Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA. 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	Office of Regulatory Affairs (ORA)
Funding Opportunity Title	**Manufactured Food Regulatory Program Alliance (U18)**
Activity Code	U18 Research Demonstration – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-16-017**
Companion Funding Opportunity	None

Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) is issued to announce the availability of a cooperative agreement to be awarded under a Limited Competition. The goal of FDA/ORA's Cooperative Agreement Program is to facilitate long-term improvements to the national food safety system by strengthening interagency collaboration, improving States' regulatory and surveillance protection programs for manufactured foods, conducting research, and promotion of the Manufactured Food Regulatory Program Standards (MFRPS). This will be accomplished through the provision of funding and will require extensive cooperation and coordination with FDA program offices. Effective leveraging of resources and harmonization of efforts will require collaboration with relevant initiatives, including those of federal partners, national initiatives and associations, state, and local partners.

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	May 2, 2016
Letter of Intent Due Date(s)	May 20, 2016
Application Due Date(s)	July 1, 2016, by 11:59 PM Eastern Time. 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. Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date.

	Late applications will not be accepted for this FOA.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	August 2016
Advisory Council Review	Not Applicable
Earliest Start Date	September 2016
Expiration Date	July 2, 2016
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.
Applications that do not comply with these instructions may be delayed or not accepted for review.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Program Objectives

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Partnerships (OP) is announcing the availability of a cooperative agreement to be awarded under a Limited Competition. FDA can guarantee one year of funding with the possibility of up to four years of additional, non-competitive support, dependent on performance and continued availability of federal funds. Only National Associations/Organizations representing State manufactured food regulatory programs as a primary purpose are eligible to apply for this funding opportunity.

FDA can guarantee one year of funding with the possibility of up to four years of additional, non-competitive support, dependent on performance and continued availability of federal funds.

The goal of the FDA/ORA's Cooperative Agreement Program is to facilitate long-term improvements to the national food safety system by strengthening interagency collaboration, improving States' regulatory and surveillance protection programs for manufactured foods, conducting research, and promotion of the Manufactured Food Regulatory Program Standards (MFRPS). The FDA Food Safety Modernization Act (FSMA) gave FDA a new public health mandate. The law applies to human food as well as to food for animals, including pets. It directed FDA to establish standards for adoption of modern food safety prevention practices by those who grow, process, transport, and store food. Congress recognized that the more than 3,000 state, local, and tribal government agencies involved in food safety which must be fully integrated in FDA's work to fulfill FSMA's mandate that consumers be protected by a food safety system based on prevention and risk. This National Integrated Food Safety System will ensure the quality, consistency, and effectiveness of local, state, and federal efforts to protect the food supply.

Effective leveraging of resources and harmonization of efforts will require collaboration with relevant initiatives, including those of federal partners, national initiatives and associations, state, and local partners. This will be accomplished through the provision of funding and will require extensive cooperation and coordination with FDA, national organizations and initiatives, State and local regulatory programs, and other food safety stakeholders.

The Manufactured Food Regulatory Program Standards (MFRPS) establish a uniform foundation for the design and management of State programs responsible for the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Conformance with these program standards will help Federal and State agencies better direct their regulatory activities at reducing foodborne illness hazards in plants that manufacture, process, pack, or hold foods.

The primary objectives of this cooperative agreement are:

1. Assist FDA in meeting provisions of the FDA Food Safety Modernization Act;

2. Support the efforts of Federal, State, and local government agencies to build an Integrated National Food Safety System;

3. Establish systems for sharing, promotion, and collaboration of best practices, guidance documents, sampling plans, procedures, memorandums of understanding, and other tools to foster mutual reliance between Federal, State and local manufactured food regulatory programs and public health agencies;

4. Assist FDA in the identification, development, delivery, promotion, and/or attendance of food safety and defense training programs to support conformance with the Manufactured Food Regulatory Program Standards (MFRPS) and provisions of FSMA;

5. Support the advancement of the Manufactured Food Regulatory Program Standards (MFRPS) and the Manufactured Food Regulatory Program Alliance (Alliance).

Specific activities of this cooperative should be:
1. Building an on-line program portal to serve as a learning exchange, subject matter expert registry, topical index of regulatory guidance, regulatory updates and other information that impacts manufactured food regulatory programs.

2. Providing forums to elicit, discuss and address concerns identified by State -manufactured food regulatory program relative to the MFRPS, food safety inspection contract, training, FSMA, and other activities impacting Federal-State relations.

3. Updating and continuous improvement of a web based directory of State and local food protection officials for use by Federal, State, local, tribal and territorial regulatory agencies. Continuous improvement activities include expanding the directory to include new agencies and individual roles. The directory should be maintained in an electronic format that is publicly available. A system for maintaining the accuracy of the data should be developed and maintained. At minimum, semi-annual verification of data and updates is anticipated.

4. Providing support to the Manufactured Food Regulatory Program Alliance (Alliance) and other initiatives that advance an integrated food safety system by:

- Supporting a committee structure environment and encourage involvement from State food program managers to assist in technical guidance solutions, implementing changes, and increase sharing of best practices for the Manufactured Food Regulatory Program Standards.
- Scheduling and hosting of meetings (in-person and remote), establishing workgroups, recruiting members, recording of meeting minutes, and other duties necessary to support the goals of the Alliance.
- Maintaining the official repository of all documents created by the Alliance, such as meeting minutes, by-laws, governance structure, suggested changes to the MFRPS, and position statements.
- Hosting of at least one annual face-to-face (minimum of 3 days) meeting to assist State and local manufactured food regulatory programs in achieving conformance with the MFRPS including scheduling, meeting facilities, invitations, registration, materials, and AV needs and support. Grantee will work to ensure the meeting facilities and arrangements are adequate to support the agenda. Feedback should be elicited from attendees through onsite evaluation forms, online surveys, or a combination to identify strengths and opportunities for improvement in future meetings.
- Hosting of at least one annual face-to-face meeting (minimum of 3 days) to assist State laboratories to achieve, maintain, and expand the scope of accreditation, including scheduling, meeting facilities, invitations, registration, materials, and AV needs and support. Grantee will work to ensure the meeting facilities and arrangements are adequate to support the agenda. Feedback should be elicited from attendees through onsite evaluation forms, online surveys, or a combination to identify strengths and opportunities for improvement in future meetings.
- Providing administrative support to the Rapid Response Teams (RRT) Program's annual face to face meeting (minimum of 3 days), including scheduling, meeting facilities, invitations, registration, materials, AV needs, and on-site support during the meeting. Grantee will work to ensure the meeting facilities and arrangements are adequate to support the agenda developed by the RRT Face to Face Meeting Planning Committee. Feedback should be elicited from attendees through onsite evaluation forms, online surveys, or a combination to identify strengths and opportunities for improvement in future meetings.
- Providing administrative support to other meetings the grantee identifies that will support the advancement of an integrated food safety system, including scheduling, meeting facilities, invitations, registration, materials, AV needs, and on-site support during the meeting. Grantee will work to ensure the meeting facilities and arrangements are adequate to support the agenda developed in conjunction with FDA. Feedback should be elicited from attendees through onsite evaluation forms, online surveys, or a combination to identify strengths and opportunities for improvement in future meetings.
- Supporting the training needs for State and local regulatory program's conformance with the

Manufactured Food Regulatory Program Standards (MFRPS) by:

- Identifying, developing, delivering, and/or promoting food safety and defense training programs to support conformance with the Manufactured Food Regulatory Program Standards (MFRPS) and provisions of FSMA.
- Providing financial assistance to State and local food regulatory programs to attend manufactured food training courses and other meetings, as needed.
- Conducting research in the form of surveys of State and local food regulatory programs and perform data analysis to determine the capabilities and capacity of an Integrated National Food Safety System. The research should aim to quantify the efforts of State and local food safety efforts, such as surveillance activities, regulatory actions pursued, and outbreak and emergency response activities. Information on the infrastructure of State and local manufactured food programs may also be collected and studied, such as program resources, funding streams, regulatory structures and authorities, IT support, licensing protocols, use of general funds, and training requirements. The grantee should anticipate performing at least 1 national survey including State and local food regulatory programs per budget period. This information will be important for establishing an Integrated Food Safety System that is better able to control foodborne disease.
- Developing task oriented guidelines to address issues that can be adopted or referenced by manufactured food regulatory programs.
- In support of FSMA, working with FDA to establish, participate, and promote operational partnerships that assist in building an Integrated National Food Safety System. Operational partnerships may include other national associations, alliances (such as the Seafood HACCP Alliance and Preventative Controls Alliance), Partnership for Food Protection (PFP), and Food Protection Task Forces (FPTF).
- Providing financial support for manufactured food regulatory programs to develop, host, or attend training courses, meetings, conferences, and other events that support building an integrated food safety system. Examples include the MFRPA meeting, RRT meeting, ISO 17025 Laboratory Accreditation meeting, Seafood HACCP Alliance, and training courses that support conformance with the MFRPS. An application and approval process for subawarding of funds must be performed in collaboration with and approved by FDA.

5. Establish a system for continuous improvement of all activities being performed under this cooperative agreement. The grantee should actively request feedback from State manufactured food programs on activities being performed under this cooperative agreement. The feedback solicited should then be used to identify future activities.

6. Establish a program for subawarding of funds to food (human and animal) regulatory programs for attending and delivery of courses related to the Preventive Controls Rules (human and animal food) and other FSMA-related rules:

- A minimum of $1,875,000 of funds awarded should be set aside for subawarding to human and animal food regulatory programs to attend training courses related to the Preventive Controls Rules (human and animal food) and other FSMA-related rules. Approximately, 1,000 subawards will be made in Year 1 nationally and must comply with 45 C.F.R 75.327-335 as it relates to procurement standards and subawards
- The applicant should provide in detail the process for subawardees and how they plan to use the funds.
- The applicant should provide in detail the process for selecting subawardees that includes active, direct involvement with FDA.
- Contains a communication strategy that includes advertising the availability of funds and training courses.
- Establishes a system for verification the course was successfully completed by the attendee.
- Reimburses the attendees for registration fees, course materials, and travel expenses, including transportation, hotel, meals, and other reasonable expenses.

Applicants are strongly encouraged to identify additional activities that will support the goals and objectives of this cooperative agreement. Baseline data, targets and performance measures for each activity should be included in the application. The applicant should also suggest the reporting criteria for each activity.

Background

Historically the food supply has encountered risks and emergencies of significant national concern. To provide safe food to consumers, efforts have been undertaken at all levels, including consumers, industry, regulators, and even international organizations, to identify and implement improvements to the food safety system.

- National Integrated Food Safety System

FDA continues to work with its partners to create a national, fully integrated food safety system that is characterized by effective communication and efficient processes among federal, state, and local partners in the food safety system.

Various initiatives, such as the Food Safety Task Force Program, Innovative Food Defense Program, and federal cooperative agreements, work to engage partners across multiple sectors of the food safety system to collaborate and identify means to improve and optimize the nation's food safety system.

The Partnership for Food Protection (http://www.fda.gov/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/default.htm) is a major driving force in the establishment of a national integrated food safety system.

- FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, provides FDA with tools to protect public health by strengthening the food safety system. FSMA will allow FDA to focus on the prevention of foods safety problems by providing new enforcement authorities and risk-based food safety standards. The expanded enforcement authorities include: mandatory recalls, expanded administrative detention, suspension of facility registration, enhanced product tracing abilities, and additional recordkeeping requirements for high-risk foods. FSMA also gives FDA new tools to hold imported foods to the same standards as domestic foods.

FSMA directs FDA to build an integrated national food safety system in partnership with State and local authorities, explicitly recognizing that all food safety agencies need to work together to achieve national public health goals. FSMA identifies some key priorities in working with partners in areas, such as: reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Full text of the law: http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

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

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.
Application Types Allowed	New

	The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
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. Future year amounts will depend on annual appropriations, availability of funding and awardee performance. FDA/ORA intends to fund up to $2,943,750, for fiscal year 2016 in support of this grant program. It is anticipated that up to one (1) award will be made, not to exceed $2,943,750 in total costs (direct plus indirect), per award.
Award Budget	Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: $2,943,750 YR 02: $2,943,750 YR 03: $2,943,750 YR 04: $2,943,750 YR 05: $2,943,750
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 in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

- National Associations/Organizations

The national associations /organizations eligible to apply for funding under this cooperative agreement must be a national organization that represents State and Local manufactured food regulatory programs as a primary purpose. National Associations/Organizations have the membership, resources, structure, and expertise necessary to build national consensus amongst state and local agencies on key food safety issues. They are the primary means for communication and collaboration on issues of national significance for state and local agencies. The outcomes are position statements, resolutions, and legislation that are uniformly supported by state and local agencies. National Associations/Organizations are also viewed as primary sources for educational opportunities and current information, such as proposed legislation and emerging food safety issues.

The association's principle purpose must be to act as a leader and a resource to State and local manufactured food regulatory agencies in developing strategies to resolve and promote public health and consumer protection related to the regulation of manufactured foods. Additionally, the association must have knowledge on the infrastructure, capacity, strengths and needs of State and local food protection programs. The association must have successful experience in carrying out national efforts to build an integrated food safety system, which includes Federal, State, and local agencies. The association must be comprised of regular members that are officials of State and Local regulatory agencies that administer manufactured foods inspection programs in conjunction and in collaboration with FDA.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **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 HHS Grants Policy Statement*, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application 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.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – 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.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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 DUNS number and 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 research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for FDA support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The FDA will not accept duplicate or highly overlapping applications under review at the same time. This means that the FDA will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

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), email 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 via electronic mail as a PDF file with the FOA Number and the Institution's Name in the message subject heading to:

Martin Bernard
Email: Martin.Bernard@fda.hhs.gov

A technical session will be held for prospective applicants in June 2016. The conference call information will be provided to prospective applicants that submit a letter of intent. 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 SF424 Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:

- For this specific FOA, the Research Strategy section is limited to 30 pages.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.

- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

- If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.

- A minimum of $1,875,000 of the award must be allocated for subawarding to State and local

manufactured food (human and animal) regulatory programs to attend training and meetings to support conformance with the MFRPS, Animal Food Regulatory Program Standards (AFRPS), obtaining ISO accreditation, and other training that supports implementation of FSMA and building an integrated food safety system.

R&R Subaward Budget
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:
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- Note: Generally, Resource Sharing Plans are expected, but not for this FOA

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report
When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

PHS Assignment Request Form
All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)
See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times
Part I. Overview Information 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.

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. eRA Commons 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. **Late applications will not be accepted for this FOA.**

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 SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the *HHS Grants Policy Statement*.

Pre-award costs are allowable only as described in the *HHS Grants Policy Statement*.

The purpose of this cooperative agreement is to promote the development and enhancement of State and local manufactured food regulatory programs, including the adoption and implementation of the MFRPS.

A minimum of $1,875,000 of the award must be allocated for subawarding to State and local manufactured food (human and animal) regulatory programs to attend training and meetings to support conformance with the MFRPS, obtaining ISO accreditation, and other training that supports implementation of FSMA and building an integrated food safety system. An estimated 1,000 regulatory officials will need to attend the Preventive Controls Alliance course in Year 1. Other training courses and needs may also be identified in Year 1 and in subsequent years including attending, delivery, and development of training courses to support FSMA related rules. The grantee may request a budget modification based upon the actual funds requested by State and local food regulatory programs and laboratories.

Non-allowable costs:

1) Vehicle purchases are not permitted.

2) Cooperative agreement funds may not be utilized for new building construction or remodeling.

Additional funding restrictions may be part of the Notice of Award.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) 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 Applying Electronically. 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 Component of the SF424(R&R) Application Package**.** 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 FDA. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for

Award Management. Additional information may be found in the SF424 (R&R) 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 Grants Management Specialist and responsiveness by components of participating organizations, in FDA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit.

1. The rationale and design to accomplish the goals and objectives of the cooperative agreement (total weight = 40 points).

2. Performance measures proposed will produce quantitative and/or qualitative data to clearly demonstrate progress towards accomplishing the goals, objectives and activities of the cooperative agreement (total weight = 20 points).

3. Demonstration of effectiveness in working with Federal, State, and local partners to implement the goals and objectives of the cooperative agreement (total weight = 20 points).

4. Demonstration of resources, personnel, and infrastructure necessary to meet the goals and objectives of the cooperative agreement (total weight = 20 points).

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items, but will not give separate scores for these items and should not consider them in providing an overall score.

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 research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an Objective Review Committee using the stated review criteria.

As part of the objective review, all applications:

- Will receive a written critique.

Appeals of objective review **will not** be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. 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.

3. 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.

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found in the HHS Grants Policy Statement.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the *HHS Grants Policy Statement* as part of the NoA.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS

Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

FDA considers the sharing of research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of research. When research resources have been developed with FDA funds and the associated research findings published, those findings must be made readily available to the scientific community.

Upon acceptance for publication, scientific researchers must submit the author's final manuscript of the peer-reviewed scientific publication resulting from research supported in whole or in part with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. Please see the FDA Public Access Policy.

Additional terms and conditions regarding FDA regulatory and ORA programmatic requirements may be part of the Notice of Award.

Cooperative Agreement Terms and Conditions of Award

Support will be in the form of a cooperative agreement. Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement, including participating, guiding, coordinating, and participating in project activities.

Substantive involvement includes, but is not limited to, the following:

- FDA review and approval of task oriented guidelines and other documents developed under the award.
- FDA assistance and coordination in the sharing of information to Federal, State, and local agencies and other stakeholders.
- FDA review and approval of publications/web applications or any revisions to existing systems.
- FDA review and approval of subawards made using cooperative agreement funds. FDA has discretion when making final subaward decisions, and can approve changes to funding amount, priority, and other aspects to ensure the subaward meets the FDA's intended goals.
- Other assistance or collaboration as requested by associations and State/local agencies.
- Minimum of one (1) meeting per year with the Program Office to review grantee progress and discuss cooperative agreement goals and objectives.
- Coordination of surveys conducted.

Monitoring Activities

The program project officer will monitor the recipient periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the principal investigator. Periodic site visits with officials of the recipient organization may also occur. There may be other regular meetings with recipients to assist in fulfilling the requirements of the cooperative agreement. At minimum, an annual meeting will be held with the grantee to discuss progress and review cooperative agreement goals and objectives.

The results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations. Also, the grantee organization must comply with all terms and conditions of the cooperative agreement, including those which state that future funding of the project will depend on recommendations from the Project Officer.

The scope of the recommendation will confirm that:
(1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; and (3) if necessary, there is an indication that corrective action has taken place.

Principal Investigator Rights and Responsibilities

The Principal Investigator will have the primary responsibility for and dominant role in planning, directing, and executing the proposed project, with the FDA staff being substantially involved as a partner with the PI.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and FDA policies.

FDA Responsibilities

a. FDA will have prior approval of the appointment of all key administrative and scientific personnel proposed by the grantee.

FDA scientists and subject matter experts will participate, with the grantee, in determining and carrying out scientific and technical activities. Collaboration will also include data analysis, interpretation of findings and, where appropriate, co-authorship of publications.

In addition, work proposed and conducted under this cooperative agreement may not be duplicated or funded by other cooperative agreements, contracts or grants or other funding mechanisms. Projects proposed and conducted under this cooperative agreement must remain distinct and separate from other projects and funding sources.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the Notice of Award.

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*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees 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 $25,000.

Mid-year progress and annual progress reports must contain the elements below as applicable to their proposal and award, but are not limited to, the following:

- Content, usage, and improvements to the on-line Manufactured Food State Program Manager's portal, including the subject matter expert registry, topical index of regulatory guidance, regulatory updates, etc. Statics on baseline and current of these systems and feedback received should be included.
- Summary of issues elicited related to the implementation of MFRPS, FSMA, food safety inspection contract, training and other issues impacting State and local manufactured food regulatory programs.

- Impact and recommendations from forums to address concerns identified by State and local manufactured food regulatory program relative to the MFRPS, FSMA, and other activities impacting Federal-State relations.
- Improvements and updates made to the web based directory of State and local food protection officials for use by Federal, State, local, tribal and territorial regulatory agencies. The directory shall be maintained in an electronic format easily accessible to all interested parties and updated at least semi-annually. Statistics on baseline and current use of these systems should be provided. Feedback and opportunities for improvement should be identified.
- Status updates on the MFRPA and associated committees, including involvement from State and local food regulatory program managers, technical guidance provided, best practices shared, and changes recommended for the Manufactured Food Regulatory Program Standards (MFRPS). Updates should include meetings held, participants, summaries of issues discussed, decisions made, action items, and responsible parties.
- Summaries, outcomes, and evaluations of meetings (in-person and remote) held to support the goals of the Alliance and building an integrated food safety system, such as the annual MFRPA, ISO 17025 Laboratory Accreditation, and RRT meetings. The feedback solicited should be used to improve the quality of future meetings.
- Content, usage, and improvements to the MFRPA portal (or other platform for storing the official records generated for the MFRPA). Statics on baseline and current usage should be provided. Feedback and opportunities for improvement should be identified.
- Summary on the identification, development, and/or delivery of food safety and defense training programs to support conformance with the Manufactured Food Regulatory Program Standards (MFRPS) and provisions of FSMA.
- Financial assistance provided to State, local, territorial, and tribal attendees to attend, develop, or host manufactured foods training courses, meetings, and other initiatives to support an integrated food safety system.
- Data, analysis, and response rates of surveys conducted of State manufactured foods programs.
- Development and distribution of task oriented guidelines to address issues that can be adopted or referenced by manufactured food regulatory programs.
- Support, outreach and involvement in operational partnerships that assist in building an Integrated Food Safety System.

Mid-year and annual progress reports must report against the progress made for each of the objectives and activities outlined in the application and agreed upon by the grantee and FDA. The grantee and FDA will determine the specific progress reporting requirements within 90 days of the award.

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 registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

Wendy Campbell
FDA/ORA/OP
Telephone: 615-310-0483
Email: wendy.campbell@fda.hhs.gov

Objective Review Contact(s)

Martin Bernard
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-7564
Email: Martin.Bernard@fda.hhs.gov

Financial/Grants Management Contact(s)

Martin Bernard
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-7564
Email: Martin.Bernard@fda.hhs.gov

Section VIII. Other Information

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 301 of the Public Health Service Act (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.