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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Food and Drug Administration/Industry Exchange Conference and Workshop on
Clinical Trial Requirements; Public Workshop**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, and Center for Devices and Radiological Health, in cooperation with the Pharmaceutical Quality Institute (PQI) is announcing a conference entitled "Clinical Trials 2000." The conference concerns FDA's requirements for the conduct of clinical trials in support of new drug applications, abbreviated new drug applications, biologics license applications, premarket approval applications, and 510(k) product marketing applications. The conference is targeted towards those individuals engaged in patient recruitment for clinical trials; and those conducting, recording, reporting, and overseeing clinical trials including clinical investigators, supporting medical staff, institutional review board members, testing laboratories, software developers, sponsors, monitors, and contract research organizations.

Date and Time: Thursday, October 5, 2000, 8:30 a.m. to 4:45 p.m. and Friday, October 6, 2000, 8:30 a.m. to 12 noon.

Location: Doubletree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact:

For information regarding this notice, workshop content, and who should attend: Diann

Shaffer, Food and Drug Administration, Baltimore District, 900 Madison Ave., Baltimore, MD 21201-2199, 410-962-3590, FAX 410-962-2219 or e-mail: dshaffer@ora.fda.gov.

For registration information: Satish K. Laroia, Registrar, PQI, 33 Aspen Circle, Edison, NJ 08820, 973-812-9033, FAX 732-549-7487. As an alternative, the registration form and agenda can also be obtained from the Internet at www.fda.gov/cder/calendar/meeting/Clintrials2000.

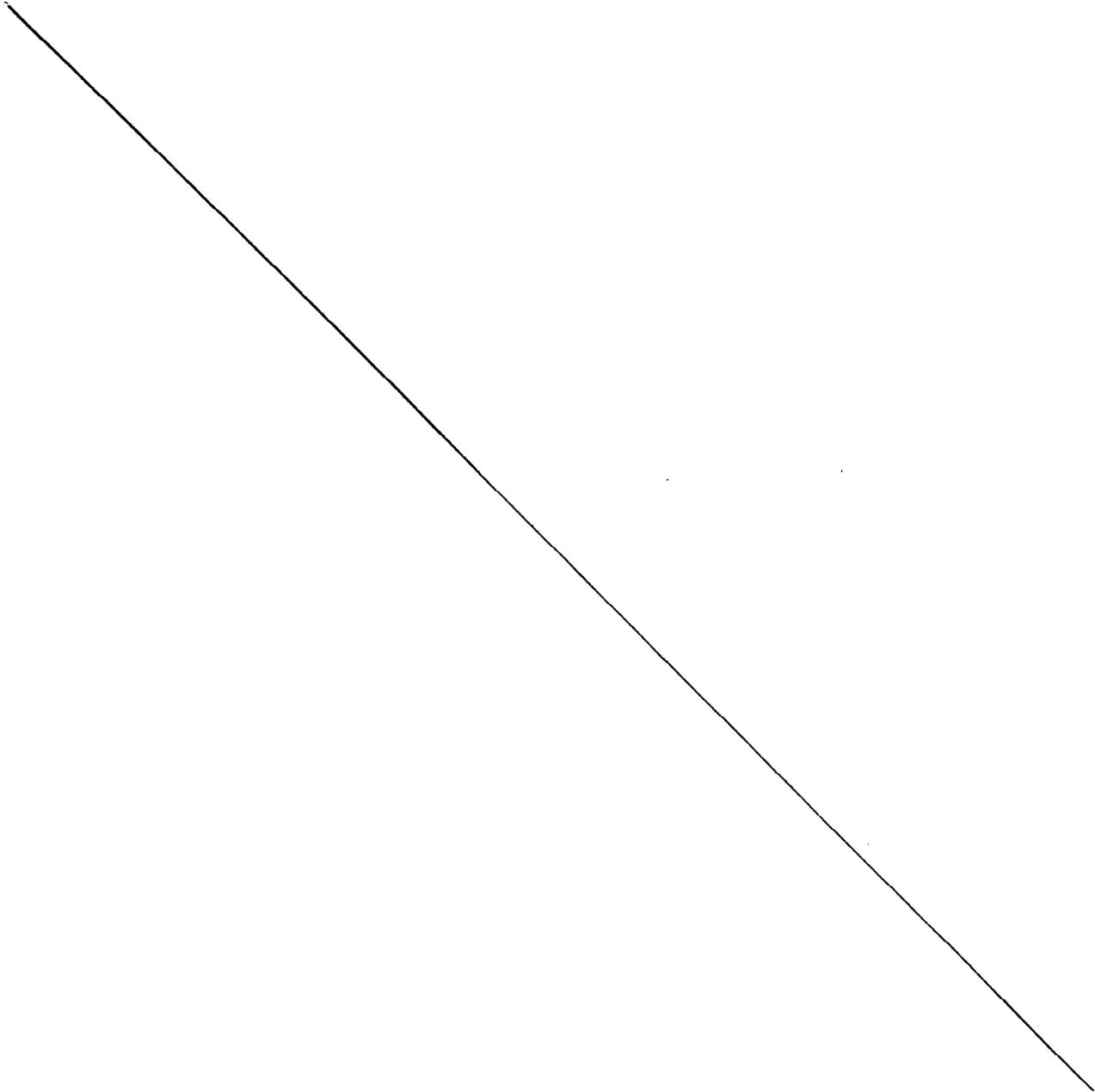
Registration: The full conference and workshop registration fee is \$349, or \$325 each for three or more from the same affiliation registering at the same time. The fee includes breakfast on both days, all refreshment breaks, and lunch on the first day, and conference materials. One-day registration is also available (see registration form for details). For registration forms and other registration details contact Satish K. Laroia (address above). As an alternative, the registration form and agenda can be obtained from the Internet at www.fda.gov/cder/calendar. Registration is due by September 25, 2000. Space is limited, therefore, interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. Persons needing hotel rooms at the Doubletree Hotel should call 301-468-1100 or 800-222-TREE and mention that they are attending the FDA/PQI workshop. A special rate is available until September 13, 2000, or until the room block is exhausted, whichever comes first.

If you need special accommodations due to a disability, please contact PQI at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshops are designed to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) and discussed in the FDA Plan for Statutory Compliance, which include working more closely with stakeholders; maximizing the availability of, and clarifying information about the process for generating data for review and submissions; and ensuring access to needed scientific and technical expertise.

The workshops also are consistent with the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), as outreach activities by Government agencies directed to small businesses.

The topics to be discussed include the following: (1) Overview and direction of FDA programs for regulating clinical research involving human drugs, biologics, and medical devices; (2) Anatomy of an FDA clinical investigator inspection; (3) What happens after an FDA inspection; (4) Clinical equipoise and recruitment for clinical trials; (5) Human subject protection; (6) Institutional review boards; (7) Special requirements for the Department of Health and Human Services funded studies; (8) Modification of FDA's Privacy Act systems notice; (9) Effective contract research organization-sponsor partnerships; (10) Industry perspective in case studies on contract research organization—



sponsor partnerships; (11) Gene therapy products; (12) Cellular product studies; (13) Fraud within clinical trials; (14) Preparing for an FDA audit; (15) Computerized systems used in clinical trials; and (16) Providing regulatory submissions in electronic format.

Dated: August 11, 2000



William K. Hubbard,
Senior Associate Commissioner
for Policy, Planning, and Legislation.

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