Part I Overview Information

Department of Health and Human Services

Issuing Organization
Food and Drug Administration (http://www.fda.gov/)

Components of Participating Organizations
Office of Regulatory Affairs (ORA)
Center for Food Safety and Applied Nutrition (CFSAN) and
Center for Veterinary Medicine (CVM),

Title: Food Protection Rapid Response Team and Program Infrastructure Improvement Prototype Project (U18)

Note: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH.

Announcement Type
New – Limited Competition

Request For Applications (RFA) Number: RFA FD08-007

Catalog of Federal Domestic Assistance Number(s)
93.103 http://12.46.245.173/cfda/cfda.html

Key Dates

Application Receipt Dates(s): August 15, 2008

Council Review Date(s): September, 2008
Earliest Anticipated Start Date: September, 2008
Expiration Date: September, 2008

Due Dates for E.O. 12372
See http://www.whitehouse.gov/omb/grants/spoc.html

Additional Overview Content

Executive Summary

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) in collaboration with Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM), is announcing the availability of an agreement of Limited Competition. Only States with current FDA Food Safety contracts to provide funding to State agency food protection regulatory programs are eligible for a 3 year cooperative agreement to develop and sustain an all Food Hazards Rapid Response team, encompassing both food and feed protection programs, through a process to further enhance and build the infrastructure of State food protection programs.

The goal of FDA's ORA Cooperative Agreement Program is to enhance, complement, develop and improve State manufactured food protection regulatory and surveillance programs. This will be accomplished through the provision of funding for program assessment, additional equipment, supplies, funding for personnel, and training including ICS, rapid response team development and coordination, and exercises of the response team. This will also require extensive cooperation and coordination with FDA District Offices to minimize duplication of inspections, an FDA contractor (the Western Institute for Food Safety and Security (WIFSS)) in the development of Rapid Response Teams, and other FDA program offices.

- **Mechanism of Support.**

  This funding opportunity will use the cooperative agreement award mechanism(s) (U18).
  The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

  This funding opportunity will use a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA staff being substantially involved as a partner with the Principal Investigator, as described under the Section VI. 2. Administrative Requirements, "Cooperative Agreement Terms and Conditions of Award

  Funding for an additional three year of non-competitive support is contingent on cooperative agreement performance, program progress and the availability of funds.

- **Funds Available and Anticipated Number of Awards.**

  The total amount of funding available in Fiscal Year (FY) 2008 is $3 million.
  It is anticipated that FDA will make up to six awards in FY 2008. The number of projects funded will depend on the quality of the applications received and is subject to availability of Federal funds to support the projects. In addition, if a cooperative agreement is awarded, grantees will be informed if any additional

documentation should be needed to support their award. Funds may be requested in the budget to travel to FDA for meetings with program staff about the progress of the project. The project office will have continuous interaction with the grantee through inspection field audits, collection of quarterly progress reports, and provision of training, joint inspections, and compliance, program standards audits, rapid response team exercises and coordination and others as needed in the development of the self assessment, strategic improvement plan and its implementation. There may be other regular meetings with grantees to assist in fulfilling the requirements of the cooperative agreement.

- **Budget and Project Period.**

  The length of support is three years and the applicants must apply for the three (3) years of currently projected funding. The applicants must provide three years worth of budgets and program objectives. The initial competitive review and award process will provide all awardees with one year of funding. The second year and third years of funding of noncompetitive continuation of support will depend on performance during the preceding year and availability of Federal funds. Cooperative agreements will be awarded up to $500,000 in total (direct plus indirect) costs per year for up to three (3) years and can be modified, depending on the availability of funds and review of prior year's accomplishments.

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. in the full text of the RFA are eligible to apply. This cooperative agreement program is only available to State food safety agencies and their manufactured food regulatory programs that currently have an FDA food safety inspection contract. All cooperative agreement prototype projects that are developed at State agency level must have existing food safety inspection and surveillance programs under contract to FDA for food safety inspections.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/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.

- **Number of Applications.** Applicants may submit more than one application, provided they are scientifically distinct.

- **Resubmissions.** Resubmission applications are not permitted in response to this Funding Opportunity Announcement (FOA).

  Renewals. Renewal applications are not permitted in response to this FOA.

- **Special Date(s).**

  Applications will be accepted from 8 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, until the established receipt date. Please do not send

applications to the Center for Scientific Review (CSR) at the National Institutes of Health (NIH). Any application sent to NIH/CSR that is forwarded to the FDA Grants Management Office and not received in time for orderly processing will be judged nonresponsive and returned to the applicant. Applications submitted electronically must be received by the close of business on the established receipt date. No addendum material will be accepted after the established receipt date.

Application Receipt Date(s): August 15, 2008
Council Review Date(s): September, 2008
Earliest Anticipated Start Date(s): September, 2008

- See Receipt, Review and Anticipated Start Dates in the full text of the RFA available at Grants.gov and the FDA/ORA website: http://web.ora.fda.gov/dfsr/detail.jsp?id=66

- **Application Materials.** See Section IV.1 for application materials in the full text of the RFA available at Grants.gov and the FDA/ORA website: http://web.ora.fda.gov/dfsr/detail.jsp?id=66
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-0088.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) in collaboration with Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM), is announcing the availability of an agreement of Limited Competition only to states with current FDA Food Safety contracts to provide funding to State agency food protection regulatory programs. Such programs are eligible to apply for a 3 year cooperative agreement to develop and sustain an all Food Hazards Rapid Response team, encompassing both food and feed protection programs, through a process to further enhance and build the infrastructure of State food protection programs.

The goal of FDA's ORA Cooperative Agreement Program is to enhance, complement, develop and improve State manufactured food protection regulatory and surveillance programs. This will be accomplished through the provision of funding for program

assessment, additional equipment, supplies, funding for personnel, and training including ICS, rapid response team development and coordination, and exercises of the response team. This will also require extensive cooperation and coordination with FDA District Offices to minimize duplication of inspections, an FDA contractor (the Western Institute for Food Safety and Security (WIFSS)) in the development of Rapid Response Teams, and other FDA program offices.

These cooperative agreements are intended to develop, implement and exercise an all hazards food and foodborne illness Rapid Response Team (RRT) concept within the food protection program in conjunction with other food and feed *agencies* within State programs, other State RRTs, FDA District Offices, and State Emergency Operations Centers (EOC) to respond to all food hazard incidents in the farm-to-table continuum using expandable ICS protocols and structures as needed. The infrastructure necessary to develop and sustain an RRT is accomplished through the assessment and continuous improvement to the infrastructure and equivalency of the State food regulatory program using the FDA Manufactured Food Regulatory Program Standards (MFRPS). State food program enhancements will also include the incorporation of the FDA Food Protection Plan to implement a strategy of prevention, intervention and response to build safety into every step of the food supply chain. The cooperative agreements will provide funding for additional personnel, equipment, supplies and training to support activities related to the FDA MFRPS and the RRT concept.

Under the cooperative agreement, the State would assess and implement a continuous program improvement/enhancement strategy (strategic plan) using the FDA Manufactured Food Regulatory Program Standards (MFRPS), and in addition, under Standard #5, develop, train and implement a foodborne illness rapid response team that incorporates Incident Command System (ICS) concepts and conceptual elements outlined in this RFA. This standard applies to the surveillance, investigation, response and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate that may result in illness, injury, and outbreaks. Post assessment, these funds should be used to enhance or establish systems to:

a. Use epidemiological information supplied by local, State, or Federal agencies to detect incidents or outbreaks of foodborne illness or injury
b. Investigate reports of illness, injury, and suspected outbreaks
c. Correlate and analyze data
d. Disseminate public information effectively
e. Distribute outbreak reports and surveillance summaries to relevant agencies
f. Disseminate current guidance to industry on food defense
g. Provide guidance for immediate notification of law enforcement agencies when intentional food contamination or terrorism is suspected or threatened
h. Collaborate as necessary with FDA and other Federal authorities under conditions of increased threat of intentional contamination.

The goal of developing and sustaining an RRT is in concert with long term goals to enhance the food inspection and foodborne illness response programs, to increase the ability to inspect and obtain compliance for firms in their jurisdiction involved in the processing, manufacturing, distribution, transportation and warehousing of food, verify compliance with the State laws and regulations, good manufacturing practices, food defense, and other food protection requirements in support of the State program and

the FDA Food Protection Plan (FPP), Action Plan for Import Safety (ISAP) and the Food and Drug Administration Amendments Act of 2007 (FDAAA).

Funds could be used to increase State personnel to support the RRT, team coordinators, technical experts and epidemiologist team members. Funds could also be used for supplies, training, and equipment for inspections and rapid response including investigational, GPS interface, communication and laboratory. The goal of enhancing State food programs is to ensure that the necessary infrastructure is available to support an RRT along with the States regulatory and food protection responsibilities of inspections and oversight of food processing, manufacture, distribution, transportation and warehousing.

Finally, these Support Project funds are intended to supplement, not replace, State funding for program improvement and activities. States funded under these cooperative agreements will be required to provide the previous years and subsequent Years State funding to demonstrate that these funds have not replaced State allocations for the food protection program.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism of Support

This funding opportunity will use the cooperative agreement award mechanism(s) (U18). The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity will use a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA staff being substantially involved as a partner with the Principal Investigator, as described under the Section VI. 2. Administrative Requirements, "Cooperative Agreement Terms and Conditions of Award.

Funding for an additional two years of non-competitive support is contingent on cooperative agreement performance, program progress and the availability of funds.

2. Funds Available

Award Amount: The total amount of funding available in Fiscal Year (FY) 2008 is $3 million. Cooperative agreements will be awarded up to $500,000 in total (direct plus

indirect) costs per year for up to three (3) years and can be modified, depending on the availability of funds and review of prior year's accomplishments.

Length of Support: The length of support is three years and the applicants must apply for the three (3) years of currently projected funding. The applicants must provide three years worth of budgets and program objectives. The initial competitive review and award process will provide all awardees with one year of funding. The second and third years of funding of noncompetitive continuation of support will depend on performance during the preceding year and availability of Federal funds.

Funding Plan: It is anticipated that FDA will make up to six awards in FY 2008. The number of projects funded will depend on the quality of the applications received and is subject to availability of Federal funds to support the projects. In addition, if a cooperative agreement is awarded, grantees will be informed if any additional documentation should be needed to support their award. Funds may be requested in the budget to travel to FDA for meetings with program staff about the progress of the project. The project office will have continuous interaction with the grantee through inspection field audits, collection of quarterly progress reports, and provision of training, joint inspections, and compliance, program standards audits, rapid response team exercises and coordination and other activities as needed in the development of the self assessment, strategic improvement plan and its implementation. There may be other regular meetings with grantees to assist in fulfilling the requirements of the cooperative agreement.

The purpose of these cooperative agreements is the development and enhancement of existing State Food regulatory programs in providing outbreak response capabilities. Funding will be provided for items such as: supplies, lab equipment, surveillance, team development and exercise, sample collection, personnel, for the provision of training independently and with an FDA contract for rapid response team training, and meetings with FDA District response teams. Successful applications will be selected for funding to ensure a broad geographic distribution of the program. Size of the existing or new State/territory/tribal program and number of facilities to be covered under the cooperative agreement will also be a determining factor. States with current Food Safety Inspection contracts from FDA can maintain these contracts at the discretion of the State and FDA. However, the facilities and work covered under the contract cannot be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement. These cooperative agreements are not to fund licensed medicated feed or routine feed safety good manufacturing practice (GMP) inspections, or retail food or foodservice inspections.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the FDA provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

FDA grants policies as described in the DHHS Grants Management Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

1. A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- State Governments – This cooperative agreement program is limited to State food safety agencies and their manufactured Food regulatory programs that currently have an FDA food safety inspection contact. In addition, all cooperative agreement prototype projects that are developed at State agency level must have existing food safety inspection and surveillance programs under contract to FDA for food safety inspections.

1. B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her institution 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 or Matching

This program does not require cost sharing as defined in the current DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm .

3. Other-Special Eligibility Criteria

- Applicants are not permitted to submit a resubmission application in response to this Request for Application.
- Renewal applications are not permitted in response to this RFA

Applicants may submit more than one application, provided each application is scientifically distinct.

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 424/5161-1 application instructions are available at http://www.hhs.gov/forms/PHS-5161-1.pdf. Applicants must use the currently approved version of the PHS424. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

The title and number of this funding opportunity must be included on the face page of the application.

The applicant will be judged on, and must specifically address, the following in the cooperative agreement application:

- Program goals as stated in the RFA
- Demonstrate the availability of adequately trained food program staff including field staff, supervisory staff and support staff and the criteria to hire and/or train personnel to conduct food program activities including assessment and implementation.
- Demonstrate the availability of adequately trained personnel to support the activities required under this cooperative agreement and agency commitment and support for this project including the development of the Rapid Response Team.
- Provide a detailed description of current food regulatory program including types of inspections performed, and types and numbers of food establishments in the State inventory. Provide an indication of how many of each of these facilities would be covered each year under this agreement.
- Provide a properly detailed budget (one for each of three years) that is intended to develop the Rapid Response Team and enhance the food protection program in the State. Included will be the previous and current years State funding for the program including program staffing and costs.
- Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3.A of this notice.
- Provide current funding level certification for their food safety program from State funding appropriations.
- Outline detailed methodology for program assessment improvement or program development to accomplish the work.
- Provide justification for hiring new staff, hiring qualifications, their training needs and any new equipment.
- It is noted that the grantee should provide a clearly detailed description on how the State food program will follow procedures for notifying FDA of violative facilities for enforcement under FDA jurisdiction.

B. Laboratory Facilities

If funds or equipment from the cooperative agreement are provided to the State food laboratory, the applicant must provide at the completion of the first year of funding a complete description of the facilities, including the following information: The name and address of the State facility conducting the food sample testing; the name of the most responsible individual for the facility where the testing will be conducted; and, the location and installation requirements of any equipment purchased with cooperative agreement funds. Other facilities information that may be required includes:

- Operational support areas to be used for the project, including details about the availability of ancillary laboratory safety and support equipment and facilities;
- Details describing the sample receiving and sample storage areas and a description of any existing chain-of-custody procedures;

- A detailed description of the proposed upgrades to existing laboratory facilities to accommodate new equipment including drawings and cost estimates.
- A summary description of any quality management system defined, in development, or in place as it relates to quality control and quality assurance procedures and practices;
- A summary description of staffing management, specifically to include food sample testing abilities and procedures;
- A summary description of procedures in place to monitor food sample workflow, including the tracking and monitoring of sample analyses in progress to include a description of the laboratory work product review process and provide a report of a sample analysis within a responsive and reasonable timeframe must be described. .
- The ability or an agreement with another laboratory to perform and complete the feed sample analyses and provide a report of a sample analysis within a responsive and reasonable timeframe must be described. At a minimum, the grantee shall utilize and follow the laboratory testing procedures, methodology, and protocol employed and accepted by FDA in the assessment of feed samples

The funds from this cooperative agreement may not be used to construct, renovate or remodel laboratories or other physical facilities.

To download a SF424 Application Package for this RFA, link to http://www.grants.gov/Apply/ and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/GetStarted)

Several additional separate actions are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Started

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
  Grants.gov Customer Support
  Contact Center Phone: 800-518-4726
  Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
  Email support@grants.gov

Data and information included in the application will generally not be publicly available prior to the funding of the application. After funding has been granted, data and information included in the application will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b) (4)) and FDA's

implementing regulations (including 21 CFR 20.61, 20.105, and 20.106). By accepting funding, the applicant agrees to allow FDA to publish specific information about the cooperative agreement. Information collection requirements requested on Form PHS 5161–1 (Rev. 7/00) have been sent by PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number 0348–0043.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below (Section IV.3.A). Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Application Receipt Date(s): August 15,, 2008
Council Review Date(s): September, 2008
Earliest Anticipated Start Date(s): September, 2008

Applications will be accepted from 8 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, until the established receipt date. Please do not send applications to the Center for Scientific Review (CSR) at the National Institutes of Health (NIH). Any application sent to NIH/CSR that is forwarded to the FDA Grants Management Office and not received in time for orderly processing will be judged nonresponsive and returned to the applicant. Applications submitted electronically must be received by the close of business on the established receipt date. No addendum material will be accepted after the established receipt date.

3. A.1. Letter of Intent

A letter of intent is not required for this RFA.

3. B. Sending an Application to the FDA

FDA is accepting new applications for this program electronically via Grants.gov. Applicants are strongly encouraged to apply electronically by visiting the Web site http://www.grants.gov and following instructions under ''APPLY.'' The required application PHS 424, which is part of the PHS 5161– 1 form, can be completed and submitted online. The package should be labeled ''Response to RFA–FDA–008-007. If you experience technical difficulties with your online submission you should contact Gladys M. Bohler, Grants Management Specialist, Division of Contracts and Grants Management (HFA– 500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7168, e-mail: gladys.melendez-bohler@fda.hhs.gov or the Grants.gov Customer Response Center for assistance.

To comply with the President's Management Agenda, the Department of Health and Human Services is participating as a partner in the new Government wide Grants.gov Apply site. Users of Grants.gov will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov site. We request your participation in the Grants.gov project. When you enter the Grants.gov site, you will find information about submitting an application

electronically through the site. In order to apply electronically, the applicant must have a DUNS number and register in the Central Contractor Registration (CCR) database as described in section IV.6 of this document.

3. C. Application Processing

Applications must be **received on or before the application receipt date** described above (Section IV.3.A.). If an application is received after that date, the application may be delayed in the review process or not reviewed. Upon receipt, applications will be evaluated for completeness and for responsiveness by the Project Officer and Grants Management Staff. Incomplete and/or non-responsive applications will not be reviewed.

The FDA will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application.

4. Intergovernmental Review

This initiative is subject to intergovernmental review (see http://www.whitehouse.gov/omb/grants/spoc.html for a list of SPOCs).

The regulations issued under Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100) apply. Applicants (other than federally recognized Indian Tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert the SPOC to the prospective application(s) and to receive any necessary instructions on the State's review process. The SPOC should send any State review process recommendations to the FDA administrative contact (see AGENCY CONTACTS in section VII of this document). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cutoff.

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. The Grants Policy Statement can be found at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

These cooperative agreements are not to fund licensed medicated feed or routine feed safety GMP or BSE inspections, or retail food or foodservice inspections that are unrelated to the food manufacturing, processing, wholesaling, transportation or warehousing of manufactured foods or are currently covered under a FDA Food safety contract. These awards may be only used for the development of new State rapid response teams and to enhance and supplement existing State food protection infrastructure. States with current FDA food inspection contracts can maintain these contracts for food inspections at the discretion of the State and FDA. However, the facilities, staff costs, travel and other costs and work covered under the contract cannot be counted towards fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement. The State must be able to account for expenditure of funds from the contract and cooperative agreement separately.

6. Other Submission Requirements and Information

FDA grants management and program staff will review all applications sent in response to this notice. To be responsive, an application must be submitted in accordance with the requirements of this notice and must bear the original signature of the applicant institutions/organization's authorized official. Applications found to be nonresponsive will be returned to the applicant without further consideration. Applicants are strongly encouraged to contact FDA to resolve any questions about criteria before submitting their application. Please direct all questions of a technical or scientific nature to the ORA program staff and all questions of an administrative or financial nature to the grants management staff (see Agency Contacts of this document).

These agreements will be subject to all applicable policies and requirements that govern the grant programs of PHS, including 45 CFR parts 92 and the PHS Grants Policy Statement. Equipment purchased under this cooperative agreement is subject to the requirements of 45 CFR part 92.31, ''Real property.'' Applicants must adhere to the requirements of this Notice. Special Terms and Conditions regarding FDA regulatory requirements and adequate progress of the study may be part of the awards notice.

The events of September 11, 2001, reinforced the need to enhance the safety and defense of the U.S. food supply. Congress responded by passing the Bioterrorism Act which President Bush signed into law on June 12, 2002. The Bioterrorism Act is divided into the following five titles:

- Title I—National Preparedness for Bioterrorism and Other Public Health Emergencies
- Title II—Enhancing Controls on Dangerous Biological Agents and Toxins
- Title III—Protecting Safety and Security of Food and Drug Supply
- Title IV—Drinking Water Security and Safety
- Title V—Additional Provisions

Subtitle A of Title III—Protection of Food Supply, Section 311—Grants to States for Inspections, amends the FD&C Act by adding section 909 to authorize the Secretary of Health and Human Services to award grants to States, territories, and Indian tribes that undertake examinations, inspections, and investigations, and related activities under section 702 of the FD&C Act. The grant funds are only available for the costs of conducting these examinations, inspections, investigations, and related activities.

In 2007 and 2008, the FDAAA, the Food Protection Plan and the Import Strategic Action Plan addressed FDA's relationship with the States in food protection activities. In addition, the Food protection Plan lays out specific new goals in protecting the food supply and in responding to incidents in a rapid and coordinated manner.

Food Protection Plan

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

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

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

- The *prevention* element involves promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, we can best address critical weaknesses.

- The *intervention* element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly.

- The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. They also include the idea of better communication with other federal, State, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as informing the public regarding what is safe to consume.

Food and Drug Administration Amendments Act of 2007 (FDAAA)

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

SEC. 1004. STATE AND FEDERAL COOPERATION

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of food, including fresh and processed

produce, so that State food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—
(1) Establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and
(2) Establish procedures and requirements for ensuring that processed produce under the jurisdiction of State food safety programs is not unsafe for human consumption.
(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—
(1) Advisory assistance;
(2) Technical assistance, training, and laboratory assistance (including necessary materials and equipment); and
(3) Financial and other assistance.
(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

Import Safety Action Plan (ISAP)

The Import Safety Action Plan acknowledges the value of mutual leveraging of state and Federal resources and recommends consideration of cooperative agreements to increase information sharing. Specifically, the ISAP provides as follows:

Federal-State Rapid Response

Recommendation 12 – Maximize Federal-State Collaboration.

The roles of and the resources used by the federal government and the States in import safety are complementary. States possess legislative authority and resources to respond to unsafe imported products within their jurisdiction. The federal government can take steps to interdict unsafe imported goods at ports-of-entry. Should an unsafe product enter domestic commerce, federal departments and agencies often work with State authorities to track it down, seize it, notify the public if it has already been purchased by consumers and impose appropriate penalties on domestic entities who violate U.S. law. Also, both the federal government and States may have access to information relevant to protecting consumers that the other does not possess. For example, federal departments and agencies may have relevant information about the foreign source of the imported product and about the importer. This information can help State officials track down an unsafe imported product within their jurisdiction. On the other hand, State officials may identify an unsafe imported product during transport or at the point-of-sale, if the product does get into the country, and can tip off federal officials to prevent future shipments from entering domestic commerce.

Several federal departments and agencies already collaborate closely with State authorities to protect consumers. For example, FDA has contracts and cooperative agreements with State governments to share information, conduct joint inspections and collaborate on laboratory analyses. Greater mutual leveraging of State and federal resources can further enhance consumer protection.

12.1 Consider cooperative agreements between the federal inspection agencies and their State counterparts for greater information-sharing. Such cooperative agreements would not infringe on the statutory authorities of federal or State regulators and would encourage a coordinated effort that would result in a more rapid and effective response. Establishing clear procedures and points-of-contact for information sharing and joint enforcement efforts can further enhance the effectiveness of federal-State actions to limit exposure and potential harm to consumers if an unsafe imported product makes it into domestic commerce.
Leads: HHS / FDA, USDA, CPSC, EPA Time Frame: Long Term

12.2 Review admissibility policies to improve the use of evidence and laboratory results from State investigations of imported products. Currently, there are limitations on the use of State-developed evidence in federal court cases due to the gathering, analysis and retention of such evidence by non-federal government entities. Being able to use this evidence would make it easier for federal departments and agencies to take enforcement actions against bad actors.
Leads: DOJ, HHS / FDA, USDA, CPSC Time Frame: Short Term

In combining these actions with the Homeland Security Presidential Directives to develop a National Incident Management System (NIMS) and to train federal, State and local government personnel in the Incident Management System (ICS), these cooperative agreements are intended to follow the constructs of all the above in supporting the infrastructure of the State programs to implement those activities and sustain them into the future.

Toward these ends, ORA is offering these PROTOTYPE cooperative agreements to State governments for them to develop new emergency response programs through the enhancement of the capabilities of their existing manufactured food regulatory programs. This will be accomplished by a through assessment of the current programs strengths and needs and planning for continuous improvement within the State program.

Copyright Material

Applicants and applicants' sub-grantees and sub-contractors must be aware that any projects developed in whole or in part with Federal funds may be made available to other State, territorial, local, and tribal regulatory agencies by FDA or its agents. Any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

Recipients of cooperative agreement awards must agree to the "Cooperative Agreement Terms and Conditions of Award in Section VI.2.A "Award Administration Information" and attached to the Notice of Grant Award.

Research/Project Plan Page Limitations
Not applicable

Appendix Materials

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the required page limitations may be delayed in the review process.

Resource Sharing Plan(s)

FDA considers the sharing of unique research resources developed through FDA sponsored research an important means to enhance the value of, and advance research. When resources have been developed with FDA funds and the associated research findings published or provided to FDA, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in the application. See http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

Applicants and applicants' sub-grantees and sub-contractors must be aware that any projects developed in whole or in part with Federal funds may be made available to other State, territorial, local, and tribal regulatory agencies by FDA or its agents.

Section V. Application Review Information

1. Criteria

The review criteria described below as well as response to the RFA guidelines and requirements will be considered in the review process.

2. Review and Selection Process

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application convened by the ORA and in accordance with FDA peer review procedures using the review criteria stated below.

Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.
As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by peer review
- Availability of funds

- Relevance of the proposed project to program priorities

In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a meritorious priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice are advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above review criteria, the following criteria will be applied to applications in the determination of scientific merit and the priority score.

Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Program criteria will include availability of funds and overall program balance in terms of geography and with respect to existing inventory of food firms within their State, including types of food products and the production, processing and distribution of produce. The ad hoc expert panel will review applications based on the ‘‘Content and Form of Application.’’. A score will be assigned based on the scientific/technical review criteria. The review panel may advise the program staff about the appropriateness of the proposal to the goals of this ORA/Office of Regional Operations (ORO)/DFSR cooperative agreement program.

2. A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the rating:

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2. B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2. C. Resource Sharing Plan(s)

Data Sharing Plan

When relevant, reviewers will be instructed to comment on the reasonableness of the following Resource Sharing Plans, or the rationale for not sharing the data developed through this cooperative agreement. However, reviewers will not factor the proposed resource sharing plan(s) into the determination of scientific merit or priority score, unless noted otherwise in the RFA. Program staff within the ORA will be responsible for monitoring the resource sharing.

3. Anticipated Announcement and Award Dates

Notification regarding the results of the review is anticipated by September 1, 2008. The expected start date for the FY 08 awards will be September 29, 2008.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will have access to his or her Summary Statement (written critique) via e-mail from the ORA Project Officer. The FDA Grants Management Office will notify applicants who have been selected for an award.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the Notice of Award will be generated via email notification from the awarding component to the grantee business official designated on the Application Face Page. If a grantee is not email enabled, a hard copy of the Notice of Award will be mailed to the business official.

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. See Also Section IV.5. Funding Restrictions.

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:

a. Interaction with FDA Districts, Regions, State Training Branch, and Office of Regional Operations Divisions.
b. Coordination, training, and exercises with FDA District Rapid Response Teams, Region and District Emergency coordinators, FDA Emergency Operations Center and CFSAN and CVM.
c. Working directly with FDA contractor, WIFFS, for training, team building and developing SOP's and other documentation for a State Rapid Response Team.
d. Working with other STATE entities in food protection such as Departments of Health or Agriculture, Emergency Operations center, environmental program, Epidemiologists, Local food protection agencies and others in development of the Rapid Response Team.

All cooperative agreement prototype projects that are developed at State agency level must have existing food safety inspection and surveillance programs under contract to FDA for food safety inspections.

2. Administrative and National Policy Requirements

Any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

All FDA grant and cooperative agreement awards include the DHHS Grants Policy Statement as part of the Notice of Award. See http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

2. A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and FDA grant administration policies.

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 the FDA as defined below.

2. A.1. Principal Investigator Rights and Responsibilities

The Principal Investigator (PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project for the following key project areas/ goals, with the FDA staff being substantially involved as a partner with the PI:

1. **All hazards Food Rapid Response Teams (RRT)**

The complex challenges in the food safety arena require new, creative responses. The scope and complexity of each outbreak/traceback varies significantly. In some cases, extensive in-plant inspection and environmental investigation including environmental and human or animal sampling from a single facility may be required. In another case, data/invoices from a web of inter-related firms throughout the State may be needed. Repeatedly, routine GMP inspection procedures have been ineffective in understanding how foodborne outbreaks occurred and why the inclusion of epidemiologically based environmental investigations is needed. In light of new, complex challenges in food safety, there is a continued need to develop a rapid response team trained and ready to respond within hours of the verification of a foodborne outbreak or other food protection emergencies.

To address these concerns, this Cooperative Agreement is the prototype for the development of uniquely qualified rapid response teams using ICS and other mechanisms to traceback and resolve food protection emergencies and incidents both within the State and collaborating with FDA, CDC or other State RRTs when the event is regional or national in scope.

Incorporated, through this cooperative agreement into the MFRPS Standard #5, Food-related Illness and Outbreaks and Food Defense Preparedness and Response, **is the requirement for** the development and implementation of an all food hazards Rapid Response Team (RRT). Standard 5 applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either natural, unintentional or deliberate that may result in illness, injury, or outbreaks. It also applies to the collection, analysis, and dissemination of information that may prevent their recurrence.

The RRT will be defined as an identifiable team within the State agency and State with the appropriate authority, expertise and training to investigate foodborne illness outbreaks and other food hazards/emergencies (e.g., natural disasters, bioterrorism, and

power outages) from “Farm to Table.” When appropriate or necessary, the RRT will use expandable ICS protocols and structures, collaborate and work with FDA, other agencies and other State RRTs, to stop an outbreak, mitigate the problem; and when possible and appropriate, to identify sources of contamination and contributing factors for the outbreak and reach conclusions and possible interventions for the prevention of future causes. It is expected that the RRT will remain viable and be incorporated into State programs beyond the term of this cooperative agreement.

Discussion and Background of Rapid Response Team Prototype to be considered are as follows:

Phases of Rapid response Investigations:

Prompt and effective investigation of foodborne outbreaks requires highly trained investigators in each of several highly specialized areas including epidemiology, microbiology, regulatory inspection and compliance, and environmental investigations. Foodborne outbreak investigations involve at least three distinct "phases."

1. Epidemiologic investigation. This phase is typically completed by local or State epidemiologists/ communicable disease staff after the outbreak cluster has been identified by clinical laboratory testing or consumer complaints. The goal of this phase of the investigation is to promptly determine the specific vehicle or vehicles responsible for foodborne illnesses. Epidemiologic investigations may require assembling and training a team of interviewers to develop questionnaires and complete food histories of ill and non ill individuals. The speed with which this part of the investigation is accomplished is critical to preventing additional exposures and for determining how the food became contaminated. Once a food vehicle is determined, the next phase, referred to as the environmental investigation, begins.

2. Environmental investigation. Investigators (generally environmental health and/or regulatory staff along with technical experts such as: epidemiologists, microbiologists, veterinarians, water supply experts) attempt to determine how the vehicle became contaminated and other contributing factors and to implement specific steps to prevent a reoccurrence of the contamination. Depending upon the epidemiologic information provided and the characteristics of the food and pathogen, investigators carefully examine each point of the food production processing, preparation, storage, transportation, and serving continuum to better understand how the food vehicle may have become contaminated. Additional subject matter expertise and technical support may be provided to the RRT, as needed. There is a significant lack of understanding of this phase of the investigation in regulatory and environmental health agencies. Many view this as an "inspection" of the facility. However, the environmental investigation must not be misunderstood as an "inspection." Although inspections may be necessary to document violations of regulations or laws, environmental investigations focus upon a step-by-step review of the food production practices from farm-to-table to determine opportunities for introduction, growth, and survival of the pathogen.

3. Communication. The overarching goal of all outbreak investigations is to stop the spread of the pathogen. However, communication throughout the entire Emergency Response process is vital. Communication is imperative to supervisors and staff

assigned to an outbreak investigation for arranging conference calls prior to the actual investigation (whenever necessary, including after business hours or weekends) to review the epidemiology, to plan and prioritize the investigation, and to assign specific roles and responsibilities. If ongoing transmission of the pathogen is suspected (recent onset dates), it is imperative that investigators take all reasonable steps to break the chain of transmission. Generally, this includes immediate determination of the distribution of the suspect product in order to 1) assist in targeted notification of local/State health jurisdictions for increased active surveillance of cases and 2) preparation of a targeted press release/health advisory to alert consumers, wholesalers, and/or retailers of the possibility of a contaminated product and provide recommendations for prompt avoidance/removal of the product to prevent additional exposures.

These new challenges in food safety present new opportunities for Rapid Response Team members. Additional duties/responsibilities of the Rapid Response Team members could include:

1. Complete detailed training in subjects including the completion of environmental investigations of foodborne outbreaks, traceback procedures, and environmental sampling.

2. Initiate and maintain contacts with major food manufacturers, processors, wholesalers, distributors and warehouses and retail chains, city or county environmental health officers, county public health officers, county agricultural commissioners and university researchers, FERN laboratories, and other information sources such as FoodShield. Obtain 24 hour emergency phone numbers for contact persons, become familiar with strengths and weaknesses of existing databases with regard to locations of grower, shipper, packer, wholesaler, and retailer, and for tracebacks.

3. Provide training to Food Team members and public health agency staff in the State in the event that additional assistance is needed:
   - Tracebacks
   - Epidemiology
   - Sampling methods
   - HACCP
   - "High Risk" commodities
   - Food technology, food microbiology, agricultural practices
   - Environmental investigations
   - Water supply safety

4. Each Rapid Response Team investigator should become an "expert" in at least one specific high-risk product area per year such as unpasteurized apple juice, alfalfa sprouts, pre-packaged lettuce, cantaloupe, or tofu. Investigators should become knowledgeable in all aspects of this commodity (farm production practices, location of commodities, specific microbial or toxicological hazards, etc.) by active participation and observation (photos/videos) of all phases. Investigators would then be responsible for training other team members in this commodity. Each Rapid Response Team should include at least one person representing the State’s feed regulatory program. The definition of “food” in the Federal Food, Drug, and Cosmetic

Act includes human food, animal feed and ingredients used in each of those classes of products. Many animal feeds contain food processing byproducts, many firms make ingredients for both types of products, and often, salvaged food products are used as animal feed. As a result, it is important that each Rapid Response Team be able to work with the State feed regulatory program to prevent food emergencies from becoming feed emergencies. Consideration of collaboration with animal health veterinarians and other food animal programs should be taken.

5. The Rapid Response Team would complete at least one annual exercise or on-site evaluation of at least one "high risk" food as identified under the MFRPS Standard #3 or commodity or specific type of manufacturer or processor such as LACF/Acidified Foods per year or participate in special study and assessment to provide additional insights into how food may become contaminated. The exercise/evaluation should be done in collaboration with the FDA district RRT and where appropriate, in accordance with guidance established in the DHS Homeland Security Exercise Evaluation Program (HSEEP). Results should be documented in the form of a final report, scientific paper and/or technical document to identify specific hazards and critical control points, strengths of the response team efforts and needed improvements. This could be in concert with the FDA contractor, Western Institute for Food Safety and Security (WIFSS).

6. The Rapid Response Team should enhance relationships and partnerships with academia and with other local, State and federal agencies involved in food protection.

7. The Rapid Response Team would receive advanced training in areas including microbiological sampling, epidemiology, emerging pathogens, tracebacks, HACCP, water systems, sanitizers and disinfectants, modified air packaging, and interviewing techniques. In turn, team members could provide training for other local, State or federal investigators and industry groups. However, it is important to note that the team should not be viewed as the group that would complete all aspects of each emergency investigation. For example, withdrawals, recalls and verifications would be completed by other State and/or federal staff.

For laboratory support, the RRT will develop the proper protocols and agreements with both the FDA and/or other federal or State labs for analytical support. The labs would support existing technology for field-based analytical methods like temperature, adenosine triphosphate (ATP) measurements (luminometers), residual chlorine, quaternary ammonium indicators, microscopy, pH, water activity, ORP, and salt content that could be used on-site. Additionally, as approved, real-time technologies could be pilot tested during actual outbreak investigations.

All lab participants on the response team should be fully trained in team inspections.

Microbiologists will provide current information on emerging pathogen analytical methodology and servicing lab capability. The microbiologists will also keep current information on the best shipping methods to the servicing lab.

Purchase of laboratory and investigation sampling equipment and supplies should be considered in the budget for the application. Sampling kits should be prepared ahead of time and possibly kept at members homes so they can immediately depart for the site.

Uniformity in sample collection will be essential for consistent results with multiple serving laboratories. The Rapid Response Team investigators could use the FDA Investigations Operation Manual (IOM) and compliance program guides or equivalent State procedures to standardize sample size and collection methods. Coordination between the RRT and Laboratory is essential to maximize the outcome of food borne illness response.

2. Manufactured Food Regulatory Program Standards (MFRPS):

The program standards can be accessed at:
http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gdl0002-vol1.pdf

The Manufactured Food Regulatory Program Standards (MFRPS or program standards) establish a uniform foundation for the design and management of State programs[1] responsible for the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation.

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets and certain standards have supplemental worksheets and forms for determining a level of conformance with such standards.

FDA will use the program standards as a tool in this cooperative agreement to assess and improve the program infrastructure within the States in support of this cooperative agreement. States that are awarded the cooperative agreements will be expected to implement the program standards to evaluate and improve their manufactured food program. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that they are moving toward full implementation in support of the food protection program and the ability to sustain a rapid response team.

The goal of fulfilling the program standards is to implement a risk-based food safety program by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities at reducing and responding to foodborne illness hazards

farm to table. Consequently, food protection (food safety and food defense) of the United States food supply will improve.

3. Performing manufactured food inspections and increasing the ability to share, on an annual or risk-based frequency, data from the State programs inspections of those facilities.

The MFRPS and both State and federal goals are to share the inspectional, enforcement and recall data between the agencies to provide for greater food protection. This data can be used to formulate better risk based prevention models that can be used by both federal and State agencies, target federal and State enforcement activities, facilitate recall information and provide for enhanced coverage of the food industry.

While FDA purchases food inspections from the States under contract, it is estimated that another 40,000 State inspections are not counted or used nationally as stated above. Currently State contractors are receiving and entering data into electronic State Access to FACTS (eSAF). Current entries are limited to contract inspections. Under this application, the State will develop or enhance the capacity to inspect all the appropriate facilities in the State on either an annual or specific risk-based priority schedule (including both contract and non-contract inspections) and enter them into eSAF by the third year of the cooperative agreement. The FDA and State will collaborate in an upgraded version of eSAF to either directly convert State data into eSAF or work with the State to use eSAF as the primary inspection data collection module. The State will also recommend/request further enhancements to eSAF to support the exchange of data. The State will also provide to FDA either through eSAF or in a jointly developed format the recall and enforcement actions completed or taken under State law/regulations. The FDA will make eSAF data available to the State for all FDA investigations/inspections both for their state and nationally to assist both the food program and RRT. FDA will work to provide food facility registration data to the States to correlate with their facility registration systems for both intraState and interState facilities to improve the data systems for both agencies.

4. Recalls and Market Withdrawals of Food Products/Foodborne Illness Reporting

Under the RRT prototype and the MFRPS improvement plan, the State would consider incorporating the effective use of its resources to remove suspect or contaminated products from commerce and consumers to maximize food protection. This could include training of State and local resources, working with industry groups, major distributors and others, and considering the use of the RRT to facilitate the effective removal of product from the State. The State would work with FDA to facilitate better and more rapid communications for national, local or regional recalls that could be the model for use with other States.

Under MFRPS Standard #5 and the RRT, the State program would work to improve the reporting and collection of foodborne illness complaints, reports and investigations throughout the State from city, county, and district or other food protection, epidemiology, public health, agriculture or regulatory entities. As Stated above (#1), this information would allow the RRT in conjunction with the local entity to rapidly and proactively locate, investigate and mitigate foodborne illness reports.

The applicant could propose using a State Food Protection task force (MFRPS Standard #7) as a mechanism to facilitate new interventions, methods, communication strategies and other tools to expedite recalls and foodborne illness reporting. See RFA FD 08-007 Located at www.Grants.gov and http://www.fda.gov/ora/fed_state/food_safety/default.htm

Other resources could include CDC and the CIFOR project (Council to Improve Foodborne Outbreak Response) or other CDC Food Safety office or Environmental Health services and could include program policies and procedures consistent with those recommended by CIFOR.

Examples can be located at.
http://www.cdc.gov/nceh/ehs/EHSNet/default.htm
http://www.cdc.gov/foodborneoutbreaks/
http://www.cifor.us/

5. Milestones/Benchmarks

For all of the awarded projects FDA has a strong desire to promote a long term working relationship, in order to provide to each project ample time to fully develop and implement its goals and objectives. FDA anticipates these cooperative agreements to be three-year projects, with milestones/benchmarks for each year that must be addressed in the application. Each year's milestones/benchmark for each project should provide a timeline to fully develop, build and achieve sustained capacity for food safety and response program objectives. It is in the best interests of the FDA to maintain all of these cooperative agreements for the full 3 year funding cycle.

This limited competition will allow for FDA to provide funding to current State manufactured food regulatory programs in order to meet FDA's goal of enhancing current food protection programs in the nation in accordance with the FDA's Food Protection Plan (FPP), Food and Drug Administration Amendments Act of 2007 (FDAAA), and Import Strategic Action Plan (ISAP). The funding will provide awardees the opportunity to maintain or develop and initiate rapid response teams and other program enhancements in their manufactured food protection programs to positively impact the public health.

Yearly Milestones/Benchmarks:

In completing the application, the following yearly benchmarks/ expected accomplishments should be taken into account:

Year 1:

1. Completion of the program self assessment using the MFRPS.
2. Development of a program improvement plan (strategic plan) based on the outcome of the self assessment.
3. Initiate and complete first phases of RRT development, training and collaboration with FDA District RRT and emergency response and FDA contractor.
4. Development of a training plan as needed for staff for RRT using the guidance in MFRPS Standard #2.

Year 2:

1. Quarterly meetings of the RRT in conjunction with FDA RRT, which should include at least one joint exercise.
2. Update of the improvement plan as State benchmarks are achieved/completed.
3. Development and implementation of annual or risk based inspections and audits of staff through States quality assurance program (STD #4).
4. Recall and foodborne illness/outbreak complaint and incident reporting improvement.

Year 3:

1. Quarterly meetings of the RRT in conjunction with FDA RRT, which should include at least one joint exercise. Teams are fully implemented.
2. Update of the MFRPS Improvement Plan.
3. Sharing of contract and non-contract inspection data, recall and complaint data with FDA.
4. Demonstration of improved foodborne illness/outbreak complaint and incident data through the State food protection and epidemiology programs.

2. A.2. FDA Responsibilities

An FDA Project Officer(s) will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below.

The program project officer will monitor the grantee 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 grantee organization may also occur

3. Reporting

Progress Reports:

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 424/5161) annually and financial statements as required in the DHHS Grants Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

For continuing cooperative agreements, an annual program progress report is also required. For such cooperative agreements, the noncompeting continuation application (PHS 5161–1) will be considered the annual program progress report. Mid-year progress reports as well as a final program progress report are required. The program office will provide a specific format template to assist in reporting progress.

Mid-year progress reports must contain, but are not limited to the following:

1. Status report on the installation and operational readiness of any analytical equipment that is purchased.

2. Status report on the hiring and training of State/territorial/tribal laboratory personnel.
3. Summary report on the facility inventory that is maintained in the State government.
4. . Report on Rapid Response Team development and status including appropriate personnel training, exercises etc.
5.. Summary of improvements (identify and quantify) in the overall State food program resulting from the cooperative agreement.
6. The grantee must file a final program progress report, FSR, invention Statement, and disposition of equipment Statement within 90 days after the end date of the project period as noted on the notice of the cooperative agreement award.

Final Status Reports and Invention Statements:

The original and two copies of the annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant.

A final program progress report and financial status report will be due 90 days after expiration of the project period of the cooperative agreement as noted on the notice of grant award.

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

Monitoring Activities

The program project officer will monitor grantees 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. The grantees will also be working with the FDA contractor (Western Institute for Food Safety and Security) and the FDA district offices in development, training and exercises for the developing Rapid Response Team. Periodic site visits with officials of the grantee organization may also occur and may include an audit of the assessment and improvement plan under the MFRPS. The results of these monitoring activities will be recorded in the official cooperative agreement file and will be available to the grantee upon request consistent with applicable disclosure statutes and FDA disclosure regulations.

Terms and Conditions:

This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including Provisions of 42 CFR Part 52 and 45 CFR Parts 74 and 92, and all grants are subject to the terms and conditions, cost principles (A87), and other considerations described in the HHS Grants Policy Statement (GPS), revised January, 2007, which supersedes in its entirety the above sited PHS GPS, dated April 1, 1994, and addendum dated January 24, 1995.

This award is subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable based on the recipient type and the purpose of this award. This includes any requirements in Parts I and II (available at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm) of the HHS GPS that apply to an award.

Although consistent with the HHS GPS, any applicable statutory or regulatory requirements, including 45 CFR parts 74 or 92, directly apply to this award apart from any coverage in the HHS GPS.

The grantee organization must comply with all special terms and conditions of the cooperative agreement, including those that 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) if necessary, there is an indication that corrective action has taken place; and (4) assurance that any replacement of personnel will meet the testing and inspection requirements.

Delineation of Substantive Involvement:

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

A. FDA will have prior approval of the appointment of all key administrative and scientific personnel proposed by the grantee.

B. FDA will be directly involved in the guidance and development of the program.

C. FDA scientists will participate, with the grantee, in determining and carrying out scientific and technical activities. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, co-authorship of publications.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Staff Contact Name: Jennifer Gabb, Project Officer
Division of Federal-State Relations (HFC-150),
Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane, Rm. 12-07

Rockville, MD 20857
Telephone: (301) 827-2899
Email:jennifer.gabb@fda.hhs.gov or access the Internet at
http://www.fda.gov/ora/fedState/default.htm

3. Financial or Grants Management Contacts:

Staff Contact Name: Gladys M. Bohler, Grants Management Specialist
Division of Acquisition Support and Grants
Food and Drug Administration
5630 Fishers Lane, Rm. 2105
Rockville, MD 20857
Telephone: (301) 827-7168
Email: gladys.melendez-bohler@fda.hhs.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent

statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the Bioterrorism Act, Subtitle A of Title III-Protection of Food Supply, Section 311 – Grants to States for Inspections, amends the FD&C Act by adding section 909 to authorize the Secretary of Health and Human Services to award grants to States, territories, and Indian tribes that undertake examinations, inspections, and investigations, and related activities under Section 702 of the FD&C Act. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.