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/pgo/funding/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*.

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*.

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]

BILLING CODE 4163–18–P

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]

BILLING CODE 4163–18–P

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

Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Paul J. Seligman, Center for Drug Evaluation and Research (HFD–030), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6276, or Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In November 2003, the ICH Steering Committee agreed that a draft guidance entitled ''E2E Pharmacovigilance Planning'' should be made available for public comment. The draft guidance is the product of the Efficacy E2E Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy E2E Expert Working Group.

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.

The draft guidance proposes a structure for a pharmacovigilance plan and sets out principles of good practice for the design and conduct of observational studies. The draft guidance does not describe other methods to reduce risks from drugs, such as risk communication.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7105 Filed 3–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0118]

International Conference on Harmonisation; Draft Guidance on Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process; 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 ''Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.'' 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 purpose of the draft guidance is to provide principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process to ensure that the process changes did not have an adverse impact on the quality, safety, and efficacy of the