

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.

[FR Doc. 97-30910 Filed 11-24-97; 8:45 am]

BILLING CODE 4160-01-F

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.

[FR Doc. 97-30914 Filed 11-24-97; 8:45 am]

BILLING CODE 4160-01-F

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.

FDA regrets that it was unable to publish this notice 15 days prior to the December 4, 1997, Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Circulatory System Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Closed Committee Deliberations: On December 4, 1997, from 9 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information on a product development protocol. 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: November 20, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-31064 Filed 11-21-97; 11:12 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, December 4, 1997, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. to adjournment. The topics proposed for discussion include: (1) Center for Scientific Review; (2) Report from the Clinical Research Panel; (3) New Investigator Awards, Modular Awards, and Clinical Research Training; (4) Report from the Working Group on Research Tools; (5) Implementation of the Government Performance and Results Act; and (6) Report on the Review of Administrative Functions at NIH. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Special Assistant to the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892-0159, telephone (301) 496-0959, fax (301)

496-7451, will furnish the meeting agenda, roster of committee members, and available substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than November 26, 1997.

Dated: November 18, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-30931 Filed 11-24-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of Public Law 92-463, as amended, notice is hereby given of a meeting of the President's Cancer Panel, National Cancer Institute. This meeting will be closed to the public in accordance with the provisions set forth in sec. 552b(c)(9)(B), Title 5, U.S.C. The purpose of this meeting is to plan the 1997 Final Report of the Chairman to the President and to set agendas for the upcoming 1998 panel meetings. Premature disclosure of the specific details of these discussions and recommendations would be likely to significantly frustrate the subsequent implementation of the proposed recommendations made by the Panel.

Linda Quick-Cameron, Committee Management Officer, National Cancer Institute, Executive Plaza North, Room 609, 6130 Executive Blvd., MSC 7410, Bethesda, MD 20892-7410 (301) 496-5708 will provide a copy of the roster of committee members upon request. Other information pertaining to the meeting may be obtained from the contact person indicated below.

Committee Name: President's Cancer Panel.

Date: December 1, 1997.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814.

Closed: 10:30 a.m. to Adjournment.

Agenda: Discussion and preparation of the 1997 Final Report of the Chairman to the President and set agendas for the 1998 meetings.

Contact Person: Maureen O. Wilson, Ph.D., Executive Secretary, National Cancer Institute, Building 31, Room 4A48, 9000 Rockville Pike, MSC 2473,

Bethesda, MD 20892-2473, Telephone: (301) 496-1148.

Dated: November 6, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-30926 Filed 11-24-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting of the National Cancer Advisory Board and Its Subcommittees

Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given of the meeting of the National Cancer Advisory Board (Board), National Cancer Institute (NCI), and its Subcommittees on December 2-3, 1997. The meetings of the Board and its Subcommittees will be open to the public as indicated below. Attendance by the public will be limited to space available.

A portion of the Board meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 U.S.C. and section 10(d) of the Federal Advisory Committee Act, as amended, for discussions pertaining to NCI personnel and programmatic issues. These discussions could reveal information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy and would be likely to significantly frustrate the subsequent implementation of personnel and programmatic recommendations made during these discussions.

The Committee Management Office, National Cancer Institute, National Institutes of Health, Executive Plaza North, Room 609, 6130 Executive Boulevard, MSC 7410, Bethesda, Maryland 20892-7410, (301) 496-5708 will provide summaries of the meetings and rosters of the Board members, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mrs. Linda Quick-Cameron, Committee Management Officer, at (301) 496-5708 in advance of the meeting.

Name of Committee: National Cancer Advisory Board.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Room