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Dated: September 6, 2010.

David K. Henderson,
Deputy Director for Clinical Care, CC National Institutes of Health.

[FR Doc. 2010-23526 Filed 9-20-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC): Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the BCCEDCAC, HHS, has been renewed for a 2-year period through September 12, 2012.

For information, contact Ms. Jameka Blackmon, Designated Federal Officer, BCCEDCAC, CDC, 1600 Clifton Road, NE., M/S K57, Atlanta, Georgia, 30333, telephone (770) 488-4740; fax (770) 488-3230.

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 the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 14, 2010.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-23588 Filed 9-20-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0456]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Critical Path Programs, in cosponsorship with the Clinical Trials Transformation Initiative (CTTI), is announcing a 3-day training course for health care

professionals responsible for, or involved in, the conduct and/or design of clinical trials (clinical investigators). This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials.

DATES: The training course will be held on November 8 and 9, 2010, from 8 a.m. to 5 p.m. and on November 10, 2010, from 8 a.m. to 3 p.m.

ADDRESSES: The training course will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT:

Nancy Masiello, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4166, Silver Spring, MD 20993-0002, 301-796-8498, Nancy.Masiello@fda.hhs.gov.

Registration: Register by November 1, 2010, at the registration/information Web site at <https://www.trials.transformation.org/fda-clinical-investigator-training-course/>. Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site. The registration fee is \$350 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets. If you need special accommodations due to a disability, please contact Nancy Masiello at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials.

The training course is designed to provide clinical investigators with an overview of the following topics:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
 - Fundamental issues in the design and conduct of clinical trials;
 - Statistical and analytic considerations in the interpretation of trial data;
 - Appropriate safety evaluation during studies;
 - The ethical considerations and regulatory requirements for clinical trials; and
 - Application and compliance issues.
- In addition, the course should:
- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
 - Promote communication between clinical investigators and FDA;
 - Enhance investigators' understanding of FDA's role in experimental medicine; and
 - Improve the quality of data while enhancing subject protection in the performance of clinical trials.

On November 8, 2010, the course will address the role of FDA in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an "investigator's brochure," i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presentations will also discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. On November 9, 2010, the course will include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 10, 2010, the course will include discussions of safety assessment in clinical trials, including hepatic and cardiovascular safety, approaches to special populations (e.g., pregnant women and pediatrics), and breakout sessions to discuss how to put together an application, including related compliance issues.

Dated: September 16, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010-23493 Filed 9-20-10; 8:45 am]

BILLING CODE 4160-01-S