

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

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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.

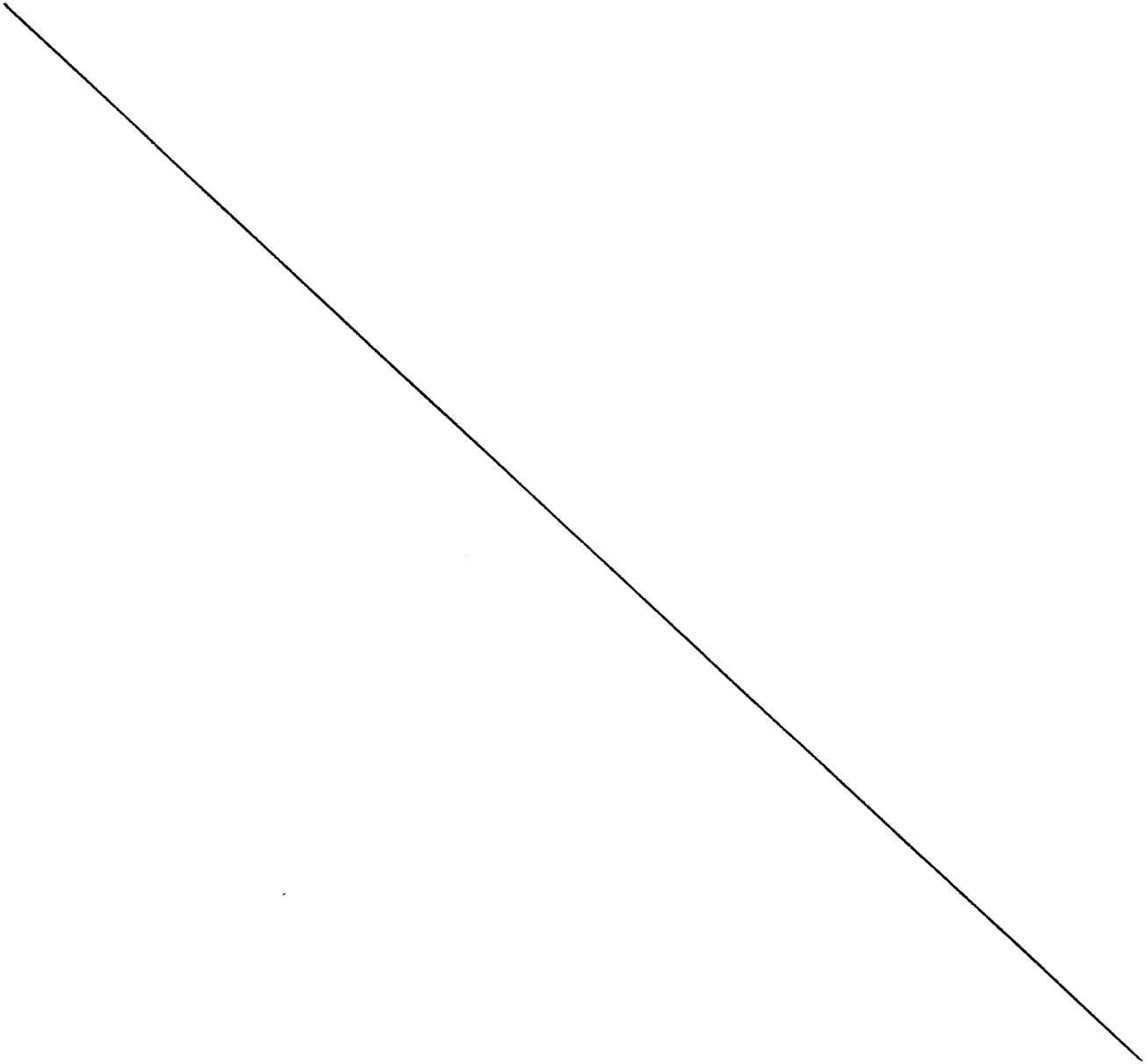
Date and Time: The meeting will be held on April 29, 1999, from 9 a.m. to 5:30 p.m., and on April 30, 1999, from 8:30 a.m. to 4 p.m.

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

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, or Lauren W. Parcover (HFD-21), 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 April 29, 1999, the committee will discuss new drug application (NDA) 19-865/S-007, Betapace® (sotalol), Berlex Laboratories, Inc., for prevention of the recurrence of chronic or paroxysmal symptomatic atrial fibrillation/atrial flutter. On April 30, 1999, the committee will discuss the interpretation of antiarrhythmic trials in patients with implanted ventricular defibrillators.

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 April 21, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 21, 1999, 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: March 26, 1999



Michael A. Friedman
Deputy Commissioner for
Operations

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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