

Information on the eCTD Module 1 Update and Implementation Plans

08/27/2014

Minor changes to the eCTD Module 1 update are being made to reflect the re-designation of 'Preview of television advertisements' from 503B to 503C (21 USC 353c). The eCTD heading, "1.15.1.5 Promotional materials submitted pursuant to section 503B" is being changed to, "1.15.1.5 Pre-dissemination review of television ads." The eCTD M1 files and documents affected by the change are listed below with their updated version numbers and are available on the eCTD Module 1 website.

The new timeframe that FDA plans to implement the eCTD M1 Update is 1st quarter 2015. FDA will provide notice on the [eCTD M1 website](#) 30 days prior to the actual date of implementation

eCTD M1 Documents:

- [Comprehensive Table of Contents Headings and Hierarchy Version 2.3](#)
- [The eCTD Backbone Files Specification for Module 1 Version 2.3](#)
- [Example Submissions using the eCTD Backbone Files Specification for Module 1 Version 1.3](#)

eCTD M1 Supportive Files:

- [us-regional-v3-3.dtd \(version 3.3\)](#)
- [promotional-material-doc-type.xml \(version 1.2\)](#)

eCTD Validation:

- [Specifications for eCTD Validation Criteria Version 3.1 - PDF](#)
- [Specifications for eCTD Validation Criteria Version 3.1 – XLS](#)