CDER SBIA Webinar Series

U.S. FOOD & DRUG ADMINISTRATION

Electronic Submission requirements for ANDAs: Are you ready?

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November 21, 2016

Agenda

- eCTD Requirements and Timeline
- Where to find eCTD resources
- The ESG (Electronic Submission Gateway)
- CDER eCTD Processing
- Common eCTD Deficiencies
- How OGD (Office of Generic Drugs) will handle eCTD deficiencies
- Questions

How would you characterize your ability to submit your ANDA in proper eCTD format?

○	I'm an experienced expert	0%	(0)
○	I'm pretty good at it	0%	(0)
○	Someone else in my company handles the eCTD	0%	(0)
○	I'm a beginner – that is why I am here.	0%	(0)
○	Wait. What is eCTD?	0%	(0)
◉	No Vote		

☑ Broadcast Results

eCTD Requirements and Timeline

- **May 5, 2017:** NDA, BLA, **ANDA** and DMFs must be in eCTD format
- **May 5, 2018:** Commercial INDs must be in eCTD format
- Do not send Paper and/or non-eCTD submissions after these deadlines!

eCTD Requirements and Timeline

STUDY Data Standards Resources

- **What's New**
  - Studies that start after **December 17, 2016** must be in standardized format for NDA, BLA and ANDA submissions
  - Study Data Technical Conformance Guide

  http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

- **Validation Codes**

  See Technical Rejection for Study Data. Currently posted on eCTD Website at www.fda.gov/ectd

- **When**

  CDER will start using the new validation criteria - TBD

eCTD Requirements and Timeline

- Submissions that do not adhere to the requirements stated in the binding eCTD Guidance will be **not be filed or received**

- Please see the eCTD web page www.fda.gov/ectd for further information

eCTD Requirements and Timeline

FDA

*See the Guidance for a *complete* list of the "musts"*

- **Must** submit electronic submissions using the eCTD version currently supported by FDA.
  - The version of eCTD currently supported is specified in the Data Standards Catalog
- **Must** obtain a pre-assigned application number by contacting the appropriate Center. *How? Go to www.fda.gov/ectd*
- **Must** follow the FDA eCTD technical specification *Table of Contents Headings and Hierarchy.*

Find it in the eCTD Submissions Standards catalog

eCTD Requirements and Timeline

Find these specifications and more in the [eCTD Submissions Standards catalog]

- **Must** adhere to the formats and versions specified in the FDA *Specifications for File Format Types Using eCTD Specifications*.
- **Must** adhere to the FDA *Portable Document Format (PDF) Specifications.*
- **Must** use the eCTD *replace* operation rather than submitting the file as *new* if a document replaces a document previously submitted …

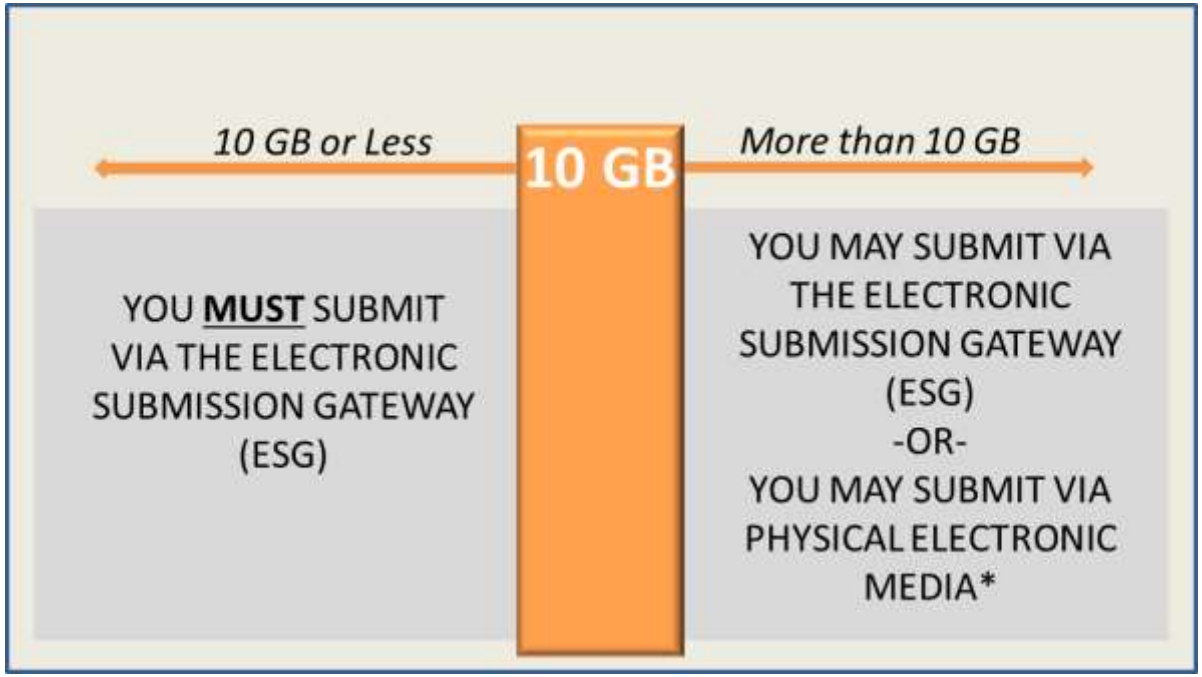
eCTD Requirements and Timeline

- **Must** include FDA fillable 356h form for ANDA, NDA, BLA and electronic signature to enable automated processing of the submission … *Scanned images of FDA forms will not be accepted.*

- **Must Not** submit paper copies of the application, including review & desk copies when *submitting in eCTD format.*

eCTD Requirements and Timeline

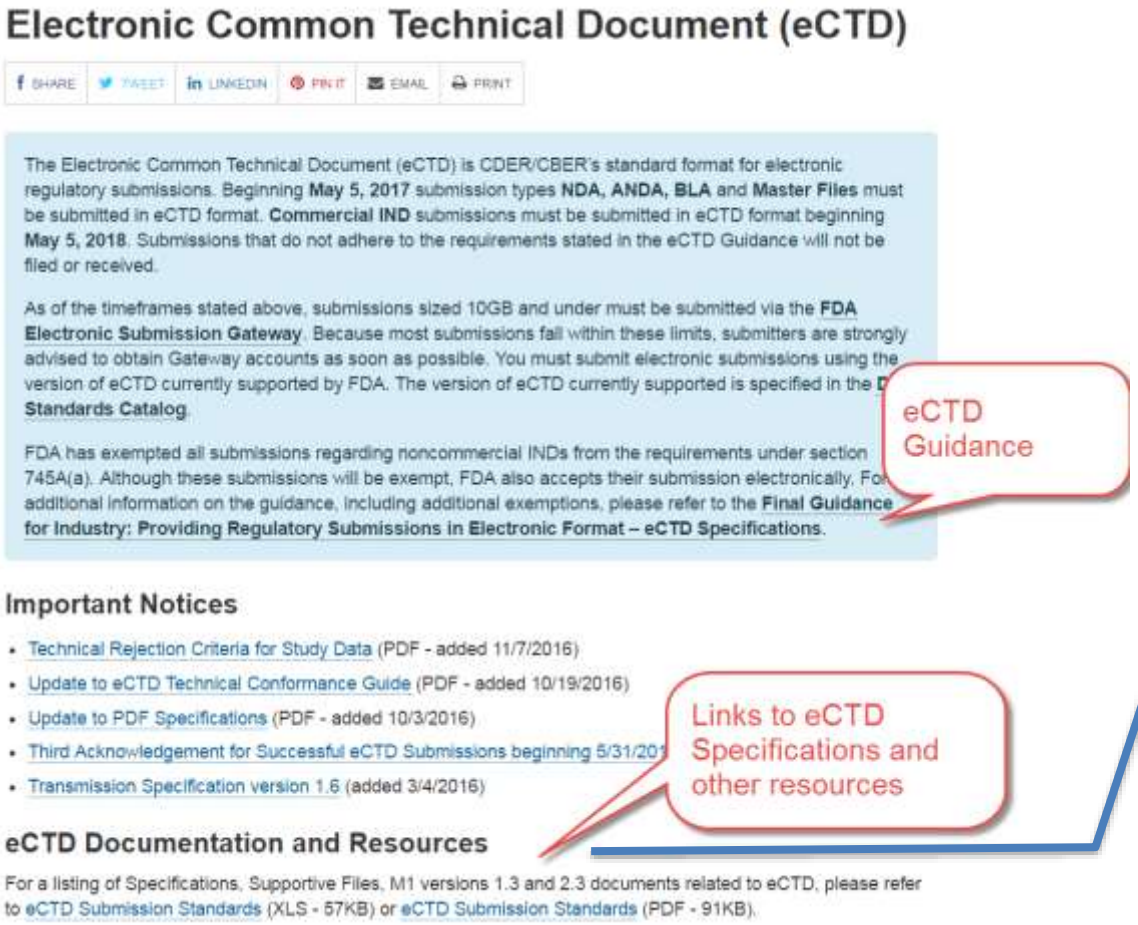
- **Must** use the FDA Electronic Submission Gateway for submissions 10 GB or smaller.
  - ✓ Submissions larger than 10GB may come via the Gateway or USB drive



*See Transmission Specification for additional details

Where to find eCTD resources

eCTD website – www.fda.gov/ectd



What are the eCTD Specifications?

ICH eCTD Specs 3.2.2
FDA eCTD - Module 1
eCTD CTOC
Validation, File Format, PDF
Supportive files & more

Where to find eCTD resources

eCTD website – www.fda.gov/ectd

Getting Started Section

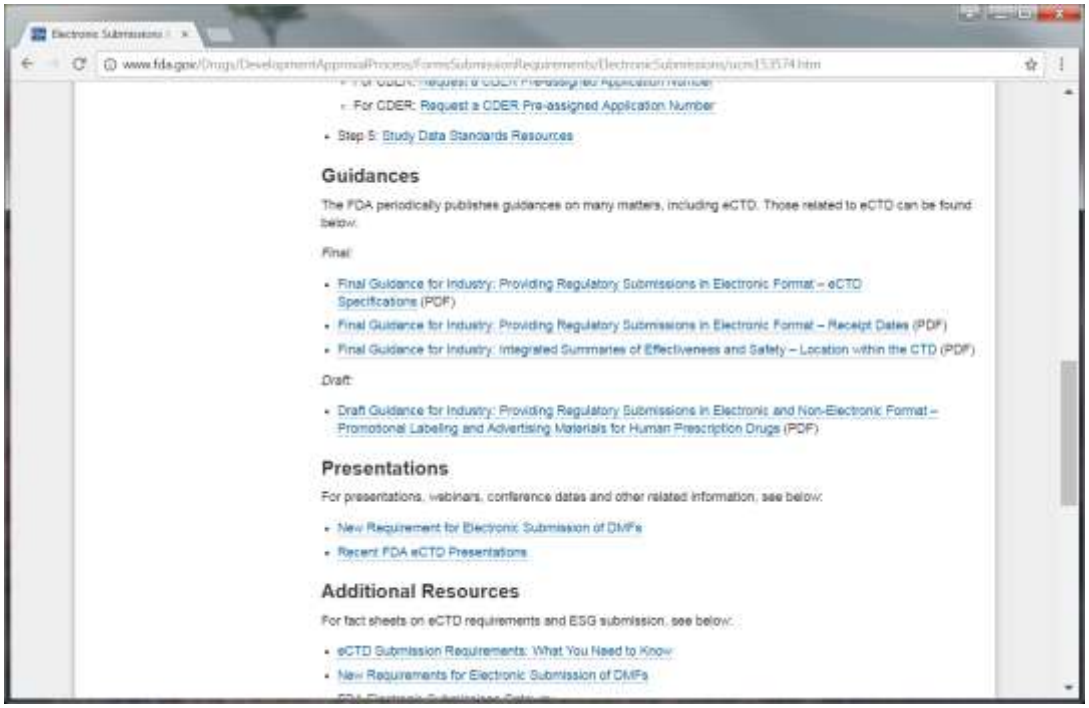
- eCTD Basics and Getting Started
- Electronic Submission Gateway (ESG)
  - Step by step instructions on obtaining an ESG account
- Submit a Sample eCTD or Standardized Data Sample
  - We offer a process to validate sample eCTD submissions and standardized study datasets
- Instructions on how to request a CDER or CBER Pre-assigned Application Number
- Study Data Standards Resources

Where to find eCTD resources

Other sections are available too..

- Guidances
- Presentations
- Additional Resources
- Technical Assistance

eCTD website – www.fda.gov/ectd



Electronic Submission Gateway (ESG)

- If you are not currently an ESG submitter, set up an account now; process can take several weeks
- Most submitters use the "WebTrader Hosted Solution"
- There is no cost for an ESG account, but you must obtain a Digital Certificate for each person in your organization who will be sending files thru the ESG
- Submissions 10 GB or less must use the ESG starting May 5, 2017.
- Submissions over 10 GB may use the ESG or be submitted via physical media
- See the ESG website for complete instructions: http://www.fda.gov/esg

CDER eCTD Processing

Common reasons for rejections which prevent submission from processing to review division:

- Duplicate Submissions
  - You send the same submission sequence more than once
- Submitted to Wrong Center
  - Selecting wrong center when using gateway (e.g., CDER instead of CBER)
- Mismatched Application/Sequence Type
  - Specifying NDA in us-regional.xml while indicating ANDA in 356h Form
- Invalid File Type
  - Submitting file types such as .zip and .exe
- Not in Standard eCTD Format
  - Missing key files such as us-regional.xml and index.xml

Common eCTD Deficiencies

Julia Lee, Pharm.D.
Acting Deputy Director
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs

Common eCTD Deficiencies

Legibility and Font Size

BAD

Font type	Font name
Sans Serif	Arial
	Arial Italic
	Arial Bold
	Arial Bold Italic
Non Proportional	Courier New
	Courier New Italic
	Courier New Bold
	Courier New Bold Italic
Serif	Times New Roman
	Times New Roman Italic
	Times New Roman Bold
	Times New Roman Bold Italic
Other	Symbol
	Zapf Dingbats

Common eCTD Deficiencies

Legibility and Font Size

GOOD

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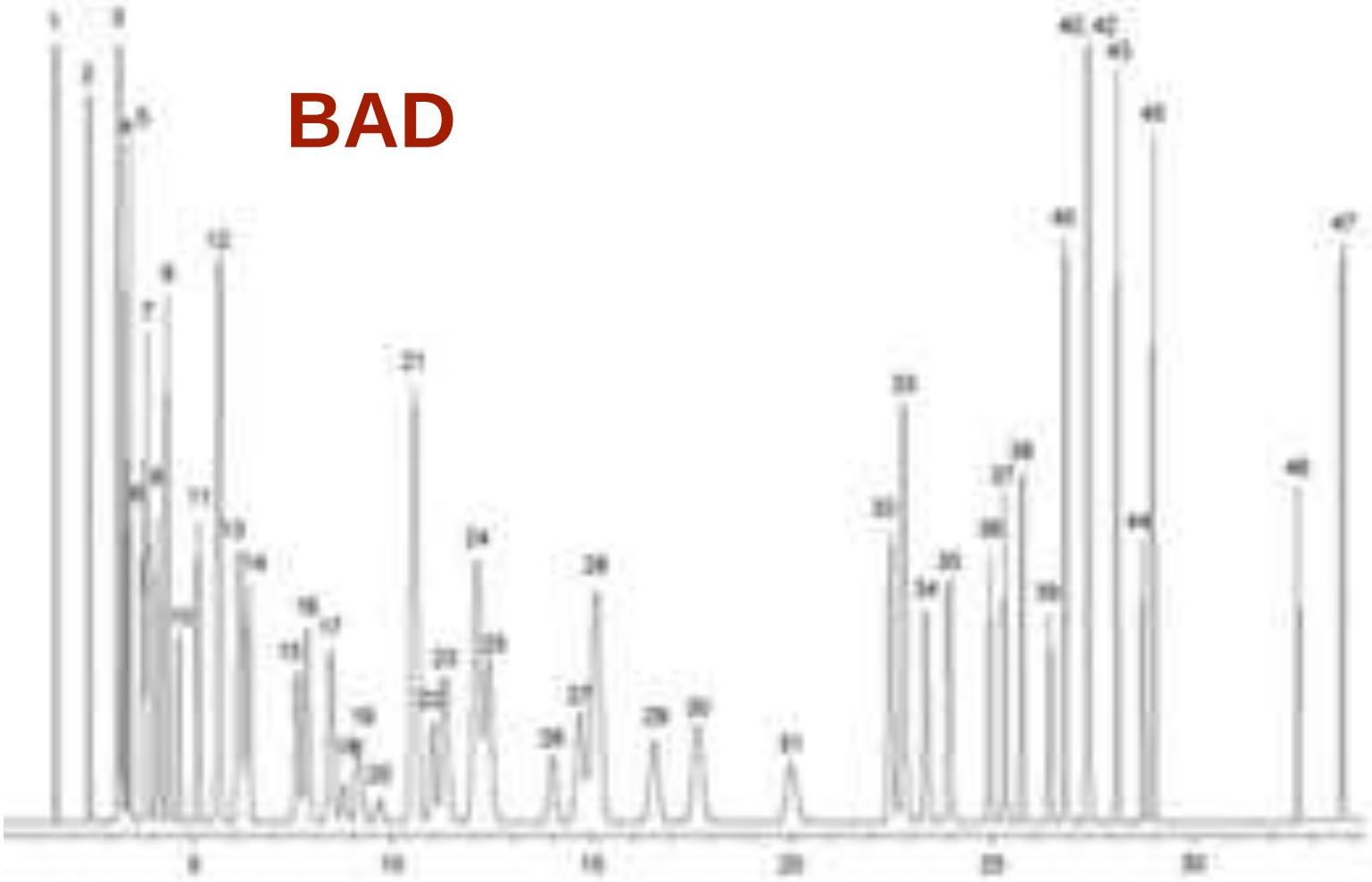
Common eCTD Deficiencies

Legibility and Font Size



Common eCTD Deficiencies

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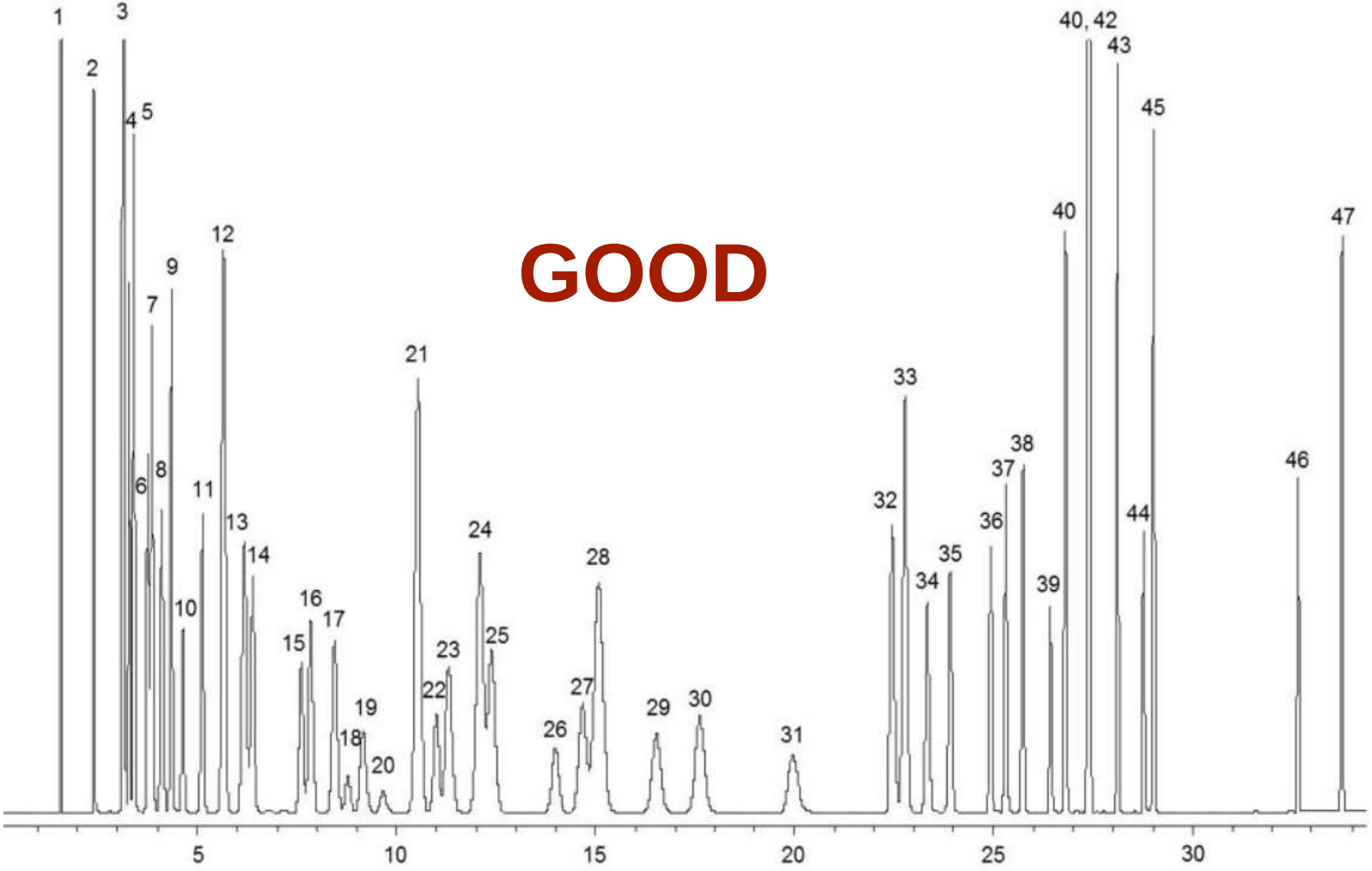

Common eCTD Deficiencies

Orientation

Any documents provided in the ANDA submission should be in the correct orientation

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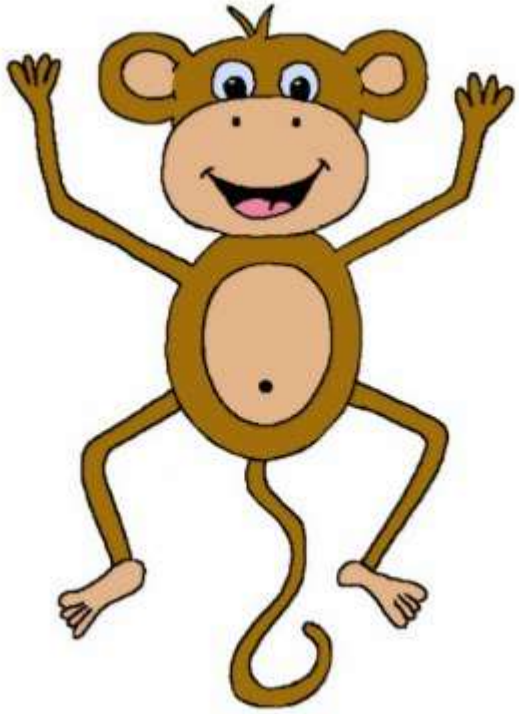


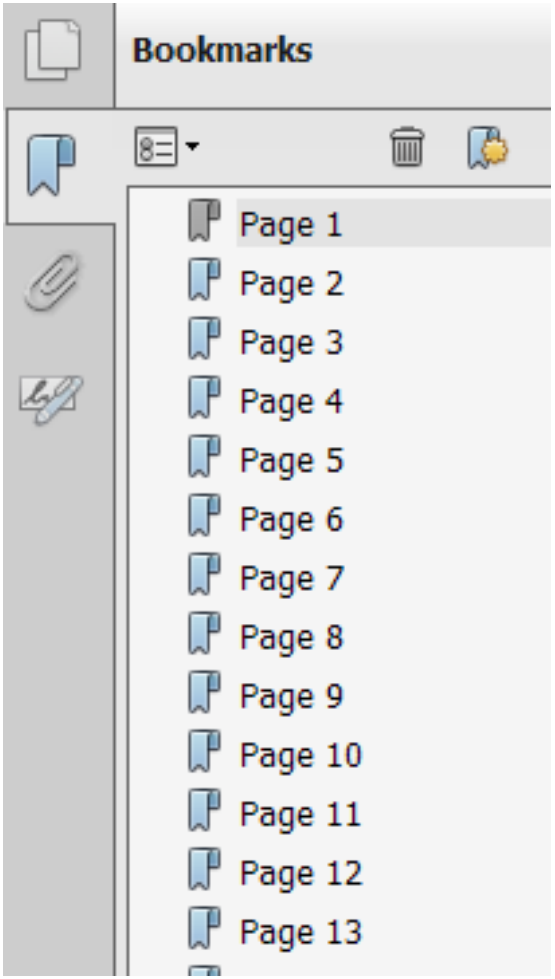
Common eCTD Deficiencies

Hypertext Table of Contents and Bookmarks

- Should be the same
- For documents 5 pages or longer
- Up to 4 levels deep in hierarchy
- Each item listed in the table of contents, which should include all tables, figures, publications, other references, and appendices that are essential for navigation
- Set magnification to Inherit Zoom

Common eCTD Deficiencies

Bookmarks



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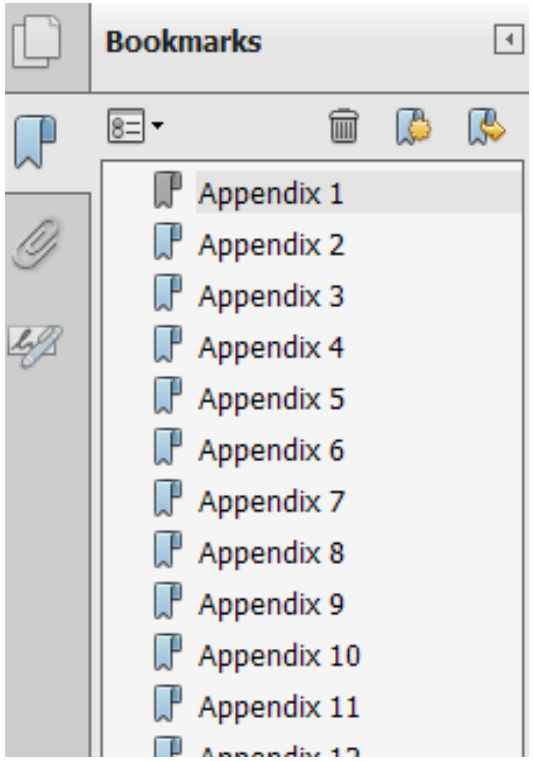

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Common eCTD Deficiencies

Bookmarks

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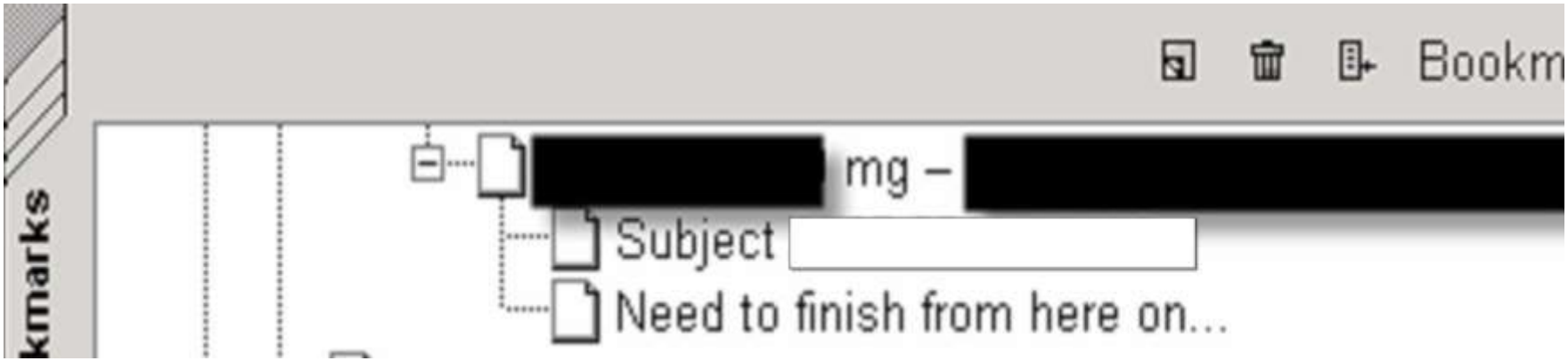

Common eCTD Deficiencies

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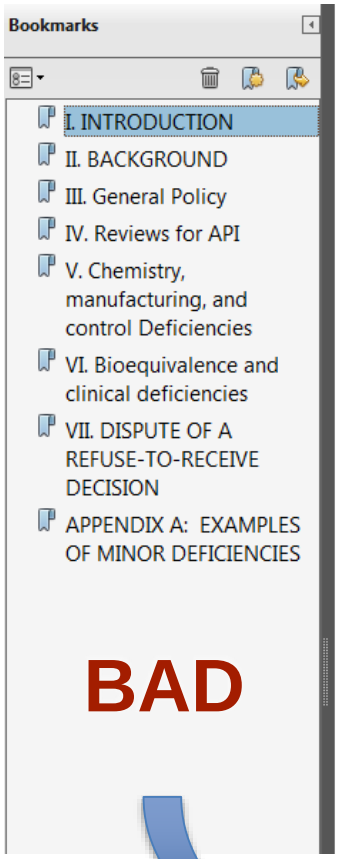

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Common eCTD Deficiencies

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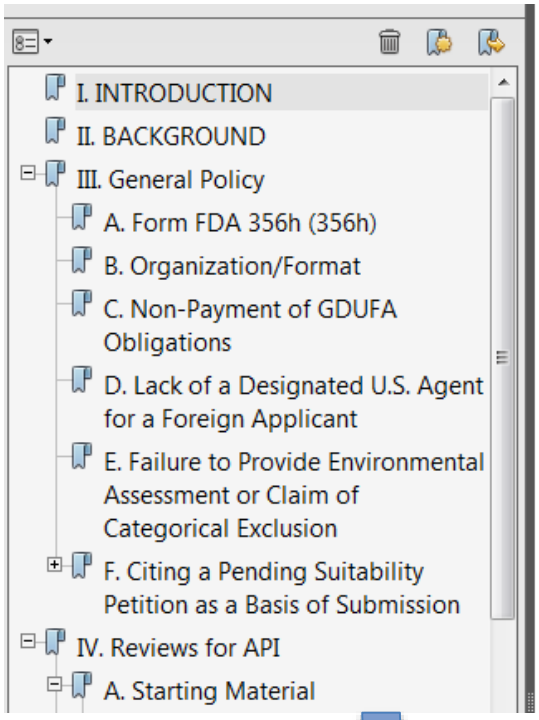

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Common eCTD Deficiencies
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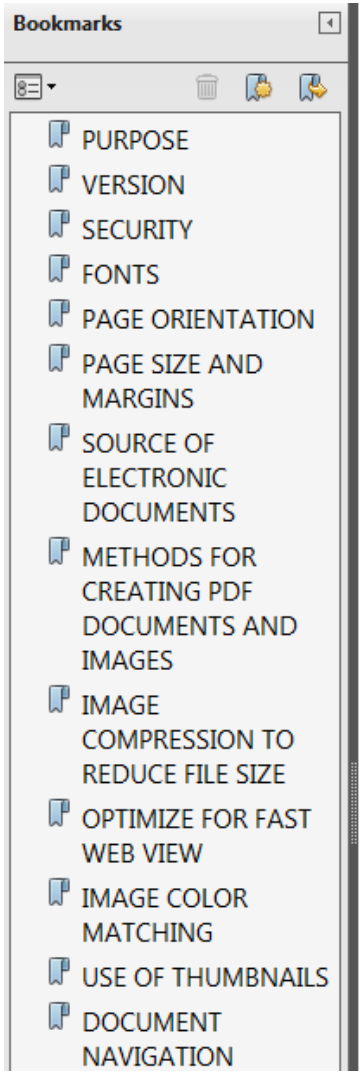

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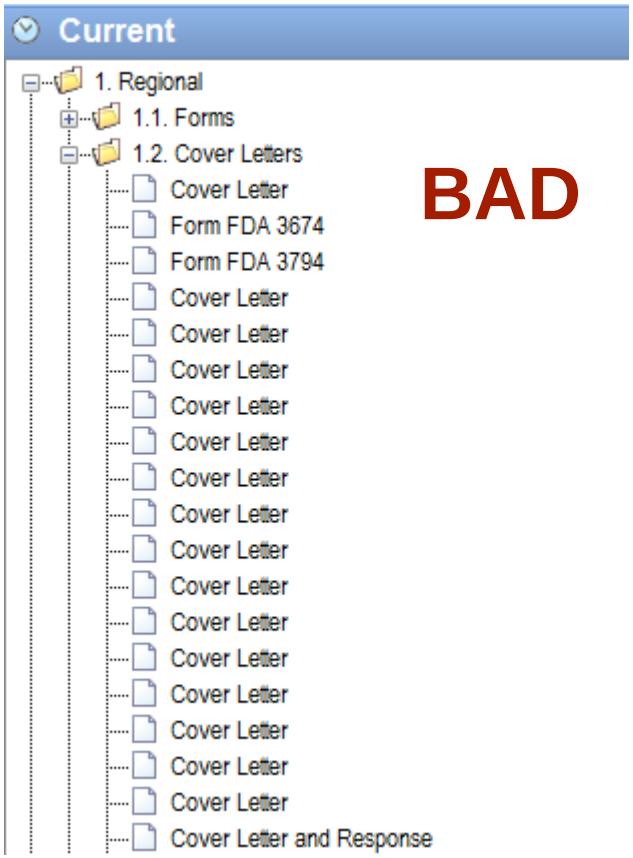
Common eCTD Deficiencies

Leaf Titles



BAD

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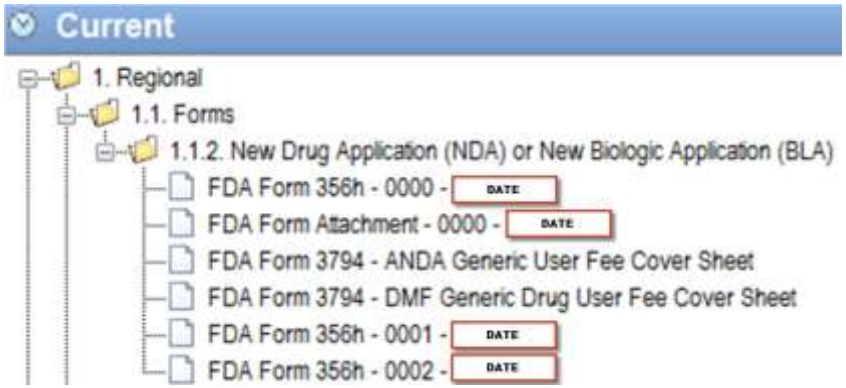
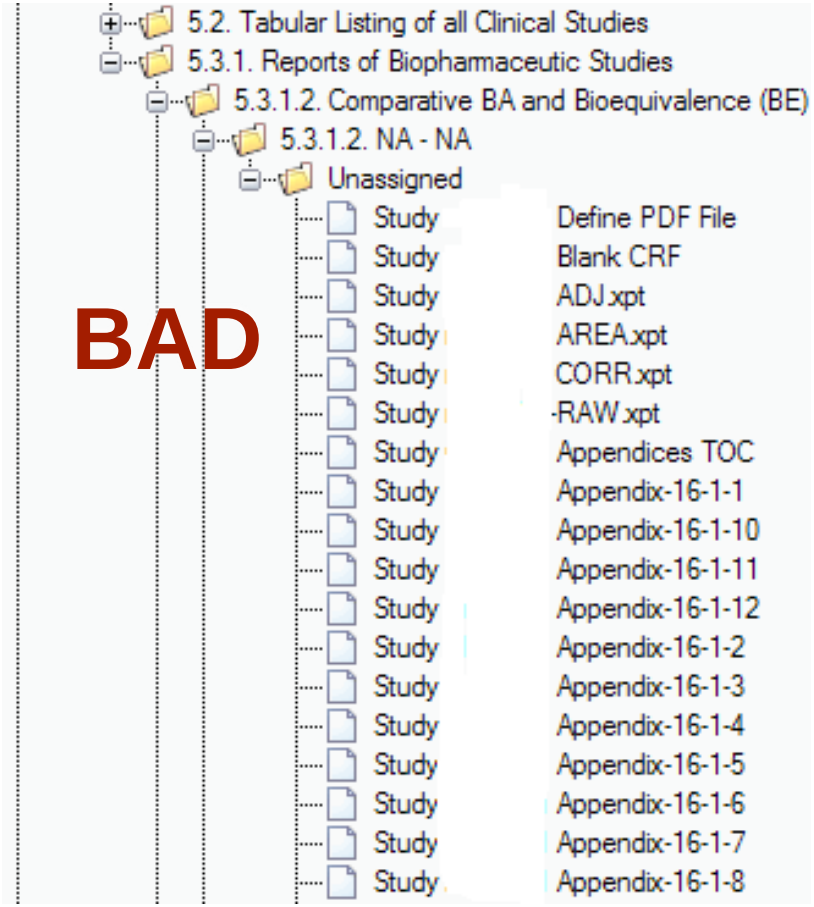


Common eCTD Deficiencies

STF .xml Study Information



How OGD will handle eCTD deficiencies

Current Practice

Separate set of 'eCTD Deficiencies'

Inadequately addressed →

LOSE GDUFA GOAL DATE

May 5, 2017

eCTD deficiencies will be counted as a minor deficiency

Inadequately addressed →

Refuse to Receive (RTR)

Summary

- All documents submitted to the Agency, including contracted documents, **must** follow the standards set forth in the binding eCTD guidance
- Currently if deficiencies are not corrected within 7 calendar days, you lose your goal date
- Beginning May 5, 2017 → RTR

Resources

- ANDA Filing Checklist
- ANDA Submissions -- Content and Format of Abbreviated New Drug Applications
- ANDA Submissions -- Refuse-to-Receive Standards
- Electronic Common Technical Document (eCTD)
- Providing Regulatory Submissions in Electronic Format -- Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- Comprehensive Table of Contents Headings and Hierarchy
- eCTD Submission Standards
- Submitting High Quality eCTD Submissions to FDA/OGD (Presentation 09/11/13)
- eCTD Web Page
- ESG Web Page

Information For Industry

Click for:

- Providing Regulatory Submissions in Electronic Format
- Electronic Common Technical Document
- eCTD Submission Standards
- ANDA Submissions - RTR Standards
- PDF of today's slides
- eCTD questions should be sent directly to CDER ESUB at:

ESUB@fda.hhs.gov

Open Q&A begins shortly – type in your questions now.

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