FDA Electronic Submissions Update

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Agenda

- Important Submission Deadlines
- Submission Metrics
- Top 3 Rejections and How to Avoid Them
- Validation Resources
- Application Lifecycle Management
- Frequently Asked Questions
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Important Submission Deadlines

eCTD Guidance became binding

- May 5, 2017: NDA, BLA, and ANDA must be in eCTD format
- May 5, 2018: Commercial IND and Master Files must be in eCTD format
Important Submission Deadlines

eCTD Submissions

▶ Must use Fillable Forms (e.g., 356H and 1571)
▶ Must use Gateway for submissions 10GB or less
▶ Must use correct lifecycle operators
  – Use the “Replace” lifecycle operator when updating content
Important Submission Deadlines

eCTD Submission

► Exemptions are outlined in the guidance
► Submissions that do not adhere to the requirements stated in the eCTD Guidance will **not be filed or received**
► Please see the eCTD website **www.fda.gov/ectd** for further information
Study Data Submission Deadlines

- Studies that start after December 17, 2016 must be in standardized format for NDA, BLA and ANDA submissions
- For IND submissions, the date is December 17, 2017

See the following resources for more information

- Study Data Standards Resources page
- Technical Rejection Criteria for Study Data
- The Study Data Guidance

Have Questions? Contact eData@fda.hhs.gov
Submission Metrics

FDA CDER eCTD Submissions by Year and Application Type

CDER Processed Nearly 180,000 eCTD Submissions In 2017
Nearly 100% of NDA, BLA, ANDA in eCTD

Excludes Promotional and Advertising Submissions
May 5, 2018: Commercial IND and Master Files (Type II, IV and V) must be in eCTD format

99% of INDs submitted in eCTD
96% of DMFs submitted in eCTD
Top 3 Rejections and How to Avoid Them
Top 3 Rejections and How to Avoid Them

A closer look at the 3 most common rejections for eCTD NDA, BLA, IND, MF, ANDA (sample size: 15,765)
# 1. Duplicate Sequence Number Received

<table>
<thead>
<tr>
<th>Issue</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitting revised content under same sequence number (e.g. trying to swap out a sequence)</td>
<td>Content should be updated by submitting changes in the next available sequence</td>
</tr>
<tr>
<td>Transfer of application but new owner is not aware of sequence numbers used</td>
<td>Recommend obtaining full sequence history from prior owner</td>
</tr>
<tr>
<td>Re-using a sequence number if submission has been withdrawn</td>
<td>Even if a submission is withdrawn, FDA continues to keep the sequence</td>
</tr>
</tbody>
</table>
Top 3 Rejections and How to Avoid Them

2. Most Common M1 (DTD 3.3) Mistake

**Issue**

**Validation Code 2022:** You have used a submission-sub-type which is not allowed for the submission-type and/or type of application.

Ex: Original Application/Correspondence

**Resolution**

See list of valid Submission Type and Sub-Type combinations.

Resource: eCTD Backbone Files Specifications for Module 1, Table 2: Submission Types and Descriptions of Use
Top 3 Rejections and How to Avoid Them

3. Invalid File Types
   - .exe, .zip, and others single file submissions are not allowed
Validation Resources

Specification documents are posted on [www.fda.gov/ectd](http://www.fda.gov/ectd) in the eCTD Submission Standards

Validation Documents Include:

- eCTD Validation Specifications
- Technical Rejection for Study Data Criteria
Lifecycle Management

- **Submission Type/Subtype**
  - Tells FDA the regulatory activity of your submission (e.g. Original, Supplement, Annual Report) and to which regulatory activity amendments belong

- **Sequences**
  - Recommend starting with 0001
  - Part of the record (FDA does not delete them)
  - Can be cross referenced

- **Use eCTD Lifecycle Operator**
  - Replace
  - Delete
Frequently Asked Questions
Frequently Asked Questions

Where do I place my content?

Resources

- The Comprehensive Table of Contents Headings and Hierarchy
- M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry
- FDA Regulatory Project Manager
Frequently Asked Questions

► Can I submit a xyz file format?

  – When creating content, follow the Specifications for File Format Types Using eCTD Specifications for guidance on file formats FDA expects under the different CTD headings

► Questions related to PDF files (e.g. hyperlinks, bookmarks, font, etc)

  – Follow FDA’s PDF Specifications and communicate to vendors the need to follow these specifications
Frequently Asked Questions

► How do I get started with eCTD?
► How do I request an application number?
► How do I get a gateway account?

These questions and more are answered on the eCTD website:
Thank You

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