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@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.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13756 Filed 6–2–03; 8:45 am]

BILLING CODE 4160–01–S

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@cder.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

Kimberly Topper at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (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, the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, 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 is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found on the Internet at http://www.ich.org.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 1 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by June 9, 2003, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The Agenda for the public meeting will be made available on June 9, 2003, via the internet at http://www.fda.gov/cder/calendar/meeting/ich2003.

Information on the ICH 6 Public Conference in Osaka, Japan on November 12–15, 2003, can be obtained via the Internet at http://www.ich.org/ich6bis.html.

Dated: May 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13830 Filed 6–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0197]

Guidance for Industry on Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy.'' This guidance discusses how FDA plans to exercise its enforcement discretion after September 1, 2002, with regard to drug products whose labeling does not use the established names for ensulizole, hypromellose, meradimate, octinoxate, and octisalate.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Wayne Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of a guidance for industry entitled ''Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy.'' This guidance explains that the agency intends to exercise enforcement discretion by not initiating any enforcement action, until September 1, 2003, based on a firm's failure to bring its products' labeling into compliance with the United State Pharmacopeia (USP) monograph title changes for ensulizole, hypromellose, meradimate, octinoxate, and octisalate, as required by section 502(e)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)(1)(A)(i)).

As explained in detail in the guidance, a series of events has lead to the development of the guidance. These events include USP monograph title changes, changes to the FDA's monograph for over-the-counter (OTC) sunscreen drug products, and the receipt of two petitions regarding these changes and their effective date (September 1, 2002).

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this issue. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative