that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 31, 2008

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0548. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey—(OMB Control Number 0910–0548)—Extension**

FDA has received four reports of medical gas mix-ups occurring during the past 9 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mix-ups, to determine if further steps are warranted to ensure the safety of patients.

In the **Federal Register** of March 7, 2008 (73 FR 12452), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 210 and 211 | 285 | 1 | 285 | .25 | 71.25 |
| Total | 285 | 1 | 285 | .25 | 71.25 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 24, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–14888 Filed 6–30–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Innovative Food Defense Projects; New Limited Competition Cooperative Agreement U13; Request for Application Number: RFA–FDA–08–010

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) is announcing the availability of grant funds for the support of innovative food defense projects. 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. FDA anticipates providing approximately $240,000 in direct plus indirect costs in support of this program in fiscal year 2008. It is anticipated that 6 awards will be made for up to $40,000 per award/per year for up to 1 year.

**DATES:** The application receipt date is July 30, 2008.

**I. Background/Funding Opportunity Description**

Food defense is a term used to describe activities associated with protecting the nation's food supply from intentional contamination. FDA (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.

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, Federal Bureau of Investigations, and the Department of Homeland Security, 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 2 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) Web site at *http://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. 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 *http://www.fda.gov/ora/fed_state/Innovative_Grants.html*.

*A. Project Emphasis*

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, Food Emergency Response Network (FERN: federal and state laboratories), and 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 percent of the total award can be used to conduct food safety/food defense exercises. Food safety agencies may subcontract up to 25 percent 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 *http://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 U.S. 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.

**II. Award Information**

*Mechanism of Support*

The U13—Support of Scientific Conferences will be used to support this program. Under the U13 Mechanism,

the Project Director/Principal Investigator (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 PD/PI.

**III. Eligibility Information**

*A. Eligible Applications*

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

*B. Cost Sharing or Matching*

None.

*C. 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).

**IV. Application and Submission**

*A. Application Information*

In order to apply electronically, the applicant must have a Data Universal Number System number and register in the Central Contractor Registration database. Please note: You must be registered with a username and password obtained from a Credential Provider to apply for opportunities. (See the following Web site: *http://www.grants.gov/applicants/get_registered.jsp*).[1]

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*, the Grants.gov Customer Support Center by e-mail at *support@grants.gov*, or the Customer Support Center by telephone at 1–800–518–4726.

*B. Content and Form of Application Submission*

FDA is accepting the application for this program electronically by the Internet at: *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 download 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 30, 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 12372.

The regulations issued under Executive Order 12372 also apply to this program and are implemented through the Department of Health and Human Services 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 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 contact listed in section VI 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 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 *http://www.whitehouse.gov/omb/grants/spoc.html*.

*E. 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.

**V. Award Administration Information**

*A. Award Notices/Administrative and National Policy Requirements*

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. These grants are subject to the A–87 cost principles.

*B. Reporting Requirements*

A final Program Progress Report and a final Financial Status Report (SF–269) are required within 90 days of the expiration date of the project period as noted on the Notice of Grant Award. In addition, the grantee must file an invention statement and disposition of equipment statement within 90 days after the end date of the project period as noted on the notice of the cooperative agreement award. An original and two

[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**.

copies of each report shall be submitted to FDA's Grants Management Office (see section VI of this document).

A Mid-Year Progress Report is also required no later than 90 days after the close of the budget period. The Mid-Year Progress Report should cover 6 months of activity.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least semi-annually 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.

When multiple years are involved, awardees will be required to submit the PHS Non-Competing Grant Progress Report (PHS 2590) *http://grants.nih.gov/grants/funding/2590/2590.htm* annually and financial statements as required in the Department of Health and Human Services Grants Policy Statement. Reports must be submitted two months prior to the next budget period start date. The Progress Report should include a report of the previous meeting supported by the current grant, as well as a full description of the next planned meeting.

**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*

*Regarding the programmatic issues of this notice*: Jennifer Gabb, Division of Federal-State Relations, Office of Regulatory Affairs (HFC–150), Food and Drug Administration, 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*: Don Kautter, Center for Food Safety and Applied Nutrition (HFS–007), 5100 Paint Branch, rm. 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*.

*B. Financial or Grants Management Contacts*

*Regarding the administrative and financial management issues of this notice*: Marc Pitts, Office of Acquisitions & Grants Services, Grants Acquisition and Assistance Team (HFA–500), Food and Drug Administration, rm. 2104, 5630 Fishers Lane, Rockville, MD 20857; e-mail: *marc.pitts@fda.hhs.gov*.

Dated: June 25, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–14876 Filed 6–30–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Review of Applications for RFA: International Research on Venue-Based Interventions for HIV/AIDS and Alcohol Use.

*Date:* July 16–18, 2008

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jose H. Guerrier, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Infectious Diseases Microbiology Fellowships.

*Date:* July 17, 2008.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Avenue Hotel Chicago, 160 Huron Street, Chicago, Il 60611.

*Contact Person:* Alexander D. Politis, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435–1150, *politisa@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Addictions, Pathways and Prevention.

*Date:* July 23–24, 2008.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Michael Micklin, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, Bethesda, MD 20892, (301) 435–1258, *micklinm@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 24, 2008.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–14837 Filed 6–30–08; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special