

specific topics related to methodologies and implementation of quality systems including areas such as global change control and corrective action preventative action (CAPA) investigations.

DATES: For the dates of the workshops, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For the locations of the workshops, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Fred Razzaghi, Consumer Healthcare Products Association, 1150 Connecticut Ave. NW., Washington, DC 20036, FAX 202-223-6835, fred.razzaghi@chpa-info.org; <http://www.chpa-info.org>; or Erik N. Henrikson, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-9004, FAX 301-827-8907, henriksone@cdcr.fda.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Should Attend?

This document is directed towards professionals involved in the manufacture, control, and regulation of pharmaceutical products. Examples of professionals who may be interested include process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, repackers and relabelers, consultants, regulatory investigators, CGMP compliance officials, and FDA center and field personnel. Other entities or individuals may also be interested in attending.

B. Where and When Will The Workshops Be Held?

We have scheduled three workshops at different times and locations to enable as many people to participate as possible. Attendees can attend the workshop that is most convenient. The times and locations of the workshops are listed in table 1 of this document.

TABLE 1.—WORKSHOP LOCATIONS AND SCHEDULES

Workshop Location	Date and Time
Sheraton Meadowlands Hotel, Two Meadowlands Plaza, East Rutherford, NJ 07073, 201-896-0500, FAX 201-896-9696.	Monday, June 16, 2003, from 8:30 a.m. to 5 p.m.

TABLE 1.—WORKSHOP LOCATIONS AND SCHEDULES—Continued

Workshop Location	Date and Time
San Juan Marriott Resort, 1309 Ashford Ave., San Juan, PR 00907, 800-981-8546, FAX 809-722-6800.	Monday, July 14, 2003, from 8:30 a.m. to 5 p.m.
Hyatt Regency Chicago, 151 East Wacker Dr., Chicago, IL 60601, 312-565-1234, FAX 312-565-2966.	Tuesday, August 12, 2003, from 8:30 a.m. to 5 p.m.

C. How Can I Participate?

You can participate in person. Anyone interested in attending a workshop can register through the **INFORMATION CONTACT**.

D. Is There a Registration Fee for This Workshop?

Yes, a registration fee of \$ 320.00 is required. The registration fee includes workshop reference materials and lunch plus a continental breakfast and coffee breaks. Government employees qualify for a discounted rate of \$75.

E. How Can I Get Additional Information?

The notice of participation form, information about the workshop, and other related documents are available from the **INFORMATION CONTACT** or from the Internet at <http://www.fda.gov.cdcr/workshop.htm>.

II. Background Information

A. Why is FDA Cosponsoring These Workshops?

FDA is cosponsoring this series of workshops to provide information and training opportunities for industry as well as FDA center and field personnel. The workshops are being scheduled for three different times and locations to enable as many participants to attend as possible.

B. What Will Be Covered?

The workshops will provide an update on the progress of the agency's CGMP initiative, the status of the part 11 draft guidance, and the agency's progress in developing ideas about risk management associated with CGMP. In addition, FDA and industry speakers will present information and training on specific topics related to methodologies and implementation of quality systems in categories such as global change control and CAPA investigations. Presentations by both FDA and industry will provide a regulatory and practical perspective on the current relevant critical topics.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0207]

Preparation for ICH Meetings in Brussels, Belgium, and ICH 6 Conference in Osaka, Japan: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing a public meeting entitled "Preparation for ICH Meetings in Brussels, Belgium, July 15-18, 2003, and ICH 6 Conference in Osaka, Japan, November 12-15, 2003" to solicit information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming Meetings in Brussels, Belgium. The topic to be discussed is the Common Technical Document, GMPs Initiative and Update on other 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 Brussels, Belgium, July 2003, at which discussion of the topics underway and the future of ICH will continue and also to inform the public about the ICH 6 Public Conference in Osaka, Japan in November 2003.

Date and Time: The public meeting will be held on June 24, 2003, from 10 a.m. to 1 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact Person: 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, email: Topperk@cdcr.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 June 9, 2003.

If you need special accommodations due to a disability, please contact