

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0330]

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**International Conference on Harmonisation Workshop on Gene Therapy;
Public Meeting**

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public meeting.

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The Food and Drug Administration (FDA) is announcing a public meeting entitled "Public Meeting: ICH Workshop on Gene Therapy." The purpose of the meeting is to solicit input and conduct discussion on gene therapy issues regarding the development of viral vector reference materials, adenovirus shedding, and the safe use of Lentivirus vectors in clinical trials.

Date and Time: The meeting will be held on September 9, 2002, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the Sheraton Premiere Tysons Corner, McLean, VA.

Contact: Stephanie Simek, Division of Cellular and Gene Therapies (HFM-591), Food and Drug Administration, Woodmont Office Complex One, 1401 Rockville Pike, suite 380 North, Rockville, MD 20852, 301-827-5102, FAX 301-827-5397.

Registration and Request for Oral Representations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by August 26, 2002. To register electronically, please see the

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Pharmaceutical Research and Manufacturers of America at <http://www.phrma.org/meetings/> and register by August 16, 2002.

If you need special accommodations due to a disability, please contact Stephanie Simek at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The International Conference on Harmonisation (ICH) was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at <http://www.ifpma.org/ich1.html>.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of gene therapy regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to participating with the international community in the development and clinical use of safer and more effective gene therapy products.

The ICH held its first workshop on Gene Therapy in Chiba Japan, May 21 through 24, 2001. The workshop was held as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for sharing information on the development of gene therapy products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

At this workshop, it was agreed that the scientific principles for the regulation of gene therapy or gene therapy products are currently harmonized in the three ICH regions. Because the field of gene therapy is extremely complex and rapidly evolving, the group suggested that an exchange of scientific expertise and experience among the ICH partners could foster prospective harmonization of technical requirements.

It was then agreed that an ICH scientific workshop would be held in conjunction with the Spring ICH Steering Committee and Expert Working Group meetings in Washington, DC.

II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) Development of viral vector reference standards, and (2) safe use of Lentivirus vectors in gene therapy clinical trials.

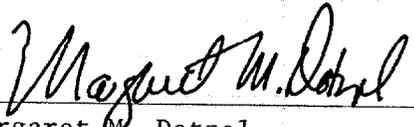
Interested persons may take part in an open discussion at two sessions during the September 9, 2002, meeting. The morning panel discussion will be between approximately 9:45 a.m. and 10:45 a.m. and will be focused on the development of viral vector reference standards. The afternoon discussion panel will be scheduled between approximately 3:40 p.m. and 4:40 p.m. and will focus on the safe use of Lentivirus vectors in gene therapy clinical trials.

The agenda for the public meeting will be made available on August 26, 2002, at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under docket number 02N-0330.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration,

5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: 7-29-02
July 29, 2002.



Margaret W. Dotzel,
Associate Commissioner for Policy.

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