

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Manufacturing Inspections; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

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Certifier N. Hawkins

The Food and Drug Administration (FDA) is announcing a series of workshops to discuss the application of a systems-based approach to drug manufacturing inspections. The workshops, which will be held in collaboration with the Consumer Healthcare Products Association (CHPA), are intended to provide a regulatory perspective on the systems-based approach to inspections.

Date and Time: See table 1 following the "Location" section of this document.

Location: See table 1 below

TABLE 1

Meeting Address	Date and Local Time	FDA Contact Person
NEW JERSEY: Sheraton Meadowlands Hotel, 2 Meadowlands Plaza, East Rutherford, NJ, 201-896-0500.	Monday, June 17, 2002, from 8:30 a.m. to 4:30 p.m.	Erik N. Henrikson
PUERTO RICO: San Juan Marriott Hotel, 1309 Ashford Ave., San Juan, PR, 800-981-8546.	Monday, July 15, 2002, from 8:30 a.m. to 4:30 p.m.	Do.
CALIFORNIA: Manhattan Beach Marriott Hotel, 1400 Parkview Dr., Manhattan Beach, CA, 310-546-7511.	Monday, August 5, 2002, from 8:30 a.m. to 4:30 p.m.	Do.

Contact:

For information regarding participation by FDA: Erik N. Henrikson, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-827-0072, FAX 301-594-2202.

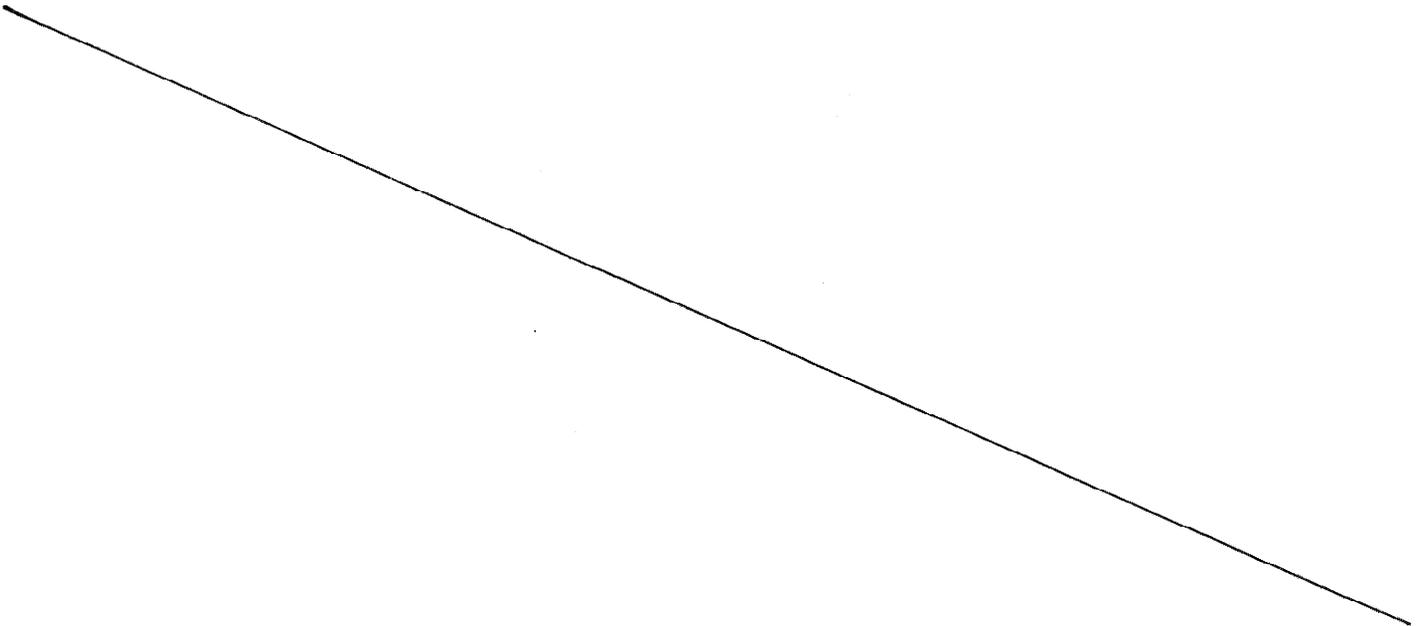
For information regarding the program or registration: Bill Bradley, Consumer Healthcare Products Association (CHPA), 1150 Connecticut Ave. NW., Washington, DC 20036, 202-429-9260, FAX 202-223-6835.

Registration: Anyone interested in the workshops can obtain registration information from Bill Bradley, CHPA (address above), or a brochure with the program and registration form is available at http://www.chpa-info.org/meetings/pdfs/2002workshops__updated__22602.pdf. This material is also available from <http://www.fda.gov.cder/calendar>. Space is limited. Please preregister by the Friday prior to each of these meetings to confirm your participation. If you need special accommodations due to a disability, please contact Erik N. Henrikson (address above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

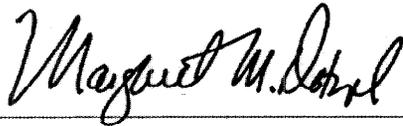
Who Should Attend? This announcement is directed toward professionals involved in the manufacture, control, and regulation of prescription or over-the-counter drugs who will benefit from these workshops, including: Process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, repackers and relabelers, consultants, regulatory investigators and good manufacturing practice compliance officials, and reviewing chemists. Other entities or individuals may also be interested in attending.

Is There a Registration Fee for This Workshop? Yes, a registration fee of \$320.00 payable to CHPA is required for this workshop. This registration fee includes workshop reference materials and lunch on each day. Government employees qualify for a discounted rate of \$75.00.



How Can I Get Additional Information, Including Copies of This Document or Other Related Documents? The notice of participation form, information about the workshops, and other related documents are available from the information contacts (addresses above) or on the Internet at <http://www.fda.gov.cder/calender>.

Dated: 3/22/02
March 22, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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