

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier	Nomani Ower

Cardiovascular and Renal 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: Cardiovascular and Renal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on August 9, 2001, from 8:30 a.m. to 5 p.m., and on August 10, 2001, from 8:30 a.m. to 3 p.m.

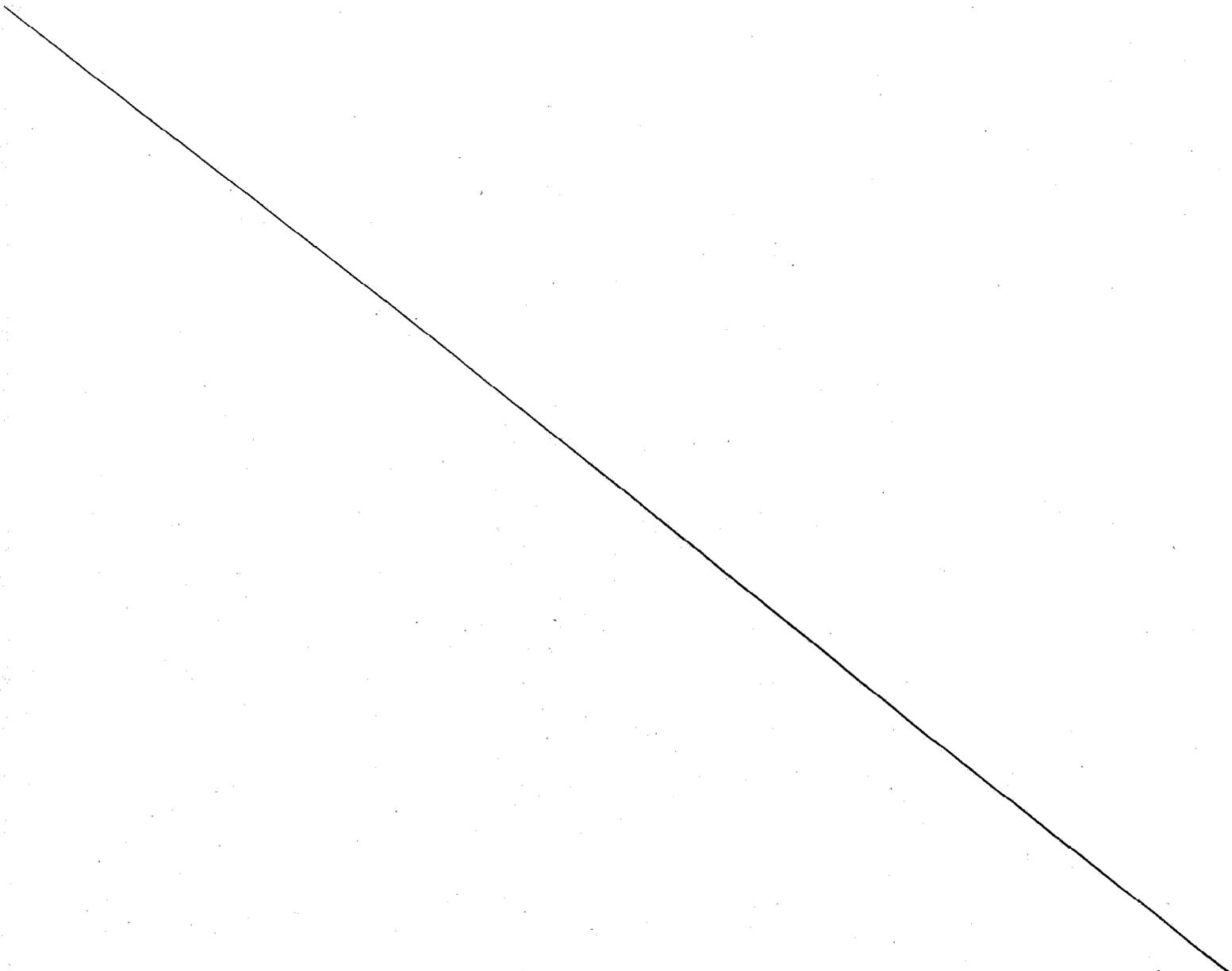
Location: National Institutes of Health, Jack Masur Auditorium, Bldg. 10, 9000 Rockville Pike, Bethesda, MD.

Contact: Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419-259-6211, or Jaime Henriquez, 301-827-6803, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 9, 2001, in the morning, the committee will discuss new drug application (NDA) 21-272, Remodulin® (treprostinil sodium injection), United Therapeutics Corp., for the treatment of pulmonary hypertension. On August 9, 2001, in the afternoon, the committee will discuss NDA 21-321, Extraneal® (7.5 percent icodextrin) peritoneal dialysis solution, Baxter

Healthcare Corp. On August 10, 2001, in the morning, the committee will discuss NDA 21-290, Tracleer® (bosentan tablets), Actelion, Ltd., for the treatment of pulmonary hypertension.

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 August 2, 2001. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. on each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 2, 2001, 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.

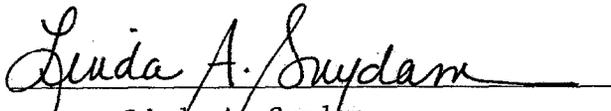


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 7-12-01
July 12, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL


Linda A. Suydam,
Senior Associate Commissioner.


Monique Oliver

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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