

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.

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 September 21, 2006, from 8 a.m. to 5 p.m.

Location: Food and Drug Administration, CDER Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, 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, FAX: 301-827-6778, e-mail: Cathy.Groupe@fda.hhs.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: The committee will discuss clinical data for aprotinin injection (trade name, TRASYOL), an approved product, new drug application (NDA)

020–304, Bayer Pharmaceuticals) with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery. This discussion follows a February 8, 2006, FDA Public Health Advisory for the use of apportioning injection (www.fda.gov/cder/drug/advisory/aprotinin.htm). The background material for this meeting will be posted 1 business day before the meeting on FDA’s Website at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the heading “Cardiovascular and Renal Drugs Advisory Committee.” (Click on the year 2006 and scroll down to the above named committee meeting.)

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 on or before September 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 13, 2006.

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 John Luttman 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: July 18, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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