

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**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance entitled "Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling."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The draft guidance provides specific information on when studies of PK in patients with impaired renal function should be performed and when they may be unnecessary.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This draft guidance represents the agency's current thinking on conducting PK/PD studies on patients with impaired renal function.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Interested persons may submit written comments on the draft guidance to the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.*

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## 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.*

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## 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