Part I Overview Information

Department of Health and Human Services

Participating Organizations

Food and Drug Administration (FDA) http://www.fda.gov

Title: Food Protection Task Force Conference

Announcement Type: New limited Competition Request for Applications

Request for Application(RFA) Number: RFA-FD-08-006

Catalog of Federal Domestic Assistance Number(s) 93.103

Key Dates

Opening Date: June 30, 2008 (Earliest date an application may be submitted to Grants.gov)

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

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1. Research Objectives

FDA is issuing a revised RFA which will replace the announcements published June 25, 2004 (69 FR 35651) and February 4, 2005 (70 FR 6015) as revised on May 3, 2005 (70 FR 22889). This revised announcement provides for the change in the name of the grant program to be consistent with the FDA Food Protection Plan and new policies that apply to the State Food Protection Task Force Meetings conference Grant Program.

FDA views State-based Food Protection Task Forces as an important mechanism for providing food safety and food defense program coordination, and information exchange within each State. ("Food" includes human food and animal feed and is defined in 21 USC 321(f)). This grant announcement is intended to encourage the development of a Task Force within each State and to provide funding for Task Force meetings. Conference grant funding is available to States that have an existing Food Safety and Food Defense Task Force, as well as to States that are in the process of developing a new Food Protection Task force. State Food Protection Task Force meetings should foster communication and cooperation among State local and tribal public health and food safety agencies and other interested parties.

The purpose of the Food Protection Task Force meetings is to foster communication and cooperation and collaboration within the States among State, local, and tribal food protection public health, agriculture, and regulatory agencies. The meetings should: (1) Provide a forum for all the stakeholders of the food protection system—regulatory agencies, academia, industry, consumers, State legislators, Boards of Health and Agriculture and other interested parties; (2) assist in adopting or implementing the Food Code and other food protection regulations; and (3) promote the integration of an efficient statewide food protection/defense system that maximizes the protection of the public health through prevention, intervention and response including the early detection and containment of foodborne illness. Each Task Force shall develop its own guidelines for work, consensus decision making, size and format, at its initial meeting. FDA's Division of Federal State Relations (DFSR) will provide meeting guidelines and organization documents as requested.

Conference grant funds will be awarded only for the direct costs incurred to secure meeting facility rental expenses, supplies, publication costs, and in-state travel expenses for meeting attendees or other such projects as approved in the application that support the task force and its goals. Each Task Force shall

develop its own guidelines for work, consensus decision making, size and format at its initial meeting. Federal agency representatives may be invited to be nonmember liaisons or advisors to the task force and its meetings. Conference grant funds may not be used for Federal employees to travel to or participate in these meetings.

A. Background

The FDA's Office of Regulatory Affairs (ORA) is the inspection component of the FDA and has 1,000 investigators and inspectors who cover the approximately 95,000 FDA- regulated businesses in the United States and inspect more than 15,000 facilities a year. In addition to the standard inspection program, FDA's investigators and inspectors conduct special investigations, food inspection recall audits, and perform consumer complaint inspections and sample collections.

In the past FDA has relied on the States in assisting with the above duties through formal contracts, partnership agreements, and other informal arrangements. The inspection demands on both the Agency and the States are expected to increase. Accordingly, procedures need to be reviewed and innovative changes made that will increase effectiveness, efficiency, and conserve resources. Examples of support include providing effective and efficient compliance of regulated products and, providing high quality, science-based work that maximizes consumer protection.

FDA Food Protection Plan:

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne disease in the Nation is substantial. Foodborne disease causes an estimated 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year, and an estimated $6.9 billion in economic costs. New challenges continue to arise, including the globalization of the food supply and the emergence of new pathogens in foods.

These facts reinforce the importance of this State Food Protection and Security Task Force program. Task Forces should consider the plans and activities listed below as a part of their goal for planning meetings and activities:

(1) FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA).

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, charged FDA with developing a comprehensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counter those before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

The Plan builds in safety measures to address risks throughout a product's life cycle, from the time a food is produced to the time it is distributed and consumed. The Plan focuses FDA efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective. The Plan also calls for a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

(2) FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

a. The prevention element means promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and

implementing risk reduction measures with industry and other stakeholders, we can best address critical weaknesses.

b. The intervention element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly.

c. The response element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. It also includes better communication with other Federal, state, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as informing the public of what is safe to consume.

(3) The focus of these grant sponsored meetings should be to discuss and resolve issues at the State and local levels relating to the following areas:

A. State/local Agency roles and responsibilities: (1) capacity and resource needs; (2) outbreak coordination and investigations; (3) information sharing and data collection; (4) uniform regulatory standards; (5) communications and education; (6) State/local laboratory operations and coordination; (7) adoption and implementation of the FDA Food Code and other food protection regulations; (8) uniform standards for foodborne illness and outbreak reporting investigation and response; (9) State and local training needs; and (10) food defense activities and coordination.

1. FOOD DEFENSE ACTIVITIES:

The following should be considered by the task forces in planning and group facilitation of meetings within their respective states:

a. Target (hard-to-reach) stakeholders focusing on cultural and small to moderate (medium) sized establishments.

b. Integrate food safety and food defense among public health, food and agriculture sectors and stakeholders for a cohesive food protection integration.

c. Establish best practices for collaboration and alignment of resources among public and private sectors.

1. A. Prevention Activities:

Awareness/Outreach – to include the FDA messages related to food defense awareness, ALERT, and FIRST.

Vulnerability/Risk Assessments - to include the extension and training related to the CARVER + Shock vulnerability assessment tool and its use within food facilities

Criticality/Key Resources – promotion and use of the Department of Homeland Security State Guidance tool (FASCAT) on identifying and prioritizing critical infrastructure and key resources within their State borders and possible regional to national effects

Food Code/Regulatory Measures - Roles/Responsibilities –to include local, state, regional and national issues in prevention and preparedness for both natural and man-made disasters

Training/Education – to include the FDA messages related to food protection, ALERT, and FIRST as highlighted in the Awareness and outreach track

1. B. Intervention Activities:

GAPs/Needs Assessment- related to what is needed and resources that will be needed to assist in recovering from an event based on what is needed on the local level, the state level and the regional/national level.

Reporting/Follow-Up – best practices recommendations for reporting structures and needed follow-up activities (as well as roles and responsibilities) after an event has occurred to return to a steady-state as it was prior to an event.

1. C. Response Activities:

Communication – evaluate communication processes and identify gaps within regulatory agencies and industry, and also coordination of public messages.

Recalls – including development of improved procedures to improve outreach to a broader audience with significant public health recall information within the state.

Traceability – to evaluate the need for improved processes for tracing of foods through the distribution chain efficiently and rapidly to minimize consumer exposure.

Reporting – brainstorm improved information sharing and reporting mechanisms within state and among states and federal agencies.

2. Food borne Illness Activities:

Develop processes that will facilitate the investigation, prevention, and control of foodborne disease outbreaks, e.g., guidelines for responding to multi-jurisdictional outbreaks, and guidelines for sharing results between and among key stakeholders including federal, state, and local governmental agencies, industry, and consumers. Establish a detailed characterization of foods implicated in foodborne outbreaks and monitor the trends of implicated foods; Identify and monitor contributing factors and their environmental antecedents, establish the chemical/biologic agent responsible for foodborne outbreaks.

Section II. Award Information

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1. Mechanism(s) of Support

This funding opportunity will use the Conference/Scientific Meeting (R13) grant award mechanism. Under the R13 mechanism, the applicant will be solely responsible for planning, directing, and executing the proposed project. Multiple year awards may be made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic. The total project period for an application requesting support may not exceed five years.

This funding opportunity uses just-in-time budget concepts. It also uses the non-modular budget format. Applicants must complete and submit a detailed categorical budget with the SF424 application.

2. Funds Available

Because the nature and scope of the proposed activities will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will

depend upon the number of applications, quality, duration, and costs of the applications received.

Under this announcement, the FDA anticipates providing approximately $160,000 in direct costs in support of this program in Fiscal Year 2008. It is estimated that about 32 grants at a level requested but not exceeding $5,000 total (direct costs only) for the first year will be awarded. An additional 5 years of support up to approximately $5,000 (direct costs only) each year will be available, depending upon fiscal year appropriations, and successful performance.

Continued funding of a noncompetitive segment is contingent upon satisfactory progress as determined annually by FDA procedures, the receipt of a noncompeting continuation application, final yearly task force report and the availability of Federal funds.

The noncompeting continuation will consist of the PHS 2590, Non-competing Continuation application, a financial status report, and conference proceedings for all conferences held the previous budget period.

A decrease in the amount of the noncompetitive segment may occur if there is an unobligated balance from the prior year, in which case prior year funds can be used as an offset for the current year award.

Section III. Eligibility Information

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1. Eligible Applicants

These grants are available to State public health, agriculture and food protection agencies that have an existing Food Safety and Food Defense Task Force, as well as to States that are in the process of developing a new Food Protection

Task Force. Only one grant will be awarded per State per year. States are urged to collaborate between agencies to submit a single application.

Any individual with the skills, knowledge, and resources necessary to conduct the proposed conference is invited to work with that individual's institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for FDA support.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current DHHS Grants Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

3. Other-Special Eligibility Criteria

Prior to submission of an application, the State shall designate one State public health or food safety agency to lead, coordinate, and host the Food Protection Task Force and its meetings. The formation of Food Protection Task Forces and meetings shall not interfere with existing Federal-State advisory mechanisms or state required committees or advisory groups. Responsiveness is defined as submission of a complete application on or before the required submission date as listed above. If applications are found to be non-responsive, they will be returned to the applicant without further consideration.

Section IV. Application and Submission Information

FDA is accepting new applications for this program electronically via www.grants.gov. To download the SF424 Application forms for this Funding Opportunity Announcement FOA, link to http://www.grants.gov/Apply/ and follow the directions provided on that site.

A one-time registration is required for institutions at:

- Grants.gov (http://www.grants.gov/GetStarted)

Several additional separate actions are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Registered

- Your organization will need to obtain a Data Universal Number System (DUNS) number
- And register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process. Information about these requirements is available at (CCR) http://www.ccr.gov and (DUNS) http://www.dnb.com/us/
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to Grants.gov Customer Support at http://www.grants.gov/help/help.jsp
  Contact Center Phone: 800-518-4726
  Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
  Email support@grants.gov

The registration process can be lengthy. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in Grants.gov. The FDA will accept electronic applications only from organizations that have completed all necessary registrations.

1. Request Application Information

Applicants must download the SF424 application forms for this FOA through http://www.grants.gov/Apply.

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 forms (e.g., sample forms, forms from another FOA); although some of the "Attachment" files may be useable for more than one FOA.

For further assistance contact Gladys M. Bohler, 301-827-7168, gladys.melendez-bohler@fda.hhs.gov

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

The SF424 application has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

The face page of the application should indicate "Response to Food Protection Task Force Conference Grant Program RFA FD 08-006".

Applications should include the following: (1) A title which has the term "state food protection task force meetings", "conference", "council", "workshop", "alliance" or other similar description to assist in the identification of the request; (2) location of the conference; (3) expected number of registrants and type of audience expected with their credentials; (4) dates of conference(s); (5) conference format and projected agenda(s), including list of principal areas or topics to be addressed; (6) physical facilities required for the conduct of the

meeting; (7) justification of the conference(s), including the problems it intends to clarify and any developments it may stimulate; (8) brief biographical sketches of individuals responsible for planning the conference(s) and details concerning adequate support staff; (9) information about all related conferences held on this subject during the last 3 years (if available); (10) details of proposed per diem/subsistence rates, transportation, printing, supplies and facility rental costs; and (11) the necessary checklist and assurances pages provided in each application package.

Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at http://www.dnb.com/us/.

The applicant must register in the Central Contractor Registration (CCR) database in order to be able to submit the application. Information about the CCR is available at http://www.ccr.gov/. The applicant must register with the Credential Provider for Grants.gov. Information about this requirement is available at **http://www.grants.gov/applicants/get_registered.jsp**

3. Submission Dates and Times

The first application receipt date is June 30, 2008. No supplemental material or addenda will be accepted after the receipt date.

Do not send applications to the Center for Scientific Research (CSR), NIH. Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant.

3. A. Submitting an Application Electronically to the FDA

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/Apply .

The required application, SF 424, can be completed and submitted online. The package should be labeled, "Response to RFA FD-08-006." If you experience technical difficulties with your online submission you should contact Gladys M. Bohler by telephone at 301-827-7168 or by e-mail at gladys.melendez-bohler@fda.hhs.gov.

PAPER APPLICATIONS WILL NOT BE ACCEPTED.

3. B. Application Processing

Applications may be submitted on or after the opening date and must be successfully received by Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization) on the application submission/receipt date(s). If an application is not submitted by the receipt date(s) and time, the application may be delayed in the review process or not reviewed.

Upon receipt, applications will be evaluated for completeness. Incomplete applications will not be reviewed.

FDA will not accept any application in response to this FOA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. FDA will not accept any application that is essentially the same as one already reviewed.

4. Intergovernmental Review

This initiative is subject to http://www.whitehouse.gov/omb/grants/spoc.html.

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*

5. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the DHHS *Grants Policy Statement* http://www.hhs.gov/grantsnet/adminis/gpd/index.htm.

Pre-award costs are allowable. A grantee may, at its own risk and without FDA prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing renewal (formerly, "competing continuation") award if such costs: are necessary

to conduct the project, and would be allowable under the grant, if awarded, without FDA prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain FDA approval before incurring the cost. FDA prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on FDA either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. FDA expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See DHHS Policy Statement http://www.hhs.gov/grantsnet/adminis/gpd/index.htm.

6. Other Submission Requirements and Information

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.

A copy of the complete RFA can also be viewed on the Grants.gov website along with the funding opportunity application package. A copy of the full RFA can be obtained from the Program or Grants Management contact listed under "Contacts" in this RFA once the RFA is published in the Federal Register.

The following instructions are to be used in conjunction with the SF424 application form:

Performance Site Locations: Enter the site of the conference or meeting as the Performance Site.

Senior/Key Person: Personnel are defined as the PD/PI and those responsible for the scientific planning and organization of the meeting. Attach a biographical sketch for PD/PI, Co-Chair, key personnel, and confirmed key speakers.

Budget Information: Enter the direct costs requested. Provide a narrative justification for each proposed personnel position, including role and proposed level of effort. Include information regarding efforts to obtain funding for this conference/meeting from other sources.

Allowable Costs: Conference grant funds will be awarded only for direct costs incurred to secure meeting facility rental expenses, supplies, publication costs, and in-State travel expenses for meeting attendees. Federal agency representatives may be invited to be non-member liaisons or advisors at the meetings. Conference Grant funds may not be used for federal employees to travel to these meetings. Allowable costs consist of: (1) salaries in proportion to the time or effort spent directly on the conference; (2) rental of necessary equipment; (3) travel and per diem; (4) supplies needed to conduct the meeting; (5) conference services; (6) publication costs; (7) registration fees (excluding cost of meals); and (8) speaker's fees.

Non-allowable costs: Include but not limited to: Travel or expenses other than local mileage for local participants; organization dues; travel or per diem costs for federal employees. Purchase of equipment; transportation costs exceeding U.S. carrier coach class fares; visas; passports; entertainment; tips; bar charges; personal telephone calls; laundry charges; dues; honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem or admiration; patient care; alterations or renovations; facilities and administrative costs/indirect costs. Please also refer to the DHHS Grants Policy Statement for additional information regarding costs.

Conference Plan: Submit one attachment, which may not exceed 10 pages. In the "Conference Plan" section of the application, describe the objectives, specific program, and logistical arrangements for the meeting. Describe the format and agenda, including the principal topics to be covered, problems to be addressed, and developments or contributions the meeting might stimulate. Provide a detailed justification for the meeting, including the scientific need, timeliness, and usefulness of the meeting to the scientific community. Describe the composition and role of the organizing committee, and provide the names and credentials of key participants in the meeting, including the basis for their selection and documentation of their agreement to participate.

Describe plans for the appropriate involvement of women, minorities, and persons with disabilities in the planning and implementation of the proposed meeting. Estimate the expected size and composition of the audience, as well as the method of selection. Describe plans for publicizing the meeting and publication of the proceedings. Identify related meetings held on the subject during the past three years.

Applications requesting multiple years of support must provide the following additional information for each future year requested, in as much detail as possible: meeting topic(s); tentative dates, locations, and participants; and contingency plans for future meetings dependent upon, for example, the outcome of the first year's meeting or developments in the field.

Appendix: The appendix is limited to announcements and reports of previous meetings under the same sponsorship. No other information or material should be submitted as appendices.

Section V. Application Review Information

Review and Selection Process

An appropriate evaluation group convened by the accepting Center/Program will evaluate the application for scientific and technical merit.

The following will be considered in making funding decisions:

- Scientific merit of the proposed conference/scientific meeting as determined by the evaluation process.
- Availability of funds.
- Relevance of program priorities.

In their critiques, reviewers will be asked to comment on each of the following criteria, which will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to deserve a high priority score.

Significance: Does this conference/scientific meeting address an important health problem? If the aims of the application are achieved, how will scientific knowledge or practice be advanced? What will be the effect of these endeavors on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Is the purpose of the conference and its relevance to FDA clear? Is the conference timely in terms of currency of issues to be addressed?

Approach: Is the format and agenda for the meeting appropriate for achieving the goals of the conference? Is the meeting timely for the subject matter? How well do the plans for inclusion of women, minorities, and persons with

disabilities provide for their appropriate representation in the planning, organization, and implementation of the proposed meeting?

Innovation: Does the meeting employ novel approaches or methods to fulfill its purpose?

Project Directors (PD): Is the PD well suited for organizing and fulfilling the goals of this conference? Are the qualifications of the PD appropriate and past performance adequate? Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference?

Environment: How appropriate is the meeting site? Does the applicant organization have the ability to contribute to the probability of success? Do the proposed meetings, exhibits, interactions, etc., take advantage of unique features of the environment or employ useful collaborative arrangements?

2. A. Additional Review Criteria:

In addition to the above criteria, the following item will continue to be considered in the determination of scientific merit and the priority score:

Inclusion of Women, Minorities and Persons with Disabilities in NIH/FDA Supported Conference Grants: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html)

FDA affirms that the value of scientific meetings is enhanced by including participants from all segments of the scientific population and, when appropriate, members of the lay community, in both the planning and conduct of such meetings. The adequacy of plans to include women, minorities and persons with disabilities in the planning and execution of a scientific meeting or conference is important to its success and relevance and will be assessed.

2. B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed plan. Does the amount requested from FDA appear reasonable as partial support of the total conference given the plan, facilities, travel, and speakers? The priority score should not be affected by the evaluation of the budget.

Previous Experience: Is there previous experience with the organization/or the principal investigator in similar undertakings? If so, what?

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. 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) The content/subject matter and how current and appropriate it is for the mission of FDA; (2) the conference plan and how thorough, reasonable, and appropriate it is for the intended audience; (3) the experience, training, and competence of the principal investigator/director and availability of support staff; (4) the adequacy of the facilities; and (5) the reasonableness of the proposed budget given the total conference plan, program, speakers, travel, and facilities.

Section VI. Award Administration Information

Administrative and National Policy Requirements

All FDA grant awards include the DHHS Grants Policy Statement as part of the NoA. For these terms of award, see the DHHS *Grants Policy Statement* Part II: Terms and Conditions of FDA Grant Awards, http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

The following Terms and Conditions will be incorporated into the NoA and will be provided to the PD/PI as well as to the appropriate institutional official, at the time of award.

1. Award Notices

If the application is under consideration for funding, FDA will request "just-in-time" information from the applicant. For details, applicants may refer to the DHHS Grants Policy Statement Part II: Terms and Conditions of FDA Grant Awards, http://www.hhs.gov/grantsnet/adminis/gpd/index.htm

A formal email notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee authorized representative.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

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. Meetings covered by this notice will be supported under section 1701-1706 (42 U.S.C. 300u-300u-5) of the Public Service Health Act. FDA's Conference Grant Program is described in the Catalog of Federal Domestic Assistance, No. 93-103.

Project Director/Principal Investigator (PD/PI) Rights and Responsibilities

Awardees have primary authorities and responsibilities to define objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusions of the conference.

FDA Responsibilities

An agency Program Official or Center Program Director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the NoA. The assigned Program Director will also serve as the Project Scientist.

3. Reporting

A final Progress Report of the meeting(s) or Conference Proceedings 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 above). The report of the meeting should include: (a) the grant number; (b) the title, date and place of time of the meeting; (c) the name of the person shown on the application as the conference director, principal investigator, or program director; (d) the name of the organization that conducted the meeting; (e) a list of individuals and their institutional affiliations who participated as speakers or facilitators in the formally planed sessions of the meeting; and, (f) a summary of topics discussed, next steps and conclusions.

A Financial Status Report and a Progress Report are also required no later than 90 days after the close of the budget period. The Progress Report should contain a description of a specific plan for the next meeting, 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 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 DHHS 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.

Section VII. 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.

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 ORA program information: Contact your Regional Food Specialist at http://www.fda.gov/ora/fed_state/DFSR_Activities/foodspecialist.htm

2. Financial or Grants Management Contacts: Regarding the administrative and financial management issues of this notice:

Gladys M. Bohler, FDA, OAGS, GAAT, HFA 500, Room 2105, 5630 Fishers Lane, Rockville, MD 20857; phone: 301-827-7168 and FAX 301-827-7101 and at email: gladys.melendez-bohler@fda.hhs.gov

Section VIII. Other Information

Required Federal Citations

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.

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 FOA 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. Meetings covered by this notice will be supported under section 1701-1706 (42 U.S.C. 300u-300u-5) of the Public Service Health Act and under Federal Regulations 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

Smoke Free Work Place:

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.

Freedom of Information: Data included in the application which have been specifically identified by the applicant as containing restricted and/or proprietary information may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Dated:

Senior Associate Commissioner for Policy, Planning and Legislation

Dated:

Director, Office of Acquisitions & Grants Services, OAGS