OPDP eCTD Test Submission Checklist – Reference Document	Revised 10/23/2019

| Application Type/Number:
Sequence:
Sponsor:
POC:
Submission Date:
COR ID: | |
| Additional Notes from Submitter: | |

Resource List

OPDP Electronic Submissions Guidance: https://www.fda.gov/media/128163/download
eCTD Validation Criteria: https://www.fda.gov/media/87056/download
Comprehensive Table of Headings: https://www.fda.gov/media/76444/download
eCTD Submission Standards: https://www.fda.gov/media/93301/download
eCTD Sample Submissions: https://www.fda.gov/media/83809/download
Technical Conformance Guide: https://www.fda.gov/media/93818/download

Field	Expected Value	Pass	Notes	Dataset
Passed Gateway Validation?	Yes			
Applicant Info	Not Null			
Company Name	Not Null			
Applicant Contact	Applicant-contact-type = fdaact4			Link
Applicant Contact	All information provided?			
Application Number	Matches cover letter			
Application Type	One application type in submission			Link
Multiple Applications	Application-Containing-Files Attribute = "True" listed first in Application-Set			
Multiple Applications	Application-Containing-Files Attribute = "True" used once			
Submission Type	Submission-type = fdast8			Link
Submission Sub-Type	Submission Sub-Type = fdasst4			Link
Submission ID	Submission ID matches Sequence of Original Submission			
Sequence Number	Not previously used			

*The information provided in this eCTD Test Submission Checklist is an example. It is not binding on FDA or the public for any future eCTD submission nor does it create any rights for any person or the public. An alternative approach may be used if it satisfies the requirements of the applicable statutes and regulations. For details regarding eCTD submissions for promotional materials please refer to the guidance at https://www.fda.gov/media/128163/download

*Contains Nonbinding Recommendations**

Form Type	No Form Submitted			Link
Cover letter	Under heading 1.15.1.10			
Section 1.14	No files submitted in Labeling section			
Promotional Material Audience Type	Matches Subject Line of cover letter			Link

Promotional Material Doc Type	Promotional-Material-Doc-Type set appropriately
	    2253 – fdapmdt1
	    Launch Advisory – fdapmdt2
	    Non-Launch Advisory – fdapmdt3
	    Launch Accelerated Approval – fdapmdt4
	    Non-Launch Accelerated Approval – fdapmdt5
				Link

Promotional Material Type	Matches materials listed on cover letter			Link
Promotional Materials	Each Material included in separate section 1.15.2.1			
Material ID	Included			
Issue Date	Included and formatted correctly			
Clean Material	Not included – if included, should be submitted as Amendment			
Material Leaf Titles	Descriptive & Informative			
Annotated Material	Included in section 1.15.2.1.2			
Annotated Material Leaf Titles	Descriptive & Informative			
Annotated Label	Included in section 1.15.2.1.3			
Annotated Label Leaf Titles	Descriptive & Informative			
Annotated References	Included in section 1.15.2.1.4			
Annotated References Leaf Titles	Descriptive & Informative			
Orphan Files	None included			
Lifecycle Operators	Used appropriately			
Content Files	All Files in acceptable file format, accessible, and reviewable			
Hypertext Links	Correct structure and format			