

Dated: April 8, 2009.

Carlton Duncan,

Deputy Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Annual Meeting

The Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), announces the following meeting:

Name: Vessel Sanitation Program: Annual Program Status Update and Experience to Date with Program Operations.

Time and Date: 9 a.m. to 4 p.m., June 12, 2009.

Location: Auditorium, Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, Florida 33316.

Status: The meeting is open to the public, but space is limited. The meeting room can accommodate approximately 100 persons. Annual attendees normally include cruise ship industry officials, private sanitation consultants, and other interested parties.

Meeting Objectives

CDC staff will update attendees on the current status of program topics, including but not limited to the following:

- 2008 Program Review.
- Proposed revisions to the Vessel Sanitation Program Operations Manual 2005.
- Proposed revisions to the Vessel Sanitation Program Construction Guidelines 2005.

• Updates on cruise ship outbreaks.

An official record of this meeting will remain open for 15 days (through June 27, 2009) so that additional materials or comments may be submitted and made part of the record.

Advanced registration is encouraged. You may contact Stephanie Lawrence to register in advance or to receive additional information about the meeting. Ms. Lawrence can be reached by phone (770-488-3141), fax (770-488-4127), or e-mail (slawrence@cdc.gov). Please provide your name, title, company name, mailing address, telephone number, fax number, and e-mail address when contacting Ms. Lawrence.

Dated: April 8, 2009.

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Deputy Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0178]

Preparation for International Conference on Harmonisation Meetings in Yokohama, Japan; 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 Yokohama, Japan" to provide information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Yokohama, Japan. 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 Groups meetings in Yokohama, Japan, scheduled for June 6 through 11, 2009, at which discussion of the topics underway and the future of ICH will continue, as well as provide comprehensive updates of the various ICH topics.

Date and Time: The meeting will be held on May 6, 2009, from 2:30 p.m. to 5 p.m.

Location: The meeting will be held in the Washington Room at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. For security reasons, all attendees are asked to arrive no later than 2:15 p.m.

Contact Person: All participants must register with Tammie Jo Bell, Office of the Commissioner (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: Tammie.Bell2@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 presentation, to the contact person by April 29, 2009.

If you need special accommodations due to a disability, please contact Tammie Jo Bell (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.fda.gov/ohrms/dockets/ac/acmenu.htm>. 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 (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 Association; 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