

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Manufacturing Inspections; Public Workshops

DMS

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Certifier G. Parsley

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of public workshops to discuss current good manufacturing practice (CGMP) issues, including quality subsystems, areas of change control, and quality management. There will also be a discussion of current compliance issues and trends and the status of the part 11 (21 CFR part 11) draft guidance. The first workshop will be held in June 2003, then repeated in July 2003 and August 2003 at different locations to enable as many people to attend as possible. Held in collaboration with the Consumer Healthcare Products Association (CHPA), the workshops are intended to update participants with respect to issues involving CGMP compliance. Participants will also hear from FDA and industry speakers on 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,

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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@cder.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.
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.cder/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.

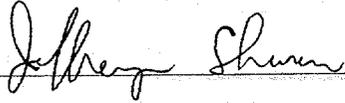
B. What Will Be Covered?

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

May 27, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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