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Adriana Calderwell

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N-1220]

**The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH); Notice of Public Meeting**

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

**ACTION:** Notice of public meeting.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled “The Future of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use” to solicit information and receive comments on the future of the ICH. The purpose of the meeting is to solicit public input prior to the next Steering Committee meeting in Brussels, Belgium, July 2000, at which discussion of the future of the ICH will be continued.

**DATES:** The public meeting will be held on May 16, 2000, from 10 a.m. to 2 p.m. Registration must be received by May 9, 2000. Written and electronic comments regarding the public meeting must be submitted by May 20, 2000.

**ADDRESSES:** The public meeting will be held in the Center for Drug Evaluation and Research, Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Written submissions must be sent to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic

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submissions must be sent to the Dockets Management Branch at <http://www.fda.gov/scripts/oc/dockets/comments/commentsmain.cfm>.

**FOR FURTHER INFORMATION CONTACT:** Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, FAX 301-827-6801, or e-mail: [Topperk@cder.fda.gov](mailto:Topperk@cder.fda.gov).

*Registration:* There is no registration fee for this public meeting, but registration by May 9, 2000, is required. Participation is limited to the first 140 registrants due to limited space. FDA employees are required to register to attend the meeting. Interested persons may register with the contact person via e-mail at: [topperk@cder.fda.gov](mailto:topperk@cder.fda.gov) or fax 301-827-6801 and provide the following information: Name, affiliation, address, phone, fax, and e-mail address. Interested persons may also register by mail with the contact person (address above).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

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. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among the following 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 and Welfare, the Japanese Pharmaceutical Manufacturers Association, 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 the IFPMA, as well as observers from the World Health Organization, the Canadian Therapeutics Products 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>.

The ICH will present the Common Technical Document and other significant achievements at the ICH 5 Conference in San Diego in November 2000. In preparing for this meeting, the ICH Steering Committee is evaluating the future direction for the ICH, including structure, processes, work program, and global cooperation. FDA is soliciting public input at this time to assist the agency in these deliberations.

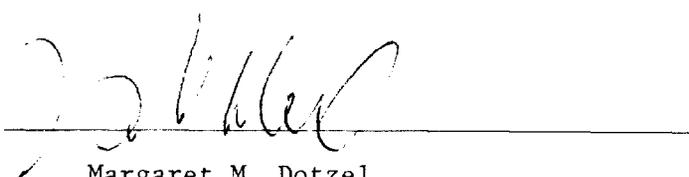
## **II. Issues to be Discussed at the Public Meeting**

The issues to be discussed include the following: (1) Administrative and technical issues, (2) future participation, (3) global cooperation, and (4) new topic areas.

Interested persons may present data, information, or views, orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 2 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 May 9, 2000, 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 full agenda for the public meeting will be available on May 10, 2000, at the Dockets Management Branch (address above). Requests should be identified with the Docket Number 00N-1220.

Dated: 4/28/00  
April 28, 2000



Margaret M. Dotzel,  
Acting Associate Commissioner for Policy.

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