

OPDP eCTD Test Submission Checklist – Response to Untitled Letter or Warning Letter	Revised 10/23/2019
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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	Amendment – fdasst4			Link
Submission ID	Submission ID matches Sequence Number of prior 2253			

*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**

Sequence Number	Not previously used			
Form Type	No Form Submitted			Link
Cover letter	Heading 1.15.1.6			
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 2253 – fdapmdt1			Link
Promotional Materials	No Materials under Section 1.15.2.1			
Orphan Files	None included			
Content Files	All Files in acceptable file format, accessible, and reviewable			
Hypertext Links	Correct structure and format			

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