

Successor organization; a discussion on the health information technology Strategic Plan; and final reports from the Confidentiality, Privacy & Security Workgroup and the Population Health/Clinical Care Connections Workgroup.

FOR FURTHER INFORMATION: Visit <http://www.hhs.gov/healthit/ahic.html>.

A Web cast of the Community meeting will be available on the NIH Web site at: <http://www.videocast.nih.gov/>.

If you have special needs for the meeting, please contact (202) 690-7151.

Dated: August 26, 2008.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

FDA Clinical Trial Requirements Regulations, Compliance, and Good Clinical Practice Conference; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Dallas District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA Clinical Trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, November 19, 2008, from 8 a.m. to 5 p.m. and Thursday, November 20, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Westin Crown Center, 1 East Pershing Rd., Kansas City, MO 64118, 816-474-4400, FAX: 816-391-4438.

Contact: David Arvelo, Food and Drug Administration, 4040 N. Central

Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail: david.arvelo@fda.hhs.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$575 (member), \$650 (nonmember), \$525 (government employee nonmember), or \$450 (government employee member). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA 18914. To register via the Internet go to http://www.socra.org/html/FDA_Conference.htm (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800-762-7292), or 215-822-8644, or via e-mail: socramail@aol.com. Attendees are responsible for their own accommodations. To make reservations at the Westin Crown Center at the reduced conference rate, contact the Westin Crown Center (see Location) before October 21, 2008. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited; therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact David Arvelo (see *Contact*) at least 21 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The FDA Clinical Trial Requirements Regulations, Compliance, and GCP Conference, helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA and confidence in the conduct of clinical research; (2) medical device, drug, biological product, and food additive aspects of clinical research; (3) investigator initiated research; (4) Pre-investigational new drug (IND) application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of Institutional Review Boards; (8)

electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections, and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

Dated: September 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the National Diabetes Education Program Comprehensive Evaluation Plan

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The National Diabetes Education Program Comprehensive Evaluation Plan. **Type of Information Collection Request:** Extension of a currently approved collection (#0925-0552). **Need and Use of Information Collection:** The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goals of the NDEP are to: Improve the treatment and health outcomes of people with diabetes, promote early diagnosis, and, ultimately, prevent the onset of diabetes. The NDEP objectives are: (1)