

FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 Implementation Package History v1.5.1

The following tables list the files included in the FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 Implementation Package and notes for the changes made in this version of the package.

MAIN IMPLEMENTATION DOCUMENTS

Document Title	Document Version	File Name	File Format	Release Notes
FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 Implementation Guide	v1.5	USFDA_eCTD_v4_0_Module1_IG_v1_5.pdf	Adobe Acrobat (PDF)	No change from v4.0 Implementation Package v1.5
USFDA eCTD v4.0 Controlled Vocabulary (CV)	v1.4	USFDA_Regional_CV_eCTD_4_v1_4.xlsx	Excel	No change from v4.0 Implementation Package v1.5
USFDA OID Listing	v1.5	USFDA_OID_Listing_v1_5.xlsx	Excel	No change from v4.0 Implementation Package v1.5
ICH eCTD v3.2.2 Transition Mapping Message Controlled Vocabulary for DTD v2.1				Removed
ICH eCTD v3.2.2 Transition Mapping Message Controlled Vocabulary for DTD v3.3				Removed

REGIONAL GENERICODE CV FILES

Document Title	Document Version	File Name	File Format	Release Notes
USFDA_eCTD_v4_0_CV				
Genericode Schema	v1.0	genericode.xsd	XML Schema	
eCTD Codelist Stylesheet	v1.0	USFDA_eCTD_Codelist.xls	Stylesheet	
USFDA code list	v1.0	usfda-logo.png	Image	
Application Type	v3.0	USFDA CL1-application-type.gc3.xml	XML	
Context of Use	v5.0	USFDA CL2-context-of-use.gc5.xml	XML	
US CoU Keyword Definition Type	v2.0	USFDA CL3-cou-keyword-definition-type.gc2.xml	XML	
Form Type	v5.0	USFDA CL5-form-type.gc5.xml	XML	
Promotional Document Type	v1.0	USFDA CL6-promotional-document-type.gc.xml	XML	
Promotional Material Audience Type	v1.0	USFDA CL7-promotional-material-audience-type.gc.xml	XML	
Promotional Material Type	v2.0	USFDA CL8-promotional-material-type.gc2.xml	XML	
Submission Contact Type	v2.0	USFDA CL11-submission-contact-type.gc2.xml	XML	
Submission Type	v4.0	USFDA CL12-submission-type.gc4.xml	XML	
Submission Unit Type	v1.0	USFDA CL13-submission-unit-type.gc.xml	XML	
Submission contact status	v1.0	usfda-submission-contact-status.gc.xml	XML	
Submission Unit Status	v1.0	usfda-submission-unit-status.gc.xml	XML	
Telecom Capabilities	v1.0	usfda-telecom-capabilities.gc.xml	XML	
Telecom Use	v1.0	usfda-telecom-use.gc.xml	XML	
v3.2.2. eCTD Transition Mapping Message DTD v2.1				

Document Title	Document Version	File Name	File Format	Release Notes
Genericode Schema				Removed
eCTD Codelist Stylesheet				Removed
USFDA code list				Removed
Application Type				Removed
Context of Use				Removed
Submission Contact Type				Removed
Submission contact status				Removed
Submission Unit Status				Removed
v3.2.2. eCTD Transition Mapping Message DTD v3.3				
Genericode Schema				Removed
eCTD Codelist Stylesheet				Removed
USFDA code list				Removed
Application Type				Removed
Context of Use				Removed
CoU Keyword Definition Type				Removed
Form Type				Removed
Promotional document type				Removed
Promotional material audience type				Removed
Promotional material type				Removed
Submission Contact Type				Removed
Submission contact status				Removed
Submission Unit Status				Removed

XML SAMPLE FILES (CONTAINED IN THE USFDA REGIONAL MODULE 1 XML SAMPLES FOLDER)

Folder Name	Version	Folder Contents	Release Notes
Life Cycle Content	v1.0	NDA111886 Sequence 1 – Establishes initial set of content for life cycle	Initial Revision
	v1.0	NDA111886 Sequence 2 – Life cycle of contents from many to one.	Initial Revision
Grouped Submission	v1.0	NDA111111 Sequence 1 – 3 Initial submission units to establish keywords	Initial Revision
	v1.0	NDA111111 Sequence 6 – Grouped Submission with applications NDA222222 and NDA333333	Initial Revision
	v1.0	NDA222222 Sequence 1 – 3 Initial submission units to establish keywords	Initial Revision
	v1.0	NDA333333 Sequence 1 – 2 Initial submission units to establish keywords	Initial Revision
Study Data	v1.0	NDA111888 Sequence 1 – Initial study data content	Initial Revision
Promotional Materials	v1.1	NDA111113 Sequence 1 – Promotional Material	Corrected Keyword Definition codes for material id and issue dates.
Document Reuse	v1.0	NDA111889 Sequence 1 – Reuse of Study Data content from NDA 111888	Initial Revision
Withdraw Content	v1.0	NDA111889 Sequence 2 – Withdraw Content	Initial Revision
NDA Original			Removed
Grouped Labeling Supplement			Removed
Grouped Labeling Supplement Amendment			Removed
Promotional Materials			Removed
Withdraw Promotional Materials			Removed
V3.2.2 TMM			Removed