

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0509]

DDM

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**International Conference on Harmonisation; Guidance on the M4 Common
Technical Document—Quality: Questions and Answers/Location Issues;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “M4: The CTD—Quality: Questions and Answers/Location Issues.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance provides further clarification for preparing the quality components of an application file in the common technical document (CTD) format. The guidance addresses the relationship between linked sections for certain parameters (such as polymorphism and particle size), and it addresses location issues (by indicating the section in which to place requested information). The guidance is intended to ease the preparation of paper and electronic submissions, facilitate regulatory reviews, and simplify the exchange of regulatory information among regulatory authorities.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the 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, or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of the document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Justina A. Molzon, Center for Drug Evaluation and Research (HFD-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400; or Christopher C. Joneckis, Center for Biologics Evaluation and Research (HFM-20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0833.

Regarding the ICH: C. Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0908.

SUPPLEMENTARY INFORMATION:

I. Background

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 drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, 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, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of October 16, 2001 (66 FR 52634), FDA made available the ICH guidance entitled “M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use” (M4 CTD), which describes a harmonized format for new product applications (including applications for biotechnology-derived products) for submission to the regulatory authorities in the three ICH regions. The M4 CTD guidance was made available in four parts: (1) A description of the organization of the M4 CTD; (2) the quality section; (3) the safety, or nonclinical, section; and (4) the efficacy, or clinical, section.

In the **Federal Register** of December 30, 2002 (67 FR 79639), FDA published a notice announcing the availability of a draft tripartite guidance entitled “Common Technical Document—Quality: Questions and Answers/ Location Issues.” The notice gave interested persons an opportunity to submit comments by February 28, 2003. After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in July 2003.

This guidance provides further clarification for preparing the quality components of an application in the CTD–Q format. The guidance addresses the relationship between linked sections for certain parameters, such as polymorphism and particle size. The guidance also addresses location issues by indicating the section in which to place requested information. The guidance is intended to ease the preparation of paper and electronic submissions, facilitate regulatory reviews, and simplify the exchange of regulatory information among regulatory authorities.

This guidance represents the agency's current thinking on this topic. 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 approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *<http://www.fda.gov/cder/guidance/index.htm>*, *<http://www.fda.gov/cber/publications.htm>*, or *<http://www.fda.gov/ohrms/dockets/default.htm>*.

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June 3, 2004.



Jeffrey Shuren,
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