DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Society of Clinical Research Associates—Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Educational Conference Co-Sponsored With the Society of Clinical Research Associates (SoCRA).'' The public workshop regarding 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; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRBs, and research sponsors.

Date and Time: The public workshop will be held on May 21 and 22, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Sheraton Indianapolis at Keystone Crossing, 8787 Keystone Crossing, Indianapolis, IN 46240, 317–846–2700.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $109.00 plus applicable taxes (available until April 20, 2014, or until the SoCRA room block is filled).

Contact: Myra K. Casey, Food and Drug Administration, 101 West Ohio St., Suite 500, Indianapolis, IN 46204, 317–226–6500, ext. 104; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: *SoCRAmail@aol.com*.

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows: SoCRA member, $575.00; SoCRA nonmember (includes membership), $650.00; Federal Government member, $450.00; Federal Government nonmember, $525.00; and 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 education activity for a maximum of 13.3 Continuing Education (CE) Credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education 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 accredited as a provider of CNE by the American Nurses Credentialing Center's Commission on Accreditation.

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*. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document is published in the **Federal Register**).

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on registration, or for questions on the public 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 public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements on related informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with FDA: Why, When and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

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 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-day Comment Request; Incident HIV/Hepatitis B Virus Infections in South African Blood Donors: Behavioral Risk Factors, Genotypes and Biological Characterization of Early Infection

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of