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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 5, 1999, 8:30 a.m. to 5:30 p.m. (this notice is for the second day of a 2-day meeting).

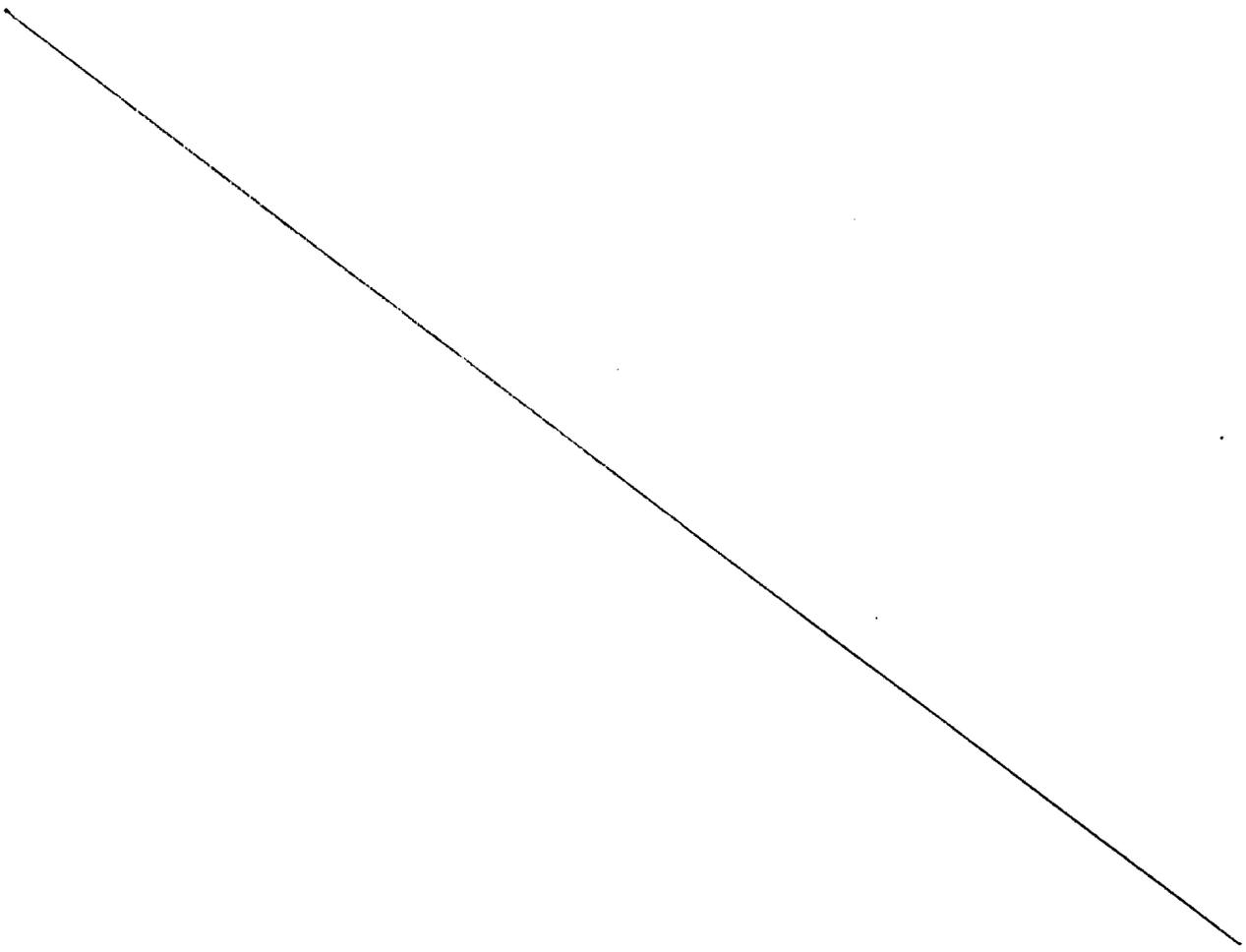
Location: Corporate Bldg., conference rm. 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss postmarketing studies of Genzyme Corporation's Carticel (autologous chondrocytes manipulated ex-vivo for structural repair) indicated for treatment and repair of clinically significant, articular cartilage defects in the knee. The discussion will focus

on issues specific to these studies and on more general ones related to the feasibility of randomized controlled trials in the field of orthopaedics.

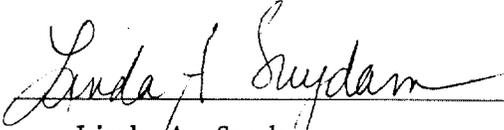
Procedure: On November 5, 1999, from 8:30 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 1, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. and between approximately 1:00 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: October 12, 1999



Linda A. Suydam
Senior Associate Commissioner

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

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