

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0384]

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**Preparation for Global Harmonization Task Force Conference in Barcelona, Spain, Including a Discussion of Guidance Proposed for Comment and Currently Under Development and Possibilities for New Topics; 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 "Preparation for Global Harmonization Task Force Conference in Barcelona, Spain, Including a Discussion of Guidance Proposed for Comment and Currently Under Development and Possibilities for New Topics." The purpose of this meeting is to solicit information and receive comments on FDA's future participation in the Global Harmonization Task Force (GHTF) as well as the upcoming meetings in Barcelona, Spain. The topics to be discussed are an overview of GHTF, guidance proposed for comment and currently under development, and possibilities for new topics. This meeting is being held to solicit public input prior to the next meeting of the GHTF Steering Committee and Study Groups in Barcelona, Spain, from October 11 to 16, 2001, at which discussion of the guidance proposed for comment and under development and possible new topics will be continued.

*Comments:* Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments are to be identified with the docket number found in brackets in the heading of this document.

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*Date and Time:* The public meeting will be held on October 1, 2001, from 1:30 p.m. to 4:30 p.m.

*Location:* The public meeting will be held at 5630 Fishers Lane, rm. 1056, Rockville, MD.

*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 e-mail: Topperk@cder.fda.gov.

*Registration and Requests for Oral Presentations:* Send registration information (including name, title, firm or organization name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by September 26, 2001.

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

#### **SUPPLEMENTARY INFORMATION:**

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

The GHTF was established in 1992 as a joint regulatory/industry project to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices; promote technological innovation; and facilitate international trade. The GHTF works to achieve these objectives by disseminating guidance documents on basic regulatory practices. These documents, which are developed by four different GHTF Study Groups, can be adopted/implemented by member national regulatory authorities. Other national regulatory authorities that are not GHTF members also are encouraged to adopt and implement GHTF guidance documents.

In recent years, regulatory authorities and industry associations have undertaken many important initiatives to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization. FDA is committed to seeking scientifically based harmonized technical procedures for medical device regulation. One of the goals of harmonization is to identify similarities and differences in technical requirements for medical

devices, increase the similarities, and reduce the differences. The GHTF was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives.

The GHTF is concerned with harmonization among three regions: the European Union, Asia-Pacific, and North America. The members of the GHTF are the European Union, Australia, Japan, Canada, and the United States. The GHTF Steering Committee is composed of four regulatory and four industry representatives from each region for a total of 12 regulatory and 12 industry representatives. The secretariat rotates from one region to another every 3 years. The Therapeutic Goods Administration of Australia currently serves as the secretariat for GHTF. Health Canada previously served as the secretariat. The Ministry of Health and Welfare of Japan will serve as the next secretariat.

GHTF study groups develop guidance documents on device regulation. There are currently four study groups: Study Group 1—premarket issues; Study Group 2—postmarket vigilance; Study Group 3—quality systems; and Study Group 4—auditing of quality systems.

The GHTF process is intended to achieve harmonization of the technical requirements for approval or clearance of medical devices, quality system requirements, procedures for auditing quality systems, and postmarket vigilance in the three regions. Information about the GHTF, its structure, proposed and final study group guidance documents, and the upcoming conference in Barcelona, Spain, can be found on the Internet at <http://www.ghf.org>.

## **II. Issues To Be Discussed at the Public Meeting**

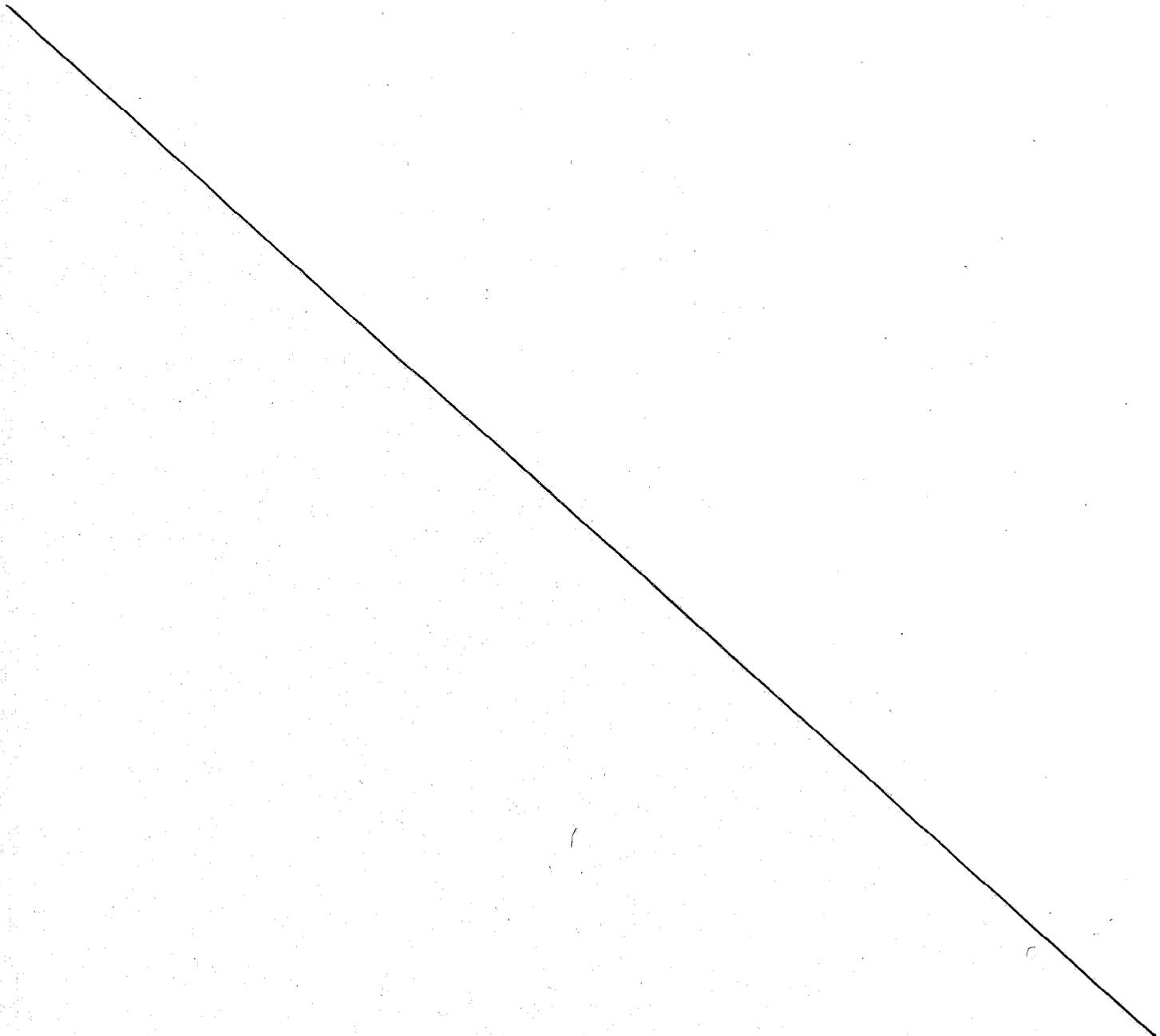
The issues to be discussed include the following: (1) GHTF overview and procedures, (2) overview of GHTF Study Group work, (3) medical device nomenclature, and (4) possibilities for new topics.

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. Time allotted for oral presentations may be limited to 10 minutes. Anyone desiring to make an oral presentation

should notify the contact person by September 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the name and address, phone number, fax and e-mail of the proposed participant, and an indication of the approximate time requested to make the presentation.

The agenda for the public meeting will be available on September 17, 2001, at the Dockets Management Branch (address above) under Docket No. 01N-0384.

*Transcripts:* A transcript of the meeting will be posted on the Internet at: <http://www.fda.gov/ohrms/dockets/dockets/docwhatsnew.htm> under Docket No. 01N-0384. A transcript of



the meeting also 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: 9/6/01

September 6, 2001.

*Margaret M. Dotzel*

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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*Suzette N. Reese*