Guidance for Industry

M2: eCTD Specification

Questions & Answers and Change Requests

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research

March 2005
ICH

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Contains Nonbinding Recommendations

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I. INTRODUCTION

This document provides guidance to applicants on how to use the electronic Common Technical Document (eCTD) specification. The guidance also answers questions that have been raised about the eCTD specifications and provides a change request table that tracks the status of all change requests that have been received by ICH since the eCTD specification was issued. The information provided here reflects the consensus of the ICH parties. The questions and answers (Q&As) and the change request table have been developed as a stand alone document that is available with this guidance. The document will be updated when the eCTD specification undergoes change control or new questions are submitted to the ICH.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] This guidance was developed within the M2 eCTD Implementation Working Group of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This document has been endorsed by the ICH Steering Committee at *Step 4* of the ICH process, November 11, 2003. At *Step 4* of the process, the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan, and the United States.

II. BACKGROUND

The ICH guidance *M2: eCTD: Electronic Common Technical Document Specification*[2] was endorsed by the ICH in September 2002 and issued by the FDA in April 2003. The eCTD specification is intended to assist industry in the electronic transfer of their marketing applications for human drug and biological products to a regulatory authority. 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.

III. QUESTIONS AND ANSWERS AND CHANGE REQUESTS

The ICH has received a number of questions with regard to the eCTD specification. In addition, some of the questions posed to the ICH address change requests to the eCTD specification. Questions and answers to the questions (Q&As) and change requests are maintained by the ICH eCTD Implementation Working Group (IWG).

A change request tracking table has been created to allow the public to monitor the status of all change requests. This table reflects all change requests that have been presented to the eCTD IWG and shows the status of the requests as: (1) out of scope, (2) approved for the next change to the eCTD specification, (3) approved but not requiring eCTD specification changes; therefore can be put in the Q&As, (4) deferred until a later date, (5) assigned for testing by the eCTD IWG, or (6) rejected.

The ICH updates the Q&As and change request tracking table periodically. The most recent versions of the Q&As and table are provided in a separate companion document available on the Internet with this guidance.

[2] The *M2: eCTD Specification* guidanceand this Q&A guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm.