

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0435]

International Conference on Harmonisation; Guidance on Electronic Common Technical Document Specification; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “M2 eCTD: Electronic Common Technical Document Specification.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The guidance is intended to assist industry in transferring electronically their marketing applications for human drug and biological products to a regulatory authority.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: 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, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the 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>. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373, or Timothy M. Mahoney, Center for Drug Evaluation and Research (HFD–73), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3540.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0865.

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's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**.

Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In the **Federal Register** of June 14, 2002 (67 FR 40948), FDA announced the availability of a second draft guidance entitled “Electronic Common Technical Document Specification.” The notice gave interested persons an opportunity to submit comments by August 1, 2002.

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 September 2002.

The eCTD guidance describes the recommended method for industry-to-agency electronic transfer of marketing applications for human drug and biological products. The guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The guidance is intended to assist industry in transferring their marketing applications for human drug and biological products to a regulatory authority. The guidance includes the following changes:

- The Document Type Definition (DTD) and specification version numbers were harmonized to 3.0.
- Throughout the guidance, references to Common Technical Document (CTD) sections were updated to reflect the current CTD specifications.

- Path names in Appendix 4 were abbreviated to avoid exceeding maximum path character limits.

- The Glossary of Terms was updated.

- Technical errors discovered during testing were corrected.

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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch 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/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: March 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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