DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Products for Treatment of Rare Plasma Protein Disorders; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Office of Public Health and Science in the Department of Health and Human Services, are announcing a public workshop entitled ''Biological Products for Treatment of Rare Plasma Protein Disorders.'' The purpose of the workshop is to discuss the scientific and regulatory challenges encountered during the development of biological products used to treat rare plasma protein disorders. The workshop also will include a discussion about options that could be used to facilitate future product development.

Date and Time: The 2-day public workshop will be held on June 13 and June 14, 2005, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the National Institutes of Health, Lister Hill Auditorium, Building 38A, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–3514, FAX: 301–827–2843, email: *dawsonr@cber.fda.gov*.

Registration: There is no registration fee for the workshop. Registration by May 30, 2005, is recommended due to limited seating. There will be onsite registration, on a space available basis, the first day of the workshop, beginning at 7:15 a.m. If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: FDA and Office of Public Health and Science in the Department of Health and Human Services are co-sponsoring a 2-day public workshop entitled ''Biological Products for Treatment of Rare Plasma Protein Disorders.'' The opening session of the workshop will include presentations from national and international regulatory officials, patient groups, health care providers, and manufacturers concerning the need for therapeutic products to treat plasma protein disorders that may affect small patient populations, and the obstacles to developing these products. The second session of the workshop will include discussions about regulatory issues affecting industry, including trial designs, statistical considerations, orphan drug provisions, product development, and case studies. The last session of the workshop will include presentations and discussions on other relevant topics, including the availability and possible use of patient registries, research support, reimbursement, potentials for international harmonization, modifying clinical trial design, and facilitating future product development.

FDA will post the agenda for this public workshop, when finalized, on CBER's Web sites at *http://www.fda.gov/cber/scireg.htm* and *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (FOI), (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page. The transcript will also be placed on the FDA Web site at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: April 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 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*, 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.

[FR Doc. 05–9010 Filed 5–5–05; 8:45 am]

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