

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMB

Display Date	4-23-01
Publication Date	4-24-01
Certifier	Spouse

Food and Drug Administration

[Docket No. 01N-0167]

Preparation for ICH Meetings in Tokyo, Japan, Including Progress on the Common Technical Document and Possibilities for New Topics; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Meetings in Tokyo, Japan, Including Progress on the Common Technical Document and Possibilities for New Topics," to solicit information and receive comments on the future of the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Tokyo, Japan. The topic to be discussed is the Common Technical Document (CTD) and possibilities for new topics. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Tokyo, Japan, May 21 to 24, 2001, at which discussion of the CTD and possible new topics will be continued.

Date and Time: The public meeting will be held on May 8, 2001, 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301-827-7001, FAX 301-827-6801, or email: Topperk@cder.fda.gov.

Registration and Requests for Oral Presentations: 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 May 1, 2001.

NM-1

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

SUPPLEMENTARY INFORMATION:

I. Background

The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (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 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>.

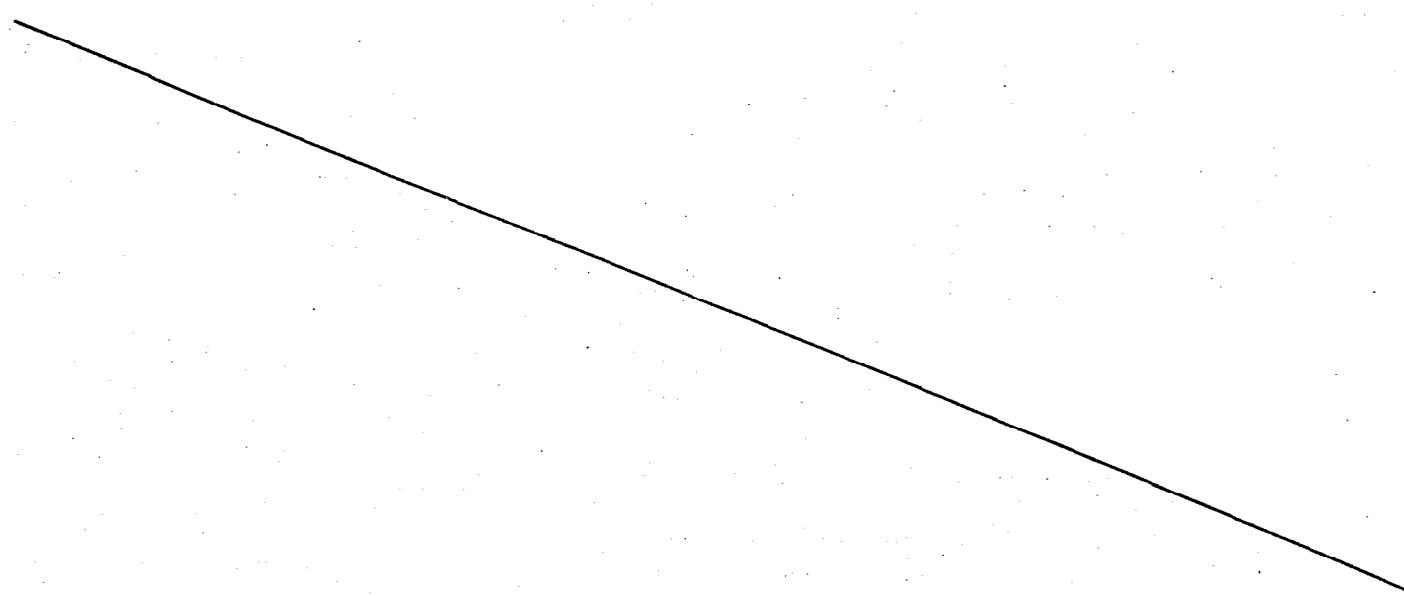
II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) ICH overview and procedures, (2) CTD, and (3) possibilities for new topics (e.g., biotech and postmarketing surveillance).

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 1, 2001, 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 available on May 2, 2001, at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under Docket Number 01N-0167.

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: April 18, 2001
April 18, 2001.



Ann M. Witt,
Acting Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

