

### V.3. Anticipated Announcement Award Date

August 1, 2004

## VI. Award Administration Information

### VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1 Human Subjects Requirements.
- AR-8 Public Health System Reporting Requirements.
- AR-9 Paperwork Reduction Act Requirements.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-14 Accounting System Requirements.
- AR-16 Security Clearance Requirement.
- AR-25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC web site at the following Internet address: <http://www.cdc.gov/od/pgofunding/ARs.htm>.

### VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
  - a. Current Budget Period Activities Objectives.
  - b. Current Budget Period Financial Progress.
  - c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report and annual progress report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be sent to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

## VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Michael Gerber, Project Officer, 4770 Buford Hwy NE, Mailstop F-48, Atlanta, Georgia 30341, Telephone: 770-488-3520, E-mail: [mcg9@cdc.gov](mailto:mcg9@cdc.gov).

For budget assistance, contact: Steward Nichols, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2788, E-mail: [shn8@cdc.gov](mailto:shn8@cdc.gov).

Dated: March 24, 2004.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-7028 Filed 3-29-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee (SRSHEs): Cancellation of Meeting

This notice announces the cancellation of a previously announced meeting.

*Federal Notice Citation of Previous Announcement:* March 11, 2004 (Volume 69, Number 48) [Notices] [Page 11635]

From the **Federal Register** Online via GPO Access.

*Previously Announced Time and Date:* 8 a.m.-3:30 p.m., April 6, 2004.

*Place:* Adam's Mark Hotel Columbia, 1200 Hampton Street, Columbia, South Carolina 29201.

*Change in the Meeting:* This meeting has been canceled.

#### FOR FURTHER INFORMATION CONTACT:

Phillip Green, Executive Secretary, SRSHEs, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE. (E-39), Atlanta, Georgia 30333, telephone (404) 498-1800, fax (404) 498-1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: March 23, 2004.

Joseph E. Salter,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-7022 Filed 3-29-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0117]

#### International Conference on Harmonisation; Draft Guidance on E2E Pharmacovigilance Planning; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "E2E Pharmacovigilance Planning." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes a method for summarizing the identified risks of a drug, the potential for important unidentified risks, and the potentially at-risk populations and situations that were not studied before the drug was approved. The draft guidance is intended to foster better and earlier planning of pharmacovigilance activities, especially in preparation for the early postmarketing period of a new drug.

**DATES:** Submit written or electronic comments on the draft guidance by May 19, 2004.

**ADDRESSES:** Submit written comments on the draft guidance to the Division of