4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0724]

Documents to Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following revised final versions of documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications: "The eCTD Backbone Files Specification for Module 1, version 2.1" (which includes the U.S. regional document type definition, version 3.1), and "Comprehensive Table of Contents Headings and Hierarchy, version 2.1." Technical files that support these documents are also available on the Agency Web site. A complete summary of the revisions made is included in the updated documents. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.1 by September 2013 and will give 30 days advanced notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your

requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA's Center for Drug Evaluation and

Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003; the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, provide clarification of business rules for submission processing and review, refine the characterization of promotional marketing and advertising material, and facilitate automated processing of submissions. FDA announced availability of final versions of technical documentation in the Federal Register of August 6, 2012 (77 FR 46763). FDA has revised the final documentation and is making available revised versions of the following documents:

- "The eCTD Backbone Files Specification for Module 1, version 2.1," which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER. It should be used in conjunction with the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions," which will be revised as part of the implementation of the updated eCTD backbone files specification.
- "Comprehensive Table of Contents Headings and Hierarchy, version 2.1," which reflects updated headings that are specified in the document entitled "The eCTD Backbone Files Specification for Module 1, version 2.1."

Supporting technical files are also being made available on the Agency Web site.

A complete summary of the revisions made are included in the updated documents. The revisions include the following:

- The 1.16 heading regarding risk management was modified and subheadings were added.
- The application-type attribute file was modified to include PMA and 510(k).
- Attribute files were modified to allow the version, date, and number to be machine readable.

FDA is not prepared at present to accept submissions utilizing this new version, because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.1 by September 2013 and will give 30 days advanced notice to industry.

II. Electronic Access

Persons with access to the Internet may obtain the documents at either http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov, or http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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