

|  |                    |
|--|--------------------|
| <b>OPDP eCTD Test Submission Checklist – Advisory/Accelerated Approval</b> | 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 (Example 13): <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  |      |       | <a href="#">Link</a> |
| Applicant Contact          | All information provided?   |      |       |                      |
| Application Number         | Matches cover letter  |      |       |                      |
| Application Type           | One application type in submission  |      |       | <a href="#">Link</a> |
| 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  |      |       | <a href="#">Link</a> |
| Submission Sub-Type        | Original Submission - fdasst1<br>Resubmission – fdasst5                         |      |       | <a href="#">Link</a> |

\*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\**

|                                    |   |  |  |                      |
|------------------------------------|---|--|--|----------------------|
| Submission ID                      | Original Submission – Sequence and Submission ID Match<br>Resubmission – Submission ID matches Sequence of Original Submissions   |  |  |                      |
| Sequence Number                    | Not previously used   |  |  |                      |
| Form Type                          | No Form Submitted   |  |  | <a href="#">Link</a> |
| Cover letter                       | Submitted under correct Heading<br>Launch Advisory – 1.15.1.1<br>Non-Launch Advisory – 1.15.1.2<br>Launch Accelerated Approval – 1.15.1.3<br>Non-Launch Accelerated Approval – 1.15.1.4                 |  |  |                      |
| Section 1.14                       | No files submitted in Labeling section  |  |  |                      |
| Promotional Material Audience Type | Matches Subject Line of cover letter  |  |  | <a href="#">Link</a> |
| Promotional Material Doc Type      | Promotional-Material-Doc-Type set appropriately<br>Launch Advisory – fdapmdt2<br>Non-Launch Advisory – fdapmdt3<br>Launch Accelerated Approval – fdapmdt4<br>Non-Launch Accelerated Approval – fdapmdt5 |  |  | <a href="#">Link</a> |
| Promotional Material Type          | Matches materials listed on cover letter  |  |  | <a href="#">Link</a> |
| Promotional Materials              | Each Material included in separate section 1.15.2.1   |  |  |                      |
| Material ID                        | Included  |  |  |                      |
| Issue Date                         | Included and formatted correctly  |  |  |                      |
| Clean Material                     | Included in section 1.15.2.1.1  |  |  |                      |
| 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  |  |  |                      |

\*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\**

|                                     |   |  |  |  |
|-------------------------------------|---|--|--|--|
| Annotated References<br>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                                    |  |  |  |

\*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>