

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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SR Reese

Food Safety and Security Monitoring Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR), is announcing the availability of cooperative agreements for equipment, supplies, personnel, training, and facility upgrades to Food Emergency Response Laboratory Network (FERN) chemistry laboratories of State, local, and tribal governments. The cooperative agreements are to enable the analyses of foods and food products in the event that redundancy and/or additional laboratory surge capacity is needed by FERN for analyses related to chemical terrorism. These grants are also intended to expand participation in networks to enhance Federal, State, local, and tribal food safety and security efforts.

DATES: Receipt Date: Applications are due within 30 days after the publication of the funding opportunity in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

For issues regarding the administrative and financial management aspects of this notice: Marc Pitts, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7162, e-mail: Marc.Pitts@fda.hhs.gov;

Regarding the programmatic aspects of this notice: Jennifer Gabb, Division

of Federal-State Relations, Food and Drug Administration (HFC-150), 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, 301-827-2899, e-mail: *jennifer.gabb@fda.hhs.gov*; and

For technical aspects of this notice: Dean Turco, Division of Field Science, Food and Drug Administration (HFC-140), 5600 Fishers Lane, rm. 12-41, Rockville, MD 20857, 301-827-4097, e-mail: *dean.turco@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Announcement Type: New Competing Cooperative Agreement (U18) under a Limited Competition

Request for Applications (RFA) Number: RFA-FD-08-009

Catalog of Federal Catalog of Federal Domestic Assistance Number: 93.448

ORA is the primary inspection and analysis component of FDA and has approximately 1,600 investigators, inspectors, and analysts who cover the country's approximately 95,000 FDA-regulated businesses. These investigators inspect more than 15,000 facilities per year and ORA laboratories analyze several thousand samples per year. ORA conducts special investigations, conducts food inspection recall audits, performs consumer complaint inspections, and collects samples of regulated products. Increasingly, ORA has been called upon to expand the testing program addressing the increasing threat to food safety and security through intentional chemical terrorism events. Toward these ends, ORA has developed a suite of chemical screening and analysis methodologies that are used to evaluate foods and food products in such situations. However, in the event of a large-scale emergent incident, analytical sample capacity in ORA field laboratories has a finite limit. Information from ongoing relationships with State partners indicates limited

redundancy in State food testing laboratories, both in terms of analytical capabilities and analytical sample capacity. Several State food testing laboratories lack the specialized equipment to perform the analyses and/or the specific methodological expertise in the types of analyses performed for screening foods and food products involving chemical terrorism events.

The events of September 11, 2001, reinforced the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188), which President George W. 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, and

Title V—Additional Provisions.

Subtitle A of the Bioterrorism Act, Protection of Food Supply, section 312—Surveillance and Information Grants and Authorities, amends part B of Title III of the Public Health Service Act to authorize the Secretary of Health and Human Services (the Secretary) to award grants to States and tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

Project Emphasis

The goal of ORA's cooperative agreement program is to complement, develop, and improve State, local, and tribal food safety and security testing programs. This will be accomplished through the provision of equipment, supplies, personnel, facility upgrades, training in current food testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, analysis of surveillance samples, and in cooperation with FDA, participation in method enhancement activities designed to extend analytical capabilities. In the event of a large-scale chemical terrorism event affecting foods or food products, the recipient may be required to perform selected chemical analyses of domestic and imported food samples collected and supplied to the laboratory by FDA or other government agencies through FDA. These samples may consist of, but are not limited to, the following: Vegetables and fruits (fresh and packaged), juices (concentrate and diluted), grains and grain products, seafood and other fish products, milk and other dairy products, infant formula, baby foods, bottled water, condiments, and alcoholic products (beer, wine, scotch).

II. Award Information

Mechanism of Support

All grant application projects that are developed at State, local, and tribal levels must have national implication or application that can enhance Federal food safety and security programs. At the discretion of FDA, successful project formats will be made available to interested Federal, State, local, and tribal government FERN laboratories.

There are four key project areas identified for this effort that must be addressed:

1. The use of gas chromatography/mass spectrometry analysis for the screening and identification of poisons, toxic substances, and unknown compounds in foods;
2. The use of liquid chromatography/mass spectrometry analysis for the screening and identification of poisons, toxic substances, and unknown compounds in foods;
3. The use of inductively coupled plasma/mass spectrometry analysis for the screening and identification of heavy metals and toxic elements in foods; and
4. The use of enzyme-linked immunosorbent assay and other antibody-based analyses for the screening and identification of unknown toxins in foods.

FDA will support the projects covered by this document under the authority of section 312 of the Bioterrorism Act. This program is described in the Catalog of Federal Domestic Assistance under number 93.448.

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: (1) How often samples will be sent, (2) directions on how tests should be executed, (3) onsite monitoring, (4) supply of equipment, (5) FDA training on processes, and (6) enhancement and extension of analytical methodology.

FDA will provide specific procedures and protocols for the four project areas to be used for the analysis of toxic chemicals and toxins in food.

FDA will provide guidance on the specific foods to be collected for analysis by the successful applicant. FDA will purchase and have all needed

major equipment for the four project areas delivered to the awardee's laboratory. The equipment purchased will remain the property of FDA until such time as it is released as surplus property.

Only proposed projects designed to address all four project areas will be considered for funding. Applicants may also apply for only facility upgrades, personnel, training, method extension, and surveillance sample analysis if they have the necessary equipment and it will be available for these projects. These grants are not to fund or conduct food inspections for food safety regulatory agencies.

It should be emphasized that in all of the projects, there is a particular desire to promote a continuing, reliable capability and capacity for laboratory sample analyses of foods and food products for the rapid detection and identification of toxic chemicals or toxins. With this in mind, it is desirable that sample analyses will be completed no later than 2 weeks after receipt, and the results will be reported to FERN. The format and reporting media will be established by FERN. Shorter timeframes may be sought for special testing such as proficiency tests or special assignments.

III. Eligibility Information

A. Eligible Applicants

This cooperative agreement program is only available to State, local, and tribal government FERN laboratories that currently are not funded under this cooperative agreement and is authorized by section 312 of the Bioterrorism Act. All grant application projects that are developed at State, local, and tribal levels must have national implication or application that can enhance Federal food safety and security programs. At the discretion of FDA, successful project

formats will be made available to interested Federal, State, local, and tribal government FERN laboratories.

B. Cost Sharing or Matching

Cost sharing is not required.

IV. Application and Submission

A. Application Information

In order to apply electronically, the applicant must complete the following steps:

Step 1: Obtain a Dun & Bradstreet Number (DUNS Number)

Same day. Your organization will need to obtain a DUNS Number. If your organization doesn't already have one, go to the Dun & Bradstreet Web site at <http://fedgov.dnb.com/webform>.

Step 2: Register with the Central Contractor Registry (CCR)

Two days or up to 1 to 2 weeks. Ensure that your organization is registered with the CCR at <http://www.ccr.gov>. If your organization is not already registered, an authorizing official of your organization must register. You will not be able to move on to Step 3 until this step is completed.

Step 3: Obtain Username and Password

Same day. Create a username and password with Operational Research Consultants (ORC), the Grants.gov credential service provider. Use your organization's DUNS Number to access the ORC Website at <http://apply07.grants.gov/apply/OrcRegister>.

Step 4: Grants.gov Registration

Same day. Register with Grants.gov at <https://apply07.grants.gov/apply/GrantsgovRegister> to open an account using the username and password you received from ORC.

Step 5: Authorized Organization Representative (AOR) Authorization

Time depends on responsiveness of your E-Business Point of Contact (E-Biz POC). The E-Biz POC at your organization must respond to the registration e-mail from Grants.gov and login at Grants.gov to authorize you as an AOR. Please note that there can be more than one AOR for your organization. In some cases the E-Biz POC is also the AOR for an organization.

Step 6: Track AOR Status

At any time, you can track your AOR status at the Applicant home page of Grants.gov in “Quick Links” by logging in with your username and password (<https://apply07.grants.gov/apply/ApplicantLoginGetID>).

FDA is accepting new applications for this program electronically via Grants.gov. Applicants must apply electronically by visiting the Web site <http://www.grants.gov> and following instructions under “APPLY FOR GRANTS.” The required application SF424, which is part of the PHS 5161–1 form, can be completed and submitted online by selecting Step 1: “Download a Grant Application Package,” then by entering the funding opportunity number “RFA–FD–08–009.” The “Selected Grant Applications For Download” page will provide you with the Additional Resources downloads for Adobe Reader and PureEdge Viewer as well as the download to the “Instructions & Application” hyperlink.

B. Content and Form of Application

1. Content of Application

The SF424 PHS–5161 has several components. Some components are required, others are optional. The forms package associated with this request for application (<http://www.Grants.gov/Apply>) includes all applicable components. If you experience technical difficulties with your online submission you should contact either Marc Pitts (see **FOR FURTHER INFORMATION CONTACT**) or the Grants.gov Customer Support Center by e-mail at support@grants.gov or by phone at 1–800–518–4726.

2. Format for Application

All applications must be submitted electronically through Grants.gov. Paper applications will not be accepted. The application must be an SF424–PHS–5161. The narrative portion, excluding appendices, of the application may not exceed 100 pages in length and must be single-spaced in 12-point font. The appendices should also not exceed 100 pages in length (separate from the narrative portion of the application).

Information collection requirements requested on Form (SF–424) PHS 5161–1, expiration date of January 31, 2009, have been sent by the Public Health Service (PHS) to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number OS–4040–0004.

C. Submission Dates and Times

The application receipt date is 30 days after the publication of the funding opportunity in the **Federal Register**. Applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday, until the receipt date. Applications

submitted electronically must be received by close of business on the receipt date. No addendum material will be accepted after the receipt date.

D. Intergovernmental Review


The regulations issued under Executive Order 12372, Intergovernmental Review of Department of Health and Human Services Programs and Activities (45 CFR part 100), apply to the Food Safety and Security Monitoring Project. 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. A current listing of SPOCs is included in the application kit or at <http://www.whitehouse.gov/omb/grants/spoc.html>. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The SPOC should send any State review process recommendations to the FDA administrative contact (see **FOR FURTHER INFORMATION CONTACT**). The due date for the State process recommendations is no later than 60 days after the application receipt date. FDA does not guarantee accommodation or explanation of SPOC comments that are received after the 60-day cutoff.

E. Funding Restrictions

These grants are not to fund or conduct food inspections for food safety regulatory agencies. They may not be utilized for new building construction, however, remodeling of existing facilities is allowed, provided that remodeling costs do not exceed 25 percent of the grant award amount.

Dated: JUL 7 2008

July 7, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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