# Department of Health and Human Services
# Part 1. Overview Information

| | |
|---|---|
| **Participating Organization(s)** | U.S. Food and Drug Administration (FDA)<br><br>NOTE: The policies, guidelines, terms, and conditions stated in this Notice of Funding Opportunity (NOFO) may differ from those used by the NIH. Where this NOFO provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this NOFO.<br><br>The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process. |
| **Components of Participating Organizations** | Human Foods Program (HFP)<br><br>Office of Inspections and Investigations (OII) |
| **Funding Opportunity Title** | Flexible Funding Model - Advancing Domestic Mutual Reliance Through Strengthened Infrastructure Development and Maintenance for Manufactured Food Regulatory Programs |
| **Activity Code** | UF4 |
| **Announcement Type** | New |
| **Related Notices** | None |
| **Funding Opportunity Number (FON)** | PAR-27-017 |
| **Companion Funding Opportunity** | None |

| | |
|---|---|
| **Number of Applications** | See Part 2, Section III. 3. Additional Information on Eligibility. |
| **Assistance Listing Number(s)** | 93.103 |
| **Funding Opportunity Purpose** | The purpose of this Notice of Funding Opportunity (NOFO) is to advance manufactured food regulatory program infrastructure capacity and capability to achieve and maintain conformance with the Manufactured Food Regulatory Program Standards (MFRPS) and advance mutual reliance in food safety. The primary objectives will assist new programs in developing foundational infrastructure necessary for effective food safety regulation and provide support in meeting the established standards outlined in the MFRPS. In addition, the objectives will aid existing programs in maintaining their high-quality regulatory programs in full conformance with the MFRPS and provide support for audit and training programs to ensure continued excellence in regulatory operations. This initiative aims to strengthen partnerships between manufactured food programs and the FDA through enhanced collaboration and shared regulatory responsibilities in co-regulated facilities. The cooperative agreement will facilitate shared regulatory data across multiple domains, including regulatory inspections, inventory management and reconciliation, enforcement actions and compliance activities, consumer complaints, and other pertinent regulatory activities and outcomes. By fostering mutual reliance through enhanced collaboration, coordinated data sharing, and synchronized enforcement efforts, this cooperative agreement will enable manufactured food programs and the FDA to jointly improve the efficiency and effectiveness of food safety oversight. |
| **Funding Opportunity Goals** | The goals of this funding opportunity announcement are to:<br>• Advance manufactured food regulatory programs and strengthen the national food safety system<br>• Support and Enhance Program Infrastructure<br>• Advance Domestic Mutual Reliance<br>• Build and Promote the Integrated Food Safety System (IFSS) Community |

## Key Dates

| | |
|---|---|
| **Posted Date** | November 5, 2026 |
| **Open Date (Earliest Submission Date)** | November 5, 2026 |
| **Letter of Intent Due Date(s)** | December 14, 2026<br>December 14, 2027<br>December 14, 2028<br>December 14, 2029 |
| **Application Due Date(s)** | January 14, 2027<br>January 14, 2028<br>January 16, 2029<br>January 14, 2030<br>All applications are due by 11:59 PM local time of applicant organization. **No late applications will be accepted for this Notice of Funding Opportunity (NOFO).** |
| **Earliest Award Date** | May 1, 2027 |
| **Late Applications** | Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.<br>**No late applications will be accepted for this Notice of Funding Opportunity (NOFO).** |
| **Expiration Date** | January 15, 2030 |
| **Due Dates for E.O. 12372** | Not Applicable |

### Required Application Instructions

Conformance to all requirements, both in the Application Instruction Guide and in the NOFO, is required and strictly enforced. When the program-specific instructions deviate from those in the Application Instruction Guide, follow the program-specific instructions.

**Applications that do not comply with these instructions will not accepted for review.**

# Table of Contents


Part 1. Overview Information ..... 1

Key Dates ..... 3

Part 2. Full Text of Announcement ..... 4

Section I. Notice of Funding Opportunity Description ..... 4

Section II. Award Information ..... 12

Section III. Eligibility Information ..... 13

Section IV. Application and Submission Information ..... 16

Section V. Application Review Information ..... 18

Section VI. Award Administration Information ..... 21

Section VII. Agency Contacts ..... 24

Section VIII. Other Information ..... 24


# Part 2. Full Text of Announcement

## Section I. Notice of Funding Opportunity Description

**Background:**

The Manufactured Food Regulatory Program Standards (MFRPS) were developed and published by the FDA in 2007 as a comprehensive framework designed to establish uniform standards for food safety regulatory programs. The MFRPS have been successfully implemented and maintained by numerous manufactured food programs across the nation, demonstrating the effectiveness and adaptability of this regulatory framework.

Manufactured food regulatory programs in full conformance with the MFRPS have developed robust, well-established systems and continued funding for the MFRPS is critical to maintain the sophisticated infrastructure, trained personnel, and operational procedures their enrollment in the MFRPS has produced. The maturity and proven effectiveness of the MFRPS programs have positioned the national food safety system at a critical juncture where advancing mutual reliance between state and federal regulatory authorities is both feasible and strategically advantageous. Manufactured food programs are focused on maintaining individual conformance with the MFRPS and simultaneously moving towards integrated collaborative approaches that leverage the collective strengths of the state-federal partnership.

The objectives in this cooperative agreement expand upon the MFRPS to enhance collaboration through seamless exchange of regulatory information across state and federal systems, leverage enforcement efforts that maximize regulatory impact while minimizing duplication and develop shared responsibility models that optimize resource utilization and regulatory coverage. The funding opportunity announcement encompasses three primary goals designed to advance manufactured food regulatory programs and strengthen the national food safety system: **Support and Enhance Program Infrastructure**, **Advance Domestic Mutual Reliance**, and **Build and Promote the Integrated Food Safety System (IFSS) Community**. Each goal includes specific objectives and supporting activities that collectively work to achieve the overarching goals of MFRPS conformance and support the FDA's initiative to further enhance collaborative food safety oversight.

Throughout this funding announcement, the terms "recipient" and "manufactured food program" are used interchangeably. The following terms and concepts are used throughout this Notice of Funding Opportunity and defined below for clarity:

> **Integrated Food Safety System (IFSS)** provides the vision, guiding principles and key components of a coordinated approach to food safety. An IFSS describes the continual improvements and collaborative activities of food safety that will be addressed through the implementation of a collection of initiatives, programs and projects. An IFSS includes the implementation of seamless partnerships and operations among federal, state, local, territorial, and tribal agencies as well as academic, foreign, industry and consumer stakeholders (strategic partners) to achieve the public health mission of realizing a safer food supply. The IFSS encourages interactions and collaborations with strategic partners, as their input and the lessons learned are critical to the advancement of this mission.
>
> **Domestic Mutual Reliance** is a seamless partnership that enables FDA and states with comparable regulatory public health systems, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of a safe national food supply.
>
> **One Integrated Workforce** is an initiative to develop a unified, cross-trained workforce capable of conducting inspections and enforcement activities across different food safety programs and regulatory areas. This approach ensures inspectors have the skills and authority to address various food safety issues during a single facility visit, improving efficiency and regulatory coverage.
>
> **Regulatory and Laboratory Training System (RLTS)** is a comprehensive training infrastructure that provides standardized education and professional development for regulatory and laboratory personnel involved in food safety oversight. The RLTS delivers consistent, science-based training programs to ensure that inspectors, analysts, and other food safety professionals across federal, state, local, and tribal agencies have the necessary knowledge and skills to effectively protect public health through regulatory activities and laboratory testing.
>
> **National Curriculum Standards (NCS)** is a set of standardized educational requirements and learning objectives that establish consistent training benchmarks for food safety professionals across all jurisdictions. These standards ensure that regardless of where inspectors are trained or employed, they meet uniform competency requirements for food safety regulation and enforcement activities.

**Objectives**

Applicants must provide detailed descriptions of how they will achieve these primary objectives and implement the associated supporting activities. The application should clearly articulate the strategies, methodologies, and measurable outcomes that will be employed to successfully accomplish each objective and demonstrate progress toward strengthening both individual manufactured food program capabilities and the broader integrated food safety system.

**1. Support and Enhance Program Infrastructure**

The Manufactured Food Regulatory Program Standards (MFRPS) provide a comprehensive framework that enables the development and maintenance of risk-based food safety programs by establishing uniform criteria for measuring and improving the performance of manufactured food programs throughout the United States. This objective focuses on strengthening the foundational elements necessary for effective regulatory oversight and ensuring sustained program excellence.

For the purpose of this funding opportunity, conformance means the fulfillment of a requirement of the MFRPS, specifically that a manufactured food program is using and can demonstrate the use of a particular element, system, or program listed in the MFRPS (most recent version).

Under Objective 1, Development Track must meet supporting activities listed in section A. Maintenance Track must conduct activities in all sections.

**A. Achieve and maintain conformance with MFRPS**- Recipient will achieve and maintain conformance with the current MFRPS to ensure consistent regulatory oversight and program effectiveness. Recipient will identify personnel with overall responsibilities for this objective, i.e. MFRPS coordinator.

1. For recipients under the Development Base Track: the recipient will develop and implement a strategic improvement plan to reach full conformance.
2. For recipients under the Maintenance Base Track: the recipient will maintain full conformance with the MFRPS. If the program fails to meet any of the program elements and documentation requirements of the MFRPS, whether identified through self-assessment or FDA assessment, the program shall develop or update a Strategic Improvement Plan including the completion of any corrective action or CAPA requirements.
3. Recipients must participate in assessments conducted by the FDA Quality Assessment Staff based upon regular assessment intervals determined by the FDA. Participation includes providing meeting space for any in-person activities, accessibility of key program management and staff, and access to records, databases, and other materials supporting MFRPS conformance.

**B. Engage in Regulatory and Laboratory Training System (RLTS)**

1. Recipients are required to ensure their inspectors are trained to the minimum elements in Standard 2 of the MFRPS.
2. In addition, recipients shall develop a plan to incorporate the National Curriculum Standards (NCS) into their training plan by the end of Year 3. The training plan requires inspectors to have the competencies defined in NCS to do the work they have been assigned. Funding under this cooperative agreement may be utilized for inspector training in RLTS courses.
3. Recipients shall identify a training point of contact such as a program manager, Qualified Field Inspection Trainer or other qualified individual to oversee the program's training program and ensure inspector training competencies are met.

**C. Develop qualified manufactured food program auditors-** Recipient will assess capacity for qualified field inspection auditors through strategic workforce development that aligns auditor numbers with program size and inspection frequency to effectively evaluate inspector's performance. Manufactured food programs plan to meet the required field inspection audits as defined in the MFRPS.

1. Manufactured food program must maintain a roster of all Qualified Field Inspection Auditors on staff. Programs with three or less manufactured food inspectors are exempted from this requirement.
   a. If the manufactured food program does not currently have a Qualified Field Inspection Auditor on staff, they shall develop a training and qualification plan by the end of year 1 to develop at least one Qualified Field Inspection Auditor as defined in the MFRPS.

b. Manufactured food programs must have at least one Qualified Field Inspection Auditor actively conducting audits of basic food inspections in Year 3 or earlier. By the end of the cooperative agreement, the program shall develop and implement a plan to identify and address the development of additional qualified field inspection auditors as necessary based on the manufactured food inventory for which the program inspects.

c. Alternatively, manufactured food programs that are unable to build trained and Qualified Field Inspection Auditor capacity may develop and implement a plan to collaborate with other regulatory partners with qualified inspection auditors to conduct field audits for their program. The plan will need to be shared with FDA for approval.

2. Field inspection audits must be completed on the most current version of the FDA Audit Form 3610-H by the end of Year 3 of the cooperative agreement.

**D. Participate in food protection task force activities-** The FDA recognizes the critical role that multi-stakeholder partnerships play in the food safety oversight and the need for systemic, coordinated approaches to emerging food safety challenges. Under this funding opportunity announcement, the FDA provides funding for Food Protection Task Force activities as described in the Coalition of Food Protection Task Forces (CFPTF) Best Practices Manual.

Task forces must perform the following activities:

1. Convene at least one task force meeting annually with the purpose of informing, educating, and soliciting input from external stakeholders on food safety priorities. Meetings can be hosted virtually, in-person, or in a hybrid format.
2. Work with membership to review and update organizational documents, including vision/mission statements.
3. Assess task force effectiveness and identify opportunities for improvement.
4. If resources such as presentations, job aids, educational resources and/or other materials are developed, share these to the CFPTF FoodSHIELD site.
5. Recipients shall attend CFPTF meetings.

Alternatively, one of the following options will be accepted (to be conducted annually):

1. Identify membership and establish or participate in an existing task force or symposium related to food safety within the recipient's jurisdiction.
2. Collaborate with other FPTFs (within or external recipient's jurisdiction) on projects related to food safety.
3. Work with stakeholders to adopt and implement the appropriate regulations (FDA's Model Food Code, Code of Federal Regulations (CFR), Food Safety Modernization Act (FSMA), etc.).
4. Work on projects with stakeholders like academia and industry that benefit public health and food safety including prevention, intervention, response, and post-response or in support of the Executive Order #14212.

**2. Domestic Mutual Reliance**

This objective works towards building a collaborative regulatory approach where FDA and manufactured food programs with comparable regulatory public health systems work together as integrated partners, leveraging and utilizing each other's data, resources, and expertise to achieve more effective and efficient food safety oversight, maximize public health impacts, and reduce duplication of efforts. This objective focuses on building operational coordination between manufactured food programs and the FDA through shared responsibilities, coordinated activities, and complementary regulatory functions and supporting seamless information exchange that enables both manufactured food programs and federal programs to make informed regulatory decisions.

**A. Firm Inventory and Reconciliation** establishes systematic firm inventory sharing and reconciliation between manufactured food programs and FDA to enhance risk-based regulatory decision-making and optimize oversight coverage. Through coordinated inventory management, participating recipients will:

**Implement reconciliation** through a phased approach:

1. All years: recipients are encouraged to participate in a workgroup to develop best practices for manufactured food programs to utilize when reconciling their inventory with the FDA's. The workgroup will meet to determine best practices in the firm inventory reconciliation processes across manufactured food programs to ensure consistent data quality and compatibility. The workgroup will consider essential data elements necessary for effective inventory reconciliation.
2. Year 1: Share and review FDA and recipient current inventories of all manufactured food facilities. Establish shared definitions. Develop a comprehensive understanding of co-regulated facility jurisdictions and regulatory responsibilities. FDA and recipient will explore data solutions to align their program and FDA inventories. **(Development track must meet supporting activity A.2. by the end of the project period)**
3. Years 2-4: Implement detailed reconciliation with targeted subsets of the inventory, building incrementally on the foundational framework established in Year 1. Focus on inventory sharing and basic reconciliation, including identification of recipient-only, FDA-only, and jointly regulated facilities. As an outcome of this reconciliation process, FDA will share the consolidated inventory with recipients.
4. Year 5: Implement detailed reconciliation with the full manufactured foods inventory, if able.

Note-recipients that are already conducting inventory reconciliation process with FDA will continue their existing efforts and should implement detailed reconciliation with the full manufactured foods inventory by Year 5 or annually.

**B. Collaborative work planning -** Facilitate the IFSS through risk-based work planning with the FDA OII divisions.

1. The recipient workplan will prioritize performing inspections pursuant to their risk-based inspection program per MFRPS Standard 3 and with consideration of FDA's FSMA inspection frequency mandate.
2. Recipient will maintain the FDA inspectional contract in good standing by completing agreed upon inspectional work, audits, and associated compliance and regulatory activities.

**C. Communication and Coordination-** Facilitate the continued development of an IFSS through meetings and continuous communications between FDA and recipients to develop and review progress in work sharing and data exchange of critical public health information and to reduce duplication of effort.

1. Biannual Planning Meetings- FDA will facilitate biannual meetings with recipients to develop and monitor progress in meeting the cooperative agreement objectives.

Meeting agenda items should include as applicable:

a. Workplan –

Minimum data elements must include:

i. Name

ii. Address

iii. Establishment type

iv. Products/Industry Codes

v. FEI/License number

vi. Seasonal status

vii. Date of last inspection

viii. Classification of last inspection

ix. Food Facility Registration/state license status

x. Previous Program Assignment Codes and/or inspectional type

b. Inspection updates - Share lists of completed inspections since the last meeting

c. Enforcement actions - Discuss outcomes of enforcement/compliance actions since the last meeting and any improvements to the enforcement action sharing process

d. Training coordination - Identify training needs (classroom and field) and available resources to conduct/receive training

e. Field audit program- Review current program field auditor roster. Discuss status of required field audits for program inspectors, successes and challenges identified in the audit program, current training needs for program auditors and any open corrections and corrective actions related to field audits

f. Consumer complaints- Discuss recent complaints of public health significance, how communication between recipients has been handled since the previous meeting and identify successes and room for improvement in collaboration in responding to consumer complaints

g. Recalls- Review communication protocols and collaboration effectiveness to identify successes and areas for improvement in responding to recalls of public health significance

h. Sampling- Identify sampling priorities and opportunities to coordinate and reduce duplication of effort for sampling collection and testing to support routine surveillance, enforcement, and investigations. Determine how requests for sampling assistance and sample results, including those for violative samples, will be communicated

i. MFRPS Objectives review- Monitor progress in meeting the MFRPS objectives of this cooperative agreement and to review CAP performance

2. Significant Enforcement Actions- Significant* enforcement actions will be shared via email or phone between FDA and recipient as soon as practical, but no more than 3 business days, upon determination that:

A significant public health hazard is identified during inspection

**and/or**

A significant regulatory action is being considered or planned

Information shared must include at minimum:
- Firm name
- Address
- Date of action taken
- Action taken
- Products/Processes affected
- Need for partner agency support, if applicable

* A significant enforcement action typically refers to formal regulatory measures taken when voluntary compliance efforts have failed or when there are serious public health risks. The threshold for what constitutes "significant" often depends on factors such as the severity of the violation, potential public health impact, scope of the problem, history of non-compliance, and whether the action involves court intervention or substantial penalties. These actions are typically distinguished from routine inspections, informal communications, or minor administrative corrections. For FDA and recipients, these can include:

FDA significant enforcement actions include issuance of warning letters for serious violations, product seizures, injunctions, mandatory recalls, consent decrees requiring court-supervised compliance programs, criminal referrals for willful violations, and facility inspections that are put forward by the OII division with an initial classification of Official Action Indicated (OAI).

Recipient significant enforcement actions vary by jurisdiction but commonly include license suspensions or revocations, facility closures, product embargos or holds, administrative penalties and fines, cease and desist orders, and criminal prosecutions under recipient food and drug laws.

3. Significant Complaints - Recipient must follow their complaint procedure including filing necessary manufactured food-related complaints through FDA's designated complaint submission mailbox (HFPComplaints@fda.hhs.gov) for regulatory partners. Recipient and FDA should share significant food complaints via email and/or phone as soon as practical when there are potential implications for a larger food outbreak, potential public health impact for any FDA regulated product, potential expanded visibility via press or other agency (state or local) engagement, and whistleblower complaints.

4. Significant Recalls (Potential FDA Class 1)- FDA and recipient share recall information via email or phone as soon as practical to enhance coordinated response and oversight capabilities. Recipient will regularly communicate recalls that indicate potential foodborne illness outbreaks, serious adverse events, or widespread product safety issues requiring multi-jurisdictional response. Each party will promptly share relevant recall details, response actions taken, and effectiveness findings to facilitate coordinated follow-up and prevent duplicative efforts.

**D. Laboratory Flexible Funding Model (LFFM) Support-** If recipients are the state regulatory program (SRP) for a laboratory that is participating in a product testing track of the Laboratory Flexible Funding Model (LFFM) they will apply their MFRPS response, enforcement and regulatory framework to conduct follow-up inspections, investigations (including traceback/forward), and enforcement actions (including embargos, recalls, warning letters, and closures) to positive and violative samples identified as part of the LFFM cooperative agreement. Coordination with the Rapid Response Team (RRT) and activation, if applicable, is required for recipients also participate in current award.

1. Recipients will commit to coordinating response and compliance follow-up on LFFM samples with the FDA in real-time, to include sharing findings and compliance actions or other follow-up activities discussing regulatory/compliance strategy with the FDA.
2. If a potentially violative LFFM sample comes to a MFRPS program but is outside of the MFRPS program's regulatory authority/jurisdiction, the MFRPS program agrees to identify and notify the appropriate state/federal agencies with jurisdiction, and to notify the FDA.
3. Potentially violative LFFM samples may come to the MFRPS program from any laboratory participating in the LFFM Human Food Product Testing track for microbiology or chemistry. This includes samples collected by LFFM laboratories within the same state as the MFRPS program (may or may not be the primary servicing laboratory for MFRPS); samples collected by other states/analyzed by other LFFM laboratories where the potentially violative product is traced back to the MFRPS program's state.
4. Recipients will collect samples at the manufacturer, and other locations, in accordance with the collection instructions for each hazard-commodity pair on the approved LFFM sample plan, as needed.
5. Recipients will build the necessary regulatory and compliance response infrastructure to investigate and respond to violative samples, including qualified personnel, IT resources, and regulatory authorities.

**3. Build and Promote Integrated Food Safety System (IFSS) Community**

An IFSS is a coordinated approach to food safety that involves collaboration and communication across various network of federal, state, local, tribal, and territorial food safety programs working collaboratively to protect public health through coordinated oversight of the nation's food supply. This objective focuses on fostering active participation, engagement, and knowledge sharing, facilitating learning opportunities, and supporting the development of sustainable partnerships that enhance the overall national food safety infrastructure.

A. Key personnel (minimum of two) must attend the annual Manufactured Food Regulatory Program Alliance (MFRPA) meeting. This meeting may occasionally be held on a less than annual basis and may be hosted in-person or virtually. (Development and Maintenance track)

B. IFSS Enhancement (every enrollee in the maintenance track must choose at least 2 of the following activities per cooperative agreement year, activities can be changed if necessary)

1. Mentor a new Program Coordinator and/or MFRPS- enrolled program from another manufactured food program by participating in the MFRPA mentor/mentee program. Alternatively, new Program Coordinator could participate as a mentee. Mentor/mentee pairs will be designated by Division of Domestic Partnerships Coordination and Integration (DDPCI).
2. Mentor a program enrolled in another Regulatory Program Standards that is not yet in full implementation/conformance. Mentor/mentee pairs will be designated by DDPCI.
3. Participate in a workgroup to plan the coordinator's meeting and/or revise The Standards Coordinator's Manual, if applicable.
4. Participate as a member on the MFRPA Board (board member, technical advisor, liaison, etc.), if applicable.
5. Participate in the MFRPA Annual Meeting planning committee, if applicable.
6. Participate in IFSS emerging training program and initiatives, such as:
   i. Participate on a RLTS advisory committee.

   ii. Develop/host/sponsor trainings with attendees from other jurisdictions, such as a seminar series, webinar or classroom-based trainings (especially those to address just-in-time training needs, commodity specific or high-risk product investigations). Collaborations with academic institutions to develop/host courses are encouraged.

   iii. Host RLTS course(s) for your own food inspection staff and invite other IFSS partners such as other RPS-enrolled programs, local health department inspectors and/or FDA staff.

   iv. Serve as a trainer for RLTS course(s).

   v. In alignment with MFRPA Board recommendations, conduct field training and/or serve as a Qualified Field Inspection Auditor for another MFRPS-enrolled program's inspectors to meet Standard 2 or Standard 4 requirement.

7. Present or facilitate a session at the MFRPA Annual Meeting or a MFRPS Coordinator's Meeting. Alternatively, prepare a presentation at the annual MFRPA meeting to share project outcomes, emerging issues, continuous improvement initiatives or lessons learned and best practices with other MFRPS enrollees. Alternatively, publish a paper regarding MFRPS related topics in a peer reviewed article or trade journal.

8. Develop and implement a field audit verification plan. Verification Audit Inspection: means an inspection in which a recipient program qualified field inspection auditor observes a program qualified field inspection auditor performing an audit of a program inspector conducting an inspection.

9. Participate on a Partnership for Food Protection workgroup, One Integrated Workforce workgroup, or similar initiatives that support holistic multi-system regulatory approaches, if applicable.

10. Develop and share best practices to support and sustain the IFSS community.

11. Activities that advance the adoption and implementation of the current Good Manufacturing Practices (cGMPs) for Dietary Supplements Rules and Regulations under 21 CFR Part 111. The activities aim to achieve equivalent and consistent application of dietary supplement cGMPs while building sustainable inspection capabilities for long-term program success. The activities may include training and personnel development, regulatory authority development, compliance and enforcement strategy, program infrastructure and auditing and/or coordination and outreach methods.

12. Additional activities proposed by the recipient with approval by FDA.

See Section VIII. Other Information for award authorities and regulations.

## Section II. Award Information

| | |
|---|---|
| **Funding Instrument** | Cooperative Agreement: A financial assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. See Section VI.2 for additional information about the substantial involvement for this NOFO. |
| **Application Types Allowed** | New<br><br>Only those application types listed here are allowed for this NOFO. |
| **Funds Available and Anticipated Number of Awards** | The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance.<br><br>FDA intends to commit up to $16,000,000 to fund up to 45 awards in FY 2026 for this program. |
| **Award Budget** | Applications budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect).<br><br>YR 01: $400,000<br><br>YR 02: $425,000<br><br>YR 03: $450,000<br><br>YR 04: $450,000<br><br>YR 05: $450,000<br><br>Applicants must refer to Section III Eligibility Information to determine which funding track they should apply for: MFRPS Development or MFRPS Maintenance. |
| **Award Project Period** | The scope of the proposed project should determine the project period. The maximum project period is five (5) years. |

HHS grants policies as described in the HHS Grants Policy Statement will apply to the applications submitted and awards made from this NOFO.

# Section III. Eligibility Information

## Eligible Organizations

- State Governments
- U.S. Territory or Possession

This opportunity is available to state or territorial manufactured food regulatory programs that:

- Must maintain an active human food program contract with a Satisfactory or higher rating in the Contractor Performance Assessment Reporting System (CPARS)
- Hold a long-term food nonpublic information sharing agreement with FDA pursuant to 21 CFR 20.88 or agree to enter into a 20.88 agreement at the earliest possible date

Competition is limited to state and territorial programs with human food safety contracts. The MFRPS was developed in 2007 following a 2000 Inspector General report that recommended FDA improve consistency between federal and state food safety standards and inspection programs. Maintaining a human food contract in satisfactory condition, or entering into a contract at the earliest possible date, is necessary to achieve the original goal of the MFRPS. Only state and territorial agencies have the regulatory authority, or ability to be HHS commissioned officials, to perform food safety inspections on behalf of the FDA and maintain manufactured food regulatory programs. State and territorial agencies have the knowledge, expertise, and regulatory authority to achieve the goals of this cooperative agreement.

Applicants are encouraged to apply for this cooperative agreement in an amount that reflects their program needs both in terms of amounts of funding and number of project years.

2. Funding Track Eligibility

**Development Track: $300,000/year**

Eligible Programs:

- Programs with 5 or **less years** of MFRPS cooperative agreement funding, OR
- Programs that have **never received** MFRPS cooperative agreement funding
- Programs may count years of MFRPS enrollment under FDA Food Inspection Contract toward the 5-year requirement

**Maintenance Track:** Tiered Base Funding

Eligible Programs:

- Programs with **more than 5 years** of MFRPS enrollment under the cooperative agreement funding
- Programs may count years of MFRPS enrollment under FDA Food Inspection Contract toward the 5-year requirement

**Base Funding Levels** (maintenance base funding + DMR):

- **Level 1**: $200,000 in Year 1, $225,000 in Year 2, $250,000 in Year 3-5
- **Level 2**: $300,000 in Year 1, $325,000 in Year 2, $350,000 in Year 3-5
- **Level 3**: $400,000 in Year 1, $425,000 in Year 2, $450,000 in Year 3-5

These are maximum funding levels and are contingent upon annual appropriations, availability of funding, progress in completion of cooperative agreement objectives, and maintaining human food contract in good standing.

**Conformance Requirement:** Programs not currently in conformance (per most recent FDA assessment) must submit a corrective action plan with their application.

Potential applicants have been classified into three (3) funding levels based on a variety of factors. Applicants may apply for funding levels up to, but not exceeding, the levels identified below. Each jurisdiction is unique and must not apply for funding exceeding these levels.

| MFRPS Level 1 | MFRPS Level 2 | MFRPS Level 3 |
|---|---|---|
| Arkansas | Alabama | California - Health |
| California-Agriculture | Alaska | Florida |
| Delaware | Arizona | Illinois |
| Hawaii | Colorado | Michigan |
| Mississippi | Connecticut | New Jersey |
| Nebraska | Georgia | New York |
| Nevada | Indiana | North Carolina |
| New Hampshire | Idaho | Ohio |
| New Mexico | Iowa | Pennsylvania |
| North Dakota | Kansas | Texas |
| Oklahoma | Kentucky | Washington |
| Rhode Island | Louisiana | Wisconsin |
| South Carolina | Maine | |
| South Dakota | Maryland | |
| Vermont | Massachusetts | |
| West Virgina-Agriculture | Minnesota | |
| West Virgina-Health | Missouri | |
| Wyoming | Montana | |
| | Oregon | |
| | Puerto Rico | |
| | Tennessee | |
| | Utah | |
| | Virginia | |

Recipient's eligibility to enter the MFRPS Maintenance Funding Track depends on date of first receiving a MFRPS Cooperative Agreement - see eligibility narrative for further details.
Data sources used to determine eligibility at the time of the funding of notice of opportunity announcement:

| Criteria | Range | Value |
|---|---|---|
| Total Non-Contract Inspections (NCI) | <33% percentile | 1 point |
| | >33-66% percentile | 2 points |
| | >66% percentile | 3 points |
| # of High Risk Inventory | <33% percentile | 1 point |
| | >33-66% percentile | 2 points |
| | >66% percentile | 3 points |
| Total FSMA Count by FEI | <33% percentile | 1 point |
| | >33-66% percentile | 2 points |
| | 66% percentile | 3 points |
| FSMA High Risk Inventory | <33% percentile | 1 point |
| | >33-66% percentile | 2 points |

| | | |
|---|---|---|
| | >66% percentile | 3 points |
| Total Weighted Contract Inspection Cost | <33% percentile | 1 point |
| | >33-66% percentile | 2 points |
| | >66% percentile | 3 points |
| Population based on 2020 Census | <25% percentile | 1 point |
| | >25-75% percentile | 2 points |
| | >75% percentile | 3 points |

## Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are not** allowed.

## Required Registrations

### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the Application Instruction Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference the HHS Grants Policy Statement for additional information

- System for Award Management (SAM) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov Applicants must have an active SAM registration in order to complete the Grants.gov registration.

### Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

## Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed project as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support.

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required.

### Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement.

### Additional Information on Eligibility

Number of Applications

## Section IV. Application and Submission Information

### Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

### Content and Form of Application Submission

It is critical that applicants follow the instructions in the Application Guide except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

### Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows FDA staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Danielle Head
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Email: Danielle.Head@fda.hhs.gov

A technical session will be held for prospective applicants. The technical session will provide an overview of the submission requirements and allow prospective applicants an opportunity to ask questions regarding the application process. Participation in the technical session is optional, but strongly encouraged.

### Page Limitations

All page limitations described in the How to Apply - Application Guide and the Table of Page Limits must be followed.

| Component | Form to use | Page limit |
|---|---|---|
| Project abstract | Project Abstract Summary form | 1 page |

| | | |
|---|---|---|
| Project narrative | Project Narrative Attachment form | 30 pages |
| Budget narrative | Budget Narrative Attachment form | No |

## Instructions for Application Submission

The following section supplements the instructions found in the Application Guide and should be used for preparing an application to this NOFO.

### Application for Federal Financial Assistance (SF-424)

All instructions in the Application Instruction Guide must be followed.

In the "Descriptive Title of Applicant's Project:" field applicants must include the applicable focus area (Development or Maintenance) and State Organization Name/Abbreviation in the Project Title.

### SF-424 A Budget Information - Non-Construction Programs Form

All instructions in the Application Guide must be followed.

### Project/Performance Site Location(s)

All instructions in the Application Guide must be followed.

### Project Abstract Summary

All instructions in the Application Guide must be followed.

### Project Narrative Attachment

All instructions in the Application Guide must be followed.

**Appendix:** Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply - Application Guide.

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

## Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration. FDA and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the FDA Policy on Late Application Submission.

**Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.**

Information on the submission process and a definition of on-time submission are provided in the How to Apply - Application Guide.

## Funding Restrictions

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations, and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate: racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

**Non-allowable costs:**

Vehicle purchases are not permitted.

### Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply - Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

**Important reminders:**

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to the FDA. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the assigned FDA Grants Management Specialist and responsiveness by components of participating organizations. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

## Section V. Application Review Information

### Criteria

Applications submitted to the FDA are evaluated for scientific and technical merit. Only the review criteria described below will be considered in the merit review process.

### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

| | |
|---|---|
| **Significance** | **Maximum Points: 25** |

- Does the awardee describe how the proposed activities will enhance program capabilities and the broader integrated food safety system?
- Does the applicant describe how the proposed activities strengthen food safety oversight capacity?
- Does the application clearly identify and prioritize the most critical regulatory gaps or enhancement opportunities that will be addressed?

| **Technical Approach and Methodology** | **Maximum Points: 25** |
|---|---|

- For Development Track: Does the awardee have a strategy to develop and implement a strategic improvement plan with measurable progress toward full conformance?
- For Maintenance Track: Is the awardee maintaining full conformance, and if deficiencies were identified, has a Strategic Improvement Plan been developed or updated?
- Does the applicant address potential challenges to maintaining or achieving conformance, and are the proposed mitigation strategies appropriate?
- Are the proposed training programs comprehensive and aligned with Standard 2 requirements and include plans to incorporate the National Curriculum Standards?
- Does the awardee have a field audit program in place with qualified field inspection auditors on staff that meets the Standard 4 requirements?
- If the awardee does not currently have qualified field inspection auditors on staff, was a training and qualification plan that would be achievable by end of Year 1?
- Does the awardee have a plan to share and review their current inventory of manufactured food facilities with FDA, establish shared definitions, and develop a comprehensive understanding of facility jurisdictions and regulatory responsibilities?
- Does the awardee include plans to build or maintain a task force or participate in alternate objectives?

| **Organizational Capacity and Infrastructure** | **Maximum Points: 15** |
|---|---|

- Is there at least one dedicated employee/equivalent to lead day-to-day oversight of this project, such as a MFRPS Coordinator?
- Are there qualified personnel identified for training coordination?
- Is there adequate agency management support, as evidenced by the selection of PD/PI(s) for the project?
- For programs that are currently not in conformance, the applicant is required to submit a corrective action plan as part of the application. If submitted, does the corrective action plan describe the cause of the non-conformance and include adequate corrective actions.
- Does the organization demonstrate adequate IT systems, facilities, and resources to support proposed activities?
- Does the organizational structure support sustained program implementation and regulatory excellence?

| **Collaboration and Partnership Development** | **Maximum Points: 20** |
|---|---|

- Does the proposed strategy and methodology in work planning support and meet manufactured food program and FDA inspection mandates?
- Do the awardee's data sharing and communication plans demonstrate the potential for reducing duplication of efforts and enhanced surveillance?
- If participating in LFFM, does the awardee apply their MFRPS response, enforcement, and regulatory framework to conduct required follow-up inspections, investigations, and enforcement actions on positive and violative samples, with proper coordination with the Rapid Response Team when applicable?
- Does the awardee have plans to consistently share significant enforcement actions, complaints and recalls with the FDA?
- Did the awardee select and develop plans to complete at least two IFSS Enhancement activities from the provided list during the cooperative agreement year?
- Does the overall approach demonstrate commitment to building and sustaining an IFSS community?

| **Sustainability and Continuous Improvement** | **Maximum Points: 15** |
|---|---|

- Are the proposed sustainability plans comprehensive and likely to ensure program continuation beyond the funding period?
- Does the applicant identify clear and measurable outcomes for the overarching cooperative agreement objectives?
- Does the proposal include realistic timelines and milestones for achieving stated objectives?

## Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

## Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed project.

## Renewals

Not applicable.

## Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Objective Review Committee convened by the FDA, using the stated review criteria. Assignment to an Objective Review Committee will be shown in eRA Commons.

## Review and Selection Process

As part of the objective review, all applications will receive a written critique.

## Funding Preference for Alignment with Agency Priorities

Before final funding decisions are made, agency leadership will review awards for consistency with applicable laws and alignment with FDA's Public Health Pillars. To the extent permitted by law and applicable court orders, award applications which are aligned with agency pillars will receive a funding preference. For example, applications that explicitly align with FDA's Public Health Pillars will be eligible for a funding preference.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by objective review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

### Anticipated Announcement and Award Dates

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

Information regarding the disposition of applications is available in the HHS Grants Policy Statement.

## Section VI. Award Administration Information

### Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the HHS Grants Policy Statement.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in FDA-funded studies, the recipient must provide FDA copies of documents related to all major changes in the status of ongoing protocols.

### Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through FDA:

- The rules listed at 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All FDA grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in the HHS Grants Policy Statement.

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. FDA may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination and HHS Grants Policy Statement.

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data. Please refer to HHS Grants Policy Statement for additional information.

## Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 2 CFR Part 200, and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the recipients in a partnership role; it is not to assume direction, prime responsibility, prime benefactor or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the FDA as defined below.

**FDA/HFP Program Staff will have substantial programmatic involvement that is above and beyond the normal programmatic oversight, monitoring, and stewardship of awards as described below:**

- Collaborate with recipients to reconcile both the recipient and FDA's inventories of manufactured food firms to ensure consistent regulatory activities. Maintaining an accurate inventory of licensed/registered food facilities for which a program has oversight is foundational to high quality inspection programs.
- Participate in collaborative work planning sessions with the recipient that will focus on coordination of inspections and inspection frequency to promote best use of available resources to protect public health.
- Provide critical field training, technical assistance, and verification of the recipient's field audit program.

- Collaborate on foodborne outbreak and emergency response activities to ensure the best public health outcome.
- Share critical complaints, significant enforcement actions and Class 1 recall information with recipients within required timeframes to control and prevent manufactured food adulteration and foodborne illness.
- Participate in recipient's Food Protection Task Force meetings when applicable.
- FDA SMEs will actively review, assess, verify, and guide self-assessments, strategic improvement plans, and implementation activities.
    - Assessments: recipients are required to participate in formal assessments, in which FDA will evaluate and verify the status of MFRPS conformance, representing decision-making authority at critical project milestones.

## Data Management and Sharing

Consistent with the FDA Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the HHS Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

## Reporting

When multiple years are involved, recipients will be required to submit the progress report annually and financial statements as required in the HHS Grants Policy Statement.

This includes:

- Completion of midyear and annual reporting templates by assigned due dates. Reporting template can be found by clicking on this link: https://www.fda.gov/media/195856/download?attachment
- Submission of required documents in required format, system and using the required naming scheme.
- Applicants shall develop a sustainability plan when designing projects proposed under this cooperative agreement to maximize the longevity of resulting outcomes, resources, and program infrastructure beyond the end of the project period.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement. FDA NOFOs outline intended project goals and objectives. Post award, the FDA will review and measure performance based on the details and outcomes that are shared within the progress report, as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the threshold. See the HHS Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (Responsibility/Qualification in SAM.gov, formerly FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

# Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

### Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

### Program/Technical Contact

Jenice Butler
Office of Domestic Partnerships (ODP)
Food and Drug Administration
Email: Jenice.Butler@fda.hhs.gov

### Financial/Grants Management Contact(s)

Danielle Head
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Email: Danielle.Head@fda.hhs.gov

# Section VIII. Other Information

Recently issued policy notices may affect your application submission. A full list of policy notices is provided in the Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

### Authority and Regulations

Awards are made under the authorization of Section 1004 of the Food and Drug Administration Amendments Act (21 USC 2104) and under Federal Regulation 2 CFR Parts 200 and 300.