

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

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**SUMMARY:** The Food and Drug Administration (FDA) Pacific Region, 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 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, January 12, 2005, from 8:15 a.m. to 4:15 p.m. and Thursday, January 13, 2005, from 8:15 a.m. to 4 p.m.

*Location:* The public workshop will be held at the Holiday Inn Fisherman's Wharf, 1300 Columbus Ave., San Francisco, CA 94133, 415-771-9000, FAX: 415-771-7006.

*Contact:* Marcia Madrigal, Small Business Representative, FDA, 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217, FAX: 510-637-3977, e-mail: *marcia.madrigal@fda.gov*.

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$485 (member) or \$560 (nonmember), \$460 (government employee nonmember) (includes a 1 year membership). The registration fee for FDA employees is waived. Make the registration fee 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**.)

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 215-345-7369 or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Holiday Inn Fisherman's Wharf, at the reduced conference rate, contact the Holiday Inn (see *Location*) before December 21, 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 Marcia Madrigal 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.

Dated: November 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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