C. Other Information

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements, as required in the HHS GPS.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0357]

Food Protection Rapid Response Team and Program Infrastructure Improvement Prototype Project (U18); Availability of an Agreement of Limited Competition; Request for Applications: RFA Number: RFA FD08–007

I. Research Objectives

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) in collaboration with the 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 Incident Command System (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 (RRT), and other FDA program offices.

These cooperative agreements are intended to develop, implement and exercise an all hazards food and foodborne illness 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 MFRPS, and in addition, develop, train and implement a foodborne illness rapid response team that incorporates 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:

1. Use epidemiological information supplied by local, State, or Federal agencies to detect incidents or outbreaks of foodborne illness or injury;
2. Investigate reports of illness, injury, and suspected outbreaks;
3. Correlate and analyze data;
4. Disseminate public information effectively;
5. Distribute outbreak reports and surveillance summaries to relevant agencies;
6. Disseminate current guidance to industry on food defense;
7. Provide guidance for immediate notification of law enforcement agencies when intentional food contamination or terrorism is suspected or threatened;
8. 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.

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. 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 RRT 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 under this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

II. Authority and Regulations

This request for applications (RFA) is subject to intergovernmental review E.O. 12372. See *http://www.whitehouse.gov/omb/grants/spoc.html*. This program is described in the Catalog of Federal Domestic Assistance (93.103) at *http://www.cfda.gov/*[1] and it is subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the Bioterrorism Act, Subtitle A of Title III-Protection of Food Supply, Section 31—Grants to States for Inspections, amends the Federal Food, Drug, and Cosmetic (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 act. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The FDA Grants Policy Statement can be found at *http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*.

See Section VIII, Other Information—Required Federal Citations, under the full text of the RFA for policies related to this announcement found in *http://www.grants.gov* and/or *http://web.ora.fda.gov/dfsr/detail.jsp?id=66*.

[1] FDA has verified the non-FDA Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

III. Mechanism of Support

A. Background

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 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 of the full RFA, under ''Cooperative Agreement Terms and Conditions of Award''.

Funding for an additional 3 years of noncompetitive support is contingent on cooperative agreement performance, program progress and the availability of funds.

B. 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.

C. Budget and Project Period

The length of support is 3 years and the applicants must apply for 3 years of currently projected funding. The applicants must provide 3 years worth of budgets and program objectives. The initial competitive review and award process will provide all awardees with 1 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 3 years and can be modified, depending on the availability of funds and review of prior year's accomplishments.

IV. Eligible Institutions/Organizations

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.

V. Applications

A. Number of Applicants:

Applicants may submit more than one application, provided they are scientifically distinct. Resubmission applications are not permitted in response to this Funding Opportunity Announcement (FOA). Renewal applications are not permitted in response to this FOA.

B. Application Materials:

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. See Section IV.1 in the full text of the RFA available at *http://www.grants.gov* and the FDA/ORA Website for application materials: *http://web.ora.fda.gov/dfsr/detail.jsp?id=66*.

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:

1. Program goals as stated in the RFA
2. 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.

3. 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 RRT.

4. Provide a detailed description of the 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.

5. Provide a properly detailed budget (one for each of 3 years) that is intended to develop the RRT 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.

6. Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3.A of the full RFA notice.

7. Provide current funding level certification for their food safety program from State funding appropriations.

8. Outline detailed methodology for program assessment improvement or program development to accomplish the work.

9. Provide justification for hiring new staff, hiring qualifications, their training needs and any new equipment.

10. 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.

C. Dates

The application receipt date is August 15, 2008.

VI. Agency Contacts:

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

A. Scientific/Research Contacts

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, e-mail: *Jennifer.gabb@fda.hhs.gov* or access the Internet at *http://www.fda.gov/ora/fedState/default.htm*.

B. Financial or Grants Management Contacts

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, e-mail: *gladys.melendez@fda.hhs.gov*.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0352]

Prescription Drug User Fee Act IV Information Technology Plan

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the information technology (IT) Plan entitled ''Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan'' to achieve the objectives defined in the PDUFA Performance Goals. This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the review process of human drug applications.

DATES: Submit written or electronic comments on the plan at any time. These comments will be considered as the agency makes annual adjustments to the plan each fiscal year.

ADDRESSES: Submit written requests for single copies of the IT plan to the Office of the Chief Information Officer (HFA–080), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the IT plan to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the plan.

FOR FURTHER INFORMATION CONTACT: Suzanne Mitri, Office of the Chief Information Officer, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–255–6700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the IT plan entitled ''Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan.'' This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications to achieve the objectives defined in section XIV, Information Technology Goals, of the PDUFA Performance Goals (*http://www.fda.gov/oc/pdufa4/pdufa4goals.html*).

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization and expansion of PDUFA. The reauthorization of PDUFA will significantly broaden and upgrade the agency's drug safety program, increase resources for review of television drug advertising, and facilitate more efficient development of safe and effective new medications for the American public. The reauthorization also includes IT Goals that are divided into four subsections: Objectives, Communications and Technical Interactions, Standards and IT Plan, and Metrics and Measures. In addition, there are IT Goals associated with the upgrade of the agency's drug safety program in section VIII, Enhancement and Modernization of the FDA Drug Safety System of the PDUFA Performance Goals.

The objectives of the PDUFA IV IT Goals are to move FDA towards the long-term goal of an automated standards-based information technology environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle. As part of this process, FDA has developed and will periodically update the 5-year IT plan.

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic