

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 wish 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.

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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 States 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 led 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