

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

1. PACKAGE REVISION HISTORY

Version	Date	Comments
1.0	2024-06	Initial Version. Separated from the FDA Module 1 eCTD v4.0 Implementation Package and added controlled vocabulary versioning. Deleted OID Listing document.

This package contains the information for the controlled vocabulary files needed to implement eCTD v4.0.

2. INVENTORY OF CONTROLLED VOCABULARY FILES

The following tables list the files (e.g., spreadsheet and genericode) included in the FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 Controlled Vocabulary Package and notes for the changes made in this version of the package.

Document Title	File Version	File Name	File Format	Release Notes
USFDA eCTD v4.0 Controlled Vocabulary (CV)	v1.6	USFDA_Regional_CV_eCTD_4_v1_6.xlsx	Excel	Updated for CV Versioning elements.
Genericode Files				
Genericode Schema	v2.0	genericode.xsd	XML Schema	Updated with CV Versioning elements.
eCTD Codelist Stylesheet	v1.0	USFDA_eCTD_Codelist.xls	Stylesheet	N/A
USFDA logo	v1.0	usfda-logo.png	Image	N/A
Application Type	v4.0	USFDA CL1-application-type.gc4.xml	XML	Updated for CV Versioning elements.
Context of Use	v6.0	USFDA CL2-context-of-use.gc6.xml	XML	Updated for CV Versioning elements.
US CoU Keyword Definition Type	v3.0	USFDA CL3-cou-keyword-definition-type.gc3.xml	XML	Updated for CV Versioning elements.

Document Title	File Version	File Name	File Format	Release Notes
Form Type	v6.0	USFDA CL5-form-type.gc6.xml	XML	Updated for CV Versioning elements.
Promotional Document Type	v2.0	USFDA CL6-promotional-document-type.gc2.xml	XML	Updated for CV Versioning elements.
Promotional Material Audience Type	v2.0	USFDA CL7-promotional-material-audience-type.gc2.xml	XML	Updated for CV Versioning elements.
Promotional Material Type	v3.0	USFDA CL8-promotional-material-type.gc3.xml	XML	Updated for CV Versioning elements.
Submission Contact Status	v2.0	usfda-submission-contact-status.gc2.xml	XML	Updated for CV Versioning elements.
Submission Contact Type	v3.0	USFDA CL11-submission-contact-type.gc3.xml	XML	Updated for CV Versioning elements.
Submission Type	v5.0	USFDA CL12-submission-type.gc5.xml	XML	Updated for CV Versioning elements.
Submission Unit Status	v2.0	usfda-submission-unit-status.gc2.xml	XML	Updated for CV Versioning elements.
Submission Unit Type	v2.0	USFDA CL13-submission-unit-type.gc2.xml	XML	Updated for CV Versioning elements.
Telecom Use	v2.0	usfda-telecom-use.gc2.xml	XML	Updated for CV Versioning elements.
Telecom Capabilities	v2.0	usfda-telecom-capabilities.gc2.xml	XML	Updated for CV Versioning elements.