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) in coordination with the Center for Veterinary Medicine (CVM)

Funding Opportunity Title

FDA Drug Residue Cooperative Agreement Program (U18)

Activity Code

U18 Research Demonstration – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-FD-15-025

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 to improve and develop State drug residue prevention programs. It is necessary to provide assistance to current State tissue residue programs that need a stronger foundation to promote the prevention of illegal drug residues in animal derived foods through educational outreach and training, properly communicate and promote effective management practices for drug residue prevention, to increase the knowledge of proper drug use, and support other activities related to drug residue prevention.

This FOA is intended to ensure current drug residue prevention programs are developed to protect consumer exposure to drug residues in the edible products of food animals. In addition, these awards will help state agencies better direct their programs to reduce the outcomes of illegal drug residues in animal derived foods. This cooperative agreement will further enhance the program by measuring the performance of existing State drug residue prevention program, identifying areas of improvement and/or developing new programs.

Key Dates

Posted Date

May 7, 2015

Open Date (Earliest Submission Dates)

May 15, 2015

Letter of Intent Due Date(s)

Not Applicable

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

This Funding Opportunity Announcement (FOA) is being issued to announce the availability of cooperative agreements to State government drug residue in animal derived food prevention programs. These cooperative agreements are intended to fund training and outreach to individuals and parties involved with treating and/or managing treated food producing animals, support activities related to Extralabel Drug Use in Food Producing Animals (21 CFR 530) and other activities related to drug residue prevention in State governments.

The goal of FDA's ORA Cooperative Agreement Program is to develop, complement and enhance State drug residue prevention programs. This will be accomplished through the provision of funding for training and outreach given to individuals and parties involved with medicating and/or managing medicated food producing animals and to support training and outreach activities related to legal Extralabel Drug Use in Food Producing Animals (21 CFR 530). This will also require extensive cooperation and coordination with FDA District Offices to ensure such activities do not duplicate or impede FDA activities under Compliance Program Guidance Manual (CPGM) 7371.006, Illegal Residues In Meat, Poultry, Seafood, and Other Animal Derived Foods.

Under these cooperative agreements, the State governments would enhance or initiate drug residue prevention programs that communicate proper drug use and effective management practices to prevent drug residues in animal derived foods in their jurisdiction. Funds should be used to conduct educational outreach activities and to develop materials needed to further treatment knowledge of and compliance with approved drug use, extralabel drug use regulations and its prohibitions, and understanding of treated animal management.

There are two key objectives identified for this effort that must be addressed:

(1) Conduct educational outreach activities and develop materials needed to further and enhance industries' knowledge of proper drug use, treated food producing animal management, and compliance with extra label drug use regulations.

(2) Be able to identify and quantify improvements to the existing State drug residue prevention program or developing new programs (i.e., personnel hiring, personnel training, increase in outreach materials and/or events) in the mid-year report as a result of the cooperative agreement.

Outcomes:

Effective treated animal management by laypersons (i.e. producers) and practitioners is expected as a result of initiating or enhancing drug residue prevention programs, increasing knowledge of proper drug use and extra label drug use regulations. A

reduction in illegal drug residues as evidenced through USDA and FDA surveillance programs is anticipated.

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.

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 SF424 (R&R) Application Guide provide details on these application types.

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations, availability of funding and awardee performance.

FDA/ORA intends to fund up to $800,000, for fiscal year 2015 in support of this grant program.

It is anticipated that up to 7 awards may be made, not to exceed $125,000 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: $125,000

YR 02: $125,000

YR 03: $125,000

Award Project Period

The scope of the proposed project will determine the project period. The total project period for an application requesting support may not exceed three (3) years

Future year amount depends on availability of funding and performance.

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

This opportunity is only available to State government agencies with current FDA tissue residue investigation contracts that will not be renewed during the project period of performance for this cooperative agreement. State government agencies that are awarded a tissue residue investigation contract for services conducted during the drug residue cooperative agreement period of performance will be ineligible to apply.

Competition is limited to these organizations to improve their current drug residue prevention program(s) and develop a stronger foundation to prevent drug residues in animal derived foods through educational outreach, training to industry and individuals to

communicate proper drug use and promote effective management practices for drug residue prevention.

Applicants shall not be under a tissue residue investigation contract with the FDA for the duration of the award.

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

Only one application per institution (normally identified by having a unique TIN number) is allowed.

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.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R Budget

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

- Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.
- If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.
- If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will

be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.

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*.

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

The purpose of these cooperative agreements is to promote the development and enhancement of existing drug residue prevention programs. The cooperative agreements will provide funding for additional equipment, supplies, and/or training to support activities related to the development and implementation of illegal drug residue prevention programs. Allowable and unallowable costs are outlined below.

Allowable costs:

1) Audiovisual materials such as videotapes, DVDs, public service announcements, etc. when identified as a necessary expense that directly impacts the milestones/aims of this award.

2) Registration fees and travel for classroom training, conference events or tabletop exercises. Travel costs (airfare) must not exceed coach class fare

3) Rental, purchasing, calibration, and maintenance of supplies and equipment relevant to the illegal drug residue program.

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

5) Consultant Services

6) Subcontracting to third party (other than state/local/tribal government agencies participating in the grantee's illegal drug residue program) is limited to 20% of each year's award

7) Attendance to committee meetings

8) Outreach materials and/or events

9) Salaries, wages and fringe benefits for personnel relevant to the milestones/aims of this award, including recruitment costs for hiring new employees

10) Travel and per diem for face-to-face meetings with FDA program staff (FDA Headquarters, Centers or District Offices) relating to the progress of the program/project and for training. Travel costs (airfare) must not exceed coach class fare. This will be determined by FDA and depends on the performance of the program/project.

Non-allowable costs:

1) Investigations or inspections that are under contract with a government regulatory agency.

2) Facilities and work covered and funded under current FDA feed safety inspection contracts shall not be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures under the feed safety inspection contracts, tissue residue investigation contracts and these cooperative agreements.

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.

4) Vehicle purchases are not permitted.

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. All applications submitted to the FDA are evaluated for scientific and technical merit through the FDA Objective review process.

Scored Review Criteria

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

Significance (25 Points)

The rationale to achieve the goals and project objectives of the cooperative agreement and project proposed.

Program Design (20 Points)

Demonstration of adequate program resources (including staff) and infrastructure, or the ability to obtain the resources necessary, to complete project needs.

Communication (15 Points)

Application outlines a plan of action for the dissemination and sharing of ideas, techniques, and solutions with relevant parties.

Implementation (25 Points)

Demonstration of the effectiveness of the drug residue prevention program can be sustained in the long-term (after the conclusion of the project period). This includes plans to achieve the incorporation of project-developed capabilities, practices and/or activities into long-term program work. The expected challenges should be addressed.

Budget Assessment (15 Points)

The budget is fair and reasonable. The budget plan does not contain unnecessary expenditures. The application includes a detailed budget plan for each year of the project.

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.

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.

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 75, 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.

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 grantee. 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 results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grant recipient, upon request, consistent with applicable disclosure statutes and FDA disclosure regulations. Also, the grantee organization must comply with all 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.

Future funding will be dependent on recommendations from the Project Officer. The scope of the recommendation will confirm that acceptable progress has been made in achieving and maintaining the requirements and conditions of the award. Specific project milestones, reporting requirements, and other project deliverables may be included as a condition of your award.

Applicants shall not be under a tissue residue investigation contract with the FDA throughout the cooperative agreement project period. Work anticipated 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.

Any equipment currently owned by FDA that is loaned out to parties as a result of a cooperative agreement will remain the property of FDA under loan to the awardee for a specified time period with a review every twelve months. FDA may terminate the loan at any time. Unless approved by ORA/Office of Partnerships, the FDA provided equipment may not be transferred by the awardees to a third party, and the awardee assumes full responsibility and liability for any claims that may arise as a result of operation of this equipment for the period it is in the possession of the awardees.

The Government, via the PO, will have access to data generated under this Cooperative Agreement and may periodically review the data and progress reports. The FDA PO may use information obtained from the data for the preparation of internal reports on the activities of the study. However, awardees shall retain custody of and have primary rights to all data developed under these awards.

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.

A mid-year Progress Report is required no later than 30 days after the mid-year point of the budget period. The annual Progress Report is required no later than 30 days after the end of the budget period. The mid-year and annual Progress Report should contain a description of project activities covering the applicable reporting period. A report template shall be provided to grantees by the Grants Management staff.

Mid-year, Annual and Final reports must contain, but are not limited to the following:

1. Progress report that covers accomplishments for each specific goal and objective outlined in grant application. Goals and objectives should be broken out and reported against.
2. Summary of improvements (identify and quantify) or developments in the overall drug residue prevention program resulting from the cooperative agreement.
4. Certification of current appropriation funding levels for the feed regulatory program.
3. Status report on the installation, operational readiness and monitoring activities of any analytical equipment or software that is purchased.
4. Status report on hiring and training personnel that are involved in the existing drug residue prevention program or developing new programs.
5. 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 support achievement of the objectives outlined in this FOA. The strategic plan should include significant milestones or action items, anticipated completion dates, responsible personnel, and other required resources.
6. Summary report on any outreach materials offered and/or events provided consisting of educating outreach relating to proper drug use; effective management practices; compliance of

extralabel drug use regulations, or such related activities in support of drug residue prevention.

Must identify the amount of training services and/or the number of outreach programs provided.

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.

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)

Jocelyn Ramos
Project Officer
FDA/ORA/Office of Partnerships/Contracts and Grants
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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.

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