Review of Infant Formula Nutrient Requirements

75F40126R00060

TABLE OF CONTENTS

Continuation of Solicitation for Commercial Products and Commercial Services 3

1. Supplies or Services and Prices/Costs 3
2. Description/Specifications/Statement of Work 3
3. Deliveries or Performance 8
4. Contract Administration Data 9
5. Special Contract Requirements 12

Contract Clauses 14

6. Contract Clauses 14

CONTRACT DOCUMENTS, EXHIBITS OR ATTACHMENTS 17

7. List of Attachments 17

SOLICITATION PROVISIONS 19

8. REPRESENTATIONS, CERTIFICATIONS, AND STATEMENTS OF OFFERORS OR RESPONDENTS 19
9. Instructions, Conditions, and Notices to Offerors or Respondents 20
10. Evaluation Factors for Award 22

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 **75F40126R00060** is issued as a request for proposals (RFP) for Review of Infant Formula Nutrient Requirements.

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 311514 (Dry, Condensed, and Evaporated Dairy Product Manufacturing). The product service code (PSC) is 8940 (Special Dietary Foods and Food Specialty Preparations).

2. DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

A description of requirements for the items and/or services to be acquired is provided below.

2.1. Purpose of the Project

The Office of Critical Foods (OCF) Infant Formula Premarket Review Staff (IFPRS) within the Food and Drug Administration's (FDA) Human Foods Program (HFP) Nutrition Center of Excellence (NCE) is seeking information to assess the feasibility of fulfilling a highly specialized requirement related to the comprehensive review of infant formula nutrient requirements mandated by the Food and Drug Omnibus Reform Act (FDORA) and a component of Operation Stork Speed.

In March 2025, in coordination with the Department of Health and Human Services (HHS), FDA launched Operation Stork Speed (OSS)— a multi-pronged initiative to expand options for safe, reliable, and nutritious infant formula for American families. These enhanced commitments are focused on making sure a strong supply of infant formula—which is often the sole source of nutrition for infants—remains available for one of our nation's most vulnerable populations. FDORA, enacted as part of the Consolidated Appropriations Act of 2023, mandates that FDA review infant formula nutrient requirements every four years, as appropriate, with the first review commencing in 2026. Although FDA regularly reviews individual nutrient requirements for infant formulas, the last comprehensive review was in 1998.

This comprehensive nutrient review for infant formulas intended for healthy, full-term infants will incorporate the latest scientific findings regarding human milk composition, infant nutritional needs, and developmental requirements to ensure infant formula products support healthy growth and development and help inform our regulatory decision-making. This process will ensure that infants

benefit from the most up-to-date science and innovation as research continues to advance our understanding of infants' dietary needs.

The Contractor shall obtain a comprehensive review of fourteen different nutrients for infant formula, including protein, fat, linoleic acid, carbohydrates, iron, copper, zinc, calcium, phosphorus, magnesium, vitamin K, DHA, ARA, alpha-linolenic acid, and L-carnitine.

- Obtain, for each nutrient, a unique Microsoft Word file including:
  - National and International Expert Body Dietary Reference Intakes (DRIs) for healthy term infants.
  - Global infant formula nutrient standards and recommendations (per 100 kcal).
  - Nutrient content of human milk.
  - Daily intake estimation, including comparison with DRIs and human milk exposure.
  - A brief background on the nutrient, including function and metabolism, biomarkers, deficiency and toxicity, and nutrient interactions.
  - Additional considerations. For example, other dietary sources of the nutrient, such as water used to reconstitute powdered infant formula.
  - New or emerging scientific evidence regarding the nutrient, including clinical studies and health outcomes, safety data, and mechanistic studies.

- Proposed action and justification related to current requirements in 21 CFR 107.100(a).

- Fulfill the requirement of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act of 2023, that FDA review infant formula nutrient requirements every four years, as appropriate, with the first review commencing in 2026. Per FDORA, such review must consider any new scientific data or information related to infant formula nutrients, including international infant formula standards.

- Use the information to initiate appropriate action to ensure that infant formulas marketed in the United States are nutritionally adequate to support healthy growth and development in infants.

2.2. Scope

The scope includes, but is not limited to:

- Evidence scan: Map the current landscape of available research and data for specific nutrients for infant formulas and integrate credible stakeholder feedback.
- Scoping review: Identify where robust evidence exists, identify significant data gaps and uncertainties, prioritize nutrients for in-depth systematic review, and incorporate international standards and, as applicable, recent regulatory actions by other countries that may inform FDA's approach.
- Strategic framework: Develop a plan for comprehensive nutrient review, including nutrient prioritization, key research questions, and recommendations for expert committee structure.

2.3. Description of the Technical Requirements

Required Expertise and Capabilities

- FDA Regulatory Expertise: Demonstrated, in-depth experience with FDA's infant formula regulatory framework (including 21 CFR 107), its history, and its policy development process.
- Scientific Synthesis: Proven track record of conducting systematic reviews in infant nutrition and translating complex scientific evidence into regulatory decision-support.
- Immediate Operational Capacity: The ability to begin work immediately without an extended onboarding or knowledge transfer phase, building directly upon work already completed by the FDA.
- Scientific Coordination: Experience coordinating multi-disciplinary experts in infant nutrition and synthesizing data while maintaining scientific credibility and confidentiality.

2.3.1. TASK 1: PROJECT MANAGEMENT AND QUALITY ASSURANCE

The Contractor shall provide overall project management and quality assurance/quality control (QA/QC) to ensure the timely, consistent, and high-quality completion of all requirements under this contract.

- Develop and submit a Project Management Plan (PMP) within 30 days of contract award to include a timeline for delivery of deliverables.
- Establish and implement QA/QC procedures to ensure accuracy, completeness, and consistency.
- Conduct regular status updates with the Government.
- Maintain documentation of all sources, assumptions, and analytical methods.
- Ensure all work is performed independently without direct Government supervision.

2.3.2. TASK 2: STANDARDIZED ANALYTICAL FRAMEWORK AND TEMPLATE ALIGNMENT

The Contractor shall implement a standardized analytical framework aligned with FDA-provided templates.

- Adhere to FDA-provided templates and guidance.
- Ensure consistency with FDA internal methodologies.
- Apply standardized assumptions (intake, thresholds, units).
- Propose deviations for Government review and approval.

2.3.3. TASK 3: NUTRIENT-SPECIFIC DATA COLLECTION AND ANALYSIS

The Contractor shall conduct comprehensive, nutrient-specific analyses as directed by the Government. The Government may prioritize and direct the order and number of nutrients evaluated.

Regulatory History and Origin of Standards

- Identify and document current U.S. regulatory requirements, including minimum and maximum levels in 21 CFR 107.100.
- Summarize regulatory history, including year, action, and Federal Register citations.
- Describe scientific and policy rationale for current standards.
- Provide a narrative summary of the scientific basis at the time of adoption.

Dietary Reference Intakes (DRIs)

- Compile DRIs for term infants from National and International Expert Bodies such as the National Academy of Medicine (NAM), European Food Safety Authority (EFSA), Word Health Organization/Food and Agriculture Organization (WHO/FAO), and German, Austrian, and Swiss (D-A-CH) nutrition societies.
- Document Adequate Intake (AI), Tolerable Upper Intake Level (UL), age ranges (no greater than 12 months), and scientific basis.
- Identify differences across organizations.
- Provide narrative synthesis including limitations.

Infant Formula Standards and International Comparison

- Compile infant formula nutrient standards from the United States, Codex Alimentarius, European Union, Canada, Australia, New Zealand, and China as well as previous recommendations from the Life Sciences Research Office (LSRO) 1998 comprehensive review report.
- Document minimum/maximum levels and rationale.
- Summarize approaches used by jurisdictions.
- Provide comparative analysis of alignment/divergence.

Nutrient Content of Human Milk

- Review current literature on nutrient concentrations in mature human milk.
- Extract study data, including population, size, and statistical measures.
- Characterize variability by lactation stage and population.
- Provide narrative synthesis and limitations.

Daily Intake Estimation and Comparative Analysis

- Estimate daily nutrient intake for each age group.
- Calculate the estimated daily intake at the current minimum and, if available, maximum infant formula specifications.
- Compare the calculated intakes to established reference values, including AI, UL, and human milk exposure data, as applicable/available.
- Document all assumptions used in calculations, including formula intake volumes, energy concentration, daily energy intakes, and age-specific AI and UL adjustment factors.
- Present results in both tabular format and narrative summary.

Scientific Background

- Describe the nutrient's function and metabolism.
- Identify relevant biomarkers.
- Summarize deficiency and toxicity.
- Describe nutrient interactions that may affect absorption or metabolism.

Additional Considerations

- Evaluate other dietary sources and environmental factors.
- Assess impact on nutrient intake and potential risk of excessive intake/toxicity.
- Provide narrative summary.

Emerging Scientific Evidence

- Review recent literature, including clinical, safety, and mechanistic studies.
- Summarize findings in structured evidence tables (What, How, Weight).
- Provide synthesis, including uncertainties and research gaps.

2.3.4. TASK 4: NUTRIENT-SPECIFIC SYNTHESIS AND REGULATORY RECOMMENDATION

The Contractor shall

- Synthesize evidence across analytical components.
- Evaluate adequacy and safety of current required nutrient levels.
- Identify data gaps and uncertainties.
- Develop proposed regulatory action with detailed rationale, including identifying data gaps.

2.3.5. TASK 5: DELIVERABLE PREPARATION AND SUBMISSION

The Contractor shall

- Prepare one Microsoft Word document per nutrient.
- Ensure alignment with FDA templates and formatting.
- Include citations, tables, supporting documentation, and copies of cited references.
- Revise deliverables based on Government feedback.

2.3.6. TASK 6: CROSS-NUTRIENT CONSISTENCY AND FINAL INTEGRATION

The Contractor Shall

- Apply consistent and reproducible methodologies across nutrients.
- Conduct cross-review for alignment and consistency.
- Resolve discrepancies across analyses.
- Provide cross-cutting summaries, if requested.

2.3.7. TASK 7: MEETINGS AND TECHNICAL SUPPORT

The Contractor Shall

- Participate in kickoff and status meetings.
- Provide technical expertise and clarification.
- Respond to Government inquiries in a timely manner.

2.4. Deliverables and Reporting Requirements

Table 1: Deliverables

Deliverable	Description	Quantity/Media	Date Completed
1	Kick-off Meeting	1	Within 15 days after award
2	Project Management Plan (PMP) and QA/QC procedures	Pdf, Microsoft	Within 30 days of award/Within 15 days of the PMP
3	Status updates	Pdf, Microsoft	Monthly

Deliverable	Description	Quantity/Media	Date Completed
4	Provide summaries	Pdf, Microsoft	As requested
5	Provide technical expertise and clarification	Pdf, Microsoft	As requested
6	Respond to Government inquiries	Pdf, Microsoft	Within 2 business days of receipt
7	Close-out: Final Report: overview of work accomplished	Pdf, Microsoft	No later than 21 calendar days prior to the last day of this contract period of performance.

Notice to Contractors: Satisfactory performance of this contract shall be deemed to occur upon performance of the work and upon delivery and acceptance by the Contracting Officer's Representative (COR) or the duly authorized Technical Point of Contact (TPOC). The Contractor shall be responsible for submitting a status report of all activities accomplished to the COR and/or TPOC. The report shall be in a format that is mutually agreed upon between Contractor project lead and COR and/or TPOC. The Contractor shall be available to discuss with the COR or TPOC any current or anticipated problems. The contractor shall provide all written reports in electronic format with read/write capability using applications that are compatible with applications used by the Government (e.g., Microsoft Office Suite, etc.).

2.5. Travel and Other Direct Costs (ODCs)

No travel is required.

3. DELIVERIES OR PERFORMANCE

3.1. Period of Performance

The anticipated period of performance is one (1) twelve (12) month Base Year and three (3) twelve (12) month Option Periods.

Base Year:	August 10, 2026, through August 9, 2027
Option Period I:	August 10, 2027, through August 9, 2028
Option Period II:	August 10, 2028, through August 9, 2029
Option Period III:	August 10, 2029, through August 9, 2030

3.2. Place of Performance

All work to produce deliverables shall be performed at the Contractor's site. Planning meetings and training with agency staff may be held at the FDA offices in College Park, Maryland or electronically. Meeting locations will depend on the business need and will be specified by the Contracting Officer's Representative.

3.3. 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.

4. CONTRACT ADMINISTRATION DATA

4.1. Government Points of Contact

The following are the names, emails, and telephone numbers of the individuals to contact for information.

4.1.1. CONTRACTING OFFICER

Ian Weiss
Ian.Weiss@fda.hhs.gov

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.

4.1.2. CONTRACT SPECIALIST

Amanda Edger
Amanda.Edger@fda.hhs.gov

4.1.3. CONTRACTING OFFICER'S REPRESENTATIVE

To be determined at time of 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).

4.1.4. TECHNICAL POINT OF CONTACT

Carrie Assar
Carrie.Assar@fda.hhs.gov

4.2. Type of Contract/Order

Firm-Fixed-Price type order.

4.3. 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.

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.

4.4. Availability of Funds

The Government's obligation to the 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.

4.5. Government Property

Government-furnished property, such as Government-furnished material, equipment, or information is not applicable for this order.

5. SPECIAL CONTRACT REQUIREMENTS

5.1. Occupational Safety and Health Terms and Conditions

5.1.1. SECTION I: GENERAL OCCUPATIONAL SAFETY AND HEALTH TERMS AND CONDITIONS

1. The contractor is responsible for ensuring contractor personnel comply with applicable OSHA requirements, report unsafe conditions or activities to the Contracting Officer's Representative (COR), and avoid actions and conditions that may result in an accident.
2. The contractor shall submit to the COR a site-specific safety and accident prevention plan and OSHA 300A reports from the past three calendar years.
3. The contractor shall report all workplace incidents, accidents, injuries, and near-misses that occur within the scope of the acquisition (whether OSHA-recordable or not) to the COR by email as soon as possible, but no more than 24-hours after discovery of the incident, illness or injury, or near-miss.
4. The contractor shall provide an investigation report at no cost to the Government for all workplace incidents, accidents, injuries, and near-misses that occur within the scope of the acquisition (whether OSHA-recordable or not) to the COR by email as soon as possible, but no more than 24-hours after the conclusion of the investigation of the incident, illness or injury, or near-miss.
5. The contractor shall report all activities or conditions that pose imminent danger or harm to persons, animals, or Government property immediately upon discovery to FDA Security or directly to local emergency services, as appropriate. In addition, the contractor shall report the incident to the COR immediately thereafter.
6. The contractor shall be responsible for any and all costs, expenses, and other obligations paid or incurred, due to the contractor's noncompliance with federal, state, and/or local laws or ordinances.
7. As applicable, the contractor shall provide personal protective equipment (e.g., hard hats, safety glasses, work gloves) for anticipated hazards and ensure that contractor personnel wear the prescribed safety and health equipment within the work area, as prescribed by

29 CFR part 1910, Subpart I. The contractor shall provide instructions to personnel on the proper wear, maintenance, and limitations of the personal protective equipment prior to commencement of any work under the acquisition.

8. Prior to bringing any hazardous material to an FDA facility, the contractor shall provide the COR copies of any Safety Data Sheets (SDS) to obtain advance, written authorization.
    8.1. Unless otherwise specified in the acquisition, the contractor is responsible for removing any hazardous material, or any material with an SDS, that the contractor brought with them for use at an FDA facility before or during performance of the acquisition.

CONTRACT CLAUSES

6. CONTRACT CLAUSES

The following contract clauses apply to this acquisition.

6.1. Federal Acquisition Regulation Clauses Incorporated in Full Text

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

6.2. Health and Human Services Acquisition Regulation 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)

6.3. 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

7. LIST OF ATTACHMENTS

7.1. Class Deviations (Incorporated by Reference)

This Contract 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
FAR CD 2025-04 Amend. #1	RFO Parts 10 and 52

Class Deviation #	Class Deviation Title
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

7.1. Pricing Worksheet

SOLICITATION PROVISIONS

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

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

8.1. 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
52.240-90	Security Prohibitions and Exclusions Representations and Certifications	DEC 2025

(End of provision)

9. 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 27, 2026**. The subject line shall read: "75F40126R00060 - Review of Infant Formula Nutrient Requirements." 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, July 13, 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:

9.1. 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:

9.1.1. TECHNICAL FACTOR 1: TECHNICAL APPROACH

The Offeror will be evaluated on their ability to meet the Government requirements and on the quality and rigor of their approach for executing each task described in the Statement of Work. This evaluation encompasses three areas:

- Subfactor 1: Literature Review Methodology: Offerors will be evaluated on their ability to describe a clear, scientifically sound, and unbiased methodology for

conducting a systematic scoping review. Proposals should address specific databases to be searched, inclusion and exclusion criteria, and quality assessment tools or frameworks to be applied. Proposals that demonstrate a proactive understanding of potential methodological challenges will be viewed most favorably.

- Subfactor 2: Expert Panel Management: Offerors will be evaluated on the comprehensiveness of their plan for identifying, vetting, and managing a diverse expert panel. This includes the process for facilitating panel activities and translating expert input into policy recommendations. Offerors should demonstrate experience successfully managing similar panels and present a well-defined plan for developing regulatory recommendations.
- Subfactor 3: Capacity, Resources, and Collaboration: Offerors will be evaluated on their demonstrated ability to meet project timelines and deliverables. This includes the adequacy of proposed staffing, team member qualifications and roles, contingency planning, and availability to begin work within the required timeframe. Offerors will also be evaluated on their approach to collaboration and transparency with FDA staff, including mechanisms for regular progress reporting, communication, and joint planning throughout the period of performance.

9.1.2. TECHNICAL FACTOR 2: EXPERIENCE

Offerors will be evaluated based on their ability to demonstrate relevant prior performance consistent with the tasks described in the Statement of Work. Offerors should provide examples of work involving scientific or systematic reviews, regulatory environments, nutritional science, and/or work with Federal agencies. Proposals that demonstrate direct experience with infant formula, nutrition, or the FDA regulatory framework will be viewed most favorably.

9.2. VOLUME II – BUSINESS/PRICE QUOTE INSTRUCTIONS

The Offeror shall complete the Pricing Worksheet (Attachment 1). The Offeror shall propose a Firm-Fixed-Price per labor category per performance period, 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.

10. EVALUATION FACTORS FOR AWARD

The following is a description of the procedures for awarding the Contract.

The Government intends to issue a Firm Fixed Price type order as a result of this solicitation to the responsible Offeror whose quote, conforming to the solicitation, represents the best value to the Government, technical, price, and other factors considered. The Offeror should demonstrate that the objectives in the statement of work are understood and offer a logical approach to their achievement. Award will be made to the offeror who is deemed most responsive, whose quote conforms to all requirements and is judged to represent the best value. Best value will be obtained using a trade-off process, which permits trade-offs among cost or price and non-cost factors and allows the Government to accept other than the lowest price quote. The following Technical Factors that establish the requirements of acceptability are stated below:

- Technical Factor 1: Technical Approach
    - Subfactor 1: Literature Review Methodology
    - Subfactor 2: Expert Panel Management
    - Subfactor 3: Capacity, Resources, and Collaboration
- Technical Factor 2: Experience

10.1. 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 and the Government will assess its level of confidence that the Offeror will successfully perform the requirements.

10.1.1. TECHNICAL FACTOR 1: TECHNICAL APPROACH

The Government will evaluate its level of confidence in the Offeror's ability to successfully perform the requirements of the Statement of Work. The evaluation will consider the extent to which the proposed technical approach demonstrates a clear, comprehensive, and effective understanding of the Government's requirements and provides a sound methodology for successfully executing each task. This evaluation encompasses the following three areas:

10.1.1.1. SUBFACTOR 1: LITERATURE REVIEW METHODOLOGY

The Government will evaluate its level of confidence in the Offeror's ability to successfully conduct a scientifically rigorous, systematic scoping review. The evaluation will consider the extent to which the proposed methodology demonstrates a clear, unbiased, and well-supported approach, including the selection of literature databases, inclusion and exclusion criteria, and quality assessment tools or frameworks. The Government will also assess its confidence in the Offeror's understanding of potential methodological challenges and the effectiveness of proposed strategies to address them.

10.1.1.2. SUBFACTOR 2: EXPERT PANEL MANAGEMENT

The Government will evaluate its level of confidence in the Offeror's ability to effectively identify, recruit, vet, manage, and facilitate a diverse expert panel. The evaluation will consider the adequacy of the proposed approach for managing panel activities, synthesizing expert input, and translating recommendations into actionable regulatory or policy recommendations. The Government will also assess its confidence based on the Offeror's demonstrated experience managing similar expert panels and the soundness of the proposed management approach

10.1.1.3. SUBFACTOR 3: CAPACITY, RESOURCES, AND COLLABORATION

The Government will evaluate its level of confidence in the Offeror's ability to successfully execute the project within the required schedule and deliver the required outcomes. The evaluation will consider the adequacy of the proposed staffing, the qualifications and assigned roles of key personnel, resource availability, contingency planning, and the ability to begin performance within the required timeframe. The Government will also assess its confidence in the Offeror's approach

to collaboration with FDA staff, including the effectiveness of proposed communication, progress reporting, transparency, and joint planning processes throughout the period of performance.

10.1.2. TECHNICAL FACTOR 2: EXPERIENCE

The Government will evaluate its level of confidence in the Offeror's ability to successfully perform the requirements of the Statement of Work based on the relevance and quality of the Offeror's demonstrated experience. The evaluation will consider the extent to which the Offeror's prior experience reflects successful performance of work similar in scope, complexity, and subject matter, including scientific or systematic reviews, work within regulatory environments, nutritional science, and support to Federal agencies. The Government will also assess its confidence based on the Offeror's demonstrated experience with infant formula, nutrition, and the FDA regulatory framework, with greater confidence afforded to proposals demonstrating directly relevant experience in these areas.

10.2. 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.

10.3. CONFIDENCE RATINGS

The Government will assess its confidence level in the Offeror’s ability to successfully perform all requirements based on the quote’s demonstration of technical understanding, personnel qualifications, and management approach. Each technical quote will be evaluated according to two (2) factors: Technical Approach and Experience. Confidence ratings of High, Some, or Low will be assigned to each factor to reflect the Government's level of confidence in the Offeror’s approach to meeting the solicitation requirements. This confidence-based evaluation framework enables a best-value assessment, where quotes demonstrating a higher confidence level may justify trade-offs in other factors to achieve the best outcome for the Government.

Confidence Rating Table

Evaluation Factor	High Confidence	Some Confidence	Low Confidence
Factor 1: Technical Approach	The proposal demonstrates a thorough understanding of the Statement of Work and presents a clear, comprehensive, and feasible technical approach for accomplishing all required tasks. The proposed methodologies are well-defined, technically sound, and likely to achieve the required outcomes. The proposal identifies potential risks and provides	The proposal demonstrates an adequate understanding of the Statement of Work and presents an approach that is generally capable of accomplishing the required tasks. While the approach is acceptable, it contains minor weaknesses, limited detail, or areas of uncertainty that moderately reduce the	The proposal demonstrates a limited or inadequate understanding of the Statement of Work or presents an approach that is incomplete, unclear, or unlikely to successfully accomplish the required tasks. Significant weaknesses, omissions, or risks substantially reduce

Evaluation Factor	High Confidence	Some Confidence	Low Confidence
	effective mitigation strategies, giving the Government a high level of confidence in the Offeror's ability to successfully perform the work.	Government's confidence in the Offeror's ability to successfully perform.	the Government's confidence in the Offeror's ability to successfully perform the work.
Factor 2: Experience	The Offeror demonstrates extensive, recent, and highly relevant experience successfully performing work of similar scope, complexity, and subject matter. Prior experience includes scientific or systematic reviews, regulatory environments, nutritional science, Federal agency support, and, where applicable, infant formula, nutrition, or FDA-related work. The demonstrated experience provides the Government with a high level of confidence in the Offeror's ability to successfully perform the requirements.	The Offeror demonstrates relevant experience performing similar work; however, the experience may differ in scope, complexity, or subject matter, or lacks depth in one or more key areas. The demonstrated experience provides the Government with a reasonable level of confidence in the Offeror's ability to successfully perform the requirements, although some uncertainty remains.	The Offeror demonstrates little or no relevant experience performing work similar in scope, complexity, or subject matter to the requirements of the Statement of Work. The proposal provides insufficient evidence of successful performance on comparable efforts, resulting in a low level of confidence in the Offeror's ability to successfully perform the requirements.