OPDP eCTD Test Submission Checklist – General Correspondence	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 = fdasst1 when stand alone			Link

	Submission Sub-Type = fdasst4 when associated to existing submission			
Submission ID	If Submission Sub-Type = fdasst1, then Sequence Number and Submission ID should match If Submission Sub-Type = fdasst4, then Submission ID should match Sequence Number of associated Submission			
Sequence Number	Not previously used			
Form Type	No Form Submitted			Link
Cover letter	Under heading 1.15.1.11			
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	No Materials Submitted			Link
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			