proprietary, continuous flow immunoadsorption technique. Bone marrow cells are harvested, fractionated for recovery of the buffy-coat and incubated with biotinylated murine anti-CD34 monoclonal antibody which selectively binds CD34+ cells. After incubation, the cells are washed to remove excess, unbound antibody and then processed through the CEPRATE® SC System. After processing through the CEPRATE® SC System, the CD34+ enriched population of autologous bone marrow cells are reinfused into the patient.

On December 6, 1996, CBER approved the application by a letter to the applicant from the Director of the Office of Therapeutics Research and Review, CBER.

In the December 6, 1996, approval letter the expiration dating period for the anti-human CD34 biotinylated antibody (murine) was approved at 18 months when stored at -70 ℃. An expiration dating period for all other components of the CEPRATE® SC Disposables Kit was approved for 12 months when stored at the appropriate temperatures. FDA received a submission from CellPro, Inc., dated December 12, 1996, in support of extending the expiration dating period for the remaining components of the CEPRATE® SC System from 12 months to 18 months. On February 19, 1997, FDA approved the 18-month expiration dating period for all components of the CEPRATE® SC System except for the Roswell Park Memorial Institute cell culture medium, which has an approved expiration dating period of 16 months.

FDA has determined that the sale, distribution, and use of the CEPRATE® SC System is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)). FDA has also determined that to ensure the safe and effective use of the device, the CEPRATE® SC System is further restricted within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act insofar as: (1) The labeling specifies the requirements that apply to the training of practitioners who may use the device; and (2) the sale, distribution, and use must not violate section 502(q) and (r) of the act (21 U.S.C. 352(q) and (r)).

A summary of the safety and effectiveness data on which CBER based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CBER's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CBER's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 27, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.53).

Dated: April 17, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–10720 Filed 4–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 the Committee: Veterinary Medicine Advisory Committee.

General Function of the Committee: Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

Date and Time: The meeting will be held on May 13 and 14, 1997, 8:30 a.m. to 4:30 p.m. Open public hearing portions are scheduled from 2:30 p.m. to 3:30 p.m. on May 13, 1997, and from 1 p.m. to 2 p.m. on May 14, 1997.

Location: Holiday Inn—Gaithersburg, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Jacquelyn L. Pace, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5920, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 13, 1997, the committee will discuss veterinary medical issues related to the quality standards for the manufacture of animal drugs, such as current good manufacturing practices. On May 14, 1997, the committee will discuss topics concerned with the Animal Drug Use Clarification Act, specifically, the part of the regulation that permits extralabel use where a drug is clinically ineffective.

Procedure: 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 May 7, 1997. Those desiring to make formal presentations should notify the contact person before May 7, 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.

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

Dated: April 21, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–10780 Filed 4–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Notice of Meeting of the Fogarty International Center Advisory Board

Pursuant to Pub. L. 92–463, as amended, notice is hereby given of the thirty-sixth meeting of the Fogarty International Center (FIC) Advisory Board, May 20, 1997, in the Lawton Chiles International House (Building 16) at the National Institutes of Health. The Research Awards Subcommittee will meet on May 19 in the FIC Conference Room, Building 31, Room B2C07, from 1 p.m. to approximately 4 p.m., and will be closed to the public.

The meeting of the Board will be open to the public from 8:30 a.m. to approximately 12 noon.

The agenda will include a report by the Director, FIC; a report on the implementation of the AIDS International Training and Research Program Review; presentations by grantees under the International Training and Research Program in Population and Health and the International Training and Research Program in Environmental and Occupational Health; and a presentation by Dr. Christopher Murray, Associate Professor of International health Economics, Harvard School of Public Health, on the Global Burden of Disease Study.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code and section 10(d) of Pub. L. 92–463, as amended, the entire meeting of the Research Awards Subcommittee will be closed to the public from 1 p.m. to approximately 4 p.m., and the Board meeting on May 20 will be closed to the public from 1 p.m. to adjournment for the review of applications for awards under the Senior International Fellowship Program and the International Research Fellowship Program; and the Fogarty International Research Collaboration Awards and HIV, AIDS, and Related Illnesses Collaboration Awards.

Paula Cohen, Committee Management Officer, Fogarty International Center, National Institutes of Health, Building 31, Room B2C08, 31 Center Dr MSC 2220, Bethesda, Maryland 20892–2220, telephone: 301–496–1491, will provide a summary of the meeting and a roster of the committee members upon request.

Irene Edwards, Executive Secretary, Fogarty International Center Advisory Board, Building 31, Room B2C08, telephone: 301–496–1491, will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Cohen at least 2 weeks in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.989, Senior International Fellowship Awards Program, and 93.934, Fogarty International Research Collaboration Award)

Dated: April 18, 1997.

LaVeen Ponds,

Acting Committee Management Officer, NIH.

[FR Doc. 97–10757 Filed 4–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Eye Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Clinical Research.
Date: May 1, 1997.
Time: 9:00 a.m.
Place: National Eye Institute, Executive Plaza South, Suite 350, 6120 Executive Blvd., Bethesda, MD 20892–7164.
Contact Person: Andrew P. Mariani, Ph.D., Executive Plaza South, Room 350, 6120 Executive Blvd., Bethesda, MD 20892–7164, (301) 496–5561.
Purpose/Agenda: Review of Grant Applications.

The meeting will be closed in accordance with provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program No. 93.867, Vision Research: National Institutes of Health)

Dated: April 18, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–10755 Filed 4–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Heart, Lung, and Blood Institute Special Emphasis Panel (SEP) meetings:

Name of SEP: Stage and Tissue Specific Animal Models of Hemophilia (Telephone Conference Call).
Date: April 30, 1997.
Time: 11:00 a.m.
Place: Two Rockledge Center, Room 7184, 6701 Rockledge Drive, Bethesda, Maryland 20892.
Contact Person: Ivan C. Baines, Ph.D., Two Rockledge Center, Room 7184, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0277.
Purpose/Agenda: To review and evaluate contract proposals.

Name of SEP: Research Program: Exercise to Prevent Cardiovascular Disease.
Date: May 12–13, 1997.
Time: 7:30 p.m.
Place: Holiday Inn Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, Maryland 20814.
Contact Person: Anthony M. Coelho, Jr., Ph.D., Two Rockledge Center, Room 7194, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0288.
Purpose/Agenda: To review and evaluate grant applications.

This notice is being published less than fifteen days prior to the above meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of SEP: Review of the Institutional National Research Service Award (T32s), Independent Scientist Award (K02s) and the Mentored Clinical Scientist Development Award (K08s) Applications.
Date: June 16–17, 1997.
Time: 8:00 a.m.
Place: Woodfin Suite Hotel, 1380 Piccard Drive, Rockville, Maryland 20850.
Contact Person: S. Charles Seldon, Ph.D., Two Rockledge Center, Room 7196, 6701