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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Detroit District Office, in co-sponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop. The public workshop 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 (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRB, and research sponsors.

Date and Time: The public workshop will be held on May 9 and 10, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Marriott Ann Arbor Ypsilanti at Eagle Crest, 1275 S. Huron St., Ypsilanti, MI 48197, 800-606-7044.

Contact: Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 1-800-762-7292 or 215-822-8644, FAX: 215-822-8633, email: SoCRAmail@aol.com, Web site: http://www.SoCRA.org. (FDA has verified the Web site

addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.); or Nancy Bellamy, Food and Drug Administration, Detroit District Office, 300 River Pl., Suite 5900, Detroit, MI 48207, 313-393-8143, FAX: 313-393-8139, email: nancy.bellamy@fda.hhs.gov.

Accommodations: Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $119 plus applicable taxes (available until April 17, 2012 or until the SoCRA room block is filled).

Cost of Registration

SoCRA member	$575
SoCRA nonmember (includes membership)	$650
Federal Government member	$450
Federal Government nonmember	$525
FDA Employee	(free) Fee Waived

If you need special accommodations due to a disability, please contact SoCRA (see Contact) at least 21 days in advance. Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this educational activity for a maximum of 13.3 Continuing Education Credits for SoCRA CE and Nurse CNE. SoCRA designates this live activity for a maximum of 13.3 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. CME for Physicians: SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. CNE for Nurses: SoCRA 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 on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205-3-A-09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to "SoCRA". Mail to: SoCRA (see Contact for address). To register via the

Internet, go to http://www.socra.org/html/FDA_Conference.htm. Payment by major credit card is accepted (Visa/ MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SoCRA (see Contact).

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, IRB 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; (12) The Inspection is Over--What Happens Next? Possible FDA Compliance Actions; (13) Ethical Issues in Subject Enrollment; (14) Medical Device Aspects of Clinical Research); (15) Are We There Yet? An Overview of the FDA GCP Program.

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 public 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 public 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: _February 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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