

Dated: April 8, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Preparation for International Conference on Harmonisation Steering Committee and Expert Working Group Meetings in Tallinn, Estonia; Regional Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Steering Committee and Expert Working Group Meetings in Tallinn, Estonia" to provide information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Tallinn, Estonia. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Tallinn, Estonia, June 5 through 10, 2010, at which discussion of the topics underway and the future of ICH will continue.

**Date and Time:** The meeting will be held on Wednesday, May 5, 2010, from 2:30 p.m. to 4:30 p.m.

**Location:** The meeting will be held at the Washington Theater at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** All participants must register with Jennifer Haggerty, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: [jennifer.haggerty@fda.hhs.gov](mailto:jennifer.haggerty@fda.hhs.gov) or FAX: 301-827-0003.

**Registration and Requests for Oral Presentations:** Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentations, to the contact person by April 30, 2010.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will

be scheduled between approximately 4 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 30, 2010, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available via the Internet at: <http://www.fda.gov/Drugs/NewsEvents/ucm204924.htm>.

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

**Transcripts:** Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:** The 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 Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. 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 Manufactures

Association; the Centers for Drug Evaluation and Research and 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 (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area, and the World Health Organization. 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 at the following Web site: <http://www.ich.org>.

Dated: April 5, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Prevention Research Centers Comparative Effectiveness Research Program, DP 10-003, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

**Times and Dates:** 8:30 a.m.-6 p.m., May 4, 2010 (Closed); 8:30 a.m.-5 p.m., May 5, 2010 (Closed).

**Place:** W Hotel, 1111 Perimeter Center W., Atlanta, GA 30346.

**Telephone:** (770) 396-6800.

**Status:** The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

**Matters To Be Discussed:** The meeting will include the initial review, discussion, and evaluation of applications received in response to "Prevention Research Centers Comparative Effectiveness Research Program, DP 10-003."

**Contact Person for More Information:** Donald Blackman, PhD, Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program