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 on the Agency Web site of revised final versions of the following four 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 2.2 (which includes the U.S. regional document type definition (DTD), version 3.2); "The Comprehensive Table of Contents Headings and Hierarchy," version 2.2; "Specifications for eCTD Validation Criteria," version 3.0; and "Example Submissions using eCTD Backbone Files Specification for Module 1," version 1.2. 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 2.2 by June 2014, and 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: Constance Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1105, Silver Spring, MD 20993, 301-796-1065, email: constance.robinson@fda.hhs.gov; or Joseph Montgomery, Center for Biologics Evaluation and Research, Food and Drug Administration, 11400 Rockville Pike, HFM-165, rm. 4155, Rockville, MD 20857, 301-827-1332, email: joseph.montgomery@fda.hhs.gov.

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, 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 previously announced availability of final versions of technical documentation in a Federal Register notice dated February 13, 2013 (Docket No. FDA–2011–N–0724). The Agency has revised the final documentation and is making available revised versions of the following documents:

- "The eCTD Backbone Files Specification for Module 1, version 2.2," which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER (This document should be used in conjunction with the guidance for industry Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications, which will be revised as part of the implementation of the updated eCTD backbone files specification (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf)).
- "The Comprehensive Table of Contents Headings and Hierarchy," version 2.2, which reflects updated headings that are specified in the document entitled "The eCTD Backbone Files Specification for Module 1," version 2.2
- "Specifications for eCTD Validation Criteria," version 3.0
- "Example Submissions using eCTD Backbone Files Specification for Module 1," version 1.2

Supporting technical files are 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:

eCTD Backbone Files Specification for Module I

- changed DTD version references from 3.1 to 3.2, where applicable
- replaced the copy of DTD Version 3.1 in Appendix I with DTD Version 3
- revised text, revised Table 1, and added Table 13 to indicate the new required attribute **material-id** and the new optional attribute **issue-date** which applies to m1-15-2-1

The Comprehensive Table of Contents Headings and Hierarchy

- added two new attributes for 1.15.2.1

Specifications for eCTD Validation Criteria

- incorporated changes to US eCTD Module 1

Example Submissions using eCTD Backbone Files Specification for Module 1

- modified example 7 to reference the Form FDA 356h in the Admin section
- modified examples 13 through 17 to reference the material-id and issue date attributes as applicable, and include the Promotional Labeling and Advertising Regulatory Contact

FDA is not prepared at present to accept submissions utilizing this new version of the eCTD Backbone Files Specification for Module 1, version 2.2, 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 2.2 by June 2014, and 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: August 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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