4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

AGENCY: Food and Drug Administration, HHS.

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following 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 2.0" (which includes the U.S. regional document type definition (DTD), version 3.0) and "Comprehensive Table of Contents Headings and Hierarchy, version 2.0." Supporting technical files are also being made available on the Agency Web site. These documents represent FDA's major updates to Module 1 of the eCTD, which contains regional information. 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 2.0 by September 2013, but this is not a firm date and we will give 30 days advance 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, and 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, to provide clarification of business rules for submission processing and review, to refine the characterization of promotional marketing and advertising material, and to facilitate automated processing of submissions. In preparation for the Module 1 update, FDA made available draft technical documentation for public comment in a Federal Register notice dated October 26, 2011 (Docket No. FDA-2011-N-0724). After considering comments submitted, FDA revised the draft documentation and is making available final versions of the following documents:

- "The eCTD Backbone Files Specification for Module 1, version 2.0," 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 "Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications," which can be found online (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf), and which will be revised as part of the implementation of the updated eCTD backbone files specification.

- "Comprehensive Table of Contents Headings and Hierarchy, version 2.0," which reflects updated headings that are specified in the draft document entitled "The eCTD Backbone Files Specification for Module 1, version 2.0," as well as mappings to regulations and legislation.

Supporting technical files are also being made available on the Agency Web site. The documents include changes that:

- Allow submission of promotional label and advertising materials to CDER in eCTD format;
- Provide for processing of grouped submissions (e.g., a supplement that can be applied to more than one new drug application or biologics license application);
- Provide detailed contact information so that companies can specify points of contact to discuss technical matters that may arise with a submission;
- Clarify headings;
- Use attributes in place of certain headings to provide flexibility for future changes without revising the specification itself.

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 2.0 by September 2013, but this is not a firm date and we will give 30 days advance 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: July 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19087 Filed 08/03/2012 at 8:45 am; Publication Date: 08/06/2012]