FDA Flu Vaccine Immunization Program

75F40126Q00257

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CONTINUATION OF SOLICITATION FOR COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

1. SUPPLIES OR SERVICES AND PRICES/COSTS

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 **75F40126Q00257** is issued as a request for quotation (RFQ) for FDA Flu Vaccine Immunization Program.

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

The North American Industry Classification System (NAICS) code is 325412 (Pharmaceutical Preparation Manufacturing). The product service code (PSC) is 6505 (Drugs and Biologicals).

The following is a list of line-item number(s) and items, quantities, and units of measure:

Firm-Fixed-Price Type Purchase Order				
Period	**Deliverable**	**Quantity**	**Unit Price**	**Total**
Base Year	FLUAD TIV 0.5mL Prefilled Syringe (65yrs+)	20		
	Flucelvax TIV 0.5mL Prefilled Syringe	200		
GRAND TOTAL (ALL YEARS)				

2. DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

The following is a description of requirements for the items to be acquired.

2.1. Scope

The Food and Drug Administration (FDA) is responsible for enforcing the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws that safeguard public health. As part of its commitment to employee health and regulatory compliance, the FDA's Occupational Health Services (OHS) delivers a comprehensive, work-related medical program. This program includes critical services such as immunizations. The annual influenza vaccination effort supports FDA's workforce health initiatives and aligns with CDC recommendations for influenza prevention.

As a direct result of Contract performance, the FDA expects to purchase and deliver seasonal influenza vaccine doses to FDA Occupational Health Units (OHUs) at the White Oak Campus in Silver Spring, MD, and the Jefferson Laboratories Campus in Jefferson, AR.

2.2. Description of Requirements

The Contractor Shall:

- Procure and deliver 2,200 units of seasonal influenza vaccine that meet the following specifications:
  - Vaccines must be FDA-approved and recommended for the 2026–2027 influenza season.
  - All doses shall be provided in single-dose pre-filled syringes.
  - Vaccines shall be shipped, stored, and handled in compliance with CDC cold chain requirements.
  - Each unit's packaging shall clearly indicate the manufacturer, National Drug Code (NDC) number, lot number, and expiration date.
- The total order shall consist of:
  - 2,000 units formulated for adults under 65 years of age.
  - 200 units formulated for adults 65 years of age and older.
- The following services are excluded from this Order:
  - On-site storage or refrigeration,
  - Inventory or tracking systems,
  - Clinical staffing or administrative services,
  - Logistical planning or coordination, and
  - Recordkeeping or documentation support.

3. PACKAGING AND MARKING

Vaccines shall be shipped, stored, and handled in compliance with CDC cold chain requirements. Each unit's packaging shall clearly indicate the manufacturer, National Drug Code (NDC) number, lot number, and expiration date.

4. INSPECTION AND ACCEPTANCE

The Contractor shall provide proof of shipment (e.g., tracking, packing slip). Upon receipt, shipments will be inspected for quantity, condition, adherence to cold chain compliance, and accuracy of lot documentation. Non-conforming deliveries may be rejected at the Contractor's expense.

5. DELIVERIES OR PERFORMANCE

The Contractor shall deliver 2,200 units of seasonal influenza vaccine on or before September 1, 2026, as follows:

- FDA White Oak Campus:
  - Quantity: 2,000 units.
  - Includes 1,920 units for adults under 65 years of age and 80 units for adults 65 years and older.
  - Address: 10903 New Hampshire Ave., Building 2, Room 1037, Silver Spring, MD 20993.

- FDA Jefferson Laboratories Campus:
  - Quantity: 200 units.
  - Includes 180 units for adults under 65 years of age 20 units for adults 65 years and older
  - Address: 3900 NCTR Road, Jefferson, AR 72079.

5.1. Period of Performance

Seasonal influenza vaccine is required to be delivered on or before September 1, 2026.

Ther anticipated period of performance for this order is:

Base Year: July 20, 2026, through September 2, 2026

5.2. Place of Performance

N/A.

5.3. Method of Delivery

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.

6. CONTRACT ADMINISTRATION DATA

6.1. Government Points of Contact

The name, address, and contact information for the contracting officer is provided below.

6.1.1. CONTRACTING OFFICER

Maeve Xavier
Maeve.Xavier@fda.hhs.gov
11601 Landsdown St, 13C65
North Bethesda, MD 20852

Only Contracting Officers have authority to enter into, administer, or terminate contracts and make related determinations and findings. Only Contracting Officers acting within the scope of their authority are empowered to execute contract modifications on behalf of the Government. Contracting Officers may designate and authorize, in writing and in accordance with agency procedures, a Contracting Officer's Representative.

6.1.2. CONTRACT SPECIALIST

Amanda Edger
Amanda.Edger@fda.hhs.gov

6.1.3. CONTRACTING OFFICER'S REPRESENTATIVE

To be determined at award

The Contracting Officer's Representative has no authority to make any commitments or changes that affect price, quality, quantity, delivery, or other terms and conditions of the contract nor in any way direct the contractor or its subcontractors to operate in conflict with the contract terms and conditions. The Contracting Officer's Representative shall be designated in writing, with copies furnished to the contractor and the contract administration office: specifying the extent of the Contracting Officer's Representative's authority to act on behalf of the contracting officer; identifying the limitations on the Contracting Officer's Representative's authority; specifying the period covered by the designation; stating the authority is not redelegable; and stating that the Contracting Officer's Representative may be personally liable for unauthorized acts.

The Contracting Officer's Representative may be changed at any time by the Government without prior notice to the Contractor by a unilateral modification that is signed only by the Contracting Officer in accordance with FAR 43.103(b).

6.2. Purchase Order Type

This is anticipated to be a Firm-Fixed-Price type Purchase Order.

6.3. Invoicing

The Contractor shall comply with FAR 52.212-4, Contract Terms and Conditions—Commercial Products and Commercial Services, with regard to Firm-Fixed-Price tasks/deliverables. The Contractor may submit invoices for one or more individual quantities of a deliverable after the successful delivery and acceptance of that individual quantity, not to exceed the individual unit Firm-Fixed-Price of each deliverable and not to exceed the total Firm-Fixed-Price of each period of performance.

Note: The Contractor shall only invoice for the actual number of parking spots, new key fobs, and replacement key fobs actually required and provided throughout the period of performance.

The Contractor shall include the payment address, if it is different from that shown for the Contractor.

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (JAN 2022)

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

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

c.

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

SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.

2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

3. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

4. If your company is already registered to use IPP, you will not be required to re-register.

5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

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

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

(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted

(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying

that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

6.4. Availability of Funds

The Government's obligation for performance of this contract is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise for performance under this contract until funds are made available to the Contracting Officer for performance and until the Contractor receives notice of availability, to be confirmed in writing by the Contracting Officer.

6.5. Government Property

Government-furnished property is not anticipated.

Independently, and not as an agent of the Government, the Contractor shall furnish the necessary services, personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform this contract.

7. SPECIAL CONTRACT REQUIREMENTS

None.

CONTRACT CLAUSES

8. CONTRACT CLAUSES

The following is a list of contract clauses that apply to the acquisition.

8.1. Federal Acquisition Regulation (FAR) Clauses

FAR 52.217-6 Option for Increased Quantity (MAR 1989)
The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor *any time before the contract expires*. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.
(End of clause)

FAR 52.217-8 Option to Extend Services (NOV 1999)
The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor *any time prior to the expiration date of the contract*.
(End of clause)

FAR 52.217-9 Option to Extend the Term of the Contract (MAR 2000)
(a) The Government may extend the term of this contract by written notice to the Contractor *any time prior to the expiration date of the* contract; provided that the Government gives the Contractor a preliminary written notice of its intent to extend *any time* before the contract expires. The preliminary notice does not commit the Government to an extension.
(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed *the identified period of performance, inclusive of any options if exercised*.
(End of clause)

FAR 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://www.acquisition.gov/far-overhaul

Clause	Title	Date
52.203-6	Restrictions on Subcontractor Sales to the Government--Alternate I	NOV 2021
52.204-13	System for Award Management Maintenance	OCT 2018
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	JAN 2025
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	NOV 2015
52.212-4	Contract Terms and Conditions—Commercial Products and Commercial Services	NOV 2023

Clause	Title	Date
52.219-8	Utilization of Small Business Concerns	JAN 2025
52.222-3	Convict Labor	JUN 2003
52.222-35	Equal Opportunity for Veterans	JUN 2020
52.222-36	Equal Opportunity for Workers with Disabilities	JUN 2020
52.222-37	Employment Reports on Veterans	JUN 2020
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	OCT 2025
52.222-53	Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements	MAY 2014
52.222-54	Employment Eligibility Verification	JAN 2025
52.222-90	Addressing DEI Discrimination by Federal Contractors	JAN 2022
52.223-23	Sustainable Products	MAY 2024
52.226-8	Encouraging Contractor Policies to Ban Text Messaging While Driving	MAY 2024
52.229-12	Tax on Certain Foreign Procurements	FEB 2021
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	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.240-91	Security Prohibitions and Exclusions	DEC 2025
52.244-6	Subcontracts for Commercial Products and Commercial Services	OCT 2025

(End of clause)

8.2. Health and Human Services Acquisition Regulation (HHSAR) Clauses Incorporated in Full Text

The full text of a Health and Human Services Acquisition Regulation (HHSAR) clause may be accessed electronically at this/these address(es): https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html.

HHSAR 352.232-71 Electronic submission of payment requests (FEB 2022)

(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 identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at *www.ipp.gov* or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

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

(End of clause)

8.3. Health and Human Services Acquisition Regulation (HHSAR) Clauses Incorporated by Reference

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/hhsar

Clause	Title	Date
352.203-70	Anti-Lobbying	DEC 2015
352.208-70	Printing and Duplication	FEB 2026 (RFO DEVIATION)
352.211-3	Paperwork Reduction Act	NOV 2025 (RFO DEVIATION)

CONTRACT DOCUMENTS, EXHIBITS OR ATTACHMENTS

9. LIST OF ATTACHMENTS

9.1. Class Deviations (Incorporated by Reference)

This Purchase Order incorporates one or more active Federal Acquisition Regulation (FAR) and Health and Human Services Acquisition Regulation (HHSAR) class deviations 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 class deviation may be accessed electronically at this/these address(es): FAR (https://www.acquisition.gov/caac-letters and https://www.acquisition.gov/far-overhaul/far-part-deviation-guide); HHSAR (https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/index.html and https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/hhsar-overhaul/index.html)

Class Deviation #	Class Deviation Title
HHSAR CD 2026-08	Revolutionary FAR Overhaul; Deviation to HHSAR Part 314
HHSAR CD 2026-07	Revolutionary FAR Overhaul; Deviation to HHSAR Part 332 and Applicable Portions of 302 & 352
HHSAR CD 2026-06	Revolutionary FAR Overhaul; Deviation to HHSAR Part 370& Applicable Portions of 352
HHSAR CD 2026-05	Revolutionary FAR Overhaul; Deviation to HHSAR Part 316 & Applicable Portions of 352
HHSAR CD 2026-04	Revolutionary FAR Overhaul; Deviation to HHSAR Part 313
HHSAR CD 2026-03	Revolutionary FAR Overhaul; Deviation to HHSAR Part 312
HHSAR CD 2026-02 Amend. #1	HHSAR Class Deviation 2026-02-Revolutionary FAR Overhaul; Deviation to HHSAR Parts 307, 308, 331, 335, 336 and 352 - AMENDMENT 1
HHSAR CD 2026-01	Revolutionary FAR Overhaul; Deviation to HHSAR Parts 306, 311, and 352
HHSAR CD 2025-03	Revolutionary FAR Overhaul; Deviation to HHSAR Parts 301, 310, and 334
HHSAR CD 2025-02	Updates to HHSAR Parts 309, 322, 323, 337, and 352
HHSAR CD 2025-01	Supply Chain Risk Assessments
HHSAR CD 2024-01 Amend. #1	Part 339, Acquisition of Information Technology; Other Parts; Supply Chain Risk Management – AMENDMENT 1
HHSAR CD 2023-02	Implementation of the Make Personal Protective Equipment (PPE) in America Act Requirements
HHSR CD 2023-01	Part 339, Acquisition of Information Technology; Standards for Health Information Technology
FAR CD 2026-01 Amend. #2	RFO Deviation to FAR Parts 13, 14, 15, 16, 19, 22, 23, 25, 32, 37, 41, 42, 47, 53, and Applicable Portions of 52
FAR CD 2025-12	RFO Deviation to FAR Parts 3, 17, 27, 45, and Applicable Portions of 52
FAR CD 2025-11	RFO Deviation to FAR Parts 7, 24, 28, 30, 44, 48, and Applicable Portions of 52
FAR CD 2025-10 Amend. #1	Executive Order (EO) 14275, “Restoring Common Sense to Federal Procurement;” Deviation to FAR Parts 9, 33, 46, 49 and Applicable Portions of 52
FAR CD 2025-09 Amend. #2	RFO Deviation to FAR Parts 4, 8, 12, 38, 40, 51, and Applicable Portions of 52
FAR CD 2025-08	RFO Deviation to FAR Parts 5, 26, and Applicable Portions of 52
FAR CD 2025-07	RFO Deviation to FAR Parts 35, 36, 50, and Applicable Portions of 52
FAR CD 2025-06	RFO Parts 29, 31, and Applicable Portions of 52
FAR CD 2025-05	RFO Deviation to FAR Parts 6, 11, 18, 39, 43 and Applicable Portions of 52

Class Deviation #	Class Deviation Title
FAR CD 2025-04 Amend. #1	RFO Parts 10 and 52
FAR CD 2025-03	RFO Parts 1, 34, and 52
FAR CD 2025-02 Amend. #1	Section 2 of the Executive Order (EO) 14148, “Initial Rescissions of Harmful Executive Orders and Actions,” which revoked EO 14057 and Section 2 of EO 14208, “Ending Procurement and Forced Use of Paper Straws."
FAR CD 2025-01 Amend. #1	Executive Order (EO) 14173 and EO. 14168
FAR CD 2022-01	Requirements for Nonavailability Determinations Under the Buy American Act
FAR CD 2020-04	Eliminate Hard Copy Original Documents, Signatures, Notarization, Seal on Bonds and Other Seals for Certain Contract Requirements

9.2. Pricing Worksheet

SOLICITATION PROVISIONS

10. REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS OR RESPONDENTS

The following is a list of solicitation provisions that apply to the acquisition.

10.1. Federal Acquisition Regulation (FAR) Provisions

FAR 52.212-2 Evaluation—Commercial Products and Commercial Services (NOV 2021)

(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors shall be used to evaluate offers: *The significant evaluation factors and the relative order of importance of the evaluation factors are provided in the Evaluation Factors for Award section below.*

Technical and past performance, when combined, are: *The relative importance of all other evaluation factors, when combined, when compared to price, is provided in the Evaluation Factors for Award section below.*

(b) *Options*. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

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

FAR 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)

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

Provision	Title	Date
52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions	SEP 2024
52.204-7	System for Award Management	NOV 2024
52.212-1	Instructions to Offerors—Commercial Products and Commercial Services	SEP 2023
52.217-5	Evaluation of Options	JUL 1990
52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns	OCT 2022
52.222-52	Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Certification	MAY 2014
52.229-11	Tax on Certain Foreign Procurements—Notice and Representation	JUN 2020

Provision	Title	Date
52.240-90	Security Prohibitions and Exclusions Representations and Certifications	DEC 2025

(End of provision)

11. INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS OR RESPONDENTS

The following are the date, time, and place for receipt of offer and point of contact. All responsible sources may submit a quotation, which will be considered by the agency. In order to be eligible for award, an Offeror must meet the qualification requirements described below.

Responses shall be submitted electronically via email to Amanda Edger at Amanda.Edger@fda.hhs.gov **by 10:00AM (Eastern) on Monday, July 6, 2026**. The subject line shall read: "75F40126Q00257- FDA Flu Vaccine Immunization Program." Late submissions may not be evaluated. Fax submissions are not authorized. By responding to the solicitation, the Offerors acknowledges validity through September 30, 2026.

Questions/clarifications regarding this requirement shall be submitted via email to Amanda Edger at Amanda.Edger@fda.hhs.gov **by 10:00AM (Eastern) on Monday, June 22, 2026**. FDA may not answer questions received after this date and time and may not answer questions submitted to individuals other than the named contacts. Questions submitted by another means may not be answered, including phone calls. It is the Offeror's responsibility to confirm receipt of all quotations and/or questions by the closing date of this announcement by contacting the above Contract Specialist.

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of "macros". When submitting responses 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.

All proposed contractor personnel are subject to the security requirements delineated in the FDA Security Article entitled, Contractor Personnel Security Clearance Standards and Residency Requirements, dated October 2017, as found in this solicitation. This includes the requirement pursuant to Homeland Security Presidential Directive-12 (HSPD-12), that proposed personnel must have resided in the U.S. for a total of at least three (3) of the past five (5) years. All Offerors must inquire with all proposed personnel to ensure each individual meets such residency requirements prior to submittal of any key personnel, management or staffing plans in response to this solicitation. Thus, any proposal submitted in response to this solicitation will constitute an implied certification that all such residency requirements have been met. Offerors are hereby notified that noncompliance with the subject FDA Security Article may detrimentally impact eligibility for award, and remain grounds for cancellation, equitable adjustment, or termination after award.

All text in the quote shall be single-spaced, and each paragraph shall be separated by at least one (1) blank line. The Offeror is encouraged to use Calibri 11-point font. However, a font of equivalent size may be used.

Tables and illustrations may use a reduced font size not less than 9-point and may be landscape. The Offeror shall use the following page setup parameters: Page size – 8.5" x 11", Margins (top, bottom, left and right) – 1", Gutter – 0", From edge (header and footer) – 0.5".

The FDA is not responsible for any costs incurred in preparing the documents described in this RFQ. Offeror employees responsible for preparing material that may be proprietary information must mark each page that the Offeror believes contains proprietary information with the legend "Proprietary Information."

A complete quote shall consist of two (2) separate volumes:

- Volume I, Technical Quote: limited to 25 pages, not including cover pages, table of contents, dividers, glossaries, or bibliographies.
- Volume II, Business/Price Quote: no page limitation, with Pricing Worksheet (Attachment 2)

The Technical Quotation and Business/Price Quotation must be kept separate from each other. Kept separate is defined as not including any cost/price information in the Technical Quotation. The Technical Quotation must not make reference to pricing data in order that the technical evaluation may be made strictly on the basis of technical merit. For submission purposes, it is acceptable for the Technical Quotation and Business/Price Quotation to be submitted in the same email (along with the other required attachments); however, each attachment must be clearly marked to which Volume it belongs to.

The Offeror must ensure all evidence of meeting the criteria for each factor is submitted within the quote section corresponding with that factor. The Technical Quote must be tailored to ensure that all information reflects a one-to-one relationship to the evaluation criteria. Simple statements of compliance without the detailed description of how compliance will be accomplished will not be considered sufficient evidence that the Offeror can meet the technical requirements. Any assumptions forming the basis of the submittal must be clearly identified in the Offeror's quote.

The Government reserves the right to evaluate only the information provided by the Offeror within each section response in formulating the Government evaluation for the corresponding factor. The Government reserves the right to make an award decision without conducting post-solicitation communications with Offerors. The Government reserves the right to evaluate only the lowest priced quote(s) until technical acceptability has been met. Final issuance of award depends on the availability of funding. The Government reserves the right to conduct a price realism analysis. The Government reserves the right to negotiate any changes to line-item contract types after competition, through mutual agreement of the Government and the Contractor, based on the labor categories and rates proposed and awarded in response to this solicitation.

A complete response shall consist of the following:

11.1. TECHNICAL QUOTE INSTRUCTIONS

The Offeror shall provide sufficient information for the Government to determine the Offeror's technical acceptability, which includes the following Technical Factors:

11.1.1. TECHNICAL FACTOR 1: QUANTITY

The Offeror shall procure and deliver a total of 2,200 units of seasonal influenza vaccine, consisting of 2,000 units formulated for adults under 65 years of age and 200 units formulated for adults 65 years of age and older.

11.1.2. TECHNICAL FACTOR 2: REGULATORY APPROVAL

The Offeror shall specify that all vaccine units are FDA-approved and recommended for the 2026–2027 influenza season in accordance with applicable federal regulatory standards.

11.1.3. TECHNICAL FACTOR 3: PACKAGING

The Offeror shall confirm that all 2,200 doses will be provided in single-dose pre-filled syringes; no multi-dose vial formats will be accepted. Each unit's packaging must clearly display the following information: manufacturer name, National Drug Code (NDC) number, lot number, and expiration date.

11.2. VOLUME II – BUSINESS/PRICE QUOTE INSTRUCTIONS

The Offeror shall complete the Pricing Worksheet (Attachment 1). The Offeror shall propose Firm-Fixed-Pricing, including any fees and charges. Any charges after award shall not be accepted. Include any pricing notes or assumptions not described elsewhere in the quotation.

12. EVALUATION FACTORS FOR AWARD

The following is a description of the procedures for awarding the Purchase Order.

The Government intends to issue a Firm-Fixed-Price type Purchase Order as a result of this solicitation to the responsible Offeror whose quote, conforming to the solicitation, represents the best value to the Government. Best value will be obtained using a lowest Price Technically Acceptable (LPTA) source selection process, which does not permit tradeoffs and allows the Government to award on the basis of the lowest evaluated price of responses meeting or exceeding the acceptability standards for non-cost factors. The following Technical Factors that establish the requirements of acceptability are stated below:

- Technical Factor 1: Quantity
- Technical Factor 2: Regulatory Approval
- Technical Factor 3: Packaging

The Offeror must demonstrate that it meets the requirements of all Technical Factors in order to be considered technically acceptable.

12.1. VOLUME I – TECHNICAL QUOTE EVALUATION CRITERIA

The Government will evaluate the Offeror to determine whether the Offeror meets the requirements of all the following Technical Factors.

12.1.1. TECHNICAL FACTOR 1: QUANTITY

The Government will evaluate whether the Offeror can deliver a total of 2,200 units of seasonal influenza vaccine, consisting of 2,000 units formulated for adults under 65 years of age and 200 units formulated for adults 65 years of age and older.

12.1.2. TECHNICAL FACTOR 2: REGULATORY APPROVAL

The Government will evaluate whether the Offeror provided confirmation that all vaccine units are FDA-approved and recommended for the 2026–2027 influenza season in accordance with applicable federal regulatory standards.

12.1.3. TECHNICAL FACTOR 3: PACKAGING

The Government will evaluate whether the Offeror is capable of providing confirmation that all 2,200 doses will be provided in single-dose pre-filled syringes; no multi-dose vial formats will be accepted.

12.2. VOLUME II – BUSINESS/PRICE QUOTE EVALUATION CRITERIA

The Government will evaluate the Offeror's business/price volume to ensure that it is complete and accurate and fully aligns with the technical volume; that the proposed unit prices and quantities are reasonable and in line with the solicitation; that any assumptions as listed are appropriate and do not provide any concerns to the Government; and that the price is considered fair and reasonable.