SMG 2150.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

GRANTS ADMINISTRATION

FDA GUIDELINES FOR PARTIAL FUNDING OF SMALL SCIENTIFIC CONFERENCE GRANTS

Effective Date: 04/18/2002

1. PURPOSE

This guide states the policies and procedures of the Food and Drug Administration (FDA) for the application, review and award of small grants in support of scientific conferences. Such grants provide some, but not all, funding support for the direct costs associated with a conference which has objectives clearly within FDA's mission and its areas of program interest and priorities.

2. DEFINITIONS

A. Scientific Conferences. These include symposia, seminars, workshops or other formal meetings held to:

1. Exchange scientific information, and explore or clarify a scientific subject area.

2. The conference proceedings are usually published as a report or journal article.

B. Grantee. A grantee is a United States institution or an established scientific or professional society with a U.S. component eligible to receive grants. Faith-based organizations are eligible to apply for these conference grants. Individuals are not eligible to receive a grant for the support of a scientific conference. Organizations which engage in lobbying

activities (IRS Code Section 501 {c} 4) are ineligible to receive grant funds.

C. Application. Form PHS-398, "Application for Public Health Service Grant," should be used to apply to FDA. State and local governments may use PHS 5161-1 (rev 7/00) Application forms and special instructions are available from:

Grants Management Office
Food and Drug Administration
5630 Fishers Lane
HFA-520
Rockville, Maryland 20857

Telephone: 301-827-7180

http://www.fda.gov/oc/ofacs/grants/

D. Center. As used in this Staff Manual Guide, the term includes the Office of Regulatory Affairs and all components of the Office of the Commissioner.

E. Allowable Costs. Special instruction for completing the application and determining what costs may be charged to a grant are available from the Office of Facilities, Acquisitions and Central Services (OFACS) at the telephone number listed above (2c).

F. Domestic and International Conferences.

1. Grant funds may be awarded to provide general support for those conferences, both domestic and international, that are held either in the United States or Canada.

2. For international conferences held outside the United States and Canada, grant funds may be awarded to the U.S. component of the international organization for support of specific aspects or segments of the conference (e.g., a panel which is part of the conference), but not for general support of the whole conference.

3. POLICY

It is FDA policy to participate with other organizations in support of a scientific conference rather than provide the sole financial support. Partial funding will be predicated on the following criteria:

A. Conferences proposed for partial FDA funding support must be related to FDA's overall mission and must meet the objectives and the funding priorities of the FDA program area concerned;

B. Under these circumstances, FDA may provide partial support for a limited number of scientific conferences designed to coordinate, exchange and disseminate scientific information;

C. Such grants will ordinarily be awarded in amounts between $1,000 and $25,000 for direct cost expenditures associated with the conference. However, exceptions to those amounts may be made by the Director, OFACS, when appropriate.

D. Applicants are required to follow the Special Information and Instructions included in the application kit which address allowable costs and necessary budgetary information.

E. Applications received after the quarterly deadline date will be held for the next review cycle or returned to the applicant if time is not sufficient for FDA to conduct a review prior to the scheduled date of the proposed conference.

4. APPLICATION PROCESS

A. Potential applicants should contact the Grants Management Office (see 2.c. above) to determine interest, current plans and program priorities before preparing and submitting a grant application to the Agency.

B. When an FDA employee in any program area is contacted by a potential applicant, that employee should inform their Center liaison (Attachment A).

C. Center liaisons should, in turn, advise the Grants Management Office (2.c. above).

D. When the institution or professional society decides to submit a conference grant application, their representative should request a package of material (PHS-398 and FDA Special Information and Instructions) from FDA (2.c. above).

E. The institution or professional society should plan to submit its conference grant application as far in advance of the conference as possible, but at a minimum of three months before the conference is scheduled to begin.

F. Applications should be submitted to the Grants Management Office (2.c. above).

G. Schedule. Complete applications that meet all the requirements for submission will be reviewed as follows:

Received by	Reviewed by	Awarded by
January 15	February 15	March 15
April 15	May 15	June 15
July 15	August 15	September 15
October 15	November 15	December 15

5. REVIEW PROCESS

After receipt and initial review for responsiveness by the Grants Management staff, the application will be sent to the appropriate Center(s) for a decision on mission relatedness, program interest and funding priority. If the Center(s) indicates an interest in potentially funding the application, an ad hoc review panel will be convened. The ad hoc review panels meet each month as needed, at the convenience of the reviewers.

A. Review Panel. A minimum of three senior FDA staff knowledgeable in the subject areas of the application will constitute the ad hoc review panel.

B. Conflict of Interest. The Department of Health and Human Services (DHHS) Standards of Conduct and the FDA Supplement to the DHHS Standards of Conduct apply. No FDA employee will participate in or be present during any review of an application from an organization in which the member, his or her spouse, parent, child or partner has a financial interest or is serving as an officer, director, trustee, presenter, partner, or employee, or is negotiating any arrangement concerning prospective employment.

C. Review Criteria. The committee will review the application and evaluate it based on criteria published as part of the Request for Applications in the Federal Register notice (see Attachment B).

D. Review Scoring. Each reviewer will score the application independently based solely on the review criteria. The range of scoring is 100-500 with 100 being the highest rating and 500 the lowest. The Summary Statement will reflect the average of all the reviewers' scores.

1. If the majority of the reviewers on the panel disapprove, the conference grant application it will be disapproved, with no score on the Summary Statement.

2. If a minority of the reviewers on the panel disapprove, a score of 500 will be used to indicate those reviewers' scores when calculating the average for the Summary Statement.

E. Executive Secretary. OFACS personnel will serve as the Executive Secretary to the review panel, document the review, average the scores given by the reviewers and write the Summary Statement.

F. Recommendation for Funding. The Summary Statement, with the recommendation for approval or disapproval, will be sent to the appropriate Center(s). Appropriate Center staff will make the final funding decision based on the Center's interests, mission and budgetary priorities.

6. AWARD OF THE GRANT

If the Center(s) decides to fund the application based on the above criteria, Center Staff will notify the Grants Management Office by memo of their decision and will indicate the level of funding approved. Grants Management Staff will process the application as a new award according to criteria set forth in Staff Manual Guide FDA 2150.2, with the following exceptions:

A. The project period for the conference grant award will be for a period of up to one fiscal year only;

B. The award will be for direct costs only and will exclude travel for federal employees, honoraria, and any awards presented at the conference;

C. No grant award will be awarded after the start date of a conference. If the conference grant application is not recommended for approval by the Center(s), Center staff must notify OFACS of its decision. OFACS will notify the applicant in writing within thirty (30) days of Center notification.

7. PROCEDURES

A. Applicants should submit a completed Form 398, " Public Health Service Grant Application," to FDA at the above address (2.c) State and local governments may use PHS 5161-1 (rev 7/00).

B. Applications should NOT be mailed or delivered to the National Institutes of Health.

C. Any FDA employee receiving a conference grant application should immediately refer it to OFACS, HFA 520, through their Center's liaison (see Attachment A).

D. Review procedures will follow those described above (see #5). Committee review will be based on criteria contained in the "Review Guidelines," (Attachment B) and will be documented accordingly by the Executive Secretary, OFACS.

E. Funding decisions will be made by the Center(s) based on its overall objectives and funding priorities.

F. Grant awards will be made by the Grants Management Officer, OFACS, with the approval of the Center(s) and the Office of Financial Management.

G. The earliest date for award of a conference grant is three months after the Agency receives a complete application that meets all the requirements for submission.

H. For any information regarding scientific conference grants, contact, OFACS, DCPM HFA-520, Phone: 301-827-7180.

SMG 2150.1 Attachment A

Program Contacts

Office of the Commissioner (OC)	Executive Officer HF-60, Parklawn, Room 14C03 301-827-3440
Center for Veterinary Medicine (CVM)	Health Science Administrator HFV-502, MOD 2, Room G105 301-827-8021
Center for Food Safety and Nutrition (CFSAN)	Extramural Resource Specialist HFS-669, CPK1, Room 4C012 301-436-2390
Center for Drug Evaluation and Research (CDER)	Research Coordinator HFD-006, WOC 2, Room 6049 301-594-6779
Center for Biologics Evaluation and Research (CBER)	Contract Liaison Officer HFM-145, Rockwall 4th Floor 301-827-1434
Center for Devices and Radiological Health (CDRH)	Budget Analyst HFZ-30, Oak 8, Room 300 301-594-3006 x 159
Office of Orphan Products (OPD)	Grants Program Director, OPD HF-35, Parklawn, Room 15A09 301-827-0017
National Center for Toxicological Research (NCTR)	Director, Division of Financial Management HFT-323, NCTR 870-543-7248
Office of Regulatory Affairs (ORA)	Assistant to the Director HFC-150, Parklawn, Room 1207 301-827-2911

SMG 2150.1 Attachment B

SCIENTIFIC CONFERENCE GRANT APPLICATIONS REVIEW GUIDELINES

The following criteria should be considered when reviewing any scientific conference grant applications. (Basic submission requirements have already been considered.)

1. APPROPRIATE CONTENT/SUBJECT MATTER

   The proposed scientific conference should address a subject or theme which is consistent with and related to the mission of FDA.

   Is the purpose of the conference and its relevance to FDA clear?

   Is the conference timely in terms of currency of the issues to be addressed and the amount of interest that may be generated in response?

   Is there an identifiable audience who might be expected to attend such a conference?

2. SUFFICIENCY OF THE CONFERENCE PLAN

   The applications should present sufficient information to demonstrate that such a conference could be held.

   Is there a clearly stated conference plan?

   Is it reasonable in terms of the length of the symposium and the anticipated results?

   Do the presentations/speaker subjects carry through the main subject matter of the conference?

   Do the different agenda items combine to create a unified conference?

3. PERSONNEL/SUPPORT STAFF

   Does the experience, training, or other indication of competence support the selection of the principal investigator/director as the key person to manage this particular conference? Is support staff included in the plan? Is it sufficient?

4. CONFERENCE FACILITIES

   Are the facilities appropriate and adequate? Does the application indicate that facilities have been planned and any unusual conference needs anticipated?

5. BUDGET

   Does the amount requested from FDA appear reasonable as partial support of the total conference given the plan, facilities, travel, and speakers?

6. PREVIOUS EXPERIENCE

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