4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Society of Clinical Research Associates-Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

Summary: The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The conference on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents, and regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, IRBs, and research sponsors.

Date and Time: The conference will be held on May 15 and 16, 2013, from 8 a.m. to 5 p.m.

Location: The conference will be held at the Renaissance Seattle Hotel, 515 Madison St., Seattle, WA 98104.

Contact Person: Jane Kreis, Food and Drug Administration, 1301 Clay St., suite 1180N, Oakland, CA 94612, 510-287-2708, FAX: 510-287-2739; or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., suite 109, Chalfont, PA 18914, 800-762-7292, FAX: 215-822-8633, email: SoCRAmail@aol.com, Web site: www.socra.org.

Registration and Meeting Information: See SOCRA Web site, www.SoCRA.org. http://www.socra.org/html/FDA_Conference.htm. Registrations fees are as follows: $575.00 for SOCRA members; $650.00 for nonmembers (includes membership); $450.00 for Federal Government members; $525.00 for Federal Government nonmembers; FDA employee rate is fee-waived. The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. If you need special accommodations due to a disability, please contact Jane Kreis (see Contact Person) at least 10 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, institutional review board inspections, electronic record requirements, and investigator-initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting--Science, Regulation, Error, and Safety; (3) Part 11 Compliance--Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator-Initiated Research; (10) Medical Device Aspects

of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; and (12) The Inspection is Over--What Happens Next? Possible FDA Compliance Actions.

Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of continuing medical education (CME) and continuing nursing education (CNE) credit. CME for Physicians: The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. CNE for Nurses: Society of Clinical Research Associates is an approved provider of continuing nursing education by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission (ANCC) on Accreditation. ANCC/PSNA Provider Reference Number: 205-3-A-09.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government agencies to small businesses.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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