

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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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 May 24, 2001, from 8:30 a.m. to 5 p.m., and on May 25, 2001, from at 9 a.m. to 3:30 p.m.

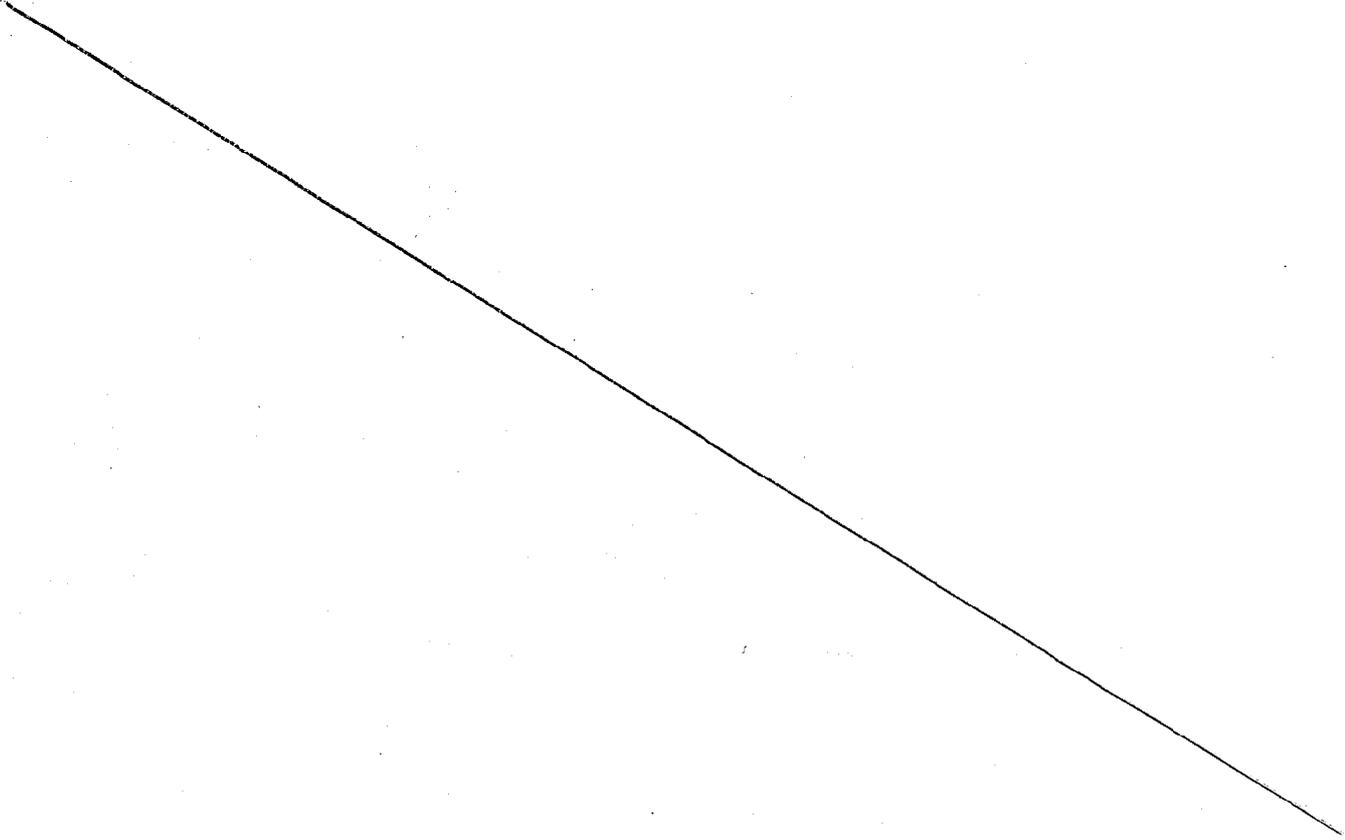
Location: National Institutes of Health (NIH), 9000 Rockville Pike, Bldg. 10, Clinical Center, Jack Masur Auditorium, Bethesda, MD.

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 John M. Treacy, 301-827-7001, 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 May 24, 2001, the committee will discuss: (1) Published interim analyses of ALLHAT (antihypertensive and lipid lowering treatment to prevent heart attack trial) sponsored by the National Heart, Lung, and Blood Institute, NIH, and (2) response to the citizen's petition of Lawrence D. Bernhardt and Arnold Liebman, regarding new drug application (NDA) 19-668,

Cardura® (doxazosin), Pfizer, Inc. On May 25, 2001, the committee will discuss NDA 20-920 Natrecor® (nesiritide), Scios, Inc., for treatment of acute heart failure.

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 May 18, 2001. 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 May 18, 2001, and submit a brief statement on 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: 4/11/01

April 11, 2001.

Linda A. Suydam

Linda A. Suydam,
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

[Signature]

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

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