DDM Immediate Display
Display Date 5-20-05 @ 2:41p
Publication Date 5-25-05
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Security Monitoring Project; Availability of Cooperative Agreements; Request for Applications: RFA–FDA–ORA–05–1; Catalog of Federal Domestic Assistance Number: 93.448

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

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) 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.

The goal of ORA's cooperative agreement program is to complement, develop, and improve State, local, and Indian tribal food safety and security testing programs. With cooperative agreement grant funds this will be accomplished through the provision of supplies, personnel, facility upgrades, training in current food testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, and

oc0569

N ADI

analysis of surveillance samples. 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 Federal 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).

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:

(1) The use of Gas Chromatography/Mass Spectrometry (GC/MS) analysis for the screening and identification of poisons, toxic substances, and unknown compounds in foods;

(2) The use of Liquid Chromatography/Mass Spectrometry (LC/MS) analysis for the screening and identification of poisons, toxic substances, and unknown compounds in foods;

(3) The use of Inductively Coupled Plasma/Mass Spectrometry (ICP/MS) analysis for the screening and identification of heavy metals and toxic elements in foods; and,

(4) The use of Enzyme-Linked Immunosorbent Assay (ELISA) and other antibody-based analyses for the screening and identification of unknown toxins in foods.

FDA will support the projects covered by this notice under the authority of section 312 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188). This program is described in the Catalog of Federal Domestic Assistance under number 93.448.

1. Background

ORA is the primary inspection and analysis component of FDA and has some 1,600 investigators, inspectors, and analysts who cover the country's approximately 95,000 FDA regulated businesses. These investigators inspect more that 15,000 facilities a 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 United States food supply. Congress responded by passing the Bioterrorism Act, 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 Indian 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.

2. Program Research Goals

The goal of ORA's cooperative agreement program is to complement, develop, and improve State, local, and Indian 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, and participation in proficiency testing to establish additional reliable laboratory sample analysis capacity and analysis of surveillance samples. 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 Federal 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

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) on-site monitoring, (4) supply of equipment, and (5) FDA training on processes.

FDA will provide specific procedures and protocols for the four project areas (see section I of this document) to be used for the analysis of toxic chemicals and toxins in food.

FDA will provide guidance on the specific foods to be collected and analyzed by the successful applicant. State personnel will be responsible for the collection and analysis of surveillance samples.

FDA will purchase and have all equipment delivered to the awardee's laboratory. The equipment purchased will remain the property of FDA until such time as released as surplus property.

Proposed projects designed to fulfill the specific objectives of any one or more of the project areas will be considered for funding. Applicants may also apply for only facility upgrades, personnel, training, and surveillance sample collection 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 within 2 weeks of receipt, and the results will be reported to FERN. The format and reporting media will be established by FERN.

1. Award Amount

The total amount of funding available in Fiscal Year (FY) 2005 is $2,100,000. Cooperative agreements will be awarded up to $350,000 in total (direct plus indirect) costs per year for up to 3 years. It is anticipated that six awards will be made. Support of these cooperative agreements will be for the funding of supplies, facility upgrades, surveillance sample collection, personnel, the provision of training in current analytical methodology, and for the analysis of foods and food products.

2. Length of Support

The length of support will depend on the nature of the project. For those projects with an expected duration of more than 1 year, a second or third year of noncompetitive continuation of support will depend on performance during the preceding year and availability of Federal funds.

3. Funding Plan

It is anticipated that FDA will make six awards in FY 2005 for this program. 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.

Funds may be requested in the budget to travel to FDA for meetings with program staff about the progress of the project.

III. Eligibility Information

1. Eligible Applicants

This cooperative agreement program is only available to State, local, and tribal government FERN laboratories 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.

2. Cost Sharing or Matching

Cost sharing is not required.

3. Other

A. Dun and Bradstreet Number (DUNS)

As of October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number that uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1–866–705–5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun & Bradstreet, Inc.

IV. Application and Submission

1. Addresses to Request Application

The application request and the completed application should be submitted to Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.gov* or *cpolit@oc.fda.gov*. If the application is hand-carried or commercially delivered it should be addressed to 5630 Fishers Lane, rm. 2105, Rockville, MD 20857.

The original and two copies of the completed grant application form PHS 5161–1, with copies of the appendices for each of the copies, should be submitted to Cynthia Polit (see previous paragraph). The outside of the mailing package should be labeled "Response to RFA–FDA–ORA–05–1."

FDA is also accepting 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 the instructions under "APPLY." 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.A of this document.

If the submission is electronic, the application package is posted under the "APPLY" section of this announcement under *http://www.grants.gov*. The required application PHS 424, which is part of the PHS 5161–1 form, can be completed and submitted online.

2. Content and Form of Application

A. Content of Application

The applicant must specifically address the following in the cooperative agreement application:

Laboratory Facilities. A complete description of the name and address of the facility, and the name of the most responsible individual of the facility where the equipment will be installed must be provided.

For the facility, the following information must be provided:

(1) Floor diagrams of the laboratory;

(2) Area where the equipment is to be installed. The installation of equipment in a laboratory will require adequate and appropriate space and physical plant supplies (power, water, etc.);

(3) A description of the envisaged space, to include a floor-plan diagram;

(4) Operational support areas to be used for the project, including details about the availability of ancillary laboratory safety and support equipment and facilities, such as the numbers and types of chemical fume hoods available;

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

(6) A detailed description of the proposed facilities upgrade including drawings and cost estimates; and

(7) A detailed description of laboratory access procedures, including a description of practices and systems which limit access to laboratory space by unauthorized personnel. Additional procedures for access to the space(s) dedicated to the equipment provided, if any, should also be provided.

Laboratory Personnel Qualifications. Qualifications of all personnel that will be assigned to the project must be provided. In particular, information on personnel that have experience in GC/MS, LC/MS, ICP/MS, and ELISA must be provided.

Laboratory Management Practices. For the laboratory, the following management information must be provided:

(1) A summary description of any security procedures or processes to evaluate the background of laboratory personnel. This should include any procedures to evaluate subcontractors who have access to laboratory space, such as cleaning personnel;

(2) 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;

(3) A summary description of staffing management, specifically to include abilities and procedures in place to recall personnel, establish extended workweeks, etc.; and

(4) A summary description of procedures in place to monitor sample workflow, including the tracking and monitoring of sample analyses in progress to include a description of the laboratory work product review process. Additionally, the ability to perform and complete the analyses and provide a report of a sample analysis within a 2-week time frame must be described.

Sample Analysis Commitment. The laboratory will be required to analyze surveillance and emergency response food samples. Therefore, an estimate of the number of food samples that will be analyzed for toxic chemicals and toxins by each project area (i.e., GC/MS, LC/MS, ICP/MS, ELISA), must be submitted. This estimate should be for a 3-year period. The estimate should also address the number of samples that can be analyzed in a 2-week period. The procedures to be used will be supplied by FDA. This information will be provided after the award is given so recipients will be aware of requirements/responsibilities.

In addition, if a cooperative agreement is awarded, awardees will be informed of any additional documentation that should be submitted to FERN.

B. Format for Application

Submission of the application must be on grant application form PHS 5161–1 (revised 7/00). All "General Information Instructions" and specific instructions in the application kit must be followed. The face page of the application should reflect the request for application number RFA–FDA–ORA–05–1 under "Federal Identifier."

Data and information included in the application will generally not be available publicly prior to the funding of the application. After funding has been awarded, 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 (21 CFR 20.61, 20.105, and 20.106)). By accepting funding, the applicant agrees to allow ORA to publish specific information about the grant.

The requirements requested on form PHS 5161–1 (revised 7/00) have been sent by PHS to the Office of Management and Budget (OMB) and have been approved and assigned OMB control number 0248–0043.

3. Submission Dates and Times

The application receipt date is [*insert date 30 days after date of publication in the* **Federal Register**].

Applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday, until the established receipt date. Applications will be considered received on time if hand delivered to the address noted previously (see *Addresses to Request Application* in section IV of this document) before the established receipt date, or sent or mailed by the receipt date as shown by a legible U.S. Postal Service dated postmark or a legible dated receipt from a commercial carrier. Private metered postmarks shall not be acceptable as proof of timely mailing. If not received on time applications will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office). Please do not send applications to the National Institutes of Health (NIH). Any application sent to NIH that is forwarded to FDA's Grants Management Office and not received in time for orderly processing will be judged nonresponsive and returned to the applicant. Applications must be submitted via U.S. mail or commercial carrier or hand delivered as stated previously in this document.

Applications submitted electronically must be received by close of business on the published receipt date.

No addendum material will be accepted after the receipt date.

4. 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 *Addresses to Request Application* in section IV 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

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.

6. Other Submission Requirements

A. CCR

In anticipation of the Grants.gov electronic application process applicants are encouraged to register with the CCR database. This database is a governmentwide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR will eventually become a requirement and is consistent with the governmentwide management reform to create a citizen-centered web presence and build e-gov infrastructures in and across agencies to establish a "single face to industry." The preferred method for completing a registration is via the Internet at *http://www.ccr.gov.* (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**.) This web site provides a CCR handbook with detailed information on data needed prior to beginning the online registration, as well as steps to walk applicants through the registration process. The applicant must have a DUNS number to begin registration. Call Dun & Bradstreet, Inc., at the number listed in the previous paragraph of this document if you do not have a DUNS number.

In order to access Grants.gov an applicant will be required to register with the Credential Provider. Information about this requirement is available at *http://www.grants.gov/CredentialProvider.* (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**.)

V. Application Review Information

1. Criteria

A. Scientific/Technical Review Criteria

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.

The ad hoc expert panel will review the application based on the following scientific and technical merit criteria which will carry equal weight:

- The adequacy of facilities, expertise of project staff, equipment, support services, commitment to analyze surveillance samples, commitment to analyze emergency response samples, and quality management practices needed for the project;
- Expertise in the use of GC/MS for the analysis of foods or animal tissues;
- Expertise in the use of LC/MS for the analysis of foods or animal tissues;
- Expertise in the use of ICP/MS for the analysis of foods or animal tissues;
- Expertise in use of ELISA and other antibody-based analyses for the identification of toxins in foods or animal tissues;
- Current food or animal tissue analysis programs;
- The rationale and design to meet the goals of the cooperative agreement;
- Quality control and quality assurance procedures and practices; and
- Abilities and procedures in place to recall personnel and establish extended workweeks.

2. Review and Selection Process

A. General Information

FDA grants management and program staff will review 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 institution's/organization's authorized official. If submitted electronically the original signature requirement does not apply.

If an application is found to be nonresponsive it will be returned to the applicant without further consideration. Applicants are strongly encouraged to contact FDA to resolve any questions about criteria before submitting an application. Please direct all questions of a technical or scientific nature to ORA program staff and all questions of an administrative or financial nature to the grants management staff (see section VII of this document).

B. Program Review Criteria

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.

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 with respect to existing and projected laboratory sample analysis and testing capacity. Final funding decisions will be made by the Commissioner of Food and Drugs (the Commissioner) or his designee.

A responsive application 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. Funding decisions will be made by the Commissioner or his designee.

A score will be assigned to each responsive application 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 the ORA/ORO/ DFSR cooperative agreement.

3. Anticipated Announcement and Award

Notification regarding the results of the review in the form of a summary statement is anticipated by September 1, 2005. It is anticipated that all awards will be made by September 29, 2005.

VI. Award Administration Information

1. Award Notices

FDA's Grants Management Office will notify applicants who have been selected for an award. Awards will either be issued on a Notice of Grant Award (PHS 5152) signed by the FDA Chief Grants Management Officer and be sent to the applicant by mail or transmitted electronically.

2. Administrative and National Policy Requirements

These agreements will be subject to all policies and requirements that govern the research grant programs of PHS, including provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and the PHS Grants Policy Statement.

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.

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the "Healthy People 2010" objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD-ROM format, S/N 017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at *http://www.healthypeople.gov* under "Publications." (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**.)

3. Reporting

A. Reporting Requirements

The original and two copies of an 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. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant. A final FSR will be due 90 days after the expiration of the project period as noted on the Notice of Grant Award.

For continuing cooperative agreements, quarterly reports and an annual program progress report are also required. For such cooperative agreements,

the noncompeting continuation application (PHS 5161–1) will be considered the program progress report for the fourth quarter of the budget period.

Quarterly progress reports must contain, but are not limited to the following:

1. A status report on the installation, training, and operational readiness of any equipment that is provided;

2. A summary report on any proficiency testing performed;

3. A summary status of samples analyzed and time to complete individual sample testing; and

4. A summary description of any other testing performed on the equipment.

A final program progress report, FSR, and invention statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

The final program progress report must provide full written documentation of the project, and summaries of laboratory operations, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other State, local, and tribal government FERN laboratories could reproduce the final project.

B. 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 office/grants management office and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon

request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the study will depend on recommendations from the project officer. The scope of the recommendation will confirm that: (1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; (3) if necessary, there is an indication that corrective action has taken place; and (4) assurance that any replacement of personnel will meet the testing requirements.

VII. Agency Contacts

Regarding the administrative and financial management aspects of this notice: Cynthia Polit (see *Addresses to Request Application* in section IV of this document).

Regarding the programmatic or technical aspects of this notice: Thomas Savage, Division of Field Science, Office of Regulatory Affairs, Food and Drug Administration (HFC–140), 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857, 301–827–1026, e-mail: *tsavage@ora.fda.gov.*

VIII. Other Information

Data included in the application, if restricted with the legend specified in this section of the document, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act and FDA's implementing regulations (21 CFR 20.61).

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552), as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page

number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: 5-19-05

May 19, 2005.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Dawn P. Hawkins