

IV. Electronic Access

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Dated: April 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Preparation for International Conference on Harmonization Steering Committee and Expert Working Group Meetings in Cincinnati, OH; Regional Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Steering Committee and Expert Working Group Meetings in Cincinnati, Ohio" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Cincinnati, OH. 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 Cincinnati, OH, scheduled on June 11 through 17, 2011, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The public meeting will be held on May 19, 2011, from 2 p.m. to 4 p.m.

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

Contact Person: All participants must register with Kimberly Franklin, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, e-mail: Kimberly.Franklin@fda.hhs.gov, or FAX: 301-595-7937.

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 (see *Contact Person*) by May 16, 2011.

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 3:30 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person (see *Contact Person*) by May 16, 2011, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, telephone number, fax, and email of proposed participants, and an indication of the approximate time requested to make their presentation.

If you need special accommodations due to a disability, please contact Kimberly Franklin (see *Contact Person*) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available 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, 12420 Parklawn Dr., 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 Manufacturers 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>. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

The agenda for the public meeting will be made available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm248489.htm>.

Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

International Consortium of Orthopedic Registries; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "International Consortium of Orthopedic Registries (ICOR)." The