DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Availability of Grants; under a Limited Competition; Request for Innovative Food Defense Projects

Office of Regulatory Affairs (ORA)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

Section I - Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of innovative food defense projects.

FDA will support projects covered by this notice under Title XVII of the Public Health Service Act (42 U.S.C.1702). FDA's project program is described in the Catalog of Federal Domestic Assistance, No. 93.103, and applicants are limited to food safety regulatory agencies of State, local, and tribal governments. Internet viewers should proceed to ``Publications.''

The Public Health Service (PHS) strongly encourages all award 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.

Background

Food defense is a term used to describe activities associated with protecting the nation's food supply from intentional contamination. The Food and Drug Administration (FDA or Agency) has adopted 3 broad strategies that encompass its food defense activities:

(1) Awareness: Prevention/Preparedness: Increase awareness among federal, state, local and tribal governments and the private sector to better understand where the greatest vulnerabilities lie and develop effective protection/mitigation strategies to shield the food supply from intentional contamination; (2) Response: Develop the capacity for a rapid coordinated response to a foodborne terrorist attack; and (3) Recovery: Develop the capacity for a rapid coordinated recovery from a foodborne terrorist attack.

Stakeholders must determine how to most effectively apply resources within this continuum of activities to best protect the food supply chain and consumers. With regard to prevention and preparedness, the FDA has employed two risk based methodologies that help stakeholders optimize the use of their resources and integrate food safety and food defense activities.

In the aftermath of 9/11, the Agency utilized an approach known as Operational Risk Management (ORM). ORM involves a determination of which combinations of foods and agents, and where on the farm-to-table continuum constitute the highest risks of being targeted for attack that may result in a large number of causalities. It is recognized that any food could potentially be contaminated and thus zero-risk foods do not exist. However, based on ORM analysis it was discovered that higher-risk foods do share several common vulnerability factors: large batch size, which implies a large number of servings; short shelf life, which implies rapid turnaround at retail and rapid consumption; uniform mixing, which would maximize the potential number of contaminated units; and accessibility of a so-called critical node, defined as a process or activity in the farm-

to-table chain during which the agent could be added and go undetected.

Currently, there is a joint program led by FDA, U.S. Department of Agriculture (USDA), Federal Bureau of Investigations (FBI) and the Department of Homeland Security (DHS) in collaboration with private industry and the states known as the Strategic Partnership Program Agroterrorism (SPPA) Initiative. The SPPA was launched in July 2005 and through industry and state volunteers vulnerability assessments are conducted locally in different states on a variety of food commodities in coordination with federal partners. These assessments not only address a specific food commodity but also facilitate interactions between the federal, state and local officials that would be involved in a response to a deliberate attack on the food supply.

Reports summarizing the results from the first two years of SPPA Assessments have been released. The report demonstrates trends seen in processing and agriculturally based commodities and also discusses potential mitigation strategies and research gaps that were identified. The full reports can be viewed at the Center for Food Safety and Nutrition,(CFSAN) website at **www.cfsan.fda.gov/fooddefense**.

As we continue to move forward in meeting our food defense goals by increasing preparedness, developing response plans and ensuring we have the tools to facilitate recovery, we must also integrate these approaches into our existing food safety infrastructure. The overlap between food safety (unintentional contamination) and food defense (intentional contamination) is extensive and the pool of resources available is often the same. Food safety and food defense are ongoing issues and it is critical that these programs be integrated to the maximum extent possible in order to ensure the most efficient use of resources as well as optimizing response to an event. FDA is committed to this approach in order to make optimal use of both human and financial resources to protect public health. As a result, FDA and State field forces may weave components of food defense awareness and education into food safety inspections. The FDA encourages other stakeholders to consider the possibilities of incorporating food defense ideas into their food safety related programs.

FDA has relied on the States in assisting with these activities through formal contracts, partnership agreements, and other arrangements. Under the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002, the demands on both the agency and the States have increased. Procedures need to be reviewed and innovative changes need to be made. These changes should increase effectiveness and efficiency and conserve resources. CFSAN will continue to support food defense programs by providing high quality, science-based work that result in maximizing consumer protection. FDA believes that these grants will be able to generate significant innovative projects and products that will benefit State and local governments, FDA, the industry and the general public in the areas of food defense just as past awards have benefited all stakeholders in food safety. It is anticipated that innovative food defense programs and concepts that are developed at the State and local levels could enhance programs that are developed at the Federal level. To view past innovative food safety awards that have been generated out of this work you can view the ORA Web site at **www.fda.gov/ora/fed state/Innovative Grants.html**.

B. Project Goals, Definitions, and Examples

The specific goal of this program is to generate products that complement, develop, or improve State and local food defense programs and that these could be applied to food defense programs nationwide. Examples of food defense projects are the ALERT Food Defense Awareness Initiative; Food Defense Surveillance Assignments (FDSA), Food Emergency

Response Network (FERN: federal and state laboratories) and the Strategic Partnership Program Agroterrorism (SPPA) Initiative. Applications that address food defense projects and fulfill the following specific project objectives will be considered for funding.

Each application must address only one project. Applicants may apply for more than one project area, but must submit a separate application for each project. If an applicant should receive a fundable score on more than one topic area only the application with the highest score will be awarded. These grants are not to be used to fund or conduct food inspections for food safety regulatory agencies. No more than 10% of the total award can be used to conduct food safety/food defense exercises. Food Safety agencies may subcontract up to 25% of the award to educational institutions for assistance with development of food defense awareness education projects and materials and training.

There are three key project areas identified for this effort:

1. Innovative Food Defense Plan Integration

One key project area is the development of innovative template food defense plans and associated programs that could be integrated with established food safety programs; including continuous improvement plans for the protection of various food establishments in order to improve food defense effectiveness and efficiency. Innovative food defense programs and methodology projects must demonstrate an effect on factors that contribute to awareness, preparedness, early response, and recovery in all, or a segment of, food industry programs. For example, projects could address key elements from the ALERT Initiative. This initiative details five key points that the food industry can use to decrease the risk of intentional food contamination. The ALERT initiative is derived from the FDA Food Security Guidance documents written for specific segments of the food industry. These proposals should focus on providing efficient and effective food defense awareness communications and/or have an effect on factors that contribute to a potential intentional food contamination. Information relative to the ALERT initiative can be found at **www.cfsan.fda.gov/fooddefense**

2. Education and Awareness Information Dissemination

Another key project area is the development of innovative food defense awareness education projects and materials for State and local food safety and food defense regulatory officials that foster consistency and uniform application of State and local food regulations. These education projects and/or materials must be reproducible by other State and local food safety regulatory agencies. These projects may incorporate concurrent education of both State and local food safety and food defense regulatory agencies and the food industry and must be consistent with the ALERT Initiative messages.

3. Innovative Food Defense Training

FDA recognizes that there are a number of new technologies and methods for distance learning and training that may be applicable to the food industry and relevant stakeholders in relation to food defense. FDA also recognizes that Federal, state, and local officials should be able to identify, in a general sense, potential risks, in relation to food defense in food industry establishments. They should also be able to encourage food defense awareness in the employees and management of food industry establishments. Innovative food defense training efforts are needed so that all stakeholders will have an increased awareness of the threat of

intentional contamination of the US food supply. Relevant stakeholders should also understand their unique responsibilities in reducing the risk of intentional contamination of the food supply. Innovative food Defense Training must also be consistent with the ALERT initiative messages.

Section II. Award Information

Mechanism of Support

The U13 – Support of Scientific Conferences will be used to support this program.

Funds Available

The FDA anticipates providing approximately $240,000 in support of this program in Fiscal Year 2008. It is anticipated that six (6) awards will be made, not to exceed $40,000 (direct and indirect costs combined) per award per year. The length of support will be for one (1) year from date of award. The number of grants funded will depend on the quality of the applications received and the availability of Federal funds to support the grant. These grants are not intended to fund food inspections.

Section III. Eligibility Information

1. Eligible Applications

This grant program is only available to State, local and tribal government food regulatory agencies. (See SPOC requirements stated in section IV.A of this document).

2. Cost Sharing or Matching

None.

3.Other.

These grants are available to State, local, and tribal levels and MUST have national implication or application that can enhance Federal, State, and local food regulatory programs and are likely to impact preparedness, response and/or recovery. At the discretion of FDA, successful project formats will be made available to interested Federal, State, local and tribal food safety regulatory agencies. Only one grant will be awarded per State per year. States are urged to collaborate between agencies to submit a single application.

FDA reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use, and to authorize others to use, for Federal Government purposes: (1) the copyright in any work developed under a grant, subgrant or contract under a grant or

subgrant; and (2) any rights of copyright to which a grantee, subgrantee, or a contractor purchases ownership with grant support (45 CFR 92.34).

Section IV. Application and Submission Information

A. Submission Instructions

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. PLEASE NOTE: You must be registered with a username and password obtained from a Credential Provider to apply for opportunities on Grants.gov.

http://www.grants.gov/applicants/get_registered.jsp

If you experience technical difficulties with your online submission you should contact either Marc Pitts, Grants

Management Specialist, Office of Acquisitions & Grants Services, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7162, Marc.Pitts@fda.hhs.gov or the Grants.gov Customer Support Center by email at **support@grants.gov** Customer Support Center by phone at 1-800-518-4726.

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.A of this document.

Applications not received on time will not be considered for review and will be returned to the applicant.

B. Content and Form of Application Submission

FDA is accepting the application 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 PHS 424, 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-08-010". 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.

The face page of the application should indicate "Innovative Food Defense Grant Program RFA-FD-08-010.

Information collection requirements requested on SF 424/PHS Form 5161-1 were approved and issued under the Office of Management and Budget Circular A-102.

C. Submission Dates and Times

The application receipt date for 2008 is July 17, 2008. Applications will be accepted from 8 a.m. to 4:30 p.m.

Eastern Time, Monday through Friday, until the established receipt date.

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

No addendum material will be accepted after the established receipt date.

D. Intergovernmental Review

Intergovernmental review applicants are limited to one State government agency per State. Applications submitted under this program are subject to the requirements of Executive Order (E.O.) 12372.

The regulations issued under EO 12372 also apply to this program and are implemented through the DHHS regulations at 45 CFR part 100. Executive Order 12372 sets up a system for State and local government review of applications for

Federal financial assistance. Applicants (other than federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert them 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. The SPOC should send any State review process recommendations to the FDA Grants Management Office address listed above. The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. The FDA does not guarantee availability to accommodate or explain SPOC comments that are received after the 60 day cut-off. A current listing of SPOCs can be found at **www.whitehouse.gov/omb/grants/spoc.html**

Funding Restrictions

Nonallowable costs include, but are not limited to: (1) Purchase of equipment; (2) transportation costs exceeding coach class fares; (3) entertainment; (4) tips; (5) bar charges; (6) personal telephone calls; (7) laundry charges; (8) travel or expenses other than local mileage for local participants; (9) organization dues; (10) honoraria or other payments for the purpose of conferring distinction or

communicating respect, esteem or admiration; (11) alterations or renovations; and (12) travel or per diem costs for federal employees.

F. Other Submission Requirements

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to submission of their application. All questions of a technical or programmatic nature must be submitted to the FDA program staff. All questions of an administrative or financial nature must be submitted to the Grants Management Staff.

Several additional separate actions are required before an applicant institution/organization can submit an application.

A. As of October 1, 2003, applications are required to have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The DUNS number is a 9 digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. The D&B number can be obtained by either calling (866) 705-5711, through the web site at **http://www.dnb.com/us/** or

http://www.grants.gov/RequestaDUNS. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

Central Contractor Registration

Applicants must register with the CCR database. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. Registration with CCR is a mandatory

requirement and is consistent with the government-wide 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 through the World Wide Web at http://www.ccr.gov. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process. You must have a DUNS number to begin your registration. The registration process can also be found under the "Organization Registration" page of Grants.gov at: http://www.grants.gov/applicants/organization_registration.jsp

V. Application Review Information

1. Criteria

All applications submitted in response to this RFA will first be reviewed for responsiveness by grants management and program staff.

2. Review and Selection Process

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Applications will be considered for funding on the basis of their overall technical merit as determined through the review process. Other award criteria will include availability of funds and overall program balance in terms of geography. Final funding decisions will be made by the Commissioner of Food and Drugs or his or her designee.

Applications will be given an overall score and judged based on all of the following criteria:

(1) Application budgets must remain within the $40,000 cap for combined direct and indirect costs. Applications exceeding this dollar amount will be returned as nonresponsive; (2) Applications must provide in DETAIL, a

sound rationale and appropriate grant design to address the objectives of the RFA; (3) The project MUST be generic enough in nature to be used by other State, local and tribal food regulatory agencies; (4) Applications must include a detailed explanation of the desired goals and outcomes of the project; (5) Applications must include a full description of the project design, a detailed implementation plan, methods of execution, and a timeline for completion. The application must include a detailed description of measures of effectiveness and a description of the source documents or data collection methods for establishing the baseline for measurement; and (6) Applications must address the adequacy of facilities, equipment, databases and support services and the expertise of project staff needed for the project.

VI. Award Administration Information

Award Notices

Support for this program will be in the form of a grant. These grants will be subject to all policies and requirements that govern the project grant programs of FDA, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92.

2. Administrative and National Policy Requirements

The grants will be subject to all policies and requirements that govern the Conference Grant Programs of the PHS, including the provisions of 42 CFR Part 52 and 45 CFR Parts 74 and 92.

3. Reporting

A final Progress Report of the outcomes of the grant and a final Financial Status Report (FSR) (SF-269) are required within 90 days of the expiration date of the project period as noted on the Notice of Grant Award. An original and two copies of each report shall be submitted to FDA's Grants Management Office (address below). The report should include full written documentation of the project, copies of any results, materials, and project deliverables, as described in the grant application, and an analysis and evaluation of the results of the project. The documentation must be in a form and contain sufficient detail such that other State and local food safety regulatory agencies could reproduce the final project.

A Financial Status Report and a mid-year Progress Report are also required no later than 180 days after the award and beginning of the budget period. The mid-year Progress Report should contain a description of activities covering a six-month period, as well as all criteria listed in the previous paragraph.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated by the project officer. Project monitoring may also be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be recorded in the official file and may be available to the recipient upon request.

VII. Agency Contacts

1. Scientific/Research Contacts: Regarding the programmatic issues of this notice:

Jennifer Gabb, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs (ORA), Food and Drug Administration (HFA-150), 5600 Fishers Lane, Rm. 12-07, Rockville, MD 20857, 301-827-2899, e-mail:

jennifer.gabb@fda.hhs.gov, or access the Internet at http://www.fda.gov/ora/fed_state/default.htm

For general Food Defense program information: Contact Don Kautter, Center for Food Safety and Applied Nutrition, 5100 Paint Branch (HFS-007) Room 3B019, College Park, MD, 20740, 301-436-1629, e-mail: donald.kautter@fda.hhs.gov, or access the internet at: http://www.cfsan.fda.gov/~dms/defterr.html

2. Financial or Grants Management Contacts:

Regarding the administrative and financial management issues of this notice:

Marc Pitts, FDA, OAGS, GAAT, HFA 500, Room 2104, 5630 Fishers Lane, Rockville, MD 20857; e-mail: marc.pitts@fda.hhs.gov

VIII. Other Information

URLs in FDA Grant Applications or Appendices:

All applications and proposals for FDA funding must be self-

contained within specified page limitations. Unless otherwise specified in an FDA solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61)

"Unless disclosure is required by FOIA as amended (5 U.S.C. 552), as determined by the Freedom of Information officials of DHHS or by a court, data contained in the portions of an application which have been specifically identified (e.g., by page number and paragraph) by the applicant as containing restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes."

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving

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

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under provisions of 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the DHHS Grants Policy Statement. The DHHS Grants Policy Statement can be found at **http://www.hhs.gov/grantsnet/adminis/gpd/index.htm**

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

advance the physical and mental health of the American people.