Recommended Contents of a Sample eCTD Submission

Please follow the sample guidelines below so that we may provide you with a meaningful, comprehensive analysis of your submission and help to ensure you are able to submit according to specifications. *(Note: if you have already successfully submitted a sample eCTD, it is not necessary to submit a second sample.)* This testing phase does not involve any regulatory review of the content of the submission. It is intended only to resolve technical issues.

The sample should include the following items and those items must comply with FDA and ICH specifications:

All five Modules in the eCTD	☐
Us-regional.xml according to ***eCTD Backbone Files Specification for Module 1***	☐
Util folder includes "dtd" and stylesheet" subfolders with applicable files Refer to ***ICH eCTD Specification 3.2.2*** and the ***FDA eCTD web page***	☐
Us-regional.xml and FDA form (e.g., 1571 or 356h) contain the same 6-digit application number, submission type, submission date	☐
Leaf titles are short, meaningful, and indicative of document content	☐
Submissions adheres to the ***PDF Specifications*** – pay close attention to: Bookmarks PDF document open properties Proper page rotation/page display PDF file and folder names	 ☐ ☐ ☐ ☐
Hypertext links adhere to the ***eCTD Guidance***	☐
Study tagging files are used correctly	☐
Valid values are used correctly for study components linked into study tagging files	☐
All submission documents adhere to ***FDA*** and ***ICH*** specifications	☐

Modules in the sample should contain the following:		
Note:	Include leafs in all modules (1 through 5)	☐
Module 1	Cover letter stating what type of sample you are submitting (eCTD, SDTM, Cross Application Linking)	☐
	An FDA form	☐
	At least one document in 1.14.1.3 in MS Word	☐
Module 2	Include at least 2 leafs	☐
Module 3	Include at least 2 leafs with at least one leaf within the 3.2.p section	☐
Module 4	Include at least one leaf in section 4.2.3.1 and one leaf in 4.2.3.2 Refer to pages 5 through 7 in the ***FDA Implementation of Study Tagging File Specification 2.6.1***	☐
Module 5	At least one study in section 5.3.5.1 Refer to pages 5 through 7 in the ***FDA Implementation of Study Tagging File Specification 2.6.1***	☐
	At least one study in section 5.3.5.2	
	Include at least 2 case report forms. FDA does not use 5.3.7. Instead CRFs should be linked into the appropriate study tagging file. Refer to pages 5-7 in the ***FDA Implementation of Study Tagging File Specification 2.6.1***	☐
	Include the following data leafs: at least one data definition leaf, an annotated case report form (blank case report form) and a dataset leaf (.xpt). Refer to ***Study Data Specifications***	☐
Util folder	Includes subfolder called, "style" with ***applicable files***	☐
	Includes subfolder called, "dtd" with ***applicable files***	☐

Note: If we are unable to evaluate your sample, load it onto our server, perform eCTD validation or cannot view the sample, you will be contacted and asked to resubmit according to specifications.

Submitting a successful sample will help ensure successful submissions in the future.

If you have questions about eCTD format, please contact the Electronic Submission Support Team at ESUB@fda.hhs.gov.

Date updated: May 1, 2009