

*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. 99-27154 Filed 10-18-99; 8:45 am]

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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.  
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*ACTION:* Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed 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 4, 1999, 9 a.m. to 4:30 p.m.

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

*Contact Person:* Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, 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:* On November 4, 1999, the committee will discuss and make recommendations on the reclassification of constrained total hip arthroplasty devices. The committee will also discuss the development of computer controlled surgical systems designed for use in orthopaedic procedures.

*Procedure:* On November 4, 1999, from 9 a.m. to 3 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 October 29, 1999. On November 4, 1999, oral presentations from the public regarding the reclassification of constrained total hip arthroplasty devices and the development of computer controlled surgical systems designed for use in orthopaedic procedures will be scheduled between approximately 11 a.m. and 11:30 a.m. and between

approximately 2:30 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by October 29, 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.

*Closed Presentation of Data:* On November 4, 1999, from 3 p.m. to 4 p.m., the meeting will be closed to permit a sponsor to present to the committee trade secret and/or confidential commercial information on a clinical study design. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

*Closed Committee Deliberations:* On November 4, 1999, from 4 p.m. to 4:30 p.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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. 99-27158 Filed 10-18-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Vaccines and Related Biological Products 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). Portions of the meeting will be closed to the public.

*Name of Committee:* Vaccines and Related Biological Products 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 4, 1999, 8 a.m. to 6