

www.ich.org/cache/html/2238-272-1.html.

The registration fee will be used to offset some expenses of hosting the workshop including speakers, meeting rooms, coffee breaks, and materials.

If you need special accommodations due to a disability, please contact Liz Cross at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in the European Union (EU), Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

ICH's steering committee recognized that in the rapidly evolving area of gene therapy medicinal products, there is a need to continue to foster the exchange of information that may impact the regulation of such products. The Gene Therapy Discussion Group (GTDG) is leading these activities within ICH.

Regulatory and industry representatives from the three ICH regions (EU, Japan, and the United States), and experts from the European Free Trade Association, Health Canada, and the World Health Organization participate in this group.

The objectives of GTDG are to monitor emerging scientific issues and proactively set out principles that may have a beneficial impact on harmonizing regulation of gene therapy products.

The current ICH process and structure can be found on the Internet at <http://www.ich.org> (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The agenda and registration form for the public workshop are available on the Internet at <http://www.ich.org/cache/html/2238-272-1.html> (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The workshop agenda includes panel discussions in addition to invited presentations. A summary of the workshop will be available through ICH after the meeting.

Dated: September 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 October 25 and 26, 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: Igor Cerny, 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: cerny@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. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the heading "Advisory Committee for Pharmaceutical Science (ACPS)." (Click on the year 2005 and scroll down to ACPS meetings.)

Agenda: On October 25, 2005, the committee will do the following: (1) Receive an update on current activities of the Parametric Tolerance Interval Test Workgroup; (2) receive and discuss presentations from the Pharmaceutical Research and Manufacturing Association, the Generic Pharmaceutical Association, and the U.S. Pharmacopeia pertaining to their perspectives on the general topic of Quality-By-Design (QBD) and drug release or dissolution specification setting; and (3) discuss and provide comments on the updated tactical plan under development for the

establishment of drug release or dissolution specifications. On October 26, 2005, the committee will do the following: (1) Discuss and provide comments on the general QBD topics of question-based review and alcohol-induced dose dumping and (2) receive and discuss an update on the establishment of a workgroup for the review and assessment of Office of Pharmaceutical Science research programs. Following those items, an awareness topic will be introduced concerning the need to enhance the pharmaceutical education system in the United States.

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 October 17, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on October 25, 2005, and between approximately 1 p.m. and 2 p.m. on October 26, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 17, 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 Igor Cerny 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: September 19, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05-19193 Filed 9-26-05; 8:45 am]

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