Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 31, 1997 (62 FR 41061), FDA announced that it would be holding a public hearing on September 12, 1997, concerning the requirements for the content and format of the pregnancy subsection of labeling for human prescription drugs. The public hearing was intended to elicit comments on the practical utility, effects, and limitations of the current pregnancy labeling categories in order to help the agency identify the range of problems associated with the categories and to identify and evaluate options that might address identified problems. Interested persons were given until November 12, 1997, to submit written comments on these issues. Because of the complexity and importance of the issues raised by pregnancy labeling, the Pharmaceutical Research and Manufacturers of America has requested an additional 60 days to prepare comments.

Interested persons may, on or before January 12, 1998, submit to the Dockets Management Branch (address above) written comments on this subject. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 97N–0289. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30561 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Subcommittee 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: Subcommittee meeting of the Antiviral Drugs Advisory Committee on immunosuppressive drugs.

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 January 14, 1998, 8:30 a.m. to 5 p.m.

Location: Quality Suites, Potomac Ballroom, Three Research Ct., Rockville, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 14, 1998, the subcommittee will discuss new drug application (NDA) 50–722, CellCept® (mycophenolate mofetil), Syntex, USA, Inc., for immunosuppression following cardiac transplantation.

Procedure: 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 January 7, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 7, 1998, 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: November 14, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–30705 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood 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). The meeting will be open to the public.

Name of Committee: Blood Products 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, 8 a.m. to 6 p.m., and December 12, 1997, 8 a.m. to 3:30 p.m.

Location: DoubleTree Hotel, Plazas I, II, and III, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 11, 1997, the committee will discuss and provide recommendations on the issue of FDA's donor deferral policy regarding men who have had sex with another man even one time since 1977.

On the morning of December 12, 1997, the committee will sit as a medical device panel and make recommendations on the issue of in vitro diagnostic detection of human immunodeficiency virus (HIV) viral load, sponsor, Roche Molecular Systems. In the afternoon, the Committee will hear an informational presentation on hepatitis C virus (HCV) risk in sexual partners of positive individuals.

Procedure: 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 1, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 4:30 p.m., on December 11, 1997, and between approximately 10 a.m. and 11 a.m. and 2 p.m. and 3 p.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 1, 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: November 14, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–30615 Filed 11-20-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Chemistry and Clinical Toxicology 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: Clinical Chemistry and Clinical Toxicology 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 10, 1997, 9:30 a.m. to 5 p.m.

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

Contact Person: Sharon K. Lappalainen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, ext. 144, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will provide advice and recommendations to the agency regarding a premarket approval application for a salivary estriol enzyme immunoassay that is to be used as a risk assessment marker for spontaneous preterm labor and preterm delivery.

Procedure: On December 10, 1997, from 10 a.m. to 5 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 will be scheduled between approximately 10 a.m. and 11 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.

Closed Committee Deliberations: On December 10, 1997, from 9:30 a.m. to 10 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)). FDA staff will present to the committee confidential information regarding pending or future submissions.

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. 97–30707 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs 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: Pulmonary-Allergy Drugs 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 15, 1997, 8 a.m. to 5 p.m.

Location: Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Committee will discuss the safety and efficacy of new drug application (NDA) 20–793, Cafcit™ (caffeine citrate injection, 10 milligram/milliliter), Roxane Laboratories, Inc., for intravenous or oral use in the treatment of apnea of prematurity.

Procedure: 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 5, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 5, 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: November 14, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–30616 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

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). At least one portion 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 regulatory issues.

Date and Time: The meeting will be held on December 4, 1997, 12:30 p.m. to 3:30 p.m.

Location: Food and Drug Administration, Bldg. 29, conference