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

Limited Competition: Advancing Conformance with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) (U18)

Activity Code

U18 Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-15-018

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

The intended outcome of this FOA is to advance efforts for a nationally integrated food safety system by assisting retail food regulatory programs in achieving conformance with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS or Retail Program Standards). The Retail Program Standards apply to the operation and management of a retail food regulatory program that is focused on the reduction of risk factors known to cause or contribute to foodborne illness and to the promotion of active managerial control of these risk factors. These cooperative agreements are intended to assist

regulatory food retail programs in developing, implementing, and improving the infrastructure necessary to support conformance with the VNRFRPS.

Key Dates

Posted Date

May 6, 2015

Open Date (Earliest Submission Date)

May 15, 2015

Letter of Intent Due Date(s)

May 28, 2015 by 11:59 PM Eastern Time.

Application Due Date(s)

July 15, 2015 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

July, 2015

Advisory Council Review

Not Applicable

Earliest Start Date

September, 2015

Expiration Date

July 16, 2015

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.**

Apply for Grant Electronically

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://www.grants.gov/contactus/contactus.jsp.

Table of Contents

Part 1. Overview Information
Part 2. Full Text of the Announcement

- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 2. Full Text of Announcement
Section I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Partnerships (OP) is announcing the availability of cooperative agreements to be awarded under Limited Competition to State, local, territorial, or tribal retail food regulatory programs. The intended outcome of this FOA is to advance efforts for a nationally integrated food safety system through the conformance with and advancement of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS or Retail Program Standards). The VNRFRPS apply to the operation and management of a retail food regulatory program that is focused on the reduction of risk factors

known to contribute to foodborne illness and the promotion of industry action to achieve active managerial control of these risk factors. The Retail Program Standards include nine individual Program Standards. Each Program Standard has one or more corresponding worksheets, forms and guidance documents.

In developing the Retail Program Standards, FDA recognized that the ultimate goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illnesses and deaths from food produced at the retail level and that there are different approaches toward achieving that goal. Federal, state, local, and tribal agencies continue to employ a variety of mechanisms with differing levels of sophistication in their attempt to ensure food safety at retail. The Retail Program Standards encourage regulatory agencies to improve and build upon existing programs. Further, the Retail Program Standards provide a framework designed to accommodate both traditional and emerging approaches to food safety.

While the Retail Program Standards represent the effective, focused food safety program to which we

ultimately aspire, they begin by providing a foundation and system upon which all regulatory programs can build through a continuous improvement process. The Retail Program Standards are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness, with the ultimate goal of reducing the occurrence of those factors.

Background

This funding opportunity furthers FDA's efforts to enhance state, local, territorial, and tribal food safety programs. Recent legislative and strategic initiatives have addressed FDA's relationship with state, local, territorial and tribal authorities in food protection activities.

a. Food Safety Initiative

Announced in October 2010, the Retail Food Safety Initiative is part of the Food and Drug Administration's overall prevention-based, farm-to-table food safety strategy to reduce foodborne illness. The FDA actions in this initiative are prompted by a 10-year study of more than 800 retail food establishments to determine compliance with five key risk factors in nine types of retail operations.

FDA's partnerships with the retail food industry; state, local and tribal authorities; and other government agencies are a foundational building block of the initiative and key to its success in four action areas:

-Make the presence of certified food protection managers common practice.

-Strengthen active managerial controls at the retail level and ensure better compliance.

-Encourage widespread, uniform, and complete adoption of the FDA Food Code.

-Create an enhanced local regulatory environment for retail food operations.

To help create an enhanced local regulatory environment for retail food operations, FDA is committed to:

(1) Promote wider implementation by state, local and tribal regulatory programs of the FDA Voluntary National Retail Food Regulatory Programs Standards.

(2) Ensure universal participation by local regulators in consistent, high quality training through increased access and increased portability and transferability of FDA courses

(3) Seek increased multi-year funding for the state, local and tribal programs as part of an integrated food safety system.

a. Food and Drug Administration Amendments Act of 2007 (FDAAA)

Under FDAAA, FDA is required to work with the states to improve food safety. Section 1004 of FDAAA states:

SEC. 1004. STATE AND FEDERAL COOPERATION

(a) IN GENERAL.—The Secretary must work with the states in undertaking activities and programs that assist in improving the safety of food, including fresh and processed produce, so that state food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary must encourage states to—

(1) Establish, continue, or strengthen state food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) Establish procedures and requirements for ensuring that processed produce under the jurisdiction of state food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a state, for planning, developing, and implementing such a food safety program—

(1) Advisory assistance;

(2) Technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) Financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a federal, state, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a state agency under this subsection may provide for training of state employees.

c. Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, provides FDA with tools to better protect public health by strengthening the food safety system. It enables FDA to focus on preventing food safety problems rather than reacting to problems after they occur. It also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. These include authorities such as mandatory recall, expanded administrative detention, suspension of facility registration, enhanced product tracing abilities, and additional recordkeeping requirements for high-risk foods. FSMA also gives FDA important 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 in an integrated way 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.

Objectives

When first enrolling in the Retail Program Standards, regulatory retail programs are encouraged to conduct a comprehensive self-assessment to identify program needs and then establish priorities to maximize the effectiveness of resources. Post-assessment, cooperative agreement funds should be used to enhance or establish systems to:

a. Identify program areas where an agency can have the greatest impact on retail food safety.

b. Promote wider application of effective risk-factor intervention strategies.

c. Promote wider application of active managerial control strategies by industry targeted to the risk factors associated with foodborne illness.

d. Assist in identifying program areas most in need of additional attention and strategies to address identified areas.

e. Develop and implement innovations in program implementation and administration.

f. Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies.

These cooperative agreements are intended to develop, implement, and continuously improve the

infra-structure and effectiveness of retail food programs using the FDA VNRFRPS. Under the cooperative agreement, the state, local, territorial, or tribal jurisdiction would implement a continuous program improvement/enhancement strategy (strategic plan) using the FDA VNRFRPS. The strategic plan may include implementing individual standards that have not yet been met, pursuing enhancements to implemented standards, or developing innovative intervention strategies designed to reduce the occurrence of contributing risk factors associated with foodborne illness. The strategic plan should identify the timeframes, personnel and other resources required for implementation. Funds may be used to increase personnel to support the FDA VNRFRPS Cooperative Agreement (such as team coordinators, technical experts, and epidemiologists). Funds may also be used for supplies, training, and equipment, including investigational, GPS interface, communication, and laboratory.

The goal of developing and sustaining the FDA VNRFRPS is in concert with long-term goals to: enhance the food inspection, food safety and foodborne illness response programs; increase the programs' ability to inspect and obtain compliance in their jurisdiction involved in retail food regulation; and verify compliance with state, local and tribal laws and regulations, food defense, and other food protection requirements in support of the state, local, territorial, and tribal program and the FDA Food Safety Initiative. Extensive cooperation and coordination with FDA Regional Offices and other FDA program offices is expected.

The applicant shall specifically address the ability to achieve the following objectives in the cooperative agreement:

1. Demonstrate the ability to develop and implement a comprehensive strategic plan that includes goals and project goals that shall significantly advance conformance with the Retail Program Standards (either within an individual regulatory program or across multiple regulatory programs).

2. Demonstrate the ability to fully participate in efforts supporting the Retail Program Standards and the FDA's Retail Food Safety Initiative, such as participating on committees, sharing of best practices, and engaging the retail food industry to promote effective management of foodborne illness risk factors and improve compliance with regulations modeled after the FDA Food Code.

3. Demonstrate the availability of adequately trained staff and the criteria and ability to hire and/or train personnel to meet the deliverables of the cooperative agreement.

4. Provide a properly detailed budget (one for each of the five years) that is intended to advance conformance with the Retail Program Standards (either within an individual regulatory program or across multiple regulatory programs).

5. Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3 of this announcement.

6. Provide the previous year and current funding level certification for the retail food regulatory program.

7. Outline a detailed methodology for program assessment, improvement, and collaboration to accomplish the work, as described in this announcement, and ensure program sustainability.

8. Provide justification for hiring new staff, including qualifications, training needs, and new equipment needs.

Finally, these cooperative agreement funds are intended to supplement, not replace, current funding for program improvement and activities. Agencies funded under these cooperative agreements may be required to provide the previous and subsequent years of state, local, territorial, or tribal funding to demonstrate that these funds have not replaced previous allocations.

Outcomes

The outcomes of the work provided under this cooperative agreement are as follows:

1. Retail food regulatory programs must achieve greater conformance with the Retail Program Standards, which promotes uniformity and an integrated national food safety system.

2. Retail food regulatory programs must contribute to the continuous improvement and advancement of the Retail Program Standards.

3. Develop strategies for achieving and sustaining conformance with the Retail Program Standards that can be shared and duplicated by other agencies.

4. Provide the retail food regulatory program the ability to implement innovative intervention strategies designed to reduce the occurrence of contributing risk factors associated with foodborne illness that can be shared and duplicated by other agencies.

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.

Application Types Allowed

New

The OER Glossary and the SF 424 (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 $1,495,000, for fiscal year 2015 in support of this grant program.

It is estimated that 22 awards may be made, not to exceed $70,000 in total costs (direct plus indirect), per award.

Future Year amounts will depend on annual appropriations and grantee performance.

Award Budget

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct plus indirect):

YR 01: $70,000
YR 02: $70,000
YR 03: $70,000
YR 04: $70,000
YR 05: $70,000

Award Project Period

The agreements include one year of funding with up to four years of additional funding, to be awarded noncompetitively dependent on performance and availability of funds. The agreements must require the development and maintenance of Retail Program Standard initiatives through processes to enhance and build the existing infrastructures of retail food protection programs.

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Only state, local, territorial, and tribal agencies with primary regulatory responsibility for retail food establishments, or those government agencies with substantial involvement and control over such agencies, are eligible to apply. Recipients of prior VNRFRPS cooperative agreement funding are eligible to apply. In addition, the retail food regulatory agency must be enrolled in the VNRFRPS and have completed a current self-assessment against the Retail Program Standards as required by Standard 9.

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

- 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 only one application.

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 download 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.

A technical review session will be held for prospective recipients. The conference call will provide information to prospective grantees that submit a letter of intent. The technical review session will provide an overview of the submission requirements and allow prospective grantees an opportunity to ask questions regarding the application process. Participation in the technical review session is optional, but strongly encouraged.

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
- Status of enrollment in the Retail Program Standards

The letter of intent should be emailed no later than May 28, 2015 to:

Dan Lukash
Grants Management Specialist
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

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 15 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.

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:

- Generally, Resource Sharing Plans are expected, but they are not applicable 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.

Planned Enrollment Report

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

PHS 398 Cumulative Inclusion Enrollment Report

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

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. 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. 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.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. 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*.

These awards may only be used for achieving and sustaining conformance with the Retail Program Standards within retail food regulatory programs.

Allowable costs include:

1) Audiovisual materials such as videotapes, DVDs, public service announcements, etc.

2) Consultant services

3) Employee salaries, wages and fringe benefits

4) Rental, purchasing, calibration, and maintenance of supplies and equipment, including investigational, GPS interface, communication, and laboratory

5) Indirect costs

6) Recruitment costs for hiring new employees

7) Registration fees

8) Purchase or development of IT equipment, software, and support

9) Shipping and mailing of equipment and supplies

10) Travel

11) Speaker fees

12) Conducting standardizations

13) Training programs, including the development, delivery, and attendance

14) Subcontracting to third parties (other than local/county/tribal agencies) is allowed but limited to 25% of each year's award. No limit exists for subcontracting to local/county/tribal agencies.

Non-allowable costs:

1) Facilities, work, and training reimbursed under other cooperative agreements, grants, contracts, and other funding mechanisms must remain distinct and separate from this cooperative agreement.

2) Vehicle purchases are not permitted.

3) Cooperative agreement funds may not be utilized for new building construction; however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 10% of the grant award amount.

Please refer to the HHS Grants Policy Statement for additional information regarding costs.

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

6. 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.

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, FDA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Post submission materials will not be accepted for this FOA.

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.

Rationale and Design (60 Points)

Does the project rationale and design meet the goals and project goals of this cooperative agreement? Are the overall strategy, methodology, and evaluations well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented?

Program Resources (20 Points)

Are adequate program resources (especially staff) and infrastructure to complete project needs, or the ability to obtain adequate program resources identified? Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Approach (20 Points)

Demonstration that capabilities can be sustained after the conclusion of the project period.

Expected challenges should be documented and addressed.

Additional Review Considerations

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or FDA-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of

Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genomic Wide Association Studies (GWAS) /Genomic Data Sharing Plan.

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 awardee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. 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.

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

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 (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and FDA grant administration policies.

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.

Monitoring Activities

The ORA Project Officer and Technical Advisor will monitor award recipients periodically. The monitoring may be in the form of face-to-face meetings, 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 will occur, including program assessments and audits. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be made available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations. Also, the grantee organization must comply with all special 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 and Technical Advisor.

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.

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) and financial statements.

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 reports must contain the elements below as applicable to their application and award, but are not limited to, the following:

1. Detailed progress report on the grantee meeting the project goals identified in the application.

2. Status report on the hiring and training of food program personnel.

3. Certification of current appropriation funding levels for the retail food regulatory program.

4. A strategic plan that accurately reflects when specific objectives and tasks have been, or will be, completed and/or implemented and when new objectives and tasks are identified to advance conformance with the Retail Program Standards. The strategic plan should include significant goals or action items, anticipated completion dates, responsible personnel, and other required resources.

5. Description of program improvements in achieving conformance with the Retail Program Standards and promoting more effective control of foodborne illness risk factors in.

The final program progress report must provide full written documentation of the entire project and summaries of accomplishments and goals, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other agencies could reproduce the final project. The final program progress report should also detail the strategy to continue advancing conformance with the Retail Program Standards (current and future versions).

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 Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)
Finding Help Online: http://grants.nih.gov/support/index.html
Email: commons@od.nih.gov

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

Scientific/Research Contact(s)

Catherine Hosman
Food and Drug Administration (FDA)
Telephone: 781-587-7443
Email: catherine.hosman@fda.hhs.gov

Objective Review Contact(s)

Daniel Lukash
Office of Acquisition & Grants Services (OAGS)
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Financial/Grants Management Contact(s)

Daniel Lukash
Office of Acquisition & Grants Services (OAGS)
Telephone: 240-402-7596
Email: daniel.lukash@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 Sections 301 of the Public Health Service Act as amended (42 USC 241), Section 1009 of the Federal Food, Drug, and Cosmetic Act (21 USC 399), and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.