meeting will be reserved for questions from interested persons.

Time for participants to make a statement will be limited according to the number of registered participants. Therefore, individuals who wish to make a statement must contact the individuals identified in the **FOR FURTHER INFORMATION CONTACT** section of this notice as soon as possible to register. Comments from individuals not registered will be heard after scheduled statements only, if time permits.

Written submissions will also be accepted.

III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mailstop: C1–09–06; Baltimore, Maryland 21244, or by e-mail at *Mellis@cms.hhs.gov.* Please provide your name, address, telephone number, and, if available, e-mail address and fax number.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on August 10, 2004. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

Individuals requiring sign language interpretation or other special accommodations must provide that information upon registering for the meeting.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 17, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 04–14273 Filed 6–24–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Conference Grants to Support State Food Safety Task Force Meetings; Availability of Funds Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) in collaboration with the Centers for Disease Control and Prevention (CDC) is announcing the availability of conference grant funding for meetings of State Food Safety and Food Security Task Forces. The original announcement of availability of funding for State Food Safety Task Force Meetings, published in the **Federal Register** of January 24, 2000 (65 FR 3720), is superseded by this announcement. This revised announcement provides new policies that apply to the State Food Safety and Food Security Task Force Meetings Conference Grant Program. FDA views this program as an ongoing program announcement, contingent on the availability of funds. FDA anticipates providing approximately $350,000 in direct costs only in support of this program in fiscal year (FY) 2004. It is anticipated that 50 awards will be made for up to $7,000 per award.

DATES: The application receipt date is August 9, 2004, for the first year and March 15 for each subsequent year this program is in effect.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Cynthia M. Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–531), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7180, e-mail: *cpolit@oc.fda.gov*. Application forms PHS 5161–1 are available via the internet at: *http://www.psc.gov/forms* (Revised 7/00). Applications handcarried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–531), rm. 2129, Rockville, MD 20857. An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. FDA cannot receive an application electronically.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (see **ADDRESSES**).

Regarding the programmatic aspects of this notice: Stephen Toigo, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs, Food and Drug Administration (HFC–150), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, or access the Internet at: *http://www.fda.gov/ora/fed__state/default.htm*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA and CDC view State-based Food Safety and Food Security Task Forces as important mechanisms for promoting food safety, food security program coordination, and information exchanges within each State. 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 Security Task Force, as well as to States that are in the process of developing such a Task Force. State Food Safety Task Force meetings should foster communication and cooperation among State and local public health and food safety agencies and other interested parties. Under this grant announcement, States may be awarded grants for up to 3 years for a maximum of $7,000 per year in direct costs only, contingent on the availability of funds. Only one grant will be awarded per State per year.

Before submission of an application, the State shall designate one State public health or food safety agency to lead, coordinate, and host the Food Safety and Food Security Task Force and its meetings. The formation of Food Safety and Food Security Task Force meetings shall not interfere with existing federal-state advisory mechanisms.

Meetings covered by this notice will be supported under section 1701–1706 (42 U.S.C. 300u–300u–5) of the Public Service Health (PHS) Act. FDA's Conference Grant Program is described in the Catalog of Federal Domestic Assistance, No. 93–103. Applicants are limited to one State government agency per State. Applications submitted under this program are subject to the requirements of Executive Order 12372.

FDA urges applicants to submit workplans that address specific objectives of ''Healthy People 2010.'' Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, Volumes I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954,

Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD-ROM format, S/N 017–001–00549–5 for $19 ($23 foreign) as well as on the Internet at *http://www.health.gov/healthypeople/*. Internet viewers should proceed to ''Publications.''

II. Background

FDA's ORA is the inspection component of 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 previously mentioned 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.

CDC is a non-regulatory Federal public health agency that works closely with FDA food safety regulatory and other agencies to prevent foodborne disease. CDC leads Federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. CDC also plays an ongoing role in identifying prevention strategies and building State and local health department epidemiology, laboratory, and environmental health capacity to support foodborne disease surveillance and outbreak response. CDC data assists in documenting whether food safety interventions are leading to reductions in the incidence of foodborne illness.

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 Safety and Security Task Force program. 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: (1) State/local agency roles and responsibilities; (2) capacity and resource needs; (3) Outbreak coordination and investigations; (4) information sharing and data collection; (5) uniform regulatory standards; (6) communications and education; (7) state/local laboratory operations and coordination; (8) adoption/implementation of FDA's Food Code; (9) uniform standards for foodborne illness and outbreak reporting investigation and response; and (10) state and local training needs for epidemiology, outbreak investigation, etc.

III. Project Goals, Definitions, and Examples

The purpose of the Food Safety and Food Security Task Force meetings is to foster communication and cooperation within the States among State and local food safety regulatory agencies. The meetings should cover the following objectives: (1) Provide a forum for all the stakeholders of the food safety system—regulatory agencies, academia, industry, consumers, State legislators, and other interested parties; (2) assist in adopting or implementing FDA's Food Code; and (3) promote the integration of an efficient statewide food safety system that maximizes the protection of the public health through early detection and containment of foodborne illness.

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. 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 at the meetings. Conference Grant funds may not be used for Federal employees to travel to these meetings.

FDA's DFSR will provide meeting guidelines and organization documents as requested.

FDA will consider funding meetings for up to 3 years. Funding after the first year will be at an amount that will be negotiated at the time of the initial competitive segment. Thus, the budgets for all 3 years of requested support must be fully justified in the original application.

Continued funding of a noncompetitive segment is contingent upon satisfactory progress as determined annually by FDA procedures, the receipt of a noncompeting continuation application, and availability of federal funds. The noncompeting continuation will consist of a Standard Form 424 (SF424) face page, 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.

Following are the allowable costs: (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, and (8) speaker's fees.

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; (12) indirect costs; and (13) travel or per diem costs for Federal employees.

IV. Reporting Requirements

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 (see **ADDRESSES**). The following items should be included in the report of the meeting: (1) The grant number; (2) the title, date and place of the meeting; (3) the name of the person shown on the application as the conference director, principal investigator, or program director; (4) the name of the organization that conducted the meeting; (5) a list of individuals, and their institutional affiliations, who participated as speakers or facilitators in the formally planned sessions of the meeting; and (6) a summary of topics discussed, next steps and conclusions.

An FSR 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 semiannually 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.

V. Mechanism of Support

A. Award Instrument

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 Conference Grant Programs of the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 also apply to this program and are implemented through the Department of Health and Human Service's (HHS) 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 FDA's Grants Management Office (see **ADDRESSES**). 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 cutoff.

B. Eligibility

These grants are available to State public health and food safety agencies. (See section V.A of this document.)

C. Length of Support

It is anticipated that FDA will fund these grants at a level requested but not exceeding $7,000 total direct costs only for the first year. An additional 2 years of support up to approximately $7,000 (direct costs only) each year will be available, depending upon fiscal year appropriations and successful performance.

D. Funding Plan

Federal funds are currently available from FDA for this program. However, awards are subject to the condition that, in addition to FDA funds, augmenting funds are transferred to FDA from CDC to fully support this program. As the lead Federal agency, FDA intends to collect funds from CDC through an Interagency Agreement. An estimated amount of $100,000 is available in FY 2004 through the Interagency Agreement for a total of $350,000. The number of grants funded will depend on the quality of the applications received, their relevance to FDA's mission, priorities, and the availability of funds.

VI. Review Procedure and Criteria

All applications submitted in response to this request for applications (RFA) will first be reviewed for responsiveness by grants management and program staff. Responsiveness is defined as submission of a complete application with original signatures on or before the required submission date as listed in the previous paragraphs. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration.

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, in consultation with the CDC Director and his or her designee.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria before the submission of their application. All technical or programmatic questions must be directed to the ORA program staff (see **ADDRESSES**). All administrative or financial questions must be directed to the Grants Management Staff (see **ADDRESSES**).

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 missions 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.

VII. Submission Requirements

The original and two copies of the completed grant application Form PHS–5161–1 (Revised 07/00) for State and local governments should be delivered to the Grants Management Office (see **ADDRESSES**). The application receipt date is August 9, 2004, for the first year and March 15 for each subsequent year this program is in effect. No supplemental material or addenda will be accepted after the receipt date.

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

Do not send applications to the National Institutes of Health's (NIH) Center for Scientific Review. 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. FDA is unable to receive applications via the Internet.

The outside of the mailing package and item 2 of the application face page should be labeled ''Response to Food Safety Task Force Conference Grant Program.'' You must submit only one application (an original and two copies) per package.

B. Format for Application

When using Form PHS 5161–1 (Revised 07/00), all instructions for the enclosed SF424 should be followed using the nonconstruction application pages.

Both the face page of the application and the outside of the mailing package should be labeled ''Response to Food Safety Task Force Conference Grant Program.'' Submit applications on SF424 and include the following: (1)

Title, which has the term ''state food safety 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 known); (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. A properly formatted sample application for grants can be accessed on the Internet at: *http://www.fda.gov/ora/fed_state/Innovative_Grants.html*.

Data included in the application, if restricted with the legend (see section X. of this document), 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).

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

IX. Dun and Bradstreet Number (DUNS) Requirement

As of October 1, 2003, applicants are now required to have a DUNS number to apply for a grant or cooperative agreement from the Federal government. 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. To obtain a DUNS number, call 1–866–705–5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

X. Legend

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

Dated: June 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14395 Filed 6–24–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004M–0024, 2004M–0147, 2004M–0145, 2004M–0031, 2004M–0022, 2004M–0012, 2004M–0064, 2004M–0116, 2004M–0084, 2004M–0090, 2004M–0134]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2004, through March 31, 2004. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.