

Errata to eCTD Module 1
04/02/2013

DTD version 3.1, the eCTD Backbone Files Specification for Module 1 version 2.1, and related supportive files

Additional minor changes to the eCTD Module 1 update are being made to ensure FDA systems can effectively and efficiently process submissions containing promotional labeling. These changes include the inclusion of two additional attributes associated with m1.15.2.1. These attributes are:

material-id	The applicant's identification code or other designation of the specific promotional material. The material-id may consist of alpha and/or numeric characters and has a 30 character limitation.
issue-date	The date of the initial dissemination of the promotional labeling or the date of initial publication for an advertisement. The format of the date should be YYYYMMDD.

Additionally, the controlled vocabulary list for applicant contact type is also being updated to add a Promotional Labeling and Advertising Regulatory Contact.

The updated documents and files affected by these changes are expected to be published in the near future. As these changes are completed and FDA has obtained final estimates for scheduling purposes, FDA will update its proposed implementation date.