Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA. The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.
Components of Participating Organizations	Office of Regulatory Affairs (ORA)
Funding Opportunity Title	**Implementation of the Animal Feed Regulatory Program Standards (AFRPS) (U18)**
Activity Code	U18 Research Demonstration – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-16-022**
Companion Funding	None

Opportunity	
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 animal feed safety system by assisting State animal feed regulatory programs to achieve and maintain full implementation of the Animal Feed Regulatory Program Standards (AFRPS). The AFRPS Cooperative Agreement will provide funding for State animal feed regulatory programs that maintain a FDA animal feed safety inspection contract to develop and implement the standards; develop and maintain best practices; enhance animal feed safety; and better direct their regulatory activities at reducing foodborne illness attributed to animal feed safety hazards in facilities that manufacture, process, pack, or hold animal feed materials/supplies. In addition, this cooperative agreement will provide options of funding for laboratories that support animal feed programs and are pursuing accreditation under the international standard ISO/IEC 17025:2005

Key Dates

Posted Date	
Open Date (Earliest Submission Date)	March 16, 2106
Letter of Intent Due Date(s)	March 30, 2016
Application Due Date(s)	May 16, 2016 by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. Applicants should be aware that on-time submission means that an

	application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date. **Late applications will not be accepted for this FOA.**
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	June, 2016
Advisory Council Review	Not Applicable
Earliest Start Date	September, 2016
Expiration Date	May 17, 2016
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

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

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Program Objectives

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Office of Partnerships (OP) is announcing the availability of up to $4,950,000 in FY 2016 to be awarded under Limited Competition to State animal feed regulatory programs. The intended outcome of this FOA is to advance efforts for a nationally integrated animal feed safety system through the implementation and advancement of the Animal Feed Regulatory Program Standards (AFRPS) by State animal feed regulatory programs.

The AFRPS allows for the development of risk-based animal feed safety programs by establishing a uniform basis for measuring and improving the performance of State animal feed regulatory programs in the United States. By achieving and sustaining implementation of these program standards, Federal and State programs can better direct their regulatory activities toward reducing foodborne illness attributed to animal feed safety hazards in animal feed material/supply facilities. Consequently, the safety and security of the United States animal feed supply will improve.

The AFRPS are comprised of eleven standards which establish foundations for the critical elements that serve as an objective framework to evaluate and improve components of a State animal feed program. These elements cover the State animal feed program's regulatory foundation, training, inspection program, auditing, animal feed-related illness or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standard implementation.

Achieving and sustaining implementation of the program standards will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation. FDA recognizes that the time required for achieving full implementation of the AFRPS program standards will vary between States. However, all State animal feed regulatory programs will be expected to implement improvement plans to ensure continuous improvement and demonstrate that they are moving towards full implementation. State animal feed regulatory programs receiving funds under this cooperative agreement will be expected to achieve significant to full implementation by the conclusion of the cooperative agreement.

For the purpose of this funding opportunity, "full implementation" is defined as the State animal feed regulatory program has policies and procedures in place that meet all of the AFRPS program elements and the program uses the policies and procedures as written for all program elements and documentation requirements within each standard. "Significant implementation" is defined as the State animal feed regulatory program has policies and procedures in place that meet 80% or more of the individual program elements within each of the eleven standards of the AFRPS and the program uses the policies and procedures as written for all elements and documentation requirements within each standard. For those individual program elements that are not met, the state program has a detailed improvement plan on how the remaining AFRPS elements and documentation requirements not yet met will be fully implemented and demonstrated. The improvement plan will include: A detailed timeline including what needs to be accomplished to implement the element and/or documentation requirement, who will be doing the work, and when the work will be completed.

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

1. State animal feed regulatory programs will achieve and sustain significant to full implementation of the AFRPS, which is recognized as a critical element to creating a national, fully integrated feed safety system.

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

3. Develop strategies for achieving and sustaining implementation of the AFRPS that can be duplicated on a national basis.

4. Provide FDA the foundation for pursuing regulatory action based upon the findings of State animal feed regulatory programs.

5. Provide laboratories supporting State animal feed regulatory programs the ability to obtain (Competition B) or maintain (Competition C) ISO/IEC 17025:2005 accreditation including:

a. conduct chemical and microbiological analysis of animal feed samples

b. produce valid and defensible testing data for possible regulatory action

c. maintain and enhance animal feed testing laboratory's capabilities

d. improve lab capacity for animal feed supply to further enhance public health

e. increase sharing of laboratory results

f. advancement of a nationally integrated animal feed safety system

Only the following State animal feed regulatory programs will be eligible to apply:

State animal feed regulatory programs with current FDA animal feed safety inspection contracts (providing funding to State agency animal feed production regulatory programs), or those that apply for a FDA animal feed safety inspection contract, at the earliest possible date, are eligible to apply for funding under this cooperative agreement. An animal feed safety inspection contract must be executed prior to the cooperative agreement being awarded. A condition of the award will be maintaining a current FDA animal feed safety inspection contract throughout the cooperative agreement project period.

The FDA will provide one year of funding with the possibility of up to four years of additional, non-competitive support, contingent on performance and continued availability of federal funds. These funds are intended to supplement, not replace, State funding for program improvement and activities. State animal feed 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 for the animal feed regulatory program.

Background

In the United States, Federal and State government agencies ensure the safety of animal feed. The Food and Drug Administration (FDA) is responsible for ensuring that all human foods and animal feeds moving in interstate commerce, except those under the United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies are responsible for conducting inspections and regulatory activities that help ensure animal feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. State agencies primarily perform inspections under their own regulatory authority. Some State agencies conduct inspections of animal feed facilities under contract with the FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed. To better facilitate a partnership among regulatory authorities, regulatory programs should be equivalent in effect.

Maximizing resources between FDA and the States supports the ongoing work of the Partnership for Food Protection (PFP) to develop an Integrated Food Safety System (IFSS). The FDA and the Association of American Feed Control Officials (AAFCO) are members of the PFP. One of the foundational principles of an IFSS is the implementation and uniform application of model standards so that Federal, State, territorial, tribal, and local regulatory agencies conduct inspections under the same set of standards. The Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Manufactured Food Regulatory Program Standards (MFRPS) are examples of such model standards. However, the VNRFRPS and MFRPS were developed for human food only and do not apply to animal feed. As further development on the IFSS progressed, there was a recognized need to develop standards for animal feed regulatory programs. One of the key recommendations that originated from the 2010 50-State workshop ("A United Approach to Public Health") was the development of standards for animal feed regulatory programs. Standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal agencies to ensure the credibility of all programs under an IFSS.

The FDA Food Safety Modernization Act (FSMA) provides further support for developing AFRPS. FSMA was signed into law in January 2011 and calls for enhanced partnerships and integration with Federal, State, local, tribal, and territorial partners. The enhanced partnerships and integration called for by FSMA will allow FDA to rely on inspections and data collected by other agencies to support regulatory activities and further the idea of an IFSS.

In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS. These standards are designed to promote uniformity and consistency among animal feed regulatory programs. This is consistent with the principles of FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for developing and implementing uniform and equitable regulations, and standards to enhance the protection of the nation's animal feed supply.

Competitions

NOTE: Competition A- Animal Feed Regulatory Program Standards (AFRPS) must be completed by ALL applicants.

Applicants may request additional funding by completing the information in Competition B or C. Those who choose this increased funding option must submit an application that contains information from both Competition A and the selected additional activities. Only one combined application should be submitted.

Competition A: Animal Feed Regulatory Program Standards (AFRPS)

All applicants must specifically address the ability to achieve the following objectives in the cooperative agreement:

1. Demonstrate the ability to develop and implement a comprehensive improvement plan that will result in significant to full implementation of the AFRPS and maintenance of the AFRPS after the cooperative agreement.

2. Demonstrate the ability to fully participate in initiatives supporting the AFRPS, such as a required annual face-to-face meeting and any required training (as determined by FDA/OP), committees, OP/AFRPS conference calls, sharing of best practices, annual on-site visits, program assessment verification audits.

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

4. Provide a properly detailed budget (one for each of the five years) that is intended to achieve implementation of the AFRPS. For applicants that choose to pursue ISO/IEC 17025:2005 Accreditation, a separate budget is required.

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

6. Provide the previous year and current funding level certification for the animal feed regulatory program from State funding appropriations.

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

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

Animal Feed Regulatory Program Standards (AFRPS)

The project goals provided below are based on new programs enrolling in the AFRPS and are applicable to all applicants. The FDA recognizes that achieving significant to full implementation of the AFRPS will vary by program based on multiple factors, such as previous enrollment in the AFRPS and current level of implementation. Applicants should adjust their project goals to reflect their previous accomplishments and current implementation level with the AFRPS.

Competition A Project Goals:

Year 1:

1. If not under a current animal feed safety inspection contract, the State animal feed program must apply for an animal feed safety inspection contract with the FDA, at the earliest possible date. An animal feed safety inspection contract must be executed prior to the cooperative agreement being awarded. A current feed safety inspection contract must be maintained throughout the cooperative agreement.

2. Participation in an on-site visit consisting of key State animal feed regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal feed regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal feed program managers and staff in an annual face-to-face meeting, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Conduct a comprehensive baseline self-assessment/baseline evaluation, including completion of all applicable appendices, worksheets, and other documents (or equivalent documents), required in each Standard.

5. Following the baseline evaluation, develop improvement plan(s) that will result in significant to full implementation of the AFRPS by Year 5 of the cooperative agreement. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) should be maintained. Improvement plan(s) should include the following, at a minimum:

a. The individual element or documentation requirement for the standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 2:

1. Participation in a verification audit conducted by FDA. Participation includes providing meeting space, accessibility of key State feed program management and staff, and access to records, databases, and other materials supporting AFRPS implementation. The audit should reveal that FDA agrees with the program's self-assessments and improvement plan.

2. Participation in an outreach training session led by FDA/OP consisting of key State animal feed regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal feed regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal feed regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Implementation of the improvement plan(s). The improvement plan(s) should be updated to accurately reflect when specific objectives and tasks have been met and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate that significant to full implementation of the AFRPS can be expected by Year 5.

5. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) should be maintained. The improvement plan(s) should include the following, at a minimum:

a. The individual element or documentation requirement for the standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 3:

1. Participation in a verification audit conducted by FDA. Participation includes providing meeting space, accessibility of key State animal feed regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation. The audit should reveal that FDA agrees with the state's self-assessments, and improvement plan.

2. Participation in an outreach training session led by FDA/OP consisting of key State animal feed regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal feed regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Attendance and participation of key State animal feed regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

4. Implementation of the improvement plan. The improvement plan should be updated to accurately reflect when specific objectives and tasks have been met and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate that significant to full implementation of the AFRPS can be expected by Year 5. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) should be maintained. The improvement plan should include the following, at a minimum:

a. The individual element or documentation requirement for the standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 4:

1. Attendance and participation of key State animal feed regulatory program managers and staff in a required annual face-to-face meeting any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

2. Participation in an outreach training session led by FDA/OP consisting of key State animal feed regulatory program and FDA personnel to discuss the implementation of program elements of the AFRPS. Participation includes providing meeting space, accessibility of key State animal feed regulatory program management and staff, and access to records, databases, and other materials supporting AFRPS implementation.

3. Implementation of the improvement plan. The improvement plan should be updated to accurately reflect when specific objectives and tasks have been met and when new objectives and tasks are identified to achieve full implementation of the AFRPS. Progress achieved should indicate that significant to full implementation of the AFRPS can be expected by Year 5. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) should be maintained.

The improvement plan should include the following, at a minimum:

a. The individual element or documentation requirement for the standard that was not fully met.

b. Improvements needed to fully meet the program element or documentation requirement(s) of the standard.

c. Lists of individual tasks that will be used to address the needed improvement(s).

d. A projected completion date for each task.

e. An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Year 5:

1. Attendance and participation of key State animal feed regulatory program managers and staff in a required annual face-to-face meeting and any required training, committee meetings, and other initiatives supporting national and program specific implementation of the AFRPS.

2. Participation in a comprehensive audit of the State animal feed program to verify significant to full implementation of the AFRPS. Participation includes providing meeting space, accessibility of State key animal feed program staff, and access to records, databases, and other materials supporting the State program's full implementation of the AFRPS. Nonconformities identified in the audit should be addressed in the subsequent self-assessment and improvement plan.

3. Development of a plan identifying personnel, funding, and resources necessary to sustain significant to full implementation of the AFRPS.

Exit Strategy for Sustainability (Maintenance):

State animal feed programs who are required or expect to achieve significant to full implementation of the AFRPS before year 5 of the cooperative agreement must develop, submit and receive FDA approval of an Exit Strategy of Sustainment (ESS) to FDA before the end of the grant year during which the grantee is required or expects to achieve significant to full implementation of the AFRPS. State animal feed programs who are required or expect to achieve significant to full implementation of the AFRPS in year 5 of the cooperative agreement will submit an ESS with the Year 5 mid-year report. The ESS will outline the State program's plans to sustain significant implementation of the AFRPS and ensure progress continues within their agency to achieve full implementation of the AFRPS.

The ESS must detail:

Strategy to sustain AFRPS implementation, including identifying personnel/FTEs, current funding sources for these personnel, and plans to sustain those personnel using grantee resources to the best of the grantee's ability.

Animal feed program data (all data should be pulled from a recent 12 month period): Number of animal feed (AF) inspectors (FTE), Number of animal feed facilities in inventory, Number of routine animal feed inspections conducted, number of animal feed-related emergency response events investigated, number of animal feed compliance actions taken (embargo, disposal, emergency closures, re-inspections and fines issued.)

Competition B: For applicants partnering with laboratories currently not ISO/IEC 17025:2005 accredited and/or not funded under the Manufactured Food Regulatory Program Standards ISO/IEC 17025:2005 Cooperative Agreement Program (ISO CAP):

Please provide in your application all the information requested in Competition A and the following:

1) Demonstrate the commitment and ability to develop, implement and maintain a quality management system that is in compliance with the managerial and technical requirements of ISO/IEC 17025:2005 and is accredited by an impartial, independent, and internationally recognized accreditation body.

2) Demonstrate the ability to fully participate in initiatives supporting the ISO/IEC 17025:2005 accreditation process and FERN activities, such as a required annual face-to-face meeting and any required training, scheduled conference calls, sharing of best practices, on-site visits, and program audits.

3) Demonstrate the ability to share appropriate and agreed upon laboratory data generated related to animal feed safety through eLEXNET, and as requested by the FDA. Ideally, an electronic data exchange will be established between the laboratory information management system (LIMS) and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

4) Demonstrate the availability of adequately trained animal feed program and/or laboratory staff and the criteria and ability to hire and/or train personnel to meet the deliverables of the cooperative agreement;

5) Provide a properly detailed budget (one for each of the five years) that is intended to achieve, maintain, and/or enhance ISO/IEC 17025:2005 laboratory accreditation;

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

7) Provide the previous year and current funding level certification for the laboratory program from State funding appropriations;

8) Outline a detailed methodology for program assessment, improvement, and collaboration to accomplish the work and program sustainability, as described in this announcement;

9) Provide justification for hiring new staff, including qualifications, training needs, and new equipment needs;

10) Demonstrate the capability to analyze animal feed samples for chemical and microbiological hazards utilizing analytical methods within the scope of accreditation for emergency response and surveillance efforts - an annual estimate of capability should be provided for chemical and microbiological testing;

11) Provide a summary description of procedures or processes in place to evaluate the process for preparing for accreditation;

12) Provide a summary description of procedures in place to monitor accreditation requirements, including the tracking and monitoring of activities and training in progress to include a description of the laboratory quality manual and technical requirements process and procedures.

13) Demonstrate participation in sampling plan development and support the testing portion of the plan.

14) The PD(s)/PI(s) will retain the primary responsibility and dominant role for planning, directing, and executing the proposed project; however, the cooperative agreement award mechanism will result in substantial involvement by the FDA. Substantial involvement includes, but is not limited to:

- Initial quality management system assessment and gap analysis
- Timeline plan execution
- Monitoring of progress through on-site visits if necessary, conference calls, emails, and other correspondence
- Monitoring of sampling agreement
- Quarterly follow-up of the laboratory's progress
- FDA training on processes
- FDA final assessment of laboratory quality management systems
- FDA technical and financial assistance to apply, maintain, and enhance laboratory accreditation

Successful applicants will undergo a quality management system assessment provided by the FDA, Office of Regulatory Science (ORS). The initial assessment will identify the gaps against the requirements of ISO/IEC 17025:2005 standard followed by the development of a plan to achieve conformance. The plan will identify the tasks necessary to address non-conformities, responsible personnel, and timeframes to ensure accreditation is achieved, maintained, and/or enhance laboratory accreditation within the established timeframe.

Laboratories applying for funding in this section must provide a complete description of the facilities, personnel qualifications, management practices, organization, and a commitment to analyze samples in their application to include the following:

1a) Operational support areas to be used for the project, including floor diagrams of the laboratories, details about the availability of ancillary laboratory safety, and support equipment and facilities.

2a) Details describing the sample receiving and sample storage areas and a description of any existing chain-of-custody procedures;

3a) Detailed description of laboratory access procedures, including a description of practices and systems which limit access to laboratory space by unauthorized personnel to include measures in place to ensure that all staff have sufficient clearance and/or background checks to work on this project or program;

4a) Qualifications of all personnel that will be assigned to the project, including the quality assurance (QA)/quality control (QC) manager, QA/QC personnel, and laboratory technical personnel;

5a) Complete description of the laboratory staffing management and structure, animal feed testing capabilities, policies, procedures, personnel, technical operations, and support services. Provide an organizational chart indicating all reporting relationships and responsibilities;

6a) A detailed description of the proposed upgrades to existing laboratory facilities to accommodate new equipment, including drawings and cost estimates;

7a) A summary description of any quality management system in place or under development as it relates to quality control and quality assurance procedures and practices;

8a) A summary description of procedures in place to monitor animal feed sample workflow, including the tracking and monitoring of sample analyses in progress, including a description of the laboratory work product review process and how reports of sample analyses will be provided within reasonable timeframes;

9a) Previous year and current funding level certification for the laboratory program from State funding appropriations.

Project goals for laboratories seeking ISO/IEC 17025:2005 accreditation:

Year 1:

1. All key laboratory staff is trained and familiar with the requirements for implementation and maintenance of the ISO/IEC 17025:2005 standard. Training records required by ISO/IEC 17025:2005 are developed as well as a training plan for ongoing training to accomplish accreditation.

2. Staffing an independent quality manager position in the laboratory organization that is qualified and trained in QMS and ISO/IEC 17025:2005. The funded laboratory will submit the contact information of the quality manager that shall be the point of contact for quality management system reports and communication with FDA.

3. Identify methods to be placed under scope of accreditation.

4. Enroll in suitable proficiency testing program(s) and document a four-year proficiency testing plan for meeting the minimum proficiency testing/calibration participation requirements.

5. Laboratory enrolls in the FERN and participates in conference calls, attends conferences, and supports FERN activities.

6. Participation in a lab assessment by the FDA Office of Regulatory Science (ORS) and establish a timeline/plan of incremental steps to accreditation.

7. Appropriate and agreed upon data generated by the laboratory is entered into eLEXNET and shared with FDA, as requested. Ideally, an automatic, electronic data exchange is established between the laboratory and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

8. Participate in a mentoring program to collaborate with other accredited laboratories to achieve ISO/IEC 17025:2005 accreditation.

9. Submit a signed sampling agreement with the State manufactured animal feed regulatory program.

Years 2 - 3:

1. Create and implement a Quality Manual and Management System policies and procedures that meet ISO/IEC 17025:2005 requirements.

2. Conduct at least one internal audit and management review per year to identify non-conformances.

3. Develop an improvement plan to address each non-conformance, including key personnel responsible, timelines, and tasks.

4. Requirements for all suitable proficiency testing are met.

5. Active participation in the FERN continues.

6. Participation in lab assessments by FDA to determine progress to accreditation if necessary, and work with FDA to establish a timeline/plan of incremental steps to accreditation.

7. Adequate training for laboratory to meet the requirements of ISO/ISE 17025:2005 accreditation and to keep abreast of scientific and technological advances in relevant areas.

8. Appropriate and agreed upon data generated by the laboratory is entered into eLEXNET, and shared with FDA, as requested. Ideally, an automatic, electronic data exchange is established between the laboratory and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

9. Participate in a mentoring program to collaborate with other accredited laboratories to achieve ISO/IEC 17025:2005 accreditation.

10. Support the implementation of the sampling agreement at the beginning of Year 2.

Year 4:

1. Submit completed application to accrediting body to initiate an assessment of the organization.

2. Assessment, or pre-assessment, is conducted by the accrediting body.

3. Laboratory addresses any areas of non-conformance or deficiencies noted by responding with a written corrective action response.

4. Requirements for all suitable proficiency testing are met.

5. Active participation in the FERN continues.

6. Adequate training for laboratory to keep abreast of scientific and technological advances in relevant areas.

7. Appropriate and agreed upon data generated by the laboratory is entered into eLEXNET and shared with FDA, as requested. Ideally, an automatic, electronic data exchange is established between the laboratory and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.
8. Participate in a mentoring program to collaborate with other accredited laboratories to achieve ISO/IEC 17025:2005 accreditation.

9. Continue support of the implementation of the sampling agreement providing testing capability.

Year 5:

1. Accreditation is granted by the accrediting body.

2. Laboratory submits a plan including the designation of personnel, resources, and funding necessary to maintain accreditation for five years beyond the cooperative agreement program period. Laboratories are also encouraged to include plans to enhance the scope of accreditation, in consultation with the State animal feed regulatory program, and the FDA. These accreditation enhancements may include accreditation for additional sections within the lab and expansion of the number and/or type of methods.

3. Active participation in the FERN continues.

4. Adequate training for laboratory to keep abreast of scientific and technological advances in relevant areas.

5. Appropriate and agreed upon data generated by the laboratory is entered into eLEXNET and shared with FDA, as requested. Ideally, an automatic, electronic data exchange is established between the laboratory and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

6. Participate in a mentoring program to collaborate with other accredited laboratories to achieve ISO/IEC 17025:2005 accreditation.

7. Continue support of the implementation of the sampling agreement providing testing capability.

Competition C: For applicants partnering with laboratories currently ISO/IEC 17025:2005 accredited and/or funded under the Manufactured Food Regulatory Program Standards ISO CAP:

Please provide in your application all the information requested in Competition A and the following:

1) Demonstrate the commitment and ability to implement and maintain a quality management system that is in compliance with the managerial and technical requirements of ISO/IEC 17025:2005 and is accredited by an impartial, independent, and internationally recognized accreditation body.

2) Demonstrate the ability to fully participate in initiatives supporting the ISO/IEC 17025:2005 accreditation process and FERN activities, such as a required annual face-to-face meeting and any required training, scheduled conference calls, sharing of best practices, on-site visits, and program audits.

3) Demonstrate the ability to share appropriate and agreed upon laboratory data generated related to animal feed safety through eLEXNET, and as requested by the FDA. Ideally, an electronic data exchange will be established between the laboratory information management system (LIMS) and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

4) Demonstrate the availability of adequately trained animal feed program and/or laboratory staff and the criteria and ability to hire and/or train personnel to meet the deliverables of the cooperative agreement;

5) Provide a properly detailed budget (one for each of the five years) that is intended to achieve, maintain, and/or enhance ISO/IEC 17025:2005 laboratory accreditation;

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

7) Provide the previous year and current funding level certification for the laboratory program from State funding appropriations;

8) Outline a detailed methodology for program assessment, improvement, and collaboration to accomplish the work and program sustainability, as described in this announcement;

9) Provide justification for hiring new staff, including qualifications, training needs, and new equipment needs;

10) Capability to analyze animal feed samples for chemical and microbiological hazards utilizing analytical methods within the scope of accreditation for emergency response and surveillance efforts - an annual estimate of capability should be provided for chemical and microbiological testing.

11) Summary description of procedures or processes in place to evaluate the process for preparing for accreditation;

12) Summary description of procedures in place to monitor accreditation requirements, including the tracking and monitoring of activities and training in progress to include a description of the laboratory quality manual and technical requirements process and procedures;

13) Demonstrate participation in sampling plan development and support the testing portion of the plan;

14) The PD(s)/PI(s) will retain the primary responsibility and dominant role for planning, directing, and executing the proposed project; however, the cooperative agreement award mechanism will result in substantial involvement by the FDA.

Substantial involvement includes, but is not limited to:

- Initial quality management system assessment and gap analysis
- Timeline plan execution
- Monitoring of progress through on-site visits if necessary, conference calls, emails, and other correspondence
- Monitoring of sampling agreement
- Quarterly follow-up of the laboratory's progress
- FDA training on processes
- FDA final assessment of laboratory quality management systems
- DA technical and financial assistance to apply, maintain, and enhance laboratory accreditation

Successful applicants will undergo a quality management system assessment provided by the FDA, Office of Regulatory Science (ORS). The initial assessment will identify the gaps against the requirements of ISO/IEC 17025:2005 standard followed by the development of a plan to achieve conformance. The plan will identify the tasks necessary to address non-conformities, responsible personnel, and timeframes to ensure accreditation is achieved, maintained, and/or enhance laboratory accreditation within the established timeframe.

Laboratories applying for funding in this section must provide a complete description of the facilities, personnel qualifications, management practices, organization, and a commitment to analyze samples in their application to include the following:

1a) Operational support areas to be used for the project, including floor diagrams of the laboratories, details about the availability of ancillary laboratory safety, and support equipment and facilities.

2a) Details describing the sample receiving and sample storage areas and a description of any existing chain-of-custody procedures;

3a) Detailed description of laboratory access procedures, including a description of practices and system which limit access to laboratory space by unauthorized personnel to include measures in place

to ensure that all staff have sufficient clearance and/or background checks to work on this project or program;

4a) Qualifications of all personnel that will be assigned to the project, including the quality assurance (QA)/quality control (QC) manager, QA/QC personnel, and laboratory technical personnel;

5a) Complete description of the laboratory staffing management and structure, animal feed testing capabilities, policies, procedures, personnel, technical operations, and support services. Provide an organizational chart indicating all reporting relationships and responsibilities;

6a) A detailed description of the proposed upgrades to existing laboratory facilities to accommodate new equipment, including drawings and cost estimates;

7a) A summary description of any quality management system in place or under development as it relates to quality control and quality assurance procedures and practices;

8a) A summary description of procedures in place to monitor animal feed sample workflow, including the tracking and monitoring of sample analyses in progress, including a description of the laboratory work product review process and how reports of sample analyses will be provided within reasonable timeframes;

9a) Previous year and current funding level certification for the laboratory program from State funding appropriations.

Project Goals for laboratories accredited under ISO/IEC 17025:2005 or funded under the Manufactured Food Regulatory Program Standards ISO CAP:

Year 1:

1. Actively participate in the FERN, including meetings, conference calls, and other activities.

2. In conjunction with the State animal feed regulatory program, and the FDA, identify areas to enhance the scope of accreditation, specifically in the animal feed area.

3. Enroll in suitable proficiency testing program(s) for the methods to be added to the existing scope.
4. Participate in a mentoring program to assist other laboratories in achieving ISO/IEC 17025:2005 accreditation.

5. Maintain current ISO/IEC 17025:2005 accreditation if applicable.

6. Implement a training program for the laboratory to keep abreast of scientific and technological advances in relevant areas.

7. Appropriate and agreed upon data generated by the laboratory is entered into eLEXNET and shared with FDA, as requested. Ideally, an automatic, electronic data exchange is established between the laboratory and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

8. Submit a signed sampling agreement with the State animal feed regulatory program.

Years 2-5:

1. Enhance the scope of accreditation in consultation with the State animal feed regulatory program, and the FDA. These accreditation enhancements may include accreditation for additional sections within the lab and expansion of the number and/or type of methods.

2. Continue to actively participate in the FERN.

3. Continue to participate in a mentoring program to assist other laboratories in the cooperative agreement in achieving ISO/IEC 17025:2005 accreditation by the end of Year 5.

4. Continue to maintain ISO/IEC 17025:2005 accreditation, which includes conducting an annual surveillance audit, continuous update and improvement of the Quality Manual and Management System policies and procedures, and a three year full system audit required for renewal.

5. Maintain training for the laboratory to keep abreast of scientific and technological advances in relevant areas.

6. Laboratory submits a plan including the designation of personnel, resources, training, and funding necessary to maintain accreditation for five years beyond the cooperative agreement program period.

7. Appropriate and agreed upon data generated by the laboratory is entered into eLEXNET and shared with FDA, as requested. Ideally, an automatic, electronic data exchange is established between the laboratory and eLEXNET. In addition, laboratories are encouraged to utilize "other systems", such as the Animal Feed Network, to report and share data related to emergency response situations.

9. Support the implementation of the sampling agreement at the beginning of Year 2.

10. Continue support of the implementation of the sampling agreement providing testing capability for Years 4-5.

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

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.
Application Types Allowed	New The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	FDA/ Office of Regulatory Affairs (ORA) intends to fund up to $2,500,000 for fiscal year 2016 in support of this grant program. An estimated breakdown of awards follows, but final awards will be based on applications received. **Competition A:** Animal Feed Regulatory Program Standards (AFRPS) (must be completed by ALL applicants). It is anticipated that up to one (1) award will be made, not to exceed $300,000 in total costs (direct plus indirect), per award. Applications will be considered an application in Competition A if the

	application only proposes those activities listed under Competition A. Applicants may broaden the scope of their application and request additional funding by submitting applications under one of the two competitions below: **Competition B:** For applicants partnering with laboratories currently **not** ISO/IEC 17025:2005 accredited and/or not funded under the Manufactured Food Regulatory Program Standards ISO CAP. In addition to completing the information requested under Competition A, the applicants must provide all of the required information under Competition B. This combined application will be considered an application in Competition B. It is anticipated that up to two (2) awards may receive additional funding, to be made to applicants partnering with non-accredited laboratories and/or laboratories not funded under the Manufactured Food Regulatory Program Standards (MFRPS) ISO/IEC 17025:2005 cooperative agreements, not to exceed $300,000 in total costs (direct plus indirect) per award. A total award under Competition B is not to exceed $600,000 in total costs. **Competition C:** For applicants partnering with laboratories currently ISO/IEC 17025:2005 accredited and/or funded under the Manufactured Food Regulatory Program Standards ISO CAP. In addition to completing the information requested under Competition A, the applicants must provide all of the required information under Competition C. This combined application will be considered an application in Competition C. It is anticipated that up to two (2) awards may receive additional funding, to be made to applicants partnering with accredited laboratories and/or laboratories funded under the MFRPS ISO/IEC 17025:2005 cooperative agreements, not to exceed $150,000 in total cost (direct plus indirect) per award. A total award under Competition C is not to exceed $450,000 in total costs. **Applicants may apply for and receive funding for only one competition.**
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: Competition A - $300,000 Competition B - $600,000 Competition C - $450,000 YR 02: Competition A - $300,000 Competition B - $600,000 Competition C - $450,000

	YR 03: Competition A - $300,000 Competition B - $600,000 Competition C - $450,000 YR 04: Competition A - $300,000 Competition B - $600,000 Competition C - $450,000 YR 05: Competition A - $300,000 Competition B - $600,000 Competition C - $450,000
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Governments

- State Governments

This opportunity is only available to the following State animal feed safety programs:
States animal feed regulatory programs with current FDA animal feed safety inspection contracts (providing funding to State agency animal feed protection regulatory programs), or those that apply for an animal feed safety inspection contract with FDA at the earliest possible date, are eligible to apply for funding under this cooperative agreement. An animal feed safety inspection contract must be executed prior to the cooperative agreement being awarded. Competition is limited to these State animal feed regulatory programs because the foundational work conducted under the current FDA animal feed safety inspection contracts is necessary for the completion of significant improvements in a nationally integrated animal feed safety system.

Current award recipients under cooperative agreement, RFA-FD-15-021 are ineligible to apply for this cooperative agreement.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** **not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** **not** eligible to apply.
Foreign components, as *defined in the HHS Grants Policy Statement*, **are** **not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for FDA support.

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

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

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

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

Section IV. Application and Submission Information

1. Requesting an Application Package

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

Applicants must download the application package associated with the Competition they are applying for by referencing the Competition ID field. The Competition ID field will state:
Competition A,
Competition B, or
Competition C

Applicants may apply for and receive funding for only one competition.

2. Content and Form of Application Submission

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

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

Letter of Intent

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

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

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

The letter of intent should be sent via electronic mail as a PDF file with the FOA Number and the Institution's Name in the message subject heading to:

REPLACE WITH GRANTS MANAGEMENT STAFF CONTACT NAME
Dan Lukash
240/402-7596
Email: daniel.lukash@fda.hhs.gov

A technical session will be held for prospective applicants in April 2016 The conference call information will be provided to prospective applicants that submit a letter of intent. The technical

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

Page Limitations

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

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R Budget

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

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

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

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

- Applicants may also apply for personnel, training, and surveillance sample analysis if they have the necessary equipment and it will be available for these projects.

- Where personnel costs are requested, documentation must be provided to associate these costs with the specific goals and deliverables.

- Funds should be requested in the budget for key project personnel to travel to meetings, on-site visits, assessments and audits with FDA program staff to discuss the state self-assessment and

implementation of the AFRPS. All anticipated meetings for attendance should be listed and referenced by name in the application.

- A portion of budgeted travel funds should also be set aside for key personnel to attend required annual face-to-face meeting and any required training (as determined by FDA/OP) and committee meetings supporting the AFRPS.

- All anticipated meetings and trainings, to include the required annual meeting and required training, for attendance should be listed and referenced by name in the application.
-
- If the application includes a request for additional funds to support activities under Competition B, or C, a break out of the costs for additional funding should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

- Funding Plan: Grantees whose State manufactured feed regulatory program receives funding from a FDA Rapid Response Team (RRT) cooperative agreement are required to participate in the RRT and should ensure that their efforts to meet the program elements of the AFRPS Standard 5 are aligned/integrated with the existing RRT and their participation therein. Funds from the AFRPS Cooperative Agreement are to be used for the program elements indicated under each standard. RRT-specific activities support the program elements under Standard 5, but it is not a requirement of Standard 5.

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. with the following additional instructions:

- For applicants enrolled in the AFRPS for a minimum of 12 months, a copy of the baseline program self-assessment and improvement plan, should be included in the application. The baseline program self-assessment and improvement plan may be included as appendices. In addition, applicants enrolled in the AFRPS for a minimum of 12 months should describe any identified or potential obstacles in achieving and sustaining significant to full implementation of the AFRPS and approaches to overcome these obstacles.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:
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- 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. Guide with the following additional instructions:

- For applicants enrolled in the AFRPS for a minimum of 12 months, a copy of the baseline program self-assessment and improvement plan, must be included in the application. The baseline program self-assessment and improvement plan may be included as appendices.

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
Not Applicable

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

4. Submission Dates and Times
Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration. eRA Commons and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. **Late applications will not be accepted for this FOA.**

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

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)
This initiative is not subject to intergovernmental review.

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

Selected list of allowable costs that have limitations specific to this announcement (including but not limited to):

1) Audiovisual materials such as videotapes, DVDs, public service announcements, etc. when identified as a necessary expense that directly impacts the goals and deliverables of this award.
2) Travel and per diem to trainings, exercises and meetings with AFRPS members (other state agencies, local agencies, FDA District/Regional Offices), FDA Headquarters, and annual AFRPS meetings.
3) Subcontracting to third parties(other than local/county/tribal agencies conducting work on behalf of the State animal feed regulatory agency) is allowed but limited to 25% of each year's award.

Non-allowable costs:

1) Pre-award costs are not allowable for this announcement.
2) Facilities, work, and training reimbursed under the FDA animal feed safety inspection contract and other funding mechanisms must remain distinct and separate from the cooperative agreement. The State must be able to account separately for fund expenditures, including employee salaries, wages, and benefits, under the feed safety inspection contracts and other funding mechanisms and these cooperative agreements.
3) Vehicle purchases are not permitted.
4) 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.

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

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. **Paper applications will not be accepted.**

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

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:
All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to FDA. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

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

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

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

Scored Review Criteria

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

1. Rationale and Design (40 points): Demonstrates ability to achieve the goals and project goals of the cooperative agreement and project proposed.

2. Cooperation (20 points): Demonstration of effectiveness in working with federal, state, and local partners and other appropriate organizations to implement the goals of the cooperative agreement.

3. Integration (20 points): Demonstration of plans to facilitate the incorporation and sustainability of project developed capabilities into the entity's feed safety system. Expected challenges are documented and addressed.

4. Resources (20 points): Demonstration of adequate program resources (including staff) and infrastructure, or the ability to obtain the resources necessary, to complete the project.

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.

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 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.

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; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

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.

2. Administrative and National Policy Requirements

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

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

HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the

National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

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

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

Additional terms and conditions regarding FDA regulatory and FDA CENTER NAME 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, 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.

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

- FDA hosting annual meetings for programs enrolled in the AFRPS.
- FDA conducting on-site technical sessions with the grantee.
- FDA conducting on-site visits and verification audits to verify grantee progress in achieving implementation of the AFRPS.
- FDA hosting monthly (or at a frequency chosen by FDA) conference calls/webinar meetings with all programs enrolled in the AFRPS.
- FDA assistance in the sharing of information developed by the grantee to achieve implementation of the AFRPS and with other programs enrolled in the AFRPS in addition to FDA and other federal agencies. Examples may include SOPs, MOUs, training programs, and record keeping systems.
- FDA assistance in coordinating multi-program pilot projects.
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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 this cooperative agreement is to advance efforts for a nationally integrated animal feed safety system by assisting State animal feed regulatory programs to achieve and maintain full implementation of the AFRPS. The AFRPS are intended to ensure that State animal feed regulatory programs develop and maintain best practices for a high-quality regulatory program. The cooperative agreements will provide funding for additional personnel, equipment, supplies, and training to support activities related to achieving implementation of the AFRPS.

The grantee must maintain an animal feed safety inspection contract with the FDA throughout the cooperative agreement. State animal feed programs funded under this cooperative agreement 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 a required annual face-to-face meeting and any required training (as determined by FDA/OP) as a condition of the award. Facilities, work, and training reimbursed under the FDA animal feed 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 animal feed safety inspection contracts and other funding mechanisms and these cooperative agreements. 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 implementation of the AFRPS, continued compliance with all FDA regulatory requirements, and, if necessary, a corrective action plan has been implemented.

Principal Investigator Rights and Responsibilities

The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, or programmatic aspects of the grant and for day-to-day management of the project or program. The PD/PI(s) will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff has sufficient clearance and/or background checks to work on this project or program. This individual will work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements.

The PD(s)/PI(s) will have the primary responsibility for:

Overall management of the study and agree to work cooperatively with FDA.

Developing and implementing systems necessary for communications among the various study organizational components. All data and samples to be shared freely by methods and within time periods to be specified by the Project Officer.

FDA staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

The awardees agree to accept assistance from the designated FDA Project Officer. This person will participate, in the monitoring of issues relating to recruitment, follow-up, and adherence to protocols and will assist in the development and/or adjustment of project activity.

Additionally, an agency program official may be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The reporting and monitoring activities may include a review of budget modification requests from the grantee. The grantee and any sub-grantees are expected to utilize the approved funding respectively as indicated in the original submitted separate budget and cost estimates. The letter of agreement will be submitted by the grantee with the aforementioned budget modification request to the grants management officer and the program project officer.

Equipment may be loaned by FDA to an awardee pursuant to FDA policy. Such equipment 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/OP, the FDA provided equipment may not be transferred by the awardee 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 awardee

Mid-year reports are required. The Research Performance Progress Report (RPPR) will be considered the annual program progress report for the budget period.

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

1. Detailed progress report on the grantee meeting the project goals detailed in the cooperative agreement and identified in the application.

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

3. Certification of current State appropriation funding levels for the State animal feed regulatory program.

4. Submission of the following documents in the most current version of the AFRPS. These documents must be current and fit for use.

Appendix 1 or alternate form that is equivalent
Appendix 2.1 or alternate form that is equivalent
Appendix 3.1 or alternate form that is equivalent
Appendix 4.1, 4.3, 4.6, 4.8, 4.10, 4.11 or alternate form that is equivalent
Appendix 5.1 or alternate form that is equivalent
Appendix 6.1 or alternate form that is equivalent
Appendix 7.1 or alternate form that is equivalent
Appendix 8.1 or alternate form that is equivalent
Appendix 9.1 and 9.2, or alternate form that is equivalent
Appendix 10 or alternate form that is equivalent
Appendix 11 or alternate form that is equivalent

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

1. An improvement 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 achieve full implementation of the AFRPS. Progress achieved should indicate significant to full implementation of the AFRPS can be expected by Year 5. Review and update improvement plan(s) on an annual basis. Documentation related to the evaluation and improvement plan(s) should be maintained.

Submission of an improvement plan will include the following at the minimum to demonstrate program advancement in achieving implementation of the AFRPS:

- The individual element or documentation requirement for the standard that was not fully met.
- Improvements needed to fully meet the program element or documentation requirement(s) of the standard.
- Lists of individual tasks that will be used to address the improvement
- A projected completion date for each task.
- An assigned AFRPS Project Coordinator with the overall responsibility for implementing the improvement plan(s).

Note: For programs with less than 12 months of enrollment in the AFRPS, this information will be required after 12 months of enrollment in the AFRPS.

2. Description of program improvements and demonstration of measurable implementation of the AFRPS.
Note: For programs with no previous enrollment in the AFRPS, this information will not be required until Year 2.

Additional reporting requirements: For programs with less than 12 months of enrollment in the AFRPS, submission of the baseline self-assessment, including applicable appendices, worksheets, and other documents required for each Standard, or equivalent alternate forms, and an improvement plan is required to be submitted after 12 months of enrollment in the AFRPS. Programs previously enrolled in the AFRPS for a minimum of 12 months should have submitted this information with their application.

The final program progress report must provide full written documentation of the project and summaries of accomplishments and goals, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other State, local, and tribal governments could reproduce the final project. The final program progress report should also detail the strategy, including commitment of personnel, resources, and funding, to sustain implementation of the AFRPS (current and future versions). An independent audit of the program by FDA should verify the program is in significant implementation of the AFRPS.

Monitoring Activities

The program project officer and technical advisors will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project office/grants management office and the principal investigator. Periodic site visits with officials of the grantee 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 grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with 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 study will depend on recommendations from the project officer.

The scope of the recommendation will confirm that:

(1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; (3) funds are being used to supplement, not supplant, the building of feed safety capacity as described in the application; and (4) if necessary, there is an indication that adequate corrective actions have taken place to address any identified problems.

3. Reporting

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

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *HHS Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000.

Section VII. Agency Contacts

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

Application Submission Contacts

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

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726

Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

Scientific/Research Contact(s)

Teresa Bills
Food and Drug Administration (FDA)
Telephone: 615-854-0019
Email: teresa.bills@fda.hhs.gov

Objective Review Contact(s)

Dan Lukash
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Financial/Grants Management Contact(s)

Dan Lukash
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Telephone: 240-402-7596
Email: daniel.lukash@fda.hhs.gov

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.