COMBINED SYNOPSIS/SOLICITATION

1. INTRODUCTION

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 **75F40126Q00201** is issued as a/an [☒ RFQ ☐ RFP ☐ IFB] for This requirement is for the purchase of an Automated Media Preparation Instrument for Dissolution Testing. This requirement will be acquired using a Firm-Fixed-Price (FFP) contract for the supply, delivery, installation, operator training, and warranty support of one (1) Automated Media Preparation Instrument for Dissolution Testing. Delivery and installation shall occur at the FDA Irvine Medical Products Laboratory (IRVLMP), Irvine, California, or other FDA-designated location identified at time of award.

This acquisition ☐ is / ☒ 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://acquisition.gov/ | https://acquisition.gov/far-overhaul | https://acquisition.gov/hhsar

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

NAICS Code: 334516 **Small Business Size Standard:** 1,000

Set-Aside: ☒ None ☐ Total Small Business ☐ WOSB ☐ SDVOSB ☐ 8(a) ☐ HUBZone ☐ Other: [specify]

2. DESCRIPTION OF REQUIREMENTS

This requirement is being conducted as a brand-name-or-equal acquisition using the Distek ezFill+ Dissolution Media Preparation Instrument as the reference standard for required performance characteristics.

Distek ezFill+ Dissolution Media Preparation instrument is referenced to describe the required performance capabilities. Systems of equal capability that meet all required characteristics will be considered.

SALIENT CHARACTERISTICS

- The instrument shall be capable of delivering a minimum volume of 250ml and a maximum volume of at least 1000ml.
- The instrument shall have a dispensing accuracy of ±5mL or less.
- The instrument shall be equipped with in-line heating that is capable of heating dissolution media to at least 45°C.
- The instrument shall have a temperature accuracy of ±2°C or better.
- The instrument shall be capable of degassing media up to a maximum of 3.0ppm.

- The instrument shall be compatible with media containing up to a maximum of 2% surfactants.
- The instrument shall have an onboard controller and user interface to select stored programs and set parameters for manual use.
- The instrument shall be capable of storing programmed methods and running in automatic or manual mode when preparing dissolution media.
- The instrument shall be capable of storing dispensing reports that include the volume and temperature dispensed.
- The instrument shall be portable with a cart or other mechanism, included, to allow the instrument to be moved to each dissolution instrument for use.
- The instrument shall be equipped with a dispensing nozzle that allows for dissolution vessels to be filled in place, while on the dissolution apparatus.
- Electrical requirement must be compatible with a standard US outlet, 115V, 50 or 60 Hz.

3. LINE ITEMS

CLIN	Description	Qty	Unit	Unit Price	Total Price
0001	Automated Media Preparation Instrument for Dissolution Testing. Manufacturer's warranty of equipment, parts and operational services	1	EA		
0002	Installation, and instrument qualification	1	EA		
0003	Training	1	EA		
0004	Qualification Documentation/ Service Report	1	EA		

4. DELIVERY AND PERFORMANCE

Place of Delivery / Place of Performance:

FDA/IRVLMP
19701 Fairchild
Irvine, CA 92612

FOB Point: ☒ Destination ☐ Origin

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

The contractor will complete installation on site. Prior to final acceptance, the vendor will demonstrate upon installation that the item meets all performance specifications by the manufacturer using supplied controls. Additionally, a verification run will be conducted to assess data generation capability and data quality using prepared research samples.

The technical point of contact will inspect instrument upon delivery, confirm the installation is satisfactory, and the instrument is acceptable for use.

Inspection and acceptance shall be performed by the Government Technical Point of Contact (TPOC) and/or Contracting Officer's Representative (COR) within five (5) business days after delivery, installation, successful operational demonstration, verification run, and completion of required end-user training.

Final Government acceptance shall occur only after confirmation that the system is fully operational and acceptable for intended use.

Government acceptance is required prior to final payment.

Acceptance shall be based on successful completion of all deliverables, including installation, operational demonstration, verification testing, and training.

Period of Performance

Supplies: Delivery Timeframe + Warranty

Delivery shall be completed within 60 days of award. The warranty shall include manufacturer-supported parts, labor, and technical support for a minimum of one (1) year from the date of Government acceptance. Delivery will be accepted during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM local Time

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
REQ	**52.203-17**	Contractor Employee Whistleblower Rights	Nov 2023
REQ	**52.203-19**	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
REQ	**52.204-13**	System for Award Management—Maintenance	Nov 2025
REQ	**52.204-91**	Contractor Identification	Nov 2025
REQ	**52.209-6**	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	Nov 2025
REQ	**52.209-10**	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2025
REQ	**52.222-3**	Convict Labor	Nov 2025

Appl.	Clause/Prov. No.	Title	Date
REQ	**52.222-19**	Child Labor—Cooperation with Authorities and Remedies	Nov 2025
REQ	**52.222-40**	Notification of Employee Rights Under the National Labor Relations Act	Nov 2025
REQ	**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
REQ	**52.223-23**	Sustainable Products and Services	Nov 2025
REQ	**52.232-33**	Payment by Electronic Funds Transfer—System for Award Management	Oct 2018
REQ	**52.232-40**	Providing Accelerated Payments to Small Business Subcontractors	Mar 2023
REQ	**52.233-3**	Protest After Award	Nov 2025
REQ	**52.233-4**	Applicable Law for Breach of Contract Claim	Nov 2025
REQ	**52.240-91**	Security Prohibitions and Exclusions (or with Alt I)	Nov 2025
REQ	**52.240-93**	Basic Safeguarding of Covered Contractor Information Systems	Nov 2025
REQ	**52.244-6**	Subcontracts for Commercial Products and Commercial Services	Nov 2025
REQ	**52.225-1**	Buy American—Supplies (or with Alt I)	Nov 2025
REQ	**HHSAR 352.232-71**	Electronic Submission of Payment Requests	Feb 2022

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. 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.

e. 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.

f. 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.

g. 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.

h. 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.

i. 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. SOLICITATION PROVISIONS

6A. 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
REQ	**52.212-2**	Evaluation—Commercial Products and Commercial Services (if applicable)	Nov 2025
REQ	**52.203-18**	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements—Representation	Jan 2017
REQ	**52.209-12**	Certification Regarding Tax Matters	Oct 2025
REQ	**52.222-18**	Certification Regarding Knowledge of Child Labor for Listed End Products	Nov 2025
REQ	**52.225-2**	Buy American Certificate	Oct 2022
REQ	**52.225-20**	Prohibition on Conducting Restricted Business Operations in Sudan—Certification	Nov 2025
REQ	**52.225-25**	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications	Nov 2025
REQ	**52.240-90**	Security Prohibitions and Exclusions—Representations and Certifications	Nov 2025

Basis for Award

Lowest Price Technically Acceptable (LPTA): Award will be made to the lowest-priced offeror whose offer is determined technically acceptable. Technical acceptability will be determined on a pass/fail basis against the salient characteristics and minimum requirements of the requirement. Offers that do not meet all salient characteristics will be determined technically unacceptable and will not be considered for award. Price will be evaluated for reasonableness.

6B. Addenda to 52.212-1

Offer Acceptance Period (if applicable):

Paragraph (b) of the provision is hereby amended to extend the period for acceptance of offers from 60 calendar days to 90 calendar days from the date specified for receipt of offers.

7. OFFER SUBMISSION AND POINTS OF CONTACT

Questions Due: Questions regarding this solicitation shall be submitted in writing to the Primary POC identified in the SAM.gov notice **Hard Date:** June 8, 2026, 12:00pm, EST TIME ZONE. Questions and answers may be posted as an amendment to this solicitation on SAM.gov.

Offers Due: As listed on the SAM.gov notice.

Submission Method: ☒ Email ☐ SAM.gov upload ☐ Other: [specify]

Preferred File Format: Searchable PDF and Excel

Page Limit (if applicable: N/A

Offerors Shall Submit:

- Technical quotation
- Price quotation
- Warranty terms (if applicable)
- UEI and confirmation of active SAM.gov registration
- Documentation demonstrating compliance with all salient characteristics
- Country of origin for all items [required if Buy American (52.225-1) or Trade Agreements (52.225-5) clause applies.

Points of Contact

As listed on the SAM.gov notice.

8. ADDITIONAL INFORMATION

Amendments:

Any amendments to this solicitation will be posted to SAM.gov. It is the offeror's responsibility to monitor SAM.gov for any amendments.

HHS/FDA-Specific Invoicing Instructions:

Invoices must be submitted electronically through IPP. See clause in Section 5B for full requirements.