Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	**U.S. Food and Drug Administration (FDA)**
Components of Participating Organizations	**Office of the Commissioner / Office of International Programs (OC/OIP)** Center for Food Safety and Nutrition (CFSAN) Center for Veterinary Medicine (CVM)
Funding Opportunity Title	**Cooperative Agreement with the World Health Organization Department of Food Safety and Zoonoses in support of strategies that address food safety problems that align domestically and globally (U01).**
Activity Code	U01 Research Project – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	**RFA-FD-11-021**
Companion FOA	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
FOA Purpose	**The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for award of a cooperative agreement to the World Health Organization (WHO) Department of Food Safety and Zoonoses (FOS) to support strategies that address food safety problems that align domestically and globally.** This Cooperative Agreement is expected to contribute to the knowledge base of the current state of food safety globally, including challenges, risks and emerging trends, through an integrated information system based on WHO's existing network efforts, such as the Global Foodborne Infections Network (GFN), International Food Safety Authorities Network (INFOSAN), Global Environment Monitoring System for Food (GEMS/Food); Global Early Warning Systems for Animal Diseases Including Zoonoses (GLEWS), and the Initiative to Estimate the Global Burden of Foodborne Diseases (FERG); as well as programs currently under development, such as the Global Laboratory Directory (GLaD); Enable the sharing of scientific findings and data through expert meetings and technical consultations; Enhance capacity at international and national levels in such areas of laboratory analyses, surveillance, and risk assessment/risk management,

	including through the Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR); Contribute to the scientific, standard-setting work of the Codex Alimentarius Commission (Codex) through scientific advisory groups including the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the FAO/WHO Joint Meetings on Microbiological Risk Assessment (JEMRA), and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) currently in development phase; and Enable participation of Member States through the Codex Trust Fund.

Key Dates

Posted Date	
Letter of Intent Due Date	Not Applicable
Application Due Date(s)	July 20, 2011
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	July, 2011
Advisory Council Review	Not Applicable
Earliest Start Date(s)	September 1, 2011
Expiration Date	July 21, 2011
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the PHS398 Application Guide except where instructed to do otherwise (in this FOA). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. While some links are provided, 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.**

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

1. Background

WHO has responsibility for the provision of technical cooperation to its 193 Member States (national governments) in the area of food safety and zoonotic diseases? Among the focus areas are: surveillance for food borne disease; identification of food contamination; management of mechanisms for information sharing; and systems for emergency response, including outbreak investigations and governments' food product recalls which may potentially have a global impact or cross national boundaries, and which may fall within the requirements of the International Health Regulations. WHO's technical support complements a paradigm shift that is emerging around the globe; a shift from a focus on food safety interventions at ports-of-entry toward an approach that emphasizes preventive, risk-based efforts. This shift entails increasing accountability of entities along the supply chain that grow, harvest, manufacture, process, store, transport, distribute, and/or import foods for ensuring the safety of their products, while at the same time strengthening national authorities' capacity and systems to be able to regulate these products efficiently and effectively. Along with the Food and Agriculture Organization of the United Nations (FAO), WHO also has a responsibility in relation to harmonizing international science-based food safety standards (e.g., as one of the founding institutions and technical advisory bodies to the Codex Alimentarius Commission (Codex)). Codex was founded in 1963 to develop food standards, guidelines, and other related texts, such as codes of practice, under the Joint FAO/WHO Food Standards Programme. Currently, 185 Member States, including the United States through FDA and other U.S. Government agency technical and scientific experts, actively participate in Codex.

A significant outcome of the 63rd World Health Assembly in May 2010 was a consensus resolution on advancing food safety initiatives, which, among other items, acknowledged the continuing need for closer collaboration between the health sector and other sectors, and increased action on food safety at the international and national levels, across the full length of the food-production chain, in order to reduce significantly the incidence of food borne disease. This resolution also closed a ten year gap in WHO governance dialogue on global food safety challenges, providing all Member States with a general pathway for global collaboration and enforcing the Secretariat's role in technical cooperation.

In support of the resolution's implementation, FDA awarded two cooperative agreements in fiscal year (FY) 2010 to WHO's FOS to: (1) support the development of a plan that delineates a global integrated information system to better report and utilize information and data that are timely, accurate, and comparable; and, through such data, increase understanding of risk factors and safety standards relative to public health outcomes; and (2) support WHO's Advisory Group on Integrated Surveillance for Antimicrobial Resistance (AGISAR), which is part of WHO's effort to minimize the public health impact of antimicrobial resistance associated with the use of antimicrobials in food animals.

For nearly 30 years, FDA, through the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), has participated with WHO's International Programme on Chemical Safety (IPCS) in a Cooperative Agreement that supported WHO's work in international risk assessment and its standard-setting activities for food ingredients, contaminants, and veterinary drug residues in food, including the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA contributes internationally-recognized science-based risk assessments of food additives, contaminants, and residues of veterinary drug reside in food. This Cooperative Agreement has also supported Joint FAO/WHO Expert Consultations on risk assessments for emerging or cross-cutting issues (e.g., the use of active chlorine species in food processing, bisphenol-A). The evaluations that are produced by JECFA and the Expert Consultations provide a sound scientific basis for Codex's standard-setting activities that contribute to improved public health and food safety worldwide.

The 63rd Health Assembly also called the continuation of sustainable preventive measures through food safety education programs such as the FIVE KEYS to safer food developed by WHO in collaboration with FDA. The WHO Five Keys to Safer Food global message and training materials for consumers in the home are now recognized as an international source for conducting national food safety education programs. In 2008, a joint Food and Agriculture Organization (FAO)/WHO Expert Meeting on the microbiological hazards in fresh leafy vegetables and herbs also acknowledged the success of the FIVE KEYS to safe food as it reviewed the scientific data and made recommendations for limiting the risks associated with microbial contamination of these products. An important recommendation from the meeting was the suggestion that WHO develop training and educational materials based on the FIVE KEYS TO SAFER FOOD concept. As a result, WHO, working together with FDA, developed FIVE KEYS to Growing Safer Fruits and Vegetables: Promoting Health by Decreasing Microbial Contamination, a training program designed for educating rural workers who grow fresh fruits and vegetables for themselves, their families and for sale in local markets.

Many of the network "building blocks" to address elements of preventive risk-base approaches to food safety reside within WHO. For example:

- The International Networks of Food Safety Authorities (INFOSAN), a joint FAO/WHO program consisting of 177 Member States, which aims to promote the rapid exchange of information during food safety related events, promote partnership and collaboration between countries, and help countries to strengthen their capacity to manage food safety risks;

- The Global Foodborne Infections Network (GFN), a network of over 1,500 individuals from 700 institutions in 177 countries, that provide human resource expertise to promote integrated, laboratory-based surveillance and intersectoral collaboration in human health, veterinary, and food-related disciplines;

- The Global Early Warning Systems for Animal Diseases Including Zoonoses (GLEWS), a joint system that coordinates alert mechanisms of the WHO, the FAO, and the World Organization for Animal Health (OIE) to assist in prediction, prevention, and control of zoonotic disease threats;

- The Global Laboratory Directory (GLaD), a support system for building, connecting, and sustaining laboratory and surveillance networks (currently in development phase);

- The Global Environment Monitoring System for Food (GEMS/Food), a program, which focuses on data collection and training related to dietary exposure of chemical hazards and involves a network of WHO Collaborating Center and national institutions from around the globe;

- The Foodborne Disease Burden Epidemiology Reference Group (FERG), established to provide guidance to WHO on the burden of foodborne disease to countries, with an anticipated publication of Global Report within the next several years;

- JECFA, the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA), and the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) currently in development phase, that serve as technical advisory bodies to Codex; and

- The management of the Codex Trust Fund.

- The FIVE KEYS to safer food training materials developed to educate food handlers in safe food handling practices

2. The Funding Opportunity

The Cooperative Agreement announced in this FOA represents the continuation of a long-standing collaboration between WHO and FDA in support of strategies and approaches that align well domestically and globally to address food safety problems. Relevant strategies include: 1) efforts to strengthen data and information systems so they are comparable, comprehensive, and robust, thereby allowing for better decision-making for all Member States; 2) enhanced capacity around the globe to improve detection of and response to food safety threats through preventive controls, data, information, surveillance systems, and risk-based approaches; and 3) global harmonization of science-based standards and adoption or adaption of international standards by national authorities.

This Cooperative Agreement is expected to support the following types of collaboration:

- Contribute to the knowledge base of the current state of food safety globally, including challenges, risks, and emerging trends, through an integrated information system based on WHO's existing network efforts, such as the GFN, INFOSAN, GEMS/Food, GLEWS, and FERG, as well as programs currently under development, such as GLaD;

- Enable the sharing of scientific findings and data through expert meetings and technical consultations;

- Enhance capacity at international and national levels in such areas of laboratory analyses, surveillance, and risk assessment/risk management, including through AGISAR;

- Contribute to the scientific, standard-setting work of Codex through scientific advisory groups including JECFA, JMPR, JEMRA, and JEMNU currently in development phase; and

- Enable participation of Member States through the Codex Trust Fund.

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will be actively engaged in the programmatic activities of the entire project funded by this cooperative agreement, including but not limited, to the following items:

- FDA will appoint a project officer who will actively monitor the FDA-supported program under this award and work closely and collaboratively with a core group of experts. This core group of technical experts (CG/TE) from CFSAN, CVM, the Office of Regulatory Affairs (ORA) and relevant offices of the Office of the Commissioner (OC) will provide technical guidance and advice, as appropriate, to WHO in the implementation of this cooperative agreement. Support can be from various sources including in-kind participation.

- Appropriate participation of FDA in multinational advisory group(s) that are working to address food safety regulatory systems, the development and implementation of science-based standards and norms, and strengthening the existing capacity of Member States in the area of food safety and preventive controls.

Section II. Award Information

Funding Instrument	Cooperative Agreement (U01).
Application Types Allowed	New The OER Glossary and the PHS398 Application Guide provide details on these application types.

Funds Available and Anticipated Number of Awards	The total funding available is up to $360,000 (total costs including indirect costs) in fiscal year (FY) 2011 in support of this project. One award will be made. Funding will be provided for one year, with the possibility of up to four additional years of support, contingent upon successful performance and available funding. DHHS grants policies as described in the DHHS Policy Statement http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html will apply to the applications submitted and awards made in response to this FOA.
Award Budget	$360,000
Award Project Period	Funding will be provided for one year with the possibility of up to four additional years of support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application, and available Federal Fiscal Year appropriations.

FDA 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

The World Health Organization (WHO) Department of Food Safety and Zoonoses (FOS).

Competition is limited to WHO because, as the only global health organization with a well-established trusted presence and high-level access to appropriate regulatory authorities in its 193 Member Countries and Territories and with its ability to coordinate programs at both the regional and international levels, it is uniquely qualified to further the food safety objectives of this cooperative agreement. This ability to advance the objectives of this cooperative agreement through Member-State participation and intersectoral action is requisite for the success of this program.

Required Registrations

Applicant organizations must complete the following registrations as described in the PHS398 Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- Central Contractor Registration (CCR) – must maintain an active registration, to be renewed at least annually
- eRA Commons

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

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/Principal Investigator (PD/PI) 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.

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

The applicant organizations may submit more than one application, provided that each application is scientifically distinct. Only one cooperative agreement will be awarded.

FDA will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. FDA will not accept any application that is essentially the same as one already reviewed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants are required to prepare applications according to the current PHS 398 application forms in accordance with the PHS 398 Application Guide.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the PHS398 Application Guide, 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.

Application Submission

Applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist in one package to:

Gladys M. Bohler
Office of Acquisition and Grant Support
Food and Drug Administration
5630 Fishers Lane, Room 1078, MSC 500
Rockville, MD 20857

At the time of submission, two additional paper copies of the application and all copies of the appendix files must be sent to:

Dr. Katherine Bond

Associate Director for Technical Cooperation/Capacity-Building

Office of International Programs

Office of the Commissioner

U.S. Food and Drug Administration

10903 New Hampshire Ave

Silver Spring, MD 20993

(301) 796-8318 Office

Email: katherine.bond@fda.hhs.gov

Page Limitations

All page limitations described in the PHS398 Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:

- Research Strategy section is limited to 30 pages.

Research Plan

All instructions in the PHS398 Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS) as provided in the PHS398 Application Guide, with the following modifications:

- Generally, Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, GWAS Sharing Plan) 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 (please note all format requirements) as described in the PHS398 Application Guide.

Foreign Organizations

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement, and procedures for foreign organizations described throughout the PHS398 Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates.

Information on the process of receipt and determining if your application is considered “on-time” is described in detail in the PHS398 Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

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

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

6. Other Submission Requirements and Information

Applications must be received on or before the due date in Part I. Overview Information. If an application is received after that date, it will not be reviewed.

All application instructions outlined in the PHS398 Application Guide are to be followed, with the following additional requirements:

Introduction -- limited to 1 page

Specific Aims -- limited to 1 page

A narrative proposal with suggested guidelines limited to 14 pages:

1. Background/problem to be addressed
2. Goals/objectives
3. Methodologies or approaches to be used
4. Landscape of others doing similar work who will be involved
5. Anticipated outcomes
6. Monitoring and evaluation plan
7. Dissemination/communication plan
8. Work plan indicating milestones and expected dates of major deliverables

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as follows:

Post-submission grant application materials are those submitted after submission of the grant application but prior to the initial peer review. This option is to be used when an unexpected event such as the departure of a participant, natural disaster, etc. has occurred, not to correct oversights/errors discovered after submission of the application.

Acceptable post-submission materials include:

Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition of equipment);
Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator);
Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator;
Adjustments resulting from natural disasters (e.g., loss of an animal colony);
Adjustments resulting from change of institution (e.g., PI moves to another university);
News of an article accepted for publication (a copy of the article should not be sent);
All post-submission materials must conform to application form policy on font size, margins, and paper size as referenced in Part I.2.6 of the applicable application instructions and additional form pages such as budget, biographical sketches, and other required forms must follow standards for required form pages as noted in the application forms;
If post-submission material is not required on a form page, each explanation or letter is limited to one page (see Acceptable Late Materials above);
If the application has subprojects or cores, each subproject or core is allowed explanations or letters (see Acceptable Late Materials above), but each explanation or letter is limited to one page.

Unacceptable post-submission materials include:

Updated Specific Aims or Research Strategy pages;
Late-breaking research findings;
New letters of support or collaboration that do not result from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the FDA Mission, all applications submitted to FDA in support of research are evaluated for scientific and technical merit through the FDA Ad Hoc review process.

Review Process

The application submitted by the World Health Organization (WHO) will initially be reviewed by grants management and program staff for responsiveness. To be considered, an application must:

1. Be received by the specified due date;
2. Be submitted according to section VIII “Submission Requirements'' of this document;
3. Not exceed $260,000 total costs (direct and indirect);
4. Address the specific program goals and objectives; and
5. Bear the original signatures of both the principal investigator and the organization's authorized official.

The application will be considered non-responsive if it is does not comply with Funding Opportunity requirements. If the application is found to be nonresponsive, the application will be returned to the applicant without further consideration. The application submitted by the organization will undergo an initial Ad Hoc Review The application will be reviewed first for technical merit by an Ad Hoc Review Group with expertise in areas associated with consumer health information and promotion and disease prevention. If the application is recommended for approval, it will then be presented to the Office of International Programs for their concurrence.

The application will be reviewed and evaluated based on four major criteria according to the following

Factor 1:
Overall Approach and Collaboration, which includes soundness and potential for innovation of the proposed approach, procedures, integration with existing programs and realistic time tables, cooperation among the lead institution and other partner organizations, and institutional commitment.

Factor 2:
Potential for Contributing to Internationalization, which includes the extent of importance or impact of the project, expected products or results, an adequate evaluation plan, a dissemination plan, and continuation plans.

Factor 3:
Management Plan – Applicant's demonstrated capability to manage the program as determined by the following: (1) Qualification and experience of proposed staff or requirements for “to be hired” staff, proposed staff effort, management experience of the organization related to the proposed program; (2) support and established network to conduct the proposed program; and (3) the thoroughness, feasibility, and appropriateness of the proposed program evaluation design, data collection, and analysis procedures.

Factor 4:
Budget and Budget Justification – Applicant: Proposed program costs are reasonable and based on activities to be carried out and the expected program outcomes.

Resubmissions
Not Applicable.

Renewals
Not Applicable

Revisions
Not Applicable.

Select Agent Research
Not Applicable

Resource Sharing Plans
Not Applicable.

2. Anticipated Announcement and Award Dates

After the Ad Hoc review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via e-mail.

Information regarding the disposition of applications is available in the HHS Grants Policy Statement .

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, FDA will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement.

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 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 the DUNS, CCR Registration, and Transparency Act requirements as referenced in this document..

2. Administrative and National Policy Requirements

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

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 74, and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and FDA as defined below.

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

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

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

- Conduct periodic program monitoring, which may be in the form of telephone conversations between the Principal Investigator and the Project Officer/Grants Management Officer/Grants Management Specialist, and meetings (in person or by telephone) with relevant FDA technical experts. Program monitoring may also be in the form of site visits.
- Appoint a Project Officer or Co-Project Officers who will actively monitor the FDA-supported program under this award.
- Retain the right to have prior approval on the appointment of all key personnel substantially supported by the grant.
- Be directly involved in the guidance and development of the program and the collaborative structure for the program.
- Participate with the grantee in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, co-authorship of publications.
- Have professional scientific and administrative/clerical personnel working in collaboration with the grantee as required.

Areas of Joint Responsibility include:

- As appropriate, FDA will actively participate in multinational advisory groups that are working to address food safety regulatory systems, the development and implementation of science-based standards and norms, and strengthening the existing capacity of member states in the area of food safety and preventative controls.

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and FDA may be brought to Dispute Resolution. A Dispute Resolution Panel will be convened. It will have three members: a designee of the Steering Committee chosen without FDA staff voting, one FDA designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

- An annual Financial Status Report (FSR) (SF-269) is required. An original and one copy of this report must be submitted to the FDA Grants Management Officer within 90 days after the end of each budget period. It is important that the grantee institute maintains internal controls to ensure that all FSRs are current, accurate and provide a complete disclosure of the financial status of the project in accordance with the terms of the award and the HHS Grants Policy Statement.

- Annual written Program Progress Reports will be due 90 days following the close of the budget period and a semi-annual written report will be due within 30 days after the first 6 months of the budget period. These reports must contain the following information:
    a. General progress of project according to proposed goals, objectives and work plan, and including a discussion of milestones and results, any possible delays, modifications or other unanticipated results.
    b. Project status in relation to established timelines.
    c. Financial report.

- A final Program Report, FSR, and Invention Statement must be submitted within 90 days after the expiration date of the project period.

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the

HHS Grants Policy Statement.

A final progress report, invention statement, and FSR are required when an award is relinquished, when a recipient changes institutions, or when an award is terminated.

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. Please contact the Grants Management Specialist for additional information on this reporting requirement.

Section VII. Agency Contacts

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

Application Submission Contacts

GrantsInfo (Questions regarding application instructions and process, finding FDA grant resources)
Telephone 301-827-7175
TTY 301-480-0434
Email: gladys.bohler@fda.hhs.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov

Scientific/Research Contact(s)

Dr. Katherine Bond
Associate Director for Technical Cooperation/Capacity-Building
Office of International Programs
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
(301) 796-8318 Office
Email: katherine.bond@fda.hhs.gov

Julie Moss
Deputy Director
International Affairs Staff
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(301) 436-2031
Email: julie.moss@fda.hhs.gov

Peer Review Contact(s)

Dr. Katherine Bond
Associate Director for Technical Cooperation/Capacity-Building
Office of International Programs
Office of the Commissioner
U.S. Food and Drug Administration

10903 New Hampshire Ave
Silver Spring, MD 20993
(301) 796-8318 Office
Email: katherine.bond@fda.hhs.gov

Financial/Grants Management Contact(s)

Gladys M. Bohler
Grants Management Officer/
Grants Management Specialist
Food and Drug Administration,
HFA 500, Room 2129
5630 Fishers Lane
Rockville, MD 20857
301-827-7175 Telephone
301-827-7039 FAX
E-mail: gladys.bohler@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 74.