DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01D–0489]

Draft FDA Guidance on the Establishment and Operation of Clinical Trial Data Monitoring Committees; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH), is announcing the following public meeting: Draft FDA Guidance on the Establishment and Operation of Clinical Trial Data Monitoring Committees (DMCs). The topics to be discussed are addressed in the draft entitled "Guidance for Clinical Trial Sponsors On the Establishment and Operation of Data Monitoring Committee." These topics include: The history of DMCs, the types of clinical trials in which DMCs are most important, DMC membership and operations, independence of DMCs, and the regulatory requirements relevant to DMCs.

Date and Time: The meeting will be held on November 27, 2001, from 9 a.m. to 5 p.m.

Location: The meeting will be held at The Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3841, FAX 301–827–3843, or e-mail: Whelan@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), to Melanie Whelan (address above) by November 20, 2001. We encourage early registration because seating is limited. There is no registration fee.

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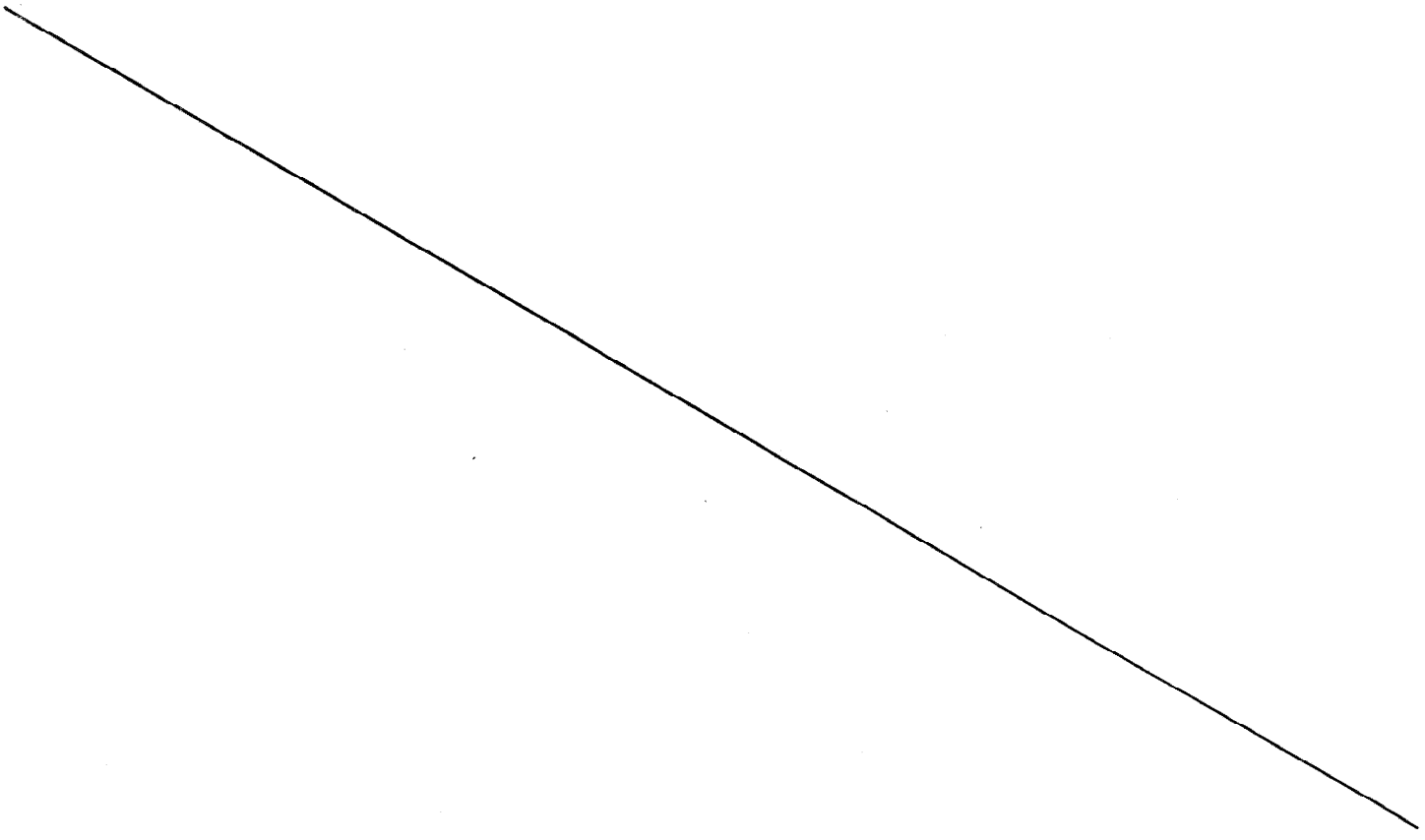
If you need special accommodations due to a disability, please contact Melanie Whelan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This meeting will provide a forum for all members of the public to express their opinions and suggestions on the draft entitled "Guidance for Clinical Trial Sponsors On the Establishment and Operation of Data Monitoring Committees." The draft guidance is intended to address scientific, ethical, and practical issues related to the establishment and operation of DMCs for clinical trials. The meeting will be of primary interest to sponsors of clinical trials evaluating FDA-regulated products. The objectives of the meeting are to: (1) Present the material in the draft guidance document and (2) solicit your comments and recommendations on the draft guidance document. The draft guidance will be announced in the **Federal Register** for public comment and posted on the Internet at http://www.fda.gov/cber/guidelines.htm.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane,



Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The public meeting transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 10/30/01
October 30, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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