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Dissemination Date	3-25-99
Approval Date	3-26-99
Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Changing Times; Clinical Trial Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Southeast Region, is announcing the following meeting: "Changing Times: Clinical Trial Regulations, Clinical Investigators and IRB's Learning to Cope." The topic to be discussed is FDA regulatory requirements for the conduct of clinical studies and practical issues such as how clinical investigators and Institutional Review Boards can cope with the regulatory process, how to prepare for a data audit, what to expect during an inspection, and how to get current information from FDA.

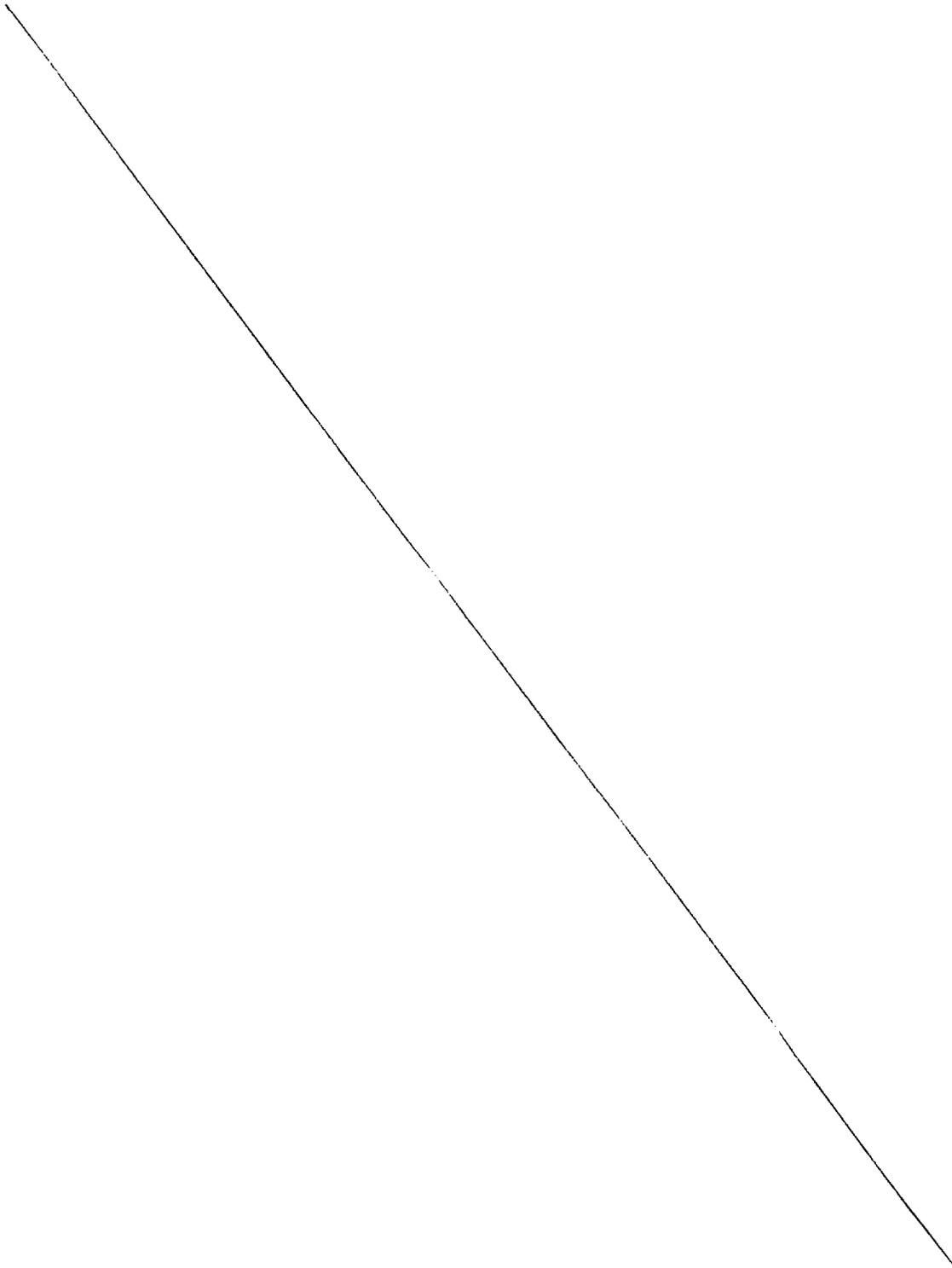
Date and Time: The meeting will be held on Friday, April 30, 1999, from 8 a.m. to 6 p.m.

Location: The meeting will be held at the Veterans Administration Medical Center Auditorium (2d floor), 1201 NW. 25th St., Miami, FL 33125.

Contact: Luz I. Collado, Food and Drug Administration, HFR-SE2575, P.O. Box 59-2256, Miami, FL 33159, 305-526-2800, ext. 926, or Brunilda Torres, Food and Drug Administration, Florida District, HFR-SE250, 407-475-4718, FAX 407-475-4768.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Gloria Allington, Director, University of Miami School of Medicine, Division of Continuing Medical Education, 1500 NW. 12th Ave., Miami, FL 33136, 305-243-6716, FAX 305-243-5613. Attendance will be limited to the first 200 applicants, therefore, interested parties are encouraged to register early. A \$100 registration fee is being charged by the University of Miami School of Medicine to help cover costs of materials, breakfast, box

lunches, and beverages for breaks. A discounted registration fee of \$90 is being offered to those who register by Thursday, April 1, 1999.



If you need special accommodations due to a disability, please contact Gustavo Godoy, Executive Director and Administrative Officer for R&D, VA Medical Center, 1201 NW. 16th St., Miami, FL 33125, 305-324-3179, FAX 305-324-3126, at least 7 days in advance.

Dated: March 19, 1999

March 19, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



William K. Hubbard
Acting Deputy Commissioner for Policy

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F"