use in the United States for the treatment of atrial fibrillation or other cardiac arrhythmias.

4.1.2 The Contractor shall provide, with its quotation, documentary evidence of the applicable FDA authorization, including the PMA approval number, 510(k) clearance number, De Novo classification number, or other applicable FDA authorization number.

4.1.3 The Contractor shall provide the current product labeling and Instructions for Use associated with the proposed system.

4.2 Equipment Condition and Commercial Availability

4.2.1 The PFA generator and all durable system components shall be new, unused, current production equipment unless otherwise authorized in writing by the Contracting Officer.

4.2.2 The system shall be an off-the-shelf commercial product that is readily available for delivery within the required delivery period stated in the contract.

4.2.3 The Contractor shall identify the manufacturer, system name, model number, and configuration of the proposed equipment in its quotation.

4.3 PFA Generator

4.3.1 The PFA generator shall produce a bipolar, biphasic pulsed electric field waveform suitable for cardiac ablation research.

4.3.2 The Contractor shall state in its quotation whether the user can alter pulse parameters from the standard manufacturer waveform. The response shall identify each user-adjustable parameter and the available adjustment range, when applicable.

4.3.3 The PFA generator shall be compatible with standard building main power of 115-120 volts, 60 hertz, single phase.

4.3.4 The PFA generator may be cart-mounted or tabletop in form factor.

4.3.5 The Contractor shall identify any required environmental, electrical, ventilation, network, or space requirements in its quotation.

4.4 Catheters

4.4.1 The Contractor shall provide five (5) unused clinical PFA catheters that are compatible with the proposed PFA generator. All five (5) catheters shall be the same model and configuration.

4.4.2 Expired catheters are acceptable solely for non-clinical research use, provided all five (5) catheters are the same model/configuration and each catheter is unused, unopened, in intact original packaging, free from recall, and clearly identified as not intended for clinical use.

4.4.3 The Contractor shall confirm in its quotation that compatible catheters are commercially available for separate purchase after award and shall identify the applicable catheter model number(s).

4.5 Accessories, Cables, Software, and Components

4.5.1 The Contractor shall provide all accessories and cables necessary to operate the PFA system in a non-clinical research environment, including power cables, interface cables, connectors, adapters, and other required components.

4.5.2 The Contractor shall provide a complete component list with its quotation and again at delivery. The list shall identify each included item by manufacturer, model or part number, quantity, and purpose.

4.5.3 The Contractor shall identify any clinical deployment sheaths or other procedure-specific accessories that are not required for operation in the Government's non-clinical research environment.

4.5.4 The Contractor shall identify all software, licenses, subscriptions, and software-enabled components associated with the proposed system and shall clearly distinguish those that are required for operation in the Government’s non-clinical research environment from those that are optional or intended primarily for clinical use. Any software or license required for the system to perform the Government’s research requirements shall be included in the quoted configuration and price.

For each required software license, the Contractor shall identify whether the license is perpetual, term-based, subscription-based, or otherwise restricted. If both perpetual and term/subscription licensing options are commercially available, the Contractor shall provide separate pricing for each option to allow the Government to determine the most appropriate configuration based on technical need and available funding.

The Contractor shall identify any software, licenses, or components that are not required for the Government’s intended non-clinical research use and shall price such items separately, if offered.

4.6 Non-Clinical Research Compatibility

4.6.1 The proposed system shall be suitable for use in a non-clinical research environment.

4.6.2 The Contractor shall describe in its quotation any configuration changes, software settings, accessories, interfaces, or other modifications necessary to enable non-clinical research use. Any required modification shall be included in the quoted price unless specifically identified as Government-furnished.

4.7 Clinical Safety Profile

4.7.1 The proposed PFA system shall have a documented hemolysis-related safety profile suitable for Government evaluation.

4.7.2 The Contractor shall provide, with its quotation, a discussion of the hemolysis-related history and safety profile of the proposed PFA system, catheter, and waveform configuration. The response should include any available peer-reviewed literature, clinical data, manufacturer test data, post-market information, or other relevant supporting documentation. The information will be used to support the Government's determination of technical acceptability.

5. Documentation Requirements

The Contractor shall provide the following documentation in electronic format at the time of delivery, unless an earlier submission is specified:

- Current Instructions for Use (IFU), operator manuals, setup instructions, and safety information.
- A complete packing list and component inventory identifying all delivered items.
- Applicable FDA approval or clearance documentation.
- Manufacturer warranty documentation and technical-support contact information.
- Software and licensing documentation, when applicable.
- Recommended preventive maintenance, cleaning, storage, calibration, and troubleshooting instructions.
- Any documentation required to safely operate the system in a non-clinical research environment.

6. Delivery, Setup, and Scheduling

6.1 Delivery Location: 10903 New Hampshire Avenue, Silver Spring, MD 20993.

6.2 Required Delivery: 30 days after receipt of order.

6.3 Delivery shall be FOB Destination unless otherwise stated in the resulting contract. The Contractor shall be responsible for all packing, shipping, transportation, insurance, and delivery costs.

6.4 The Contractor shall coordinate the delivery date and time with the Government Technical Point of Contact at least five (5) business days before delivery. The Contractor shall not deliver equipment without receiving scheduling confirmation from the Government.

6.5 The Contractor shall provide all components, cords, cables, catheters, and accessories necessary for normal system operation. The Contractor shall provide setup and startup assistance, as needed, during the required training session. Any assembly, connection, configuration, or manufacturer-standard startup verification necessary for initial operation shall be demonstrated or completed as part of the training.

6.6 The Contractor shall remove all packing materials and debris generated by delivery and setup unless the Government requests that specific packaging be retained.

7. Inspection and Acceptance

7.1 Inspection and acceptance will be performed by the Government at the delivery location identified in the contract.

7.2 The Government will inspect the delivered items to verify that:

- The manufacturer, model, configuration, quantities, and condition conform to the contract.
- The generator, catheters, accessories, cables, connectors, software, and documentation have been delivered.
- The system powers on and completes the manufacturer-standard startup or self-test, when applicable.
- The delivered catheters are compatible with the proposed generator and meet the packaging and condition requirements of this SOW.
- Required setup and configuration have been completed, when applicable.
- No visible shipping damage, missing components, or material defects are present.

7.3 Government acceptance will occur after the Government verifies that the system and all required deliverables conform to the contract. Acceptance does not waive latent defects, warranty rights, or other contractual remedies.

7.4 Acceptance Testing. Following delivery and initial setup, the Contractor shall perform functional testing of the PFA system to demonstrate that the device operates as intended and in accordance with the manufacturer's specifications. Functional testing shall include, at a minimum, verification that the system powers on, successfully completes applicable startup and self-diagnostic checks, recognizes and communicates with required components and accessories, and performs the basic operational functions necessary for the Government's intended non-clinical research use. Any deficiencies identified during functional testing shall be corrected before Government acceptance.

8. Training

8.1 The Contractor shall provide a minimum of one (1) instructor-led training session, conducted either in person or virtually, to educate FDA users on system setup and operation.

8.2 Training shall cover, at a minimum, system components, setup, startup and shutdown, catheter connection, standard operation, safety precautions, routine troubleshooting, cleaning, storage, and available technical-support procedures.

8.3 The Contractor shall provide electronic training materials to the Government.

8.4 Training shall be completed within fifteen (15) business days after delivery and prior to Government acceptance, unless the parties agree to another date in writing. Training may be conducted either in person or virtually. The Government will identify the number of attendees after delivery and prior to scheduling the training session. The Contractor shall accommodate the Government's identified attendees within the scope of the required training at no additional cost. The Government anticipates approximately four (4) to five (5) attendees; however, the final number will be determined after delivery.

9. Warranty and Technical Support

9.1 The Contractor shall provide the manufacturer's standard commercial warranty for the PFA generator and all durable components. The warranty period shall be no less than twelve (12) months beginning on the date of Government acceptance.

9.2 Warranty coverage shall include troubleshooting and repair or replacement of defective components in accordance with the manufacturer's standard warranty terms. The Contractor shall provide the warranty terms with its quotation.

9.3 The Contractor shall provide technical support by telephone and email during the warranty period. The Contractor shall identify support hours, contact methods, response times, escalation procedures, and the availability of on-site support in its quotation.

9.4 The Contractor shall describe the availability and terms of technical support, maintenance, repairs, software updates, and replacement parts after expiration of the warranty. Post-warranty support is not included unless separately ordered by the Government.

10. Contractor Responsibilities

- Provide all personnel, equipment, materials, transportation, tools, and supervision necessary to satisfy this SOW.
- Coordinate delivery, setup/startup, functional testing, training, and support activities with the authorized Government POC.
- Ensure personnel performing on-site work comply with applicable FDA facility access, safety, and security requirements.
- Promptly notify the Contracting Officer and Government Technical POC of any actual or anticipated delay, missing component, discontinued item, recall, safety notice, or other issue that may affect performance.
- Do not substitute equipment, catheters, components, or configurations without prior written authorization from the Contracting Officer.

11. Government Responsibilities

- Provide access to the designated delivery and setup location during approved hours.
- Provide standard building electrical power meeting the requirement stated in this SOW.
- Coordinate facility access and identify applicable receiving, safety, and security procedures.
- Inspect delivered items and provide acceptance or identify nonconforming items within a reasonable period.
- Make appropriate personnel available for scheduled training.

12. Government Points of Contact

The Government will identify the following points of contact in the resulting solicitation or contract:

Role	Name	Email	Telephone
Contracting Officer	Iris Johnson	Iris.Johnson1@FDA.hhs.gov	(301) 796-3353
Contracting Officer's Representative (COR)	Will be given at the time of award.		

12.1 The Contracting Officer is the only individual authorized to modify the contract, change the scope or price, authorize substitutions, waive requirements, or otherwise bind the Government.

12.2 The Contracting Officer's Representative or Technical POC may provide technical direction and coordinate performance within the existing scope but may not change contractual terms, authorize additional work, or obligate Government funds.

12.3 The Contractor shall immediately notify the Contracting Officer if it believes any Government communication constitutes a change to the contract or requires work outside the existing scope.

13. Government Operating Hours and Closures

13.1 Normal Facility Hours. Monday – Friday 6:30 am – 3:00 pm ET.

13.2 Unless specifically authorized in writing, the Contractor shall not schedule delivery, setup/startup, functional testing, training, or other on-site activity on Saturdays, Sundays, Federal holidays, or days when the FDA facility is closed.

13.3 Government closure days may include Federal holidays, weather-related closures, emergency closures, building closures, or other administrative closures announced by the Government.

13.4 When a closure prevents a previously scheduled delivery, setup/startup, functional testing, training, or service activity, the Contractor shall coordinate with the Government POC to reschedule the activity at no additional cost to the Government.

13.5 A Government closure does not, by itself, authorize an increase in contract price or an extension of the delivery schedule. Any adjustment to the contract must be approved in writing by the Contracting Officer.

13.6 The Contractor shall verify facility status with the Government POC before dispatching personnel or equipment when severe weather, emergency conditions, or other potential closures may affect access.

14. Changes, Deviations, and Substitutions

The Contractor shall not deviate from the requirements of this SOW or provide substitute equipment, catheters, components, software, or services without prior written approval from the Contracting Officer. Proposed deviations or substitutions shall be submitted in writing and shall describe the reason for the request, the effect on performance, compatibility, regulatory status, delivery, warranty, and price.

15. Final Requirement

This SOW establishes the Government's minimum requirements for the procurement of a PFA system for FDA non-clinical research use. The Contractor shall provide a complete and fully functional system that conforms to all requirements of the resulting contract.