TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

| 21 CFR section | No. of respondents | Annual responses per respondent | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 99.201(b) | 5 | 1 | 10 | 0.5 | 5 |
| 99.201(c) | 5 | 1 | 10 | 0.5 | 5 |
| 99.203(a) | 1 | 1 | 1 | 10 | 10 |
| 99.203(b) | 1 | 1 | 1 | 10 | 10 |
| 99.203(c) | 1 | 1 | 2 | 0.5 | 1 |
| 99.205(b) | 1 | 1 | 1 | 82 | 82 |
| 99.501(b)(1) | 5 | 3 | 20 | 8 | 160 |
| 99.501(b)(2) | 5 | 1 | 20 | 1 | 20 |
| 99.501(b)(3) | 5 | 1 | 20 | 20 | 400 |
| 99.501(b)(4) | 1 | 1 | 1 | 2 | 2 |
| 99.501(b)(5) | 1 | 1 | 1 | 41 | 41 |
| Total Hours | | | | | 2,018 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 99.501(a)(1) | 5 | 1 | 8 | 10 | 80 |
| 99.501(a)(2) | 5 | 1 | 8 | 1 | 8 |
| 99.501(c) | 5 | 1 | 8 | 1 | 8 |
| Total Hours | | | | | 96 |

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

The estimated burden associated with the information collection requirements for these regulations is 2,114 hours.

Dated: June 9, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–11863 Filed 6–15–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Support for Small Scientific Conference Grants; Availability of Grants; Request for Applications; Announcement Type: Modification of Notice; Funding Opportunity Number: HHS–GRANTS–110204–001; Catalog of Federal Domestic Assistance Number: 93.103

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

**ACTION:** Notice.

### I. Funding Opportunity Description

The Food and Drug Administration (FDA) is revising the Request for Applications (RFA) published in the **Federal Register** of June 6, 2002 (67 FR 39013). This revised RFA supercedes the June 6, 2002, document in its entirety. FDA's authority to enter into grants and cooperative agreements is detailed under title XVII of the Public Health Service Act (42 U.S.C. 300u–1) or the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) (21 U.S.C. 360hh-ss, formerly 42 U.S.C. 263b-n).

*1. Background*

FDA recognizes the value of partially supporting scientific meetings and conferences designed to coordinate, exchange, and disseminate information when the objectives are clearly within the scope of the agency's mission. FDA's policy is to participate with other organizations to support meetings where practicable, rather than provide sole support. In view of the diversity of interests among the various FDA centers/offices, and in order to provide maximum flexibility, FDA will not set rigid requirements concerning the type of scientific meetings to be supported so long as they are within the agency's mission.

### II. Award Information

FDA views the partial support of scientific conferences as an ongoing program and may award a limited number of grants each fiscal year. These awards are subject to availability of funds and range from $1,000 to $25,000 in direct costs only per conference. This announcement is intended to be a ''Standing Program Announcement'' and will be modified in the event of required changes to the program.

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 support for small scientific conference grant programs of FDA, including the provisions of 42 CFR part 52, and 45 CFR parts 74 and 92, as applicable. The length of support will last for up to 1 year from date of award.

**III. Eligibility**

*1. Eligible Applicants*

Conference grant support is available to any public or private nonprofit entity including State and local units of government, scientific and professional societies, faith-based organizations, and for-profit entities. For-profit entities must commit to excluding fees or profit from the conference in their request for support.

In the case of an international conference held in the United States or Canada, the U.S. component of an established international scientific or professional society is the eligible applicant. In exceptional cases, where there is no U.S. component, a grant to support a specific segment of an international conference may be awarded directly to a foreign institution provided that the following conditions are met: (1) Grants to foreign institutions or international organizations are not prohibited under the governing legislation and (2) approval of the Department of Health and Human Services (HHS) agency head or his or her designee is obtained in each case.

An individual is not eligible to receive grant funds in support of a conference. As provided in 2 U.S.C. 1611, organizations described in section 501(c)(4) of the Internal Revenue Code that engage in lobbying are not eligible to receive Federal funds constituting grant awards.

*2. Cost Sharing or Matching*

See section IV.2.B.11 of this document.

**IV. Application and Submission**

*1. Addresses to Request Applications*

FDA is accepting new applications for this program electronically via Grants.gov. Applicants are strongly encouraged to apply electronically by visiting the Web site *http://www.grants.gov* and following the instructions under ''APPLY.'' The applicant must register in the Central Contractor Registration (CCR) database in order to be able to submit the application. Information about CCR is available at *http://www.grants.gov/CCRRegister*. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**). The applicant must register with the Credential Provider for Grants.gov. Information about this requirement is available at *http://www.grants.gov/CredentialProvider.* (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**). If applicants cannot submit applications through the electronic process, application forms are available from, and completed applications should be submitted to, Tya Marks, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7179, e-mail: *tya.marks@fda.gov*. Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA–500), rm. 2139, Rockville, MD 20857. Application instructions (PHS 5161–1 revised 7/00) and application forms (SF–424 revised 9/03) are available via the Internet at: *http://www.hhs.gov/forms*.

*2. Content and Form of Applications*

A. Submission

If submission is electronic, the application package is posted under the ''APPLY'' section of this announcement under Grants.gov. The required application forms are listed under ''Mandatory Documents.'' They can be completed and submitted online.

If applicants are not submitting electronically, an original and two copies of the completed grant application form SF–424 (revised 9/03) should be delivered to the address listed in *Addresses to Request Application* in section IV of this document. The outside of the package should clearly state ''Request for Conference Grant'' and must be received by the appropriate submission date (see *Submission Dates and Times* in section IV of this document).

B. Content

Applications must include the following information:

1. Title that has the term scientific ''conference,'' ''council,'' ''workshop,'' 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, along with speaker credentials;
4. Dates of conference (inclusive). Each application must address only one specific conference;
5. Conference format and projected agenda, including list of principal areas or topics to be addressed;
6. Physical facilities required for the conduct of the meeting (e.g., simultaneous translation facilities);
7. Justification of the conference, including the problems it intends to clarify and any developments it may stimulate;
8. Brief biographical sketches of individuals responsible for planning the conference and indication of adequate support staff;
9. Information about all related conferences held by the applicant 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;
11. The budget for the entire conference, budget items requested from FDA, budget items supported by other sources, and a list, including amounts, of all other anticipated support; and
12. The necessary checklist and assurance pages provided in each application package.

Some examples of allowable costs include the following items: (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, (8) working meals where business is transacted, and (9) speaker fees.

Some examples of nonallowable costs include the following items: (1) Purchase of equipment; (2) transportation costs exceeding coach class fares; (3) visas; (4) passports; (5) entertainment; (6) tips; (7) bar charges; (8) personal telephone calls; (9) laundry charges; (10) travel or expenses other than local mileage for local participants; (11) organization dues; (12) honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem, or admiration; (13) patient care; (14) alterations or renovations; and (15) indirect costs.

Grant funds may not be used to provide general support for international scientific conferences held outside the United States or Canada. Grant funds may be awarded to a U.S. component of an international organization to provide limited support for specific segments of an international conference held outside the United States of Canada if the conference is compatible with FDA's mission. An example of such support would be a selected symposium, panel, or workshop within the conference, including the cost of planning and the cost of travel for U.S. participants for the specified segment of the scientific

conference. Any Public Health Service (PHS) foreign travel restrictions that are in effect at the time of the award must be followed, including but not limited to, limitations or restrictions on countries to which travel will be supported, and budgetary or other limitations on availability of funds for foreign travel.

C. Letter of Intent

A letter of intent is not mandatory. However, applicants may submit a letter of intent to the contact (see *Addressees to Request Applications* in section IV of this document) at least 30 days prior to the application receipt date. Potential applicants are also encouraged to talk to the contact to determine if the proposed scientific conference is clearly consistent with FDA's interest, mission, and priorities. Potential applicants may fax letters of intent to: 301–827–7101 or e-mail: *tya.marks@fda.gov*.

*3. Submission Dates and Times*

Applications will be received and reviewed quarterly during each fiscal year. The receipt dates are in direct relation to the conference date and can be seen in table 1 of this document.

TABLE 1.—KEY RECEIPT DATES

| Earliest Beginning Conference Date | Receipt Date |
|---|---|
| December 15 | October 15 |
| March 15 | January 15 |
| June 15 | April 15 |
| September 15 | July 15 |

If the receipt date falls on a weekend or holiday, it will be extended to the following workday. Responsive applications received after the quarterly deadline date will be held for the next review cycle if the conference date falls under the next cycle. Applications received after the quarterly deadline date for a conference within that review cycle will be returned to the applicant if not received in time for orderly processing.

Applications will be accepted during normal business hours, from 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered on time if sent, mailed, or electronically submitted on or before the appropriate receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier. Private metered postmarks will not be acceptable as proof of timely mailing. 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.

*4. Intergovernmental Review*

The regulations issued under Executive Order 12372 may also apply to this program and are implemented through HHS regulations under 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 processes. The names and addresses of SPOCs are listed on the Office of Management and Budget's (OMB's) Web site at *http://www.whitehouse.gov/omb/grants/spoc.html*. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**). The SPOC should send any State review process recommendations to FDA's administrative contact (see section IV of this document). The due date for the State process recommendation is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cutoff.

*5. Funding Restrictions*

See section IV.2.B of this document.

*6. Other Submission Requirements*

See section IV.1 of this document.

**V. Application Review Information**

*1. Criteria*

Upon receipt, all applications submitted in response to this announcement will be evaluated for responsiveness to this RFA. Responsiveness is defined as submission of a complete application with original signatures within the required submission dates (see *Submission Dates and Times* in section IV of this document). Applications found to be nonresponsive will be returned to the applicant without further consideration.

An application will be considered nonresponsive if any of the following criteria are not met: (1) If the applicant organization is ineligible, (2) if it is received in the grants management office after the specified receipt date (see *Submission Dates and Times* in section IV of this document), (3) if it is incomplete or if it is missing any of the elements under *Content and Form of Application* in section IV of this document, (4) if it is illegible, (5) if the proposed conference is not within FDA's mission, (6) if the material presented is insufficient to determine an adequate review, and/or (7) if it exceeds the recommended threshold amount reflected in the RFA.

*2. Review and Selection Process*

Responsive applications will be reviewed and evaluated for their scientific and technical merit by an ad hoc review panel composed of experts in the field using the following criteria:

a. The content/subject matter and how current and appropriate it is for FDA's mission;

b. The conference plan and how thorough, reasonable, and appropriate it is for the intended audience;

c. The experience, training, and competence of the principal investigator/director and support staff;

d. The adequacy of the facilities;

e. The reasonableness of the proposed budget give the total conference plan, program, speakers, travel, and facilities; and

f. Previous experience of the organization/principal investigator.

**VI. Award Administration Information**

*1. Award Notices*

Successful applicants will be notified via Notice of Grant Award signed by the Chief Grants Management Officer, FDA.

*2. Administrative and National Policy*

Applications submitted under this program may be subject to the requirements of Executive Order 12372. FDA's conference grant program is described in the Catalog of Federal Domestic Assistance, No. 93.103. The applicable administrative regulations for this program are 45 CFR parts 74 and 92. The legislative authority is title XVII of the Public Health Service Act.

*3. Reporting*

A final Financial Status Report (SF–269) and a final progress report or conference proceedings are required. An original and two copies of these reports must be submitted to the Grants Management Office (see section VII of this document), within 90 days after the end of the budget period of the grant award. Copies of conference proceedings resulting from the meeting may be substituted for the final progress report. Failure to provide these reports in a timely manner may jeopardize future grant support or delay an award.

**VII. Agency Contacts**

For information regarding this program, please contact Tya Marks (see *Addresses to Request Applications* in section IV of this document).

**VIII. Other Information**

FDA strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with FDA's mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, vols. I and II, for $70 ($87.50 foreign), S/N 017–000–00550–9, by writing to the Superintendent of Documents, U.S. Government Printing Office, 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 ($23.50 foreign), as well as on the Internet at *http://www.healthypeople.gov* under ''Publications'' (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**).

Information collection requirements requested on PHS Form SF–424 were approved and issued under OMB Circular A–102.

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

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552), as determined by the freedom of information officials of HHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: June 10, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–11957 Filed 6–14–05; 10:57 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 14, 2005, page 7509 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* The Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture: Phase III. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of this information collection is to update occupational and environmental exposure information as well as medical history information for subjects enrolled in the the Agricultural Health Study. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

*Frequency of Response:* Single-time reporting. *Affected Public:* Individuals or households; Farms; Type of Respondents: Licensed pesticide applicators and their spouses. The annual reporting burden is as follows: *Estimated Number of Respondents:* 74,320; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .5845 for 72,320 and 1.0 for 2,000; and *Estimated Total Annual Burden Hours Requested*: 44,270. The annualized cost to respondents is estimated at: $708,320.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Type of respondent | Estimated number of respondents | Frequency of response | Average hours per response | Estimated annual return hours requested |
|---|---|---|---|---|
| Private Applicators Interview only | 39,479 | 1 | 0.5845 | 23,075.0 |
| Interview and buccal cells | 1,100 | 1 | 1.0 | 1,100.0 |
| Spouses Interview only | 30,054 | 1 | 0.5845 | 17,566.0 |
| Interview and buccal cells | 820 | 1 | 1.0 | 820.0 |
| Commercial Applicators Interview only | 2,787 | 1 | 0.5845 | 1,629.0 |
| Interview and buccal cells | 80 | 1 | 1.0 | 80.0 |
| Total | 74,320 | | | 44,270 |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be