

OPDP eCTD Test Submission Checklist – Form 2253	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 (Example 16): <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 Form 2253?			
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	Appropriate for Submission			Link
Submission ID	Appropriate for 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	Form-type = fdaft5			Link
Form Leaf Title	Descriptive & Informative			
Other Form Types	Not Included			
Section 1.14.6	PDF or Reference Link present			
Promotional Material Audience Type	Matches Form 2253			Link
Promotional Material Doc Type	Promotional-Material-Doc-Type = fdapmdt1			Link
Promotional Material Type	Matches materials listed on Form 2253			Link
Promotional Materials	Each Material included in separate section 1.15.2.1			
Material ID	Included			
Material Description	Appropriate and descriptive			
Issue Date	Included and formatted correctly			
Clean Material	Included in section 1.15.2.1.1			
Material Leaf Titles	Descriptive & Informative			
Orphan Files	None included			
Lifecycle Operators	Used appropriately			
Supplemental Application List	Included with Form 2253 when submitting a Group			
Supplemental Application List	All listed Applications included in XML			
Cover Letter	Not Included			
Content Files	All Files in acceptable file format, accessible, and reviewable			
Hypertext Links	Correct structure and format			

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