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. Quotes are being requested and a separate written solicitation will not be issued. The solicitation number is 75F40126Q133126. This solicitation is issued as a Request for Quote (RFQ) for an IDIQ for the purchase of consumables (multi-well plates) for use in Axion Biosystems Multielectrode Array (MEA) Systems.

This requirement is for an Indefinite Delivery, Indefinite Quantity (IDIQ) that will consist of a Base year ordering period plus four (4) 1-year ordering periods.

This acquisition is 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 334516 – Analytical Laboratory Instrument Manufacturing; the applicable Small Business Size Standard is 1,000 employees.

SCHEDULE OF ITEMS

Note: all shipping and handling shall be included in the price. Quantities listed are for evaluation purposes only and may not be the actual quantities needed during the period.

Base Ordering Period:

Line Item	Description	QTY	Unit	Unit Price	Extended Price
1	Cytoview Multielectrode Array 96-well BLACK plate, Product #: M768-tMEA-96B	1	EA	$ _____	$ _____
2	Cytoview Multielectrode Array 96-well WHITE plate, Product #: M768-tMEA-96W	10	EA	$ _____	$ _____
3	Cytoview Multielectrode Array 48-well BLACK plate, Product #: M768-tMEA-48B	1	EA	$ _____	$ _____
4	Cytoview Multielectrode Array 48-well WHITE plate, Product #: M768-tMEA-48W	5	EA	$ _____	$ _____
5	Lumos Multielectrode Array 48-well plate, Product #: M768-tMEA-48OPT	5	EA	$ _____	$ _____
6	Cytoview Multielectrode Array 12-well WHITE plate. Product #: M768-tMEA-12W	1	EA	$ _____	$ _____
7	Cytoview Multielectrode Array24-well WHITE plate, Product #: M384-tMEA-24W	1	EA	$ _____	$ _____
8	Lumos Multielectrode Array 24-well plate, Product #: M384-tMEA-24OPT	1	EA	$ _____	$ _____
9	Cytoview Multielectrode Array 6-well BLACK plate, Product #: M384-tMEA-6B	1	EA	$ _____	$ _____
10	Cytoview Multielectrode Array 6-well WHITE plate, Product #: M384-tMEA-6W	1	EA	$ _____	$ _____

Line Item	Description	QTY	Unit	Unit Price	Extended Price
Total Evaluated Price for Base Ordering Period (Items 1-10)				**$ _____**	

Ordering Period 1:

Line Item	Description	QTY	Unit	Unit Price	Extended Price
1	Cytoview Multielectrode Array 96-well BLACK plate, Product #: M768-tMEA-96B	1	EA	$ _____	$ _____
2	Cytoview Multielectrode Array 96-well WHITE plate, Product #: M768-tMEA-96W	10	EA	$ _____	$ _____
3	Cytoview Multielectrode Array 48-well BLACK plate, Product #: M768-tMEA-48B	1	EA	$ _____	$ _____
4	Cytoview Multielectrode Array 48-well WHITE plate, Product #: M768-tMEA-48W	5	EA	$ _____	$ _____
5	Lumos Multielectrode Array 48-well plate, Product #: M768-tMEA-48OPT	5	EA	$ _____	$ _____
6	Cytoview Multielectrode Array 12-well WHITE plate. Product #: M768-tMEA-12W	1	EA	$ _____	$ _____
7	Cytoview Multielectrode Array24-well WHITE plate, Product #: M384-tMEA-24W	1	EA	$ _____	$ _____
8	Lumos Multielectrode Array 24-well plate, Product #: M384-tMEA-24OPT	1	EA	$ _____	$ _____
9	Cytoview Multielectrode Array 6-well BLACK plate, Product #: M384-tMEA-6B	1	EA	$ _____	$ _____
10	Cytoview Multielectrode Array 6-well WHITE plate, Product #: M384-tMEA-6W	1	EA	$ _____	$ _____
Total Evaluated Price for ordering period 1 (Items 1-10)				**$ _____**	

Ordering Period 2:

Line Item	Description	QTY	Unit	Unit Price	Extended Price
1	Cytoview Multielectrode Array 96-well BLACK plate, Product #: M768-tMEA-96B	1	EA	$ _____	$ _____
2	Cytoview Multielectrode Array 96-well WHITE plate, Product #: M768-tMEA-96W	10	EA	$ _____	$ _____
3	Cytoview Multielectrode Array 48-well BLACK plate, Product #: M768-tMEA-48B	1	EA	$ _____	$ _____
4	Cytoview Multielectrode Array 48-well WHITE plate, Product #: M768-tMEA-48W	5	EA	$ _____	$ _____
5	Lumos Multielectrode Array 48-well plate, Product #: M768-tMEA-48OPT	5	EA	$ _____	$ _____

Line Item	Description	QTY	Unit	Unit Price	Extended Price
6	Cytoview Multielectrode Array 12-well WHITE plate. Product #: M768-tMEA-12W	1	EA	$ _____	$ _____
7	Cytoview Multielectrode Array24-well WHITE plate, Product #: M384-tMEA-24W	1	EA	$ _____	$ _____
8	Lumos Multielectrode Array 24-well plate, Product #: M384-tMEA-24OPT	1	EA	$ _____	$ _____
9	Cytoview Multielectrode Array 6-well BLACK plate, Product #: M384-tMEA-6B	1	EA	$ _____	$ _____
10	Cytoview Multielectrode Array 6-well WHITE plate, Product #: M384-tMEA-6W	1	EA	$ _____	$ _____
Total Evaluated Price for ordering period 2 (Items 1-10)				**$ _____**	

Ordering Period 3:

Line Item	Description	QTY	Unit	Unit Price	Extended Price
1	Cytoview Multielectrode Array 96-well BLACK plate, Product #: M768-tMEA-96B	1	EA	$ _____	$ _____
2	Cytoview Multielectrode Array 96-well WHITE plate, Product #: M768-tMEA-96W	10	EA	$ _____	$ _____
3	Cytoview Multielectrode Array 48-well BLACK plate, Product #: M768-tMEA-48B	1	EA	$ _____	$ _____
4	Cytoview Multielectrode Array 48-well WHITE plate, Product #: M768-tMEA-48W	5	EA	$ _____	$ _____
5	Lumos Multielectrode Array 48-well plate, Product #: M768-tMEA-48OPT	5	EA	$ _____	$ _____
6	Cytoview Multielectrode Array 12-well WHITE plate. Product #: M768-tMEA-12W	1	EA	$ _____	$ _____
7	Cytoview Multielectrode Array24-well WHITE plate, Product #: M384-tMEA-24W	1	EA	$ _____	$ _____
8	Lumos Multielectrode Array 24-well plate, Product #: M384-tMEA-24OPT	1	EA	$ _____	$ _____
9	Cytoview Multielectrode Array 6-well BLACK plate, Product #: M384-tMEA-6B	1	EA	$ _____	$ _____
10	Cytoview Multielectrode Array 6-well WHITE plate, Product #: M384-tMEA-6W	1	EA	$ _____	$ _____
Total Evaluated Price for ordering period 3 (Items 1-10)				**$ _____**	

Ordering Period 4:

Line Item	Description	QTY	Unit	Unit Price	Extended Price
1	Cytoview Multielectrode Array 96-well BLACK plate, Product #: M768-tMEA-96B	1	EA	$ _____	$ _____
2	Cytoview Multielectrode Array 96-well WHITE plate, Product #: M768-tMEA-96W	10	EA	$ _____	$ _____
3	Cytoview Multielectrode Array 48-well BLACK plate, Product #: M768-tMEA-48B	1	EA	$ _____	$ _____
4	Cytoview Multielectrode Array 48-well WHITE plate, Product #: M768-tMEA-48W	5	EA	$ _____	$ _____
5	Lumos Multielectrode Array 48-well plate, Product #: M768-tMEA-48OPT	5	EA	$ _____	$ _____
6	Cytoview Multielectrode Array 12-well WHITE plate. Product #: M768-tMEA-12W	1	EA	$ _____	$ _____
7	Cytoview Multielectrode Array24-well WHITE plate, Product #: M384-tMEA-24W	1	EA	$ _____	$ _____
8	Lumos Multielectrode Array 24-well plate, Product #: M384-tMEA-24OPT	1	EA	$ _____	$ _____
9	Cytoview Multielectrode Array 6-well BLACK plate, Product #: M384-tMEA-6B	1	EA	$ _____	$ _____
10	Cytoview Multielectrode Array 6-well WHITE plate, Product #: M384-tMEA-6W	1	EA	$ _____	$ _____
Total Evaluated Price for ordering period 4 (Items 1-10)				**$ _____**	

STATEMENT OF WORK

Background

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), Division of Applied Regulatory Science (DARS) is conducting an ongoing research program to evaluate the usefulness of Multielectrode Array (MEA) Systems. This requirement is for the procurement of specialized consumables (multi-well plates) for use in these existing laboratory MEA Systems.

MEA technology combined with human induced pluripotent stem (hiPSC) cells have been identified as a potential alternative to traditional in-vitro models. High throughput MEA systems consist of both hardware and software for recording and analyzing electrical signals of excitable cells. MEA plates are designed to maintain cells in a controlled microenvironment to better recapitulate the in-vivo physiological environment compared to traditional cell culture methods. The MEA platform is used across multiple program areas, and the experiments conducted generate critical regulatory science research data to support drug safety and efficacy assessments.

Objective

The objective of this contract is to secure a 5-year Indefinite Delivery, Indefinite Quantity (IDIQ) vehicle for the purchase of consumables (multi-well plates) for use in the agency's Multielectrode Array (MEA) Systems to support microphysiological studies in hiPSC cells. These plates will provide the FDA with the required technology needed for ongoing laboratory experiments across multiple FDA Centers and enable scientific capabilities consistent with the mission of the Center for Drug Evaluation and Research (CDER). Other FDA Centers may order from this IDIQ provided approval by the primary Contract COR.

Scope

This requirement is for the purchase of various multi-well (12, 48, and/or 96-well) plates, with a minimum technical threshold of 700 electrodes per plate, compatible with the agency's existing MEA recording platform. The period of performance is five (5) one-year ordering periods.

Technical Requirements:

- The components and/or products shall be newly manufactured, not used, refurbished, or previously used for demonstration.
- Each plate shall have real-time well-by-well review of raw signals from each electrode simultaneously and real-time plate-wide feedback on electrophysiological activity, as well as High signal quality - ability to adjust analog and digital filters.
- Each plate shall also have temperature and electrical stimulation control, automatic search and identification of cardiac T-wave capabilities, automatic search and identification of neural network burst capabilities, and automatic calculation beat-by-beat measurements, as well as electrode and well averages for field potentials.
- Plates shall have the capability to measure parameters including: field potential duration, beat period, conduction velocity, and depolarization, spike amplitude, slope, beat amplitude, and excitation-contraction delay, viability, mean firing rate, burst duration, burst frequency, network durst duration, network burst frequency
- Plates shall have the capability to pace with electrical stimulation.

Product List Refresh Clause:

At any time and throughout the life of this IDIQ, at the request of either the Contractor or the Government, the Contractor may propose additional pricing for additional plates or as the technology refresh of existing plates may become available. Any additional products will be negotiated on a case-by-case basis and, upon determination by the Government that they are necessary for performance and are both fair and reasonable, can be issued in the order. The new category may be incorporated by modification into the Schedule of Items Pricing Table of any resulting contract.

IDIQ ORDERING LIMITS (MINIMUM & MAXIMUM)

Contract Guaranteed Minimum: The contract guaranteed minimum will be $10,000. Funding for this minimum guarantee will be obligated against the base IDIQ contract award. If the contractor is

issued a delivery order from the IDIQ, then the delivery order amount will be reduced by the minimum guarantee obligated on the IDIQ contract.

Contract Maximum (Ceiling): The contract maximum of all orders issued over five (5) year ordering periods and awarded under this contract is estimated not to exceed $349,000.00, including any shipping costs, though this ceiling can be increased via mutual agreement of the parties. The estimated maximum anticipated under this contract is not intended to imply that it is an estimate of the total products that will be required. The maximum amount in no way guarantees that the volume of purchases through this IDIQ will be higher or lower than the said estimate over the term of the IDIQ.

PERIOD(S) OF PERFORMANCE AND DELIVERY TERMS

The period of performance for this IDIQ contract shall consist of five (5), one-year ordering periods estimated to be:

Base Year Ordering Period:	08/15/2026 – 08/14/2027
Ordering Period 1:	08/15/2027 – 08/14/2028
Ordering Period 2:	08/15/2028 – 08/14/2029
Ordering Period 3:	08/15/2029 – 08/14/2030
Ordering Period 4:	08/15/2030 – 08/14/2031

Delivery Terms

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

Delivery. Within 30 days after receipt of an order, deliveries shall be made to the Center for Drug Evaluation and Research (CDER) at the following address:

US FDA/CDER
10903 New Hampshire Ave
WO 64 Room 2014
Silver Spring MD 20993

Other addresses may require delivery and will be identified if needed on each individual order.

POC: *will be appointed and contact information will be given upon contract award.*

Holidays and Government Closures

Deliveries 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
Birthday of Martin Luther King, Jr.	Columbus Day
Washington's Birthday	Veterans Day
Memorial Day	Thanksgiving Day
Juneteenth National Independence Day	Christmas Day
Independence Day	

Government Furnished Property (Equipment and/or Information)

No government-furnished property, equipment or government-furnished information will be provided in the scope of this acquisition.

ORDERING PROCEDURES

Ordering under this contract shall be accomplished by the issuance of written Delivery Orders. The only individual authorized to process Delivery Orders for the FDA is an Office of Acquisitions & Grants Services (OAGS) Contracting Officer.

All Delivery Orders issued hereunder are subject to the terms and conditions of this contract. This contract shall control in the event of conflict with any Delivery Orders. The general process for individual Delivery Orders is as follows:

a. The FDA will prepare a Statement of Need (SON), which will include, at a minimum, the following elements:
    1. Description of products required and quantity.
    2. Delivery location.
    3. Delivery schedule and Performance Period. (Each Delivery Order may have multiple shipment dates.)
    4. Anything else necessary for the Delivery Order.

b. The FDA will confirm pricing with the contractor.

c. The Contractor shall prepare and submit a price quote, if needed, addressing all areas of the requirement. The Contractor shall submit the Delivery Order quote within the time period specified in the request and adhere to the product ceiling rates established in the IDIQ. Other direct costs such as shipping shall be clearly identified, explained, and substantiated. No separate payment will be made to the contractor for the cost to prepare, submit and/or negotiate a Delivery Order quote. The Government will evaluate Delivery Order quotes as specified in the notice.

d. The FDA Contracting Officer placing the Delivery Order shall issue either an OF347, SF1449 or other designated form to the Contractor.

e. Delivery Order delivery dates may extend beyond the five (5) year ordering period provided the Delivery Order was issued prior to the ordering period expiration. Delivery Order delivery dates may extend up to and not longer than one (1) year after the end of the ordering period, and product prices shall remain at the last ordering period rates.

    Delivery Orders issued against this contract vehicle will be a Firm-Fixed-Price (FFP).

f. Specific delivery details will be provided in the delivery order, such as the delivery address, point of contact information, the plates required and delivery schedule and any specific local delivery requirements for security or loading dock delivery requirements. Changes to the delivery schedule may occur after issuance of the Delivery Order at the request of the FDA as long as adequate notice (minimum of two (2) weeks) is given to the

contractor and as long as the changes are within the period of performance of the Delivery Order. Any changes that fall outside the period of performance of the Delivery Order will require the Contracting Officer to modify the Delivery Order. No one other than the Contracting Officer is authorized to change the terms and conditions of the Delivery Order.

Each Order resulting from the IDIQ shall be funded at the time the Order is placed; Orders will be placed based on funds availability and the needs of the Federal Government.

Delivery orders may be issued up to the final day of this contract inclusive of any extensions thereto, and the contract shall remain in force to allow for the completion of all Delivery orders issued.

Contract Type: Commercial Item-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

FAR Clauses

Required
52.212-4, Contract Terms and Conditions-Commercial Items (DEVIATION)(RFO Nov 2025)

Applicable
52.203-6, Restrictions on Subcontractor Sales to the Government (Jun 2020) Alternate I (Nov 2021)
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 Nov 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 Nov 2025)
52.219-6 Notice of Total Small Business Set-Aside (DEVIATION) (RFO Nov 2025)
52.222-3, Convict Labor (DEVIATION)(RFO Nov 2025)
52.222-19, Child Labor—Cooperation with Authorities and Remedies (DEVIATION)(RFO Nov 2025)
52.222-35, Equal Opportunity for Veterans (DEVIATION)(RFO Nov 2025)
52.222-36, Equal Opportunity for Workers with Disabilities (DEVIATION)(RFO Nov 2025)
52.222-37, Employment Reports on Veterans (DEVIATION)(RFO Nov 2025)
52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEVIATION) (RFO Nov 2025)
52.222-50, Combating Trafficking in Persons (DEVIATION)(RFO Nov 2025)

52.222-90 Addressing DEI Discrimination by Federal Contractors (DEVIATION)(RFO Apr 2026)
52.223-23, Sustainable Products (DEVIATION)(RFO Nov 2025)
52.225-1, Buy American-Supplies (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 Nov 2025)
52.233-4, Applicable Law for Breach of Contract Claim (DEVIATION)(RFO Nov 2025)
52.240-91, Security Prohibitions and Exclusions (DEVIATION)(RFO Nov 2025)
52.244-6, Subcontracts for Commercial Products and Commercial Services (DEVIATION)(RFO Nov 2025)

Other applicable clauses:
52.216-18 Ordering (Aug 2020)
(a) " … from effective date of contract award through and including the last date of the contract including any extensions thereto."

52.216-19 Order Limitations (Oct 1995)
(a) "…$2,500.00 per Delivery Order, …"
(b) (1) "… in excess of $100,000.00;"
(b) (2) "… in excess of $200,000.00;"
(b) (3) "… within five (5) calendar days…"
(d) "… within five (5) calendar days…"

52.216-22 Indefinite Quantity (Deviation) (RFO Sep 2025)
(d) "…after three (3) years from date of contract expiration."

HHSAR Clauses

352.232-71 Electronic Submission of Payment Requests (RFO DEVIATION) (Apr 2026)

(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)

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.

(End of Clause)

CONTRACT ADMINISTRATION/INSPECTION/PAYMENT TERMS

Contracting Officer

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

The contact information for the Contracting Officer is:
Name: Suzanne Martella / **Email:** suzanne.martella@fda.hhs.gov/**Phone:** (301) 796-2383

Contracting Officer's Representative (COR)

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 following COR will represent the Government for this contract *(the information below will be provided upon contract award):*
Name: / Email: / Phone:

Inspection and Acceptance

The supplies and/or services delivered hereunder shall be inspected and accepted at destination by the 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.

Payment Terms. *Net 30 days after government acceptance of a proper invoice which shall only be submitted after shipment(s) have been delivered and customer is in receipt and has accepted the goods at the destination point. In accordance with the "Advance Payment Statute" at 31 U.S.C § 3324:* ***Advance payments shall not 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.

SPECIAL NOTICES & REQUIREMENTS

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.

Designation of Task Order/Delivery Order Ombudsman

In accordance with FAR 16.505(b)(5) and HHSAR 316.505(b)(5), the Director, Office of Acquisitions and Grants Services, has been designated as the FDA Ombudsman for Task Order and Delivery Order contracts:

Leonard Grant
Three White Flint North
11601 Landsdown Street
Rockville MD 20852
Phone: 240-402-7584
Email: Leonard.Grant@fda.hhs.gov

(End of Clause)

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. 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

52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (SEP 2024)
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 Nov 2025)
52.222-18 Certification Regarding Knowledge of Child Labor for Listed End Products (FEB 2021)
52.229-11 Tax on Certain Foreign Procurements—Notice and Representation (DEVIATION) (RFO Nov 2025)

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.

Full Text Provisions

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

Quoters shall provide sufficient technical information necessary for the government to conclusively determine that the offered service/equipment 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. 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.

Technical Acceptability 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 meet or exceed the technical requirements identified above. Proposed products may be supplemented with technical specifications, descriptive material, literature, brochures, publications, etc. which the offeror believes will further demonstrate their technical product capabilities. Any proprietary information shall be marked as such. The Government's determination of technical acceptability in no way relinquishes the Awardee's contractual obligation to ensure that the system meets the FDA's stated needs.

To be considered for award, quotes of "equal" products, including "equal" products of the sole source manufacturer shall meet the salient physical, functional, or performance characteristic specified in this solicitation; clearly identify the item by brand name, if any; and make or model number. "Equal" quotes shall include a narrative describing how the offer meets each salient characteristic as well as a demonstration of how each salient characteristic is fully met.

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, it is anticipated the 508 requirement will only be applicable to invoices and service records/reports.

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.

Letters of Supply (if applicable)
Quoters who are ***authorized resellers*** of an item, and not the manufacturer, shall provide a copy of their letter of supply or other documentation substantiating their relationship as an authorized reseller of the proposed manufacturer's product. The documentation shall be on the Original Equipment Manufacturer (OEM) letterhead and include contact information for the individual who has signed the letter.

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

Quoters shall complete the Schedule of Items by entering, for each item, the manufacturer/distributor information, Product ID number if available, unit price and total price for Ordering Periods 1 through

5. The Schedule of Items shall serve as the offeror's price quote for evaluation purposes, although quoters are encouraged to also submit a vendor quote with this document.

Include the firm's Unique Entity ID (UEI) number with quote. Proprietary and/or confidential information shall be clearly marked.

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

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

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.

Note that one or more of the items under this acquisition is subject to the Buy American Provision.

Refer to RFO FAR Provision 52.225-2, Buy American Certificate below for fill-in information.

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.

The provision at 52.212-2 Evaluation-Commercial Items (DEVIATION)(RFO Nov 2025) is applicable to this solicitation.

The following subparagraph (a) factors apply:

(a) 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. The lowest priced quote will be evaluated first. If the lowest priced quote is not technically acceptable, the next lowest priced quote will be evaluated and so on until a technically acceptable quote is determined.

Technical acceptability will be determined by review of information submitted by the quoter which must provide sufficient technical information necessary for the Government to conclusively determine that the quoted products meet or exceed the technical requirements identified herein. 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.

(b) Options. This requirement is for an Indefinite Delivery, Indefinite Quantity (IDIQ) contract utilizing fixed Ordering Periods. Evaluation of pricing will be conducted across the established ordering schedule.

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

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

52.225-2 Buy American Certificate (Oct 2022)
(a)
(1) The Offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product and that each domestic end product listed in paragraph (c) of this provision contains a critical component.
(2) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products. For those foreign end products that do not consist wholly or predominantly of iron or steel or a combination of both, the Offeror shall also indicate whether these foreign end products exceed 55 percent domestic content, except for those that are COTS items. If the percentage of the domestic content is unknown, select "no".
(3) The Offeror shall separately list the line item numbers of domestic end products that contain a critical component (see FAR 25.105).
(4) The terms "commercially available off-the-shelf (COTS) item," "critical component," "domestic end product," "end product," and "foreign end product" are defined in the clause of this solicitation entitled "Buy American-Supplies."
(b) Foreign End Products:

Line Item No.	Country of origin	Exceeds 55% domestic content (yes/no)
_____	_____	_____
_____	_____	_____

_____ _____ _____

(b)[*List as necessary*]
(c) Domestic end products containing a critical component:
Line Item No. ___
[*List as necessary*]
(d) The Government will evaluate offers in accordance with the policies and procedures of part 25 of the Federal Acquisition Regulation.
(End of provision)

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 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)

All responsible sources may submit a quote, which if timely received, shall be considered. The quote must reference solicitation number 75F40126Q133126. Quotes are due by email only to Suzanne Martella at suzanne.martella@fda.hhs.gov on or before **July 16, 2026, 10:30 AM Central Time**