

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

U.S. Food and Drug Administration ([FDA \(http://www.fda.gov/\)](http://www.fda.gov/))

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 \(http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm\)](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm))

Funding Opportunity Title

Conformance with the Manufactured Food Regulatory Program Standards (MFRPS) (U18)

Activity Code

[U18 \(//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u18&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u18&Search.x=0&Search.y=0&Search_Type=Activity) Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-17-005

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 State manufactured food regulatory programs to achieve and maintain conformance with the Manufactured Food Regulatory Program Standards (MFRPS). The MFRPS are intended to ensure that State manufactured food regulatory programs develop, and maintain best practices for a high-quality regulatory program. Also, the program standards are intended to enhance food safety by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. Conformance with these program standards will help Federal and State programs better direct their regulatory activities at reducing hazards in firms that manufacture, process, pack, or hold foods. Grantees may also choose to pursue special projects that will further enhance the capacity of the State manufactured food regulatory program to protect public health and safeguard the food supply.

Key Dates

Posted Date

March 1, 2017

Open Date (Earliest Submission Date)

March 1, 2017

Letter of Intent Due Date(s)

March 15, 2017

Application Due Date(s)

May 1, 2017 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

May 2017

Advisory Council Review

Not Applicable

Earliest Start Date

August 1, 2017

Expiration Date

May 2, 2017

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](http://grants.nih.gov/grants/guide/ur_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/ur_redirect.htm?id=12000](http://grants.nih.gov/grants/guide/ur_redirect.htm?id=12000)), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/) ([//grants.nih.gov/grants/guide/](http://grants.nih.gov/grants/guide/))). 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](http://www.grants.gov/help/download_software.jsp#adobe811) (http://www.grants.gov/help/download_software.jsp#adobe811) 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/web/grants/support.html> (<http://www.grants.gov/web/grants/support.html>).

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA) is announcing the availability of up to \$10,000,000 to be awarded under Limited Competition to State, Tribal, and Territorial ("State") manufactured food regulatory programs. The intended outcome of this FOA is to advance efforts for a nationally integrated food safety system through the conformance to and advancement of the Manufactured Food Regulatory Program Standards (MFRPS) by State manufactured food regulatory programs.

MFRPS advances the development of risk-based food safety programs by establishing a uniform basis for measuring and improving the performance of State manufactured food regulatory programs in the United States. By achieving and sustaining conformance with these program standards, Federal and State programs can better direct their regulatory activities toward reducing hazards in food facilities. Consequently, the safety and security of the United States food supply will improve.

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements are the program's regulatory foundation, training program, inspection program, inspection audit program, food-related illness outbreak response, compliance and enforcement, industry and community relations, program resources, program assessment, and laboratory support.

Achieving and sustaining conformance with the program standards will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation. However, all State manufactured food regulatory programs will be expected to implement strategic improvement plans to ensure continuous improvement and demonstrate that they are moving towards conformance.

For the purpose of this funding opportunity, conformance means the fulfillment of a requirement; specifically a State program is using and can demonstrate the use of a particular element, system, or program listed in the MFRPS (2016 or most recent edition).

Grantees with developed MFRPS programs are encouraged to pursue special projects that will further enhance the capacity of the State manufactured food regulatory program to protect public health and safeguard the food supply.

Examples of potential special projects include, but are not limited to:

- a) Development of a new inspections or investigations course, such as courses for a specific commodity, investigation technique, industry, or new rule.
- b) Development of a new environmental sampling methodology to enhance efficiency.
- c) Development of a system to collaborate with FDA and other agencies through IT information sharing.
- d) Development of an electronic risk based modeling program that can demonstrate increased efficiency and effectiveness.
- e) Development of a new foodborne illness prevention and/or intervention strategy designed for a specific targeted population.
- f) Development of best practices or piloting of innovative approaches/technology/tools related to inter-agency data sharing, communication and coordination during prevention, intervention and response.

g) Teaching and delivery of Preventive Controls Regulatory Course (FD 254) and other training courses to support FSMA implementation.

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

State manufactured food regulatory programs will achieve and sustain conformance with the MFRPS (2016 or most recent edition), which is recognized as a critical element to creating a national, fully integrated food safety system. If conformance is not achieved by the conclusion of the cooperative agreement, the program will have a strategic improvement plan which describes the steps and timeframe anticipated to reach conformance. As defined in the 2016 edition of the MFRPS, "Strategic Improvement Plan" means a type of improvement plan that includes the following information: (1) the individual element or documentation requirement of the standard that was not met; (2) improvements needed to meet the program element or documentation requirement of the standard; (3) projected completion dates for each task; (4) personnel responsible; and (5) date completed

State manufactured food regulatory programs will contribute to the continuous improvement of the MFRPS through attendance at an annual face-to-face meeting, active participation in committees, and other initiatives supporting the MFRPS.

Recipient programs will research and develop strategies for achieving and sustaining conformance with the MFRPS that can be duplicated on a national basis. States are also encouraged to undertake special projects that will advance MFRPS and public health protection in their proposed project.

Recipient programs will provide FDA the foundation for pursuing regulatory action based upon the findings of State manufactured food regulatory programs.

Recipient programs will ensure food safety staff successfully complete training courses required for conformance with the MFRPS and maintaining the food contract in satisfactory condition.

If the grantee is located in a state which, at the time of application submission, has a laboratory awarded a current FDA ISO Laboratory Accreditation Cooperative Agreement, the regulatory program grantee will provide for the collection of samples (FDA regulated products only) to support laboratory capacity development and product surveillance. The applicant must also demonstrate the ability to perform any enforcement or other follow-up activities based on sample results. Sampling plans will be developed collaboratively with the laboratory to support the objectives of both programs.

Background

a. FDA Food Protection Plan

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne disease in the nation is substantial. CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases <http://www.cdc.gov/foodborneburden/> (<http://www.cdc.gov/foodborneburden/>). New challenges continue to arise, including the globalization of the food supply and the emergence of new pathogens in foods. "Food" includes human food and animal feed and is defined in 21 USC 321(f).

In May 2007, Secretary of Health and Human Services, Michael O. Leavitt and Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, charged FDA with developing a comprehensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counter those before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

The Plan builds in safety measures to address risks throughout a product's life cycle, from the time a food is produced to the time it is distributed and consumed. The Plan focuses FDA efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective. The Plan also calls for a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: Prevention, intervention and response.

b. National Integrated Food Safety System

FDA is continuing to work with its state 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 Protection Task Force Program, Innovative Food Defense Program, Rapid Response Team Program, and the programs supported by these cooperative agreements, work to engage partners across multiple sectors of the food safety system to collaborate to identify means to improve and optimize the nation's food safety system.

c. 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. FSMA directs FDA to build an National Integrated Food Safety Initiative in partnership with State, local, territorial, and tribal 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.

Subtitle A of Title III—Protection of Food Supply, Section 311—Grants to States for Inspections, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 1009, which authorizes the Secretary of Health and Human Services to award grants to States, territories, and Indian tribes to enhance food safety. Full text: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm155769.htm> (<http://www.fda.gov/RegulatoryInformation/Legislation/ucm155769.htm>).

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

FDAAA amended the FD&C Act to require FDA to work with the States to undertake activities to assist in improving food safety. This requirement is contained within Title X (Food Safety) Section 1004 of the FDAAA (Full text: <http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/html/PLAW-110publ85.htm> (<http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/html/PLAW-110publ85.htm>)).

e. Import Safety Action Plan

The Import Safety Action Plan acknowledges the value of mutual leveraging of State and Federal resources and recommends consideration of cooperative agreements to increase information sharing. Specifically, the ISAP contains Recommendation 12 to maximize federal-state collaboration for federal-state rapid response (<http://archive.hhs.gov/importsafety/report/actionplan.pdf> (<http://archive.hhs.gov/importsafety/report/actionplan.pdf>); pages 37-38).

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11116\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) 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. Award(s) will provide one (1) year of support contingent upon annual appropriations, availability of funding and satisfactory awardee performance.

FDA/Office of Regulatory Affairs intends to fund up to \$10,000,000 for fiscal year 2017 in support of this grant program.

It is anticipated that up to 30 awards will be made, not to exceed \$375,000 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: \$375,000

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is one (1) year.

HHS grants policies as described in the [HHS Grants Policy Statement \(http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf\)](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Eligible organizations include the following as described in FDCA Section 1009 (21 USC 399):

Governments

State Governments

Indian/Native American Tribal Governments (Federally Recognized)

U.S. Territory or Possession

This opportunity is only available to the following State, Tribal or Territorial food safety programs:

Manufactured food regulatory programs with current FDA food safety inspection contracts (providing funding to food protection regulatory programs), or those that successfully submit a food inspection contract proposal for Federal Fiscal Year 2017 are eligible to apply for funding under this cooperative agreement. Competition is limited to State, Tribal and Territorial manufactured food regulatory programs previously funded under FD-12-007 or organizations that have not previously received a Manufactured Food Regulatory Program Standards Cooperative Agreement. Applicants currently funded under Conformance with the Manufactured Food Regulatory Program Standards PAR-13-164 are not eligible to apply.

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](#)

(<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsqps107.pdf>), **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 \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - 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 \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - 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 \(http://www.grants.gov/applicants/organization_registration.jsp\)](http://www.grants.gov/applicants/organization_registration.jsp) – 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 require cost sharing as defined in the HHS Grants Policy Statement and described in FDCA Section 1009 (21 USC 399).

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

Buttons to access the online ASSIST system or to download application forms are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research Instructions for the [SF424 \(R&R\) Application Guide \(\[//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\]\(https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)\)](#), including [Supplemental Grant Application Instructions \(<https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf>\)](#) 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 \(\[//grants.nih.gov/grants/guide/url_redirect.htm?id=41137\]\(https://grants.nih.gov/grants/guide/url_redirect.htm?id=41137\)\)](#).

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:

Allison Mandel

Email: [allison.mandel@fda.hhs.gov \(mailto:allison.mandel@fda.hhs.gov\)](mailto:allison.mandel@fda.hhs.gov)

A technical session will be held for prospective applicants in March 2017. 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](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed, with the following exceptions or additional requirements:

- For this specific FOA, the Research Strategy section is limited to 20 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:

- 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.

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

Provide a comprehensive strategic improvement plan that will result in conformance with the MFRPS and sustainability after the cooperative agreement (if previously funded) or demonstrate the ability to conduct a self-assessment and identify the tasks and resources necessary to reach conformance (for new enrollees).

Demonstrate the ability to satisfy the reporting requirements of this announcement.

Demonstrate the ability to fully participate in initiatives supporting the MFRPS, such as an annual face-to-face meeting (as determined by FDA), committees, MFRPS conference calls, sharing of best practices, annual on-site visits, program assessment validation audits (PAVA), and full program audits.

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

Provide a sufficiently detailed budget to meet all objectives and conditions of the award. Certify the cooperative agreement funds do not supplant state appropriations for the manufactured food regulatory program.

If the program is located in a state which, at the time of application submission, has a laboratory awarded a current FDA ISO Laboratory Accreditation Cooperative Agreement ("Laboratory"), the applicant must demonstrate the ability to collect samples to support laboratory capacity development and product surveillance for pathogenic organisms or analytes of interest. The applicant must also demonstrate the ability to perform any enforcement or other follow-up activities based on sample results.

The FDA recognizes that timeframe to achieve conformance with the MFRPS will vary by program based on multiple factors, such as previous enrollment in the MFRPS and current level of conformance, including changes in regulation, drafting and adoption of new administrative rules, and staff changes.

The project milestones provided below are suggested for new programs enrolling in the MFRPS who have never completed and submitted a baseline MFRPS self-assessment to FDA:

1. The State manufactured foods program should agree to enter into a food safety inspection contract with the FDA under the FY2017 Request for Proposals if not under a current food safety inspection contract. A current food safety inspection contract should be maintained throughout the cooperative agreement.
2. Participation in an on-site visit consisting of key State food regulatory program and FDA personnel to discuss the requirements of the MFRPS. Participation includes providing meeting space, accessibility of key State food regulatory program management and staff, and access to records, databases, and other materials supporting MFRPS conformance. Additionally, the recipient should agree to submit to an audit of MFRPS conformance upon request by the FDA/ORA Office of Operations Audit Staff as described in Section VI.
3. Attendance and participation of key State manufactured food program managers and staff in an annual face-to-face meeting, committee meetings, and other initiatives supporting national and program specific conformance with the MFRPS.
4. Conduct a comprehensive baseline self-assessment, including completion of all applicable appendices, worksheets, and other documents (or equivalent documents), required in each Standard.
5. New programs should develop a strategic improvement plan that will result in conformance within five (5) years.

The application must demonstrate that the funds from this cooperative agreement shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this funding opportunity announcement. The applicant must provide assurance that plans have been developed to engage in the types of activities outlined in the grant application using these grant funds, an itemization of how grant funds will be expended, a description of how grant activities will be monitored, and ability to report information required by the Secretary to conduct evaluations.

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.

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.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the [HHS Grants Policy Statement](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsqps107.pdf) (<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsqps107.pdf>), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), 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. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11142\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

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 \(http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf\)](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

Pre-award costs are allowable only as described in the [HHS Grants Policy Statement \(http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf\)](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

The FDA will provide one year of funding, contingent on continued availability of federal funds. Application budgets are limited to \$375,000 (direct and indirect costs) of funding requested and must reflect the actual needs of the proposed project.

Up to \$300,000 in direct and indirect costs may be allocated to program development and implementation of the MFRPS and Special Projects.

Up to \$75,000 in direct costs only may be allocated to support travel costs only to FDA-sponsored advanced food inspection training courses. Eligible expenses to support travel to attend FDA-sponsored manufactured food training courses include transportation, lodging, meals/per diem, parking, baggage fees, and other reasonable costs for travel to the course. Other costs, such as employee salaries, indirect costs, and other non-travel related costs, are not allowable costs for the training cost portion of the award.

Eligible FDA manufactured foods training courses include:

- FD 152 Food Processing and Technology
- FD 180 Food Good Manufacturing Practice, Application and Evidence Development

- FD 202 Conducting Acidified Food Inspections
- FD 219 Juice HACCP and Conducting Juice Inspections
- FD 249 Conducting Seafood Inspections
- FD 254 Preventive Controls for Human Food Regulators Course
- FD 304 Low Acid Canned Food Inspections
- Grantees will be notified if additional eligible courses are added

These funds are intended to supplement, not replace, State funding for program improvement and activities. State manufactured food programs funded under these cooperative agreements will be required to certify that these funds have not replaced State allocations.

Work proposed under this cooperative agreement may not be duplicated or funded by other cooperative agreements, contracts, or other funding mechanisms. Projects proposed under these cooperative agreements and the funding provided must remain distinct and separate from other projects and funding sources. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, received through contracts, cooperative agreements, grants, and other funding received by the grantee and these cooperative agreements.

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11144\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) 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 [ORA \(.../AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Conten# Components of Participating\)](#), 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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html).

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.

Significance (35 Points)

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s) (5 Points)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? Is the leadership approach, governance and organizational structure appropriate for the project?

Sustainability (25 Points)

Are potential problems, alternative strategies, and benchmarks for success presented? Does the project provide a likelihood that capabilities developed can be sustained after the project period? Does the application provide justification for hiring new staff, including qualifications, training needs, and new equipment needs?

Approach (35 Points)

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have adequate resources (including staff and infrastructure) been proposed to meet the objectives of the cooperative agreement? If not, has the ability to obtain the needed resources been demonstrated? Is there adequate demonstration of effectiveness in working with federal, state, and local partners and other appropriate organizations to implement the goals of the cooperative agreement?

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.

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11174](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174)).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11150](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150)).

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

Applications from Foreign Organizations

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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11151](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151)); (2) [Sharing Model Organisms](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11152](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152)); and (3) [Genomic Data Sharing Plan \(GDS\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11153](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153)).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

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.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 \(<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>\)](#).

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the [HHS Grants Policy Statement \(<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>\)](#) 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.

In accordance with Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), codified as amended at 41 U.S.C. § 2313, Federal award making officials are required to review and consider information about an applicant in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205. This provision will apply to all FDA grants and cooperative agreements.

HHS provides general guidance to recipients of funding on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.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> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <https://www.hhs.gov/civil-rights/for-individuals/index.html>. Recipients of an award also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<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> (<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> (<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.

Peer-reviewed articles resulting from research supported in whole or in part with FDA funds must be submitted to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines peer reviewed articles as an article describing original scientific research findings published in a scholarly scientific journal that has been peer reviewed prior to publication. The PMC archive is the designated repository for these articles for use by the public, health care providers, educators, scientists, and FDA. Please see the FDA Public Access Policy, available at <http://www.fda.gov/downloads/ScienceResearch/AboutScienceResearchatFDA/UCM435418.pdf> (<http://www.fda.gov/downloads/ScienceResearch/AboutScienceResearchatFDA/UCM435418.pdf>).

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 Part 75 and other HHS and PHS 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.

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

- FDA hosting annual meetings for programs enrolled in the MFRPS.
- FDA conducting on-site technical sessions with the grantee.
- FDA conducting on-site visits including Program Assessment Verification Audits (PAVAs) to verify grantee progress in achieving conformance with the MFRPS.
- FDA hosting monthly (or at a frequency chosen by FDA) conference calls/webinar meetings with all programs enrolled in the MFRPS.
- FDA assistance in the sharing of information developed by the grantee to achieve conformance with the MFRPS. Examples may include SOPs, MOUs, training programs, and record keeping systems.
- FDA assistance in coordinating multi-program pilot projects.
- FDA assistance in identifying opportunities to enhance laboratory capacity and cooperation.

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.

The purpose of these cooperative agreements is to advance efforts for a nationally integrated food safety system by assisting State manufactured food regulatory programs to achieve and maintain conformance with the MFRPS. The MFRPS are intended to ensure that State manufactured food regulatory programs develop and maintain best practices for a high-quality regulatory program.

For the purposes of this cooperative agreement, conformance will be determined by a program assessment performed by the FDA/ORA/Office of Operations/Immediate Office, Audit Staff.

The grantee must maintain a food safety inspection contract in satisfactory standing with the FDA throughout the cooperative agreement. State manufactured food programs funded under these cooperative agreements will be required to provide the previous, current, and subsequent years of State funding to demonstrate that these funds have not replaced State allocations. Key personnel (minimum of 2) will attend an annual face-to-face meeting (as determined by FDA) as a condition of the award. Facilities, work, and training reimbursed under the FDA food safety inspection contract and other funding mechanisms must remain distinct and separate from the cooperative agreement. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under the food safety inspection contracts and other funding mechanisms and these cooperative agreements.

Work proposed under this cooperative agreement may not be duplicated or funded by other cooperative agreements, contracts, or other funding mechanisms. Projects proposed under these cooperative agreements and the funding provided must remain distinct and separate from other projects and funding sources. The grantee must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, received through contracts, cooperative agreements, grants, and other funding received by the grantee and these cooperative agreements.

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\) \(//grants.nih.gov/grants/rppr/index.htm\)](http://grants.nih.gov/grants/rppr/index.htm) 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 \(http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsqps107.pdf\)](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsqps107.pdf).

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11170\)](http://www.fsrs.gov) on all subawards over \$25,000.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) that is made available in FAPIIS, about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons 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/ \(//grants.nih.gov/support/\)](http://grants.nih.gov/support/) (preferred method of contact) Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support \(http://www.grants.gov/web/grants/support.html\)](http://www.grants.gov/web/grants/support.html) (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 \(https://grants-portal.psc.gov/ContactUs.aspx\)](https://grants-portal.psc.gov/ContactUs.aspx)

Email: [support@grants.gov \(mailto:support@grants.gov\)](mailto:support@grants.gov)

Scientific/Research Contact(s)

Brett Weed
Food and Drug Administration (FDA)
Telephone: 404-253-2268
Email: brett.weed@fda.hhs.gov (<mailto:brett.weed@fda.hhs.gov>)

Objective Review Contact(s)

Allison Mandel
Food and Drug Administration (FDA)
Telephone: 240-402-7602
Email: allison.mandel@fda.hhs.gov (<mailto:allison.mandel@fda.hhs.gov>)

Financial/Grants Management Contact(s)

Food and Drug Administration (FDA)
Telephone: 240-402-7602
Email: allison.mandel@fda.hhs.gov (<mailto:allison.mandel@fda.hhs.gov>)

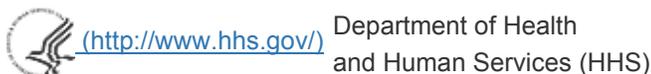
Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the [HHS Grants Policy Statement](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) (<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

Authority and Regulations

Awards are made under the authorization of Section 1009 of the Federal Food, Drug, and Cosmetic Act (21 USC 399).

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?03-03-17\)](/grants/guide/WeeklyIndex.cfm?03-03-17)
[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)



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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files \(/grants/edocs.htm\)](#).

