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 revised final versions of the following four documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD): "The eCTD Backbone Files Specification for Module 1," version 2.3 (which includes the U.S. regional document type definition (DTD), version 3.3); "The Comprehensive Table of Contents Headings and Hierarchy," version 2.3; "Specifications for eCTD Validation Criteria," version 3.1; and "Example Submissions using eCTD Backbone Files Specification for Module 1," version 1.3. Technical files that support these documents are also available on the Agency Web site. FDA estimates it will be able to receive submissions using Module 1 Specifications 2.3 by the fourth quarter of calendar year 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 the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002. 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, 10903 New Hampshire Ave., Bldg. 71, rm. 7328, Silver Spring, MD 20993-0002, 240-402-8125, email: joseph.montgomery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

The eCTD is a format for the transfer of regulatory information from the pharmaceutical industry to the FDA. It was developed by an expert working group of the International Conference on Harmonisation, and has been FDA's preferred format for electronic submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) since 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the current version of eCTD, it has become necessary to: (1) Update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, (2) clarify business rules for submission processing and review, (3) refine the characterization of promotional marketing and advertising material, and (4) facilitate automated processing of submissions. FDA previously announced availability of final versions of technical documentation in a Federal Register notice dated August 26, 2013 (78 FR 52776).

The Agency revised the final documentation to accommodate the redesignation of section 503B as new section 503C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b as

353c). We removed references to 503B and 353b and replaced them with "Pre-Dissemination Review of Television Ad" because of the redesignation of section 503B as section 503C. We also changed references to DTD version 3.2 to version 3.3 in the Specifications for eCTD Validation Criteria. In addition, we revised the wording of eCTD validation error 2001 to reflect the changes. A full description of the changes is contained in the appendices of each document. The Agency is making available revised versions of the following documents:

- "The eCTD Backbone Files Specification for Module 1, version 2.3," 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 entitled "Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications");
- "The Comprehensive Table of Contents Headings and Hierarchy," version 2.3;
- "Specifications for eCTD Validation Criteria," version 3.1; and
- "Example Submissions using eCTD Backbone Files Specification for Module 1," version 1.3.

Supporting technical files are available on the Agency Web site.

FDA is not prepared at present to accept submissions using this new version of the eCTD Backbone Files Specification for Module 1, version 2.3, 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 using Module 1 Specifications 2.3 by the fourth quarter of calendar year 2014, and will give 30 days' advance notice to industry.

## II. Electronic Access

Persons with access to the Internet may obtain the documents at 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: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-11178 Filed 05/14/2014 at 8:45 am; Publication Date: 05/15/2014]