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.

SUMMARY: The Food and Drug Administration (FDA) Chicago District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. 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 May 16, 2007, from 8:30 a.m. to 5 p.m. and May 17, 2007, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Oak Brook Hills Marriott Resort, 3500 Midwest Rd., Oak Brook, IL 60523, 630–850–5555, FAX: 630–850–5569.

Contact: Marie Falcone, Food and Drug Administration, U.S. Customhouse, 200 Chestnut St., rm. 900, Philadelphia, PA 19106, 215–717–3703, FAX: 215–597–5798, e-mail: *marie.falcone@fda.hhs.gov.*

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575

(member), $650 (nonmember), or $525 (Federal Government employee nonmember). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA, 18914. To register via the Internet go to *www.socra.org* (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 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Oak Brook Hills Marriott Resort, at the reduced conference rate, contact the Oak Brook Hills Marriott Resort (see *Location*) before April 24, 2007, citing meeting code SCRSCRA. 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 (see *Contact*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The workshop on FDA clinical trials statutory and regulatory requirements 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. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical

research; (2) medical device, drug, biological and food product aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections; and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to ensure 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: March 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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