

the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Richard C. Donohue

Acting Secretary

[FR Doc. E8-14663 Filed 6-27-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ).

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. app. 2 10(a), this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Friday, July 25, 2008, from 9 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Deborah Queenan, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427-1330. For press-related information, please contact Karen Migdail at (301) 427-1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Donald L. Inniss, Director, Office of Equal Employment Opportunity Program, Program Support Center, on (301) 443-1144, no later than July 11, 2008. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850. Ms. Campbell's phone number is (301) 427-1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality was established in accordance with section 921 (now section 931) of the Public Health Service Act (42 U.S.C. 299c). In accordance with its statutory mandate,

the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of AHRQ to enhance the quality, improve the outcomes, and reduce the costs of health care services; improve access to such services through scientific research; and promote improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members.

II. Agenda

On Friday, July 25, the Council meeting will convene at 9 a.m., with the call to order by the Council Chair and approval of previous Council minutes. The AHRQ director will present her update on current research, programs, and initiatives. The agenda will include a presentation on the National Healthcare Quality and Disparities Reports and a discussion on Employer Engagement in healthcare. The final agenda will be available on the AHRQ Web site at <http://www.ahrq.gov> no later than July 21, 2008.

Dated: June 18, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8-14565 Filed 6-27-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0360]

Cooperative Agreement to Establish and Support the Western Center for Food Safety (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a Request for Application (RFA) Number RFA-FD-08-004 and its intention to receive and consider a new sole source application for the award of a cooperative agreement in fiscal year 2008 (FY 2008) to establish and support the Western Center for Food Safety (WCFS). The WCFS will be located at the Western Institute for Food Safety and Security (WIFSS) on the University of California, Davis (UCD) campus in Davis, CA.

FOR FURTHER INFORMATION CONTACT:

Scientific/Programmatic Contact:

Steven Gendel, Center for Food Safety and Applied Nutrition (HFS-006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2290, e-mail: steven.gendel@fda.hhs.gov.

Financial or Grants Management

Contact: Gladys M. Bohler, Division of Acquisition Support and Grants (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301-827-7168, FAX: 301-827-7101, e-mail: gladys.melendez-bohler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

A. Background

FDA intends to establish a cooperative agreement to create the WCFS to address these issues through the development of approaches and data critical to understanding the risks associated with the interface between production agriculture and food protection. Such knowledge is critical to the development of scientifically validated "best practices" for mitigating those risks at the production (versus processing) level. In establishing this cooperative agreement, FDA recognizes the importance of agricultural practices in the Western states, an increasingly important food producing region for fruits, vegetables, specialty crops, and dairy products; and a key point of entry for imported foods. The development of an integrated collaborative food protection research/education/outreach program in this region will benefit both consumers and producers nationwide.

B. Program Research Goals

A proposal is being solicited to establish and operate a collaborative center that is designed to meet the objectives of the RFA. The proposal should include information on both the structure and administration of the center and the approaches that will be used to establish robust and sustainable regional, national, and international research and outreach collaborations (including collaborations with the agency's other Centers of Excellence; other Centers at UCD, such as the Center for Produce Safety; and other components of the University of California system), as well as strategies for cultivating additional base support for the center.

1. Concept

FDA faces an increasing number of critical and complex food protection and public health challenges. FDA believes that these challenges can be addressed most efficiently by expanding the available science base through collaborative partnerships. Collaborative partnerships stimulate the integration of applied research, education, and outreach programs to enhance food protection and public health and address new and emerging issues. Collaborative partnerships provide opportunities to leverage resources and to stimulate interest among academics in solving pressing national food protection challenges. Accordingly, access to scientists and facilities associated with agriculture within the Western United States increases FDA's understanding of the unique challenges and practices that must be considered when developing risk management measures that are pertinent to agricultural production in this region.

2. Project Emphasis

The collaborative partnership with WCFS will focus on the interface between food protection and the agricultural production of commodities such as produce and dairy foods. This will include studies in areas such as pre- and post-harvest practices and environmental contamination (both from point sources and from distributed sources, e.g., perchlorate in ground water) for both domestic and imported commodities. WCFS will address "real-world" problems (such as the development of technologies and practices for food safety-related sampling of fresh produce or the impact of field practices on subsequent processing) and develop knowledge leading to practical solutions and approaches that are both feasible and protective of public health. WCFS will also generate and analyze data needed to provide a scientific basis for optimizing the interactions between potentially competing national concerns, e.g., safety of food production environments versus the protection of wildlife habitats in agricultural communities. The education and outreach components of the partnership will ensure that this knowledge is available for, and useful to, all stakeholders.

3. Summary of Objectives

The cooperative research, education, and outreach programs developed through the WCFS will address scientific issues related to the interface between food protection and agriculture

for commodities such as produce, dairy foods, and seafood. These programs will include partnerships with academia, industry, non-governmental organizations, and international organizations. These partnerships will also promote and sustain collaborative domestic and international outreach and education.

The objectives of this cooperative agreement are to:

1. Carry out multidisciplinary applied research projects that address "real world" issues related to food protection, agricultural practices, and the impact of agricultural practices on subsequent food processing associated with FDA-regulated products;

2. Develop and implement outreach and communication programs with stakeholders to identify research needs and to facilitate utilization of the knowledge produced by the research program; and

3. Develop and implement education programs that address food protection problems and increase awareness of the role of science in food protection.

II. Award Information

A. Award Instrument/Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the cooperative agreement award mechanism (U01). Support will be in the form of a cooperative agreement. Accordingly, FDA will have substantial involvement in the program activities of the project. FDA will support the collaboration covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241).

B. Award Amount and Length of Support

The estimated amount of support in FY 2008 will be for up to \$1.5 million (direct plus indirect costs), with the possibility of 4 additional years of support for up to \$2.6 million, subject to the availability of funds. This award will improve public health by creating an applied research, education, and outreach program related to the interface between food protection (i.e., food safety and food defense) and agriculture.

C. Funding Plan

The estimated amount of support in FY 2008 will be for up to \$1.5 million (direct plus indirect costs), with the possibility of 4 additional years of support for up to \$2.6 million, subject to the availability of funds.

D. Delineation of Substantive Involvement

A cooperative agreement involves substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, FDA's purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and FDA. Additional information on the role and responsibility of the grantee and FDA can be found in the full text announcement of the FOA posted on FDA's Center for Food Safety and Applied Nutrition (CFSAN) Web site: <http://www.cfsan.fda.gov/list.html>.

III. Eligibility Information

A. Eligible Institutions/Organizations

Competition is limited to the University of California. FDA believes that establishing the WCFS at WIFSS is appropriate because WIFSS is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. It is an established partnership between academia, state and Federal agencies, and private industry focused on enhancing food protection using a variety of approaches that include basic and applied research; communication and connectivity with public and private partners; outreach programs that extend from farm to fork; and modern information management. WIFSS's location at the UCD facilitates interaction with numerous Centers and Departments within the School of Veterinary Medicine, School of Medicine, College of Agricultural and Environmental Sciences, and College of Engineering. The existing administrative structure at WIFSS can be readily leveraged for developing new food protection programs and fostering new partnerships. Existing collaborations with agricultural producers will promote the conduct of on-farm, pre-, and post-harvest food protection research. Such field-scale research is critical both for understanding how agricultural practice impacts food safety and for ensuring that new technologies are practical and effective.

Collaboration between the public and the private sectors has proven to be an efficient means for both FDA and

academia to remain current with scientific and technical advances associated with FDA-regulated products (e.g., foods, animal drugs and feed additives). The degree to which FDA nurtures, develops, and builds on these collaborations directly affects FDA's ability to enhance public health. The information and expertise that will be obtained through this partnership between FDA and WIFSS can be leveraged by all segments of the food protection and nutrition community, as well as by public health organizations, other Federal agencies, and academic institutions in the performance of their roles.

B. Cost Sharing

This cooperative agreement program requires that the applicant substantially share in the project costs if an award is made, including, but not limited to, partial salary support for administrative staff and in-kind support (e.g., faculty salaries and facilities costs).

IV. Application and Submission

A. Form and Content of Applications

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling 866-705-5711 or through the Web site at <http://www.dnb.com/us/>.¹ The DUNS number should be entered on line 11 of the face page of the PHS 398 form.

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance, contact Gladys M. Bohler, 301-827-7168, e-mail: gladys.melendez-bohler@fda.hhs.gov. Hearing Impaired—Telecommunications for the hearing impaired are available at: TTY 301-451-0088.

B. Address to Submit Application

Applications must be prepared using the forms found in the PHS 398 instructions for preparing a non-modular research grant application. Submit a signed, typewritten original of the paper application, including the

checklist, three signed photocopies, and appendix material in one package to: Gladys M. Bohler, Grants Management Specialist, Division of Acquisition Support and Grants (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301-827-7168, e-mail: gladys.melendez-bohler@fda.hhs.

C. Key Dates

The application is due within 30 days after publication of the Funding Opportunity Announcement in the **Federal Register**. On-time submission requires that the application be successfully submitted to <http://www.grants.gov> no later than 5 p.m. local time (of the applicant institution/organization).

D. Other Submission Requirements

The total project period for an application submitted in response to this funding opportunity may not exceed 5 years.

Applicant may submit only one application. Resubmission applications are not permitted in response to this FOA. Renewal applications are not permitted in response to this FOA.

Consent forms, assent forms, and any other information given to a subject are part of the grant application and must be provided, even if in a draft form. The applicant is referred to the Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 and 21 CFR 50.25 for details.

Awardee(s) must agree to the "Cooperative Agreement Terms and Conditions of Award" in section VI.2.A. of the full text of the FOA posted on the CFSAN Web site: (<http://www.cfsan.fda.gov>).

V. Application Review

Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by FDA, CFSAN, and in accordance with FDA peer review procedures, using the review criteria stated in the following paragraph.

As part of the scientific peer review, a responsive complete application will: (1) Undergo a review process to determine their scientific and technical merit; (2) be assigned a priority score; (3) receive a written critique; and (4) receive a second level of review by the National Institutes of Health, National Cancer Institute National Cancer Advisory Board.

VI. Award Administrative Information

A. Reporting

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:

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

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

3. 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.

4. The original and two copies of the annual Financial Status Report (FSR) (SF-269) must be sent to FDA's Grants Management Specialist within 90 days of each budget period end date.

5. 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 and/or at the end of the project period.

B. Administrative Requirements

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. All grants are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement (GPS), dated January 2007, which supersedes in its entirety the PHS GPS, dated April 1, 1994, and addendum dated January 24, 1995.

An award is subject to the requirements of the 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 of the HHS GPS (available at <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>) 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.

¹ (FDA has verified the 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**.)

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