

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Current Good Manufacturing Practice for Active Pharmaceutical Ingredients; Public Workshops**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshops.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a series of workshops to discuss the application of the International Conference on Harmonisation (ICH) guidance for industry entitled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients," which will be announced in a future issue of the **Federal Register**. The workshops, which will be held in collaboration with the Parenteral Drug Association, the Pharmaceutical Research and Manufacturers of America, and the Generic Pharmaceutical Association, are intended to provide a regulatory perspective on current good manufacturing practices (CGMPs) for active pharmaceutical ingredients (APIs). The workshops are being scheduled to help ensure that all APIs meet the standards for quality and purity they purport or are represented to possess.

**DATES:** See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

**ADDRESSES:** See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

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;

Leslie Zeck, Parenteral Drug Association, 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814, 301-986-0293, FAX 301-986-0296, e-mail: <http://www.pda.org>;

Alice E. Till, Pharmaceutical Research and Manufacturers of America, 1100 15th St. NW.,

Washington, DC 20005, 202-835-3400, FAX 202-835-3597, e-mail: <http://>

[www.phrma.org](http://www.phrma.org); or

Steve Bende, Generic Pharmaceutical Association, 1620 I St. NW., suite 800, Washington, DC 20006, 202-833-9070, FAX 202-833-9612, e-mail: <http://www.genericaccess.com>.

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Who Should Attend?

This announcement is directed towards professionals involved in the manufacture, control, and regulation of APIs who will benefit from this training, including: Process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, agents, brokers, traders, distributors, repackers and relabelers of APIs, consultants, regulatory investigators and GMP compliance officials, and reviewing chemists. Other entities or individuals may also be interested in attending.

#### B. Where and When Will These Workshops Be Held?

TABLE 1.—WORKSHOP LOCATIONS AND DATES

Workshop Address	Date and Local Time
Illinois: The Allerton Crowne Plaza, 701 North Michigan Ave., Chicago, IL	October 22 to 24, 2001, from 9 a.m. to 5 p.m.
New Jersey: Hyatt Regency Princeton, 102 Carnegie Center, Princeton, NJ	November 7 to 9, 2001, from 9 a.m. to 5 p.m.
California: The Sutton Place Hotel, 4500 MacArthur Blvd., Newport Beach, CA	February 25 to 27, 2002, from 9 a.m. to 5 p.m.
Puerto Rico: Caribe Hilton San Juan, Los Rosales St., San Geronimo Ground, San Juan, PR	April 8 to 10, 2002, from 9 a.m. to 5 p.m.

#### C. How Can I Participate?

You can participate in person. Anyone interested in the API workshops can register through any of the information contacts (addresses above).

*D. Is There a Registration Fee for This Workshop?*

Yes, a registration fee of \$995 is required for this workshop. This registration fee includes workshop reference materials, lunch on each day, and a networking reception on day 1. Government employees qualify for a discounted rate of \$395.

*E. How Can I Get Additional Information, Including Copies of This Document or Other Related Documents?*

Submit written requests for single copies of the Q7A guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your requests. Once the notice of availability is announced in a future issue of the **Federal Register**, those with electronic access will be able to obtain electronic copies of the guidance document on the Internet at three locations: <http://www.fda.gov/cder/guidance/index.htm>; <http://www.emea.eu.int/pdfs/human/ich/410600en.pdf>; or <http://www.ifpma.org/ich5q.html#gmp>. The notice of participation form, information about the workshops, and other related documents are available from any of the information contacts (addresses above) or from the Internet at <http://www.fda.gov/cder/calendar>.

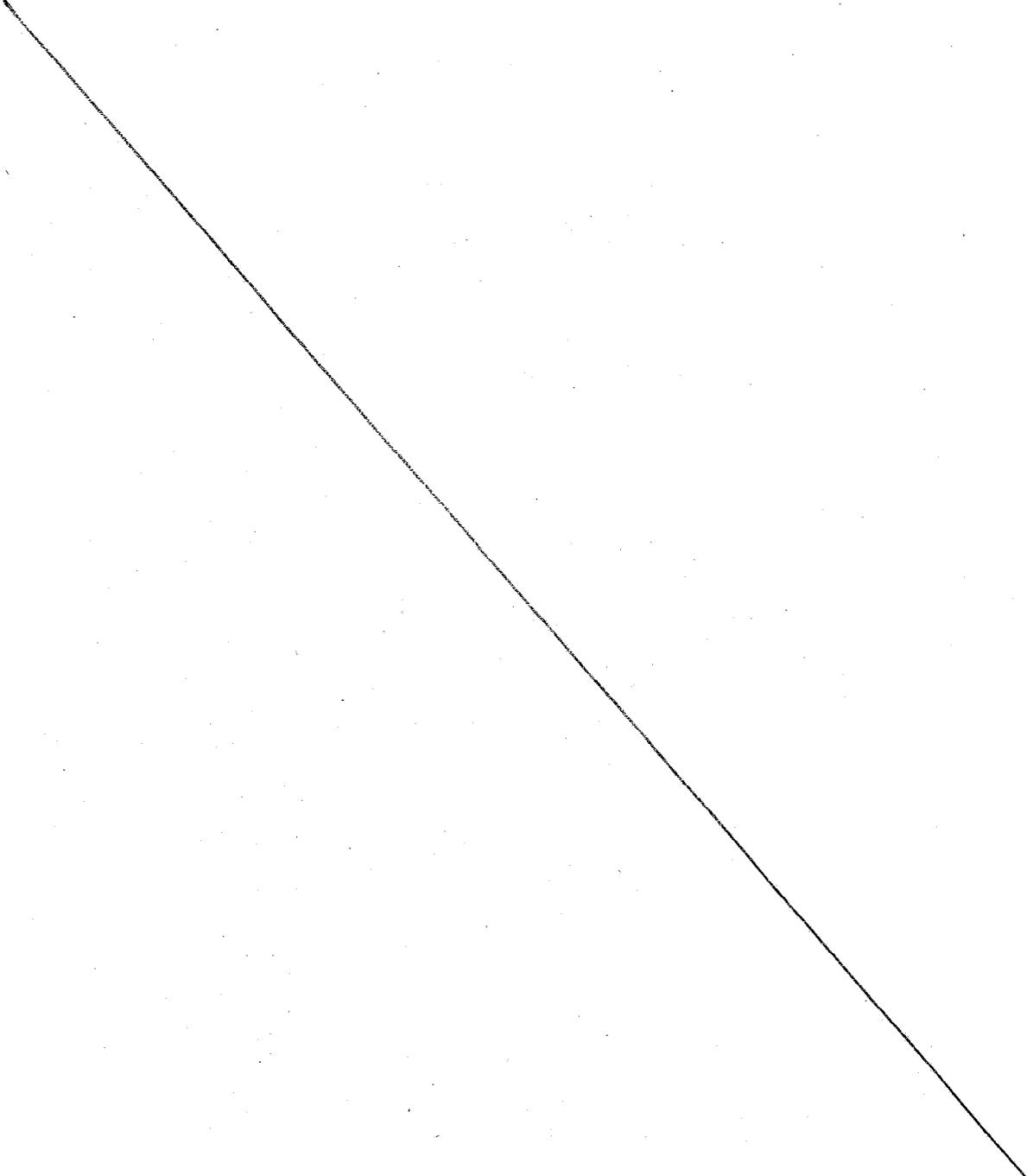
## **II. Background Information**

*A. Why is FDA Cosponsoring These Workshops?*

FDA is cosponsoring these 3-day workshops to provide training of FDA personnel alongside industry participants on the ICH Q7A CGMP guidance for APIs. This is the first CGMP guidance developed jointly by regulators and industry and is intended for use worldwide. It affects manufacturers who manufacture in, or intend to supply into, the ICH regions (United States, Europe, Japan).

*B. What Will Be Covered?*

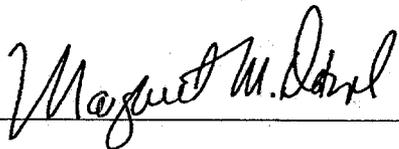
FDA participation in these workshops will provide a regulatory perspective on the critical topic of the ICH guidance "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical



Ingredients." Attendees will hear about the intent of the Expert Working Group that developed the Q7A guidance and learn how to interpret and apply the Q7A guidance, including special sections on APIs manufactured by cell culture/fermentation, and APIs for use in clinical trials.

Dated: 9-18-01

September 18, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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