

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Certifier A. P. Kelly

Industry Exchange Workshop on FDA Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Detroit District, in cooperation with the Society of Clinical Research Associates, (SoCRA) is announcing a workshop on FDA clinical trial statutory and regulatory requirements. Topics for discussion include: Pre-IND (investigational new drug application) meetings and FDA meeting process, medical device, drug and biological product aspects of clinical research, investigator initiated research, informed consent requirements, adverse event reporting, how FDA conducts bioresearch inspections, ethics in subject enrollment, FDA regulation of Institutional Review Boards, FDA and confidence in the conduct of clinical research, and what happens after the FDA inspection. This 1 1/2-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, April 21, 2004 from 8:30 a.m. to 4:45 p.m. and Thursday, April 22, 2004, from 8:45 a.m. to 12:30 p.m.

Location: The public workshop will be held at the Livonia, Michigan Holiday Inn, 17123 Laurel Park Dr. North, Livonia, MI 48152.

Contact: Nancy Bellamy, FDA, 300 River Pl., suite 5900, Detroit, MI 48207, 313-393-8143, FAX: 313-393-8139, e-mail nbellamy@ora.fda.gov or Marie Falcone, Industry and Small Business Representative, FDA, rm. 900 U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215-597-2120, ext. 4003, FAX: 215-597-5798, e-mail: mfalcone@ora.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and \$485 (member) or \$560 (non-member) registration fee made payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to http://www.socra.org/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**.

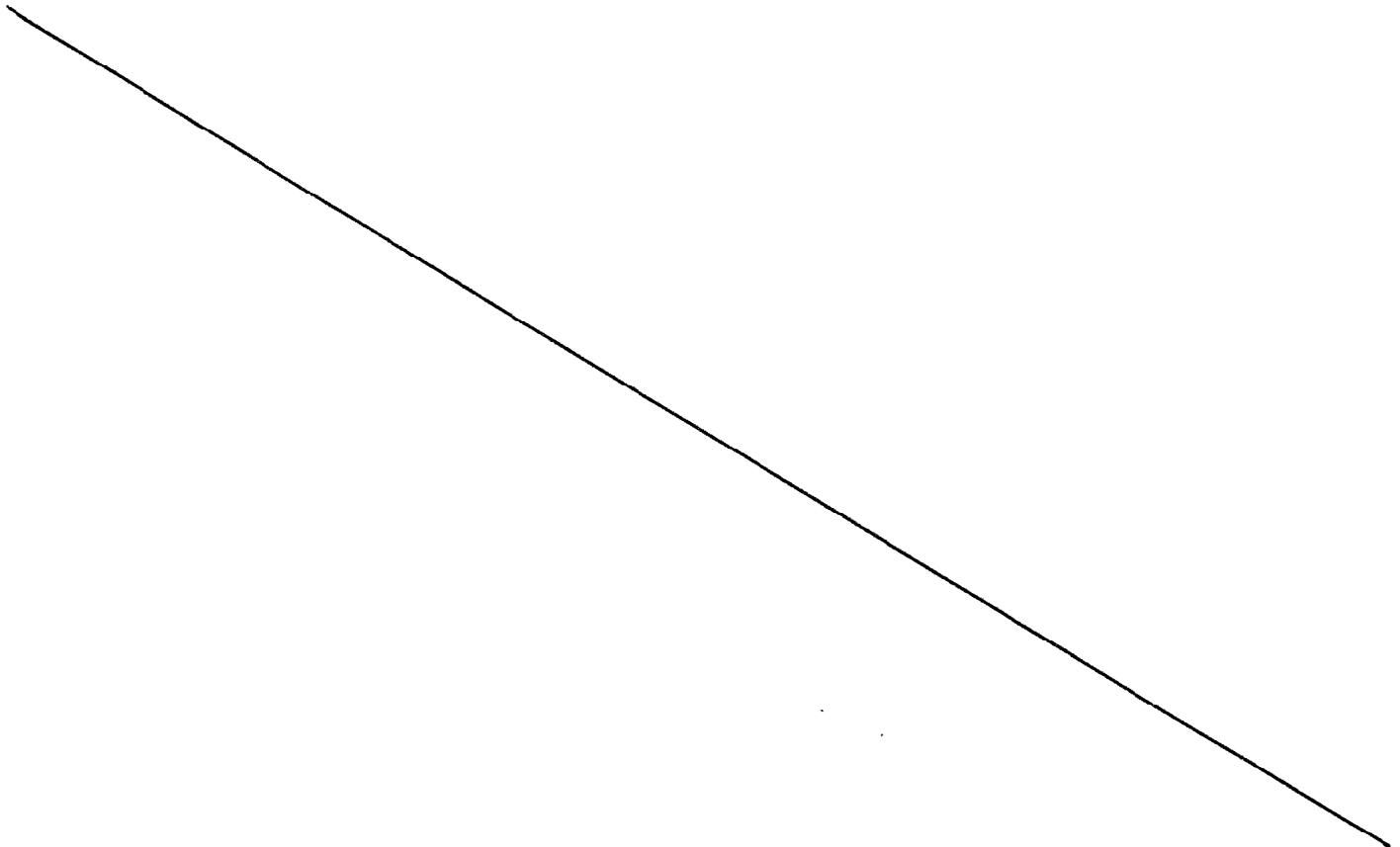
Registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800-762-7292), or 215-345-7369 or via e-mail to socramail@aol.com. Attendees are responsible for their own accommodations. To make reservations at the Holiday Inn Livonia at the reduced conference rate, contact the Holiday Inn at 734-464-1300 or at hotel FAX: 734-464-1596 before March 23, 2004.

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 Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The “FDA Clinical Trials Statutory and Regulatory Requirements” workshop 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. 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

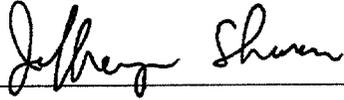


goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

MAR 5 2004

Dated: _____

March 5, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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