

Dated: April 1, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; 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: Advisory Committee for Pharmaceutical Science.

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 3 and 4, 2005, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, 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: scharenh@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 3, 2005, the committee will: (1) Receive an update from the Clinical Pharmacology Subcommittee and (2) discuss and provide comments on the general topic of establishing drug release or dissolution specifications. On May 4, 2005, the committee will: (1) Receive an update on current activities of the Parametric Tolerance Interval Test Workgroup, (2) discuss and provide comments on the general topic of considerations for assessment of pharmaceutical equivalence and product design, and (3) discuss criteria for establishing a working group for review and assessment of Office of

Pharmaceutical Science research programs.

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 25, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 25, 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 Hilda Scharen 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 1, 2005.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting of the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration, HHS.

SUMMARY: Pursuant to Pub. L. 92-463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the eighth meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on May 9, 2005, and from 9 a.m. to 3 p.m. on May 10, 2005, at the Rockville DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852. The meeting

will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

ACOT will hear presentations from staff of the Centers for Medicare and Medicaid Services (CMS) on the CMS Organ Procurement Organization Notice of Proposed Rulemaking and the Transplant Center Notice of Proposed Rulemaking. The presentations may include a discussion and summary of the comments received during the 60-day public comment period which began February 4.

The draft meeting agenda will be available on April 15 on the Department's donation Web site at <http://www.organdonor.gov/acot.html>.

A registration form will be available on March 15 on the Department's donation Web site at <http://www.organdonor.gov/acot.html>. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234-1701. Individuals without access to the Internet who wish to register may call Bryan Slattery with PSA at (703) 234-1734. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Director, Thomas E. Balbier, Jr., in advance of the meeting. Mr. Balbier may