

## 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.

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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 June 15 and 16, 2005, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Cathy Groupe, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, e-mail: [groupec@cder.fda.gov](mailto:groupec@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On June 15, 2005, the committee will discuss class labeling of antihypertensive drugs based on the proximity of their data to outcome trials.

On June 16, 2005, the committee will discuss new drug application (NDA) 20-727, proposed trade name BIDIL (hydralazine hydrochloride/isosorbide dinitrate) (tablets are 37.5 milligrams (mg) hydralazine hydrochloride/20 mg isosorbide dinitrate), NitroMed, Inc., proposed for the indication of heart failure, based on the results from the African American Heart Failure Trial.

*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 June 8, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 8, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Beverly O'Neil at 301-827-7001 at least 7 days in advance of the meeting.

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

Dated: April 28, 2005.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

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