

development, and (5) delineation of the key features of informed consent for patients who have received a porcine xenograft and who undergo screening for porcine endogenous retrovirus.

Procedure: On December 17, 1997, from 9 a.m. to 11:30 a.m., and 12 m. to 6 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 December 10, 1997. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 10, 1997, 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 Committee Deliberations: On December 17, 1997, from 11:30 a.m. to 12 m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The meeting will be closed to discuss current investigational new drug application submissions under FDA review.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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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). 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 regulatory issues.

Date and Time: The meeting will be held on December 11, 1997, 9 a.m. to 8 p.m., and December 12, 1997, 8 a.m. to 2 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Jodi H. Nashman, 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 December 11, 1997, the committee will discuss, make recommendations, and vote on one premarket approval application (PMA) for a spinal intervertebral fusion device. Additionally, there will be a general discussion of the minimum acceptable length of patient followup for marketing approval of spinal implant devices. On December 12, 1997, the committee will discuss, make recommendations, and vote on a PMA for an anti-adhesion barrier gel.

Procedure: On December 11, 1997, from 9 a.m. to 8 p.m., and on December 12, 1997, from 9 a.m. to 2 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 December 3, 1997. Oral presentations from the public regarding spinal intervertebral fusion systems and devices will be scheduled between approximately 9 a.m. and 10 a.m., on December 11, 1997. Oral presentations from the public regarding anti-adhesion barrier gels will be scheduled between 9 a.m. and 10 a.m., on December 12, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 1997, 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 Committee Deliberations: On December 12, 1997, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding present and future FDA issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 18, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on December 4, 1997, 8 a.m. to 5 p.m.

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

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Procedure: On December 4, 1997, from 8 a.m. to 9 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues appropriate for the committee. Written submissions may be made to the contact person by December 3, 1997. Oral presentations from the public will be scheduled between 8 a.m. and 9 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 1997, 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.