Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcements 328, 432, and 461, and 641, as announced in Guidance and Consideration in Planning Application for Fiscal Year 1997.

Contact Person for More Information: James E. Barrow, Division of Adult and Community Health, NCCDPHP, CDC, 4770 Buford Highway, NE, M/S K30, Chamblee, Georgia 30345. Telephone 770/488–5269.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreements for Prevention Research Centers/ National Center for Chronic Disease Prevention and Health Promotion—General Special Interest Projects, Panel Number 5, Program Announcements 328, 432, 461, and 641.

Time and Date: 1 p.m.–5 p.m., July 11, 1997.

Place: National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), CDC, 4770 Buford Highway, NE, Atlanta, Georgia 30345.

Status: Closed.

Matters to Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcements 328, 432, 461, and 641, as announced in Guidance and Consideration in Planning Application for Fiscal Year 1997.

Contact Person for More Information: Jim Holt, Division of Adult and Community Health, NCCDPHP, CDC, 4770 Buford Highway, NE, M/S K30, Chamblee, Georgia 30341–3724. Telephone 770/488–5595.

These meetings will be closed to the public in accordance with provisions set forth in section 552b (c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Dated: June 10, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–15677 Filed 6–13–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members on Public Advisory Committees; Veterinary Medicine Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Veterinary Medicine Advisory Committee (the committee) in FDA's Center for Veterinary Medicine.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, the agency encourages nominations of appropriately qualified candidates from these groups.

DATES: No cutoff date is established for receipt of nominations.

ADDRESSES: All nominations for membership should be sent to Jacquelyn L. Pace (address below).

FOR FURTHER INFORMATION CONTACT: Jacquelyn L. Pace, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5920.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members to serve on the committee. The function of the committee is to review and evaluate available data concerning 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.

Criteria for Members

Persons nominated for membership on the committee shall have adequately diversified experience that is appropriate to the work of the committee in such fields as companion animal medicine, food animal medicine, avian medicine, microbiology, biometrics, toxicology, pathology, pharmacology, animal science, epidemiology and chemistry.

The specialized training and experience necessary to qualify the nominee as experts suitable for appointment are subject to review, but may include experience in medical practice, teaching, and/or research relevant to the field of activity of the committee. The term of office is 4 years.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the committee. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the committee, and appears to have no conflict of interest that would preclude committee membership. A current copy of nominee's curriculum vitae should be included. Potential candidates will be asked by FDA to provide detailed information concerning such matters as employment, financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: June 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15636 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0214]

Draft Guidance for Industry on Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.'' The draft guidance is intended for sponsors planning to conduct studies to assess the influence of renal impairment on the pharmacokinetics and pharmacodynamics of an investigational drug.

DATES: Written comments may be submitted on the draft guidance by August 15, 1997. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of ''Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug

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

FOR FURTHER INFORMATION CONTACT: Shiew-Mei Huang, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5671.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.''

The pharmacokinetics (PK) and pharmacodynamics (PD) of drugs primarily eliminated through the kidneys may be altered by impaired renal function to the extent that the dosage regimen needs to be changed from that used in patients with normal renal function. Although the most obvious type of change arising from renal impairment is a decrease in renal excretion (or possibly renal metabolism) of a drug or its metabolites, renal impairment also has been associated with other changes, such as changes in hepatic metabolism, plasma protein binding, and drug distribution. These changes may be particularly prominent in patients with severely impaired renal function and have been observed even when the renal route is not the primary route of elimination of a drug. Thus, for most drugs that are likely to be administered to patients with renal impairment, PK/PD characterization may need to be assessed in subjects with such impairment to provide appropriate dosing recommendations.

The draft guidance provides specific information on when studies of PK in patients with impaired renal function should be performed and when they may be unnecessary. It also addresses the design and conduct of PK/PD studies in patients with impaired renal function, the design and conduct of PK/PD studies in end stage renal disease (ESRD) patients treated with hemodialysis, the analysis and reporting of the results of such studies, and representation of these results in approved product labeling.

This draft guidance represents the agency's current thinking on conducting PK/PD studies on patients with impaired renal function. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guidance is available on the Internet using the World Wide Web (www) at http://www.fda.gov/cder/guidance.htm.

Dated: June 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–15635 Filed 6–13–97; 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 public advisory committees of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Joint meeting of the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on July 16, 1997, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Andrea G. Neal or Tracy Riley, 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), codes 12541 and 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss data submitted regarding the over-the-counter status of new drug application (NDA) 20-834, Rogaine® (minoxidil 5% topical solution), The Pharmacia & Upjohn Co. for use as a hair growth stimulant by men with androgenetic alopecia.

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 July 3, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 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 July 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.

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

Dated: June 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15632 Filed 6–13–97; 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 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 July 28, 1997, 9:30 a.m. to 6 p.m., and July 29, 1997, 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn—Gaithersburg, Walker/Whetstone Salons, Two Montgomery Village Ave., Gaithersburg, 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