



# Regulatory Education for Industry (REdI): **GENERIC DRUGS FORUM**

Silver Spring, MD | April 13-14, 2016

## **ANDA Submissions – Refuse-to-Receive Considerations**

**Johnny Young, M.A.**

Acting Director

Division of Filing Review

Office of Regulatory Operations

Office of Generic Drugs

Center for Drug Evaluation and Research

	<b>FY14</b> (10/1/13-9/30/14)	<b>FY15</b> (10/1/14-9/30/15)	<b>FY16</b> (10/1/15- 3/31/16)
<b>Number of RTRs</b>	173	127	85
<b>Number of Submissions</b>	1473	539	474
<b>% RTR</b>	11.7%	23.6%	17.9%



# Common RTR Pitfalls

- **CMC (Stability, 2 API lots)**
- **English Translations**
- **Incomplete Responses**
- **Inadequate Dissolution**
- **non Q/Q same**
- **No Response within 7 or 10 days**



# Regulatory Education for Industry (REdI): **GENERIC DRUGS FORUM**

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## **ANDA Submissions – eCTD Considerations**

**Julia Lee, Pharm.D.**

Acting Deputy Director  
Division of Filing Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



# Discussion Overview

- **Regulations**
- **Timeline**
- **Common eCTD Deficiencies**
- **Resources & Questions**



# Regulations

- Approved by the 112<sup>th</sup> U.S. Congress in 2012
- Amended the FD&C Act to establish user-fee programs
- Section 745A(a) was added by Section 1136 of FDASIA
  - ANDA submission shall be submitted in electronic format 24 months after binding guidance is finalized
  - In a standard format requested by the Agency



# GDUFA Commitment Letter

- Jointly proposed by the Agency and industry
- Review metric goals only apply to submissions made **electronically** following the **Electronic Common Technical Document (eCTD)** format in effect at the date of submission





# Timeline



## 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 →

**RTR**





# Common eCTD Deficiencies

## Legibility and Font Size

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



# Common eCTD Deficiencies

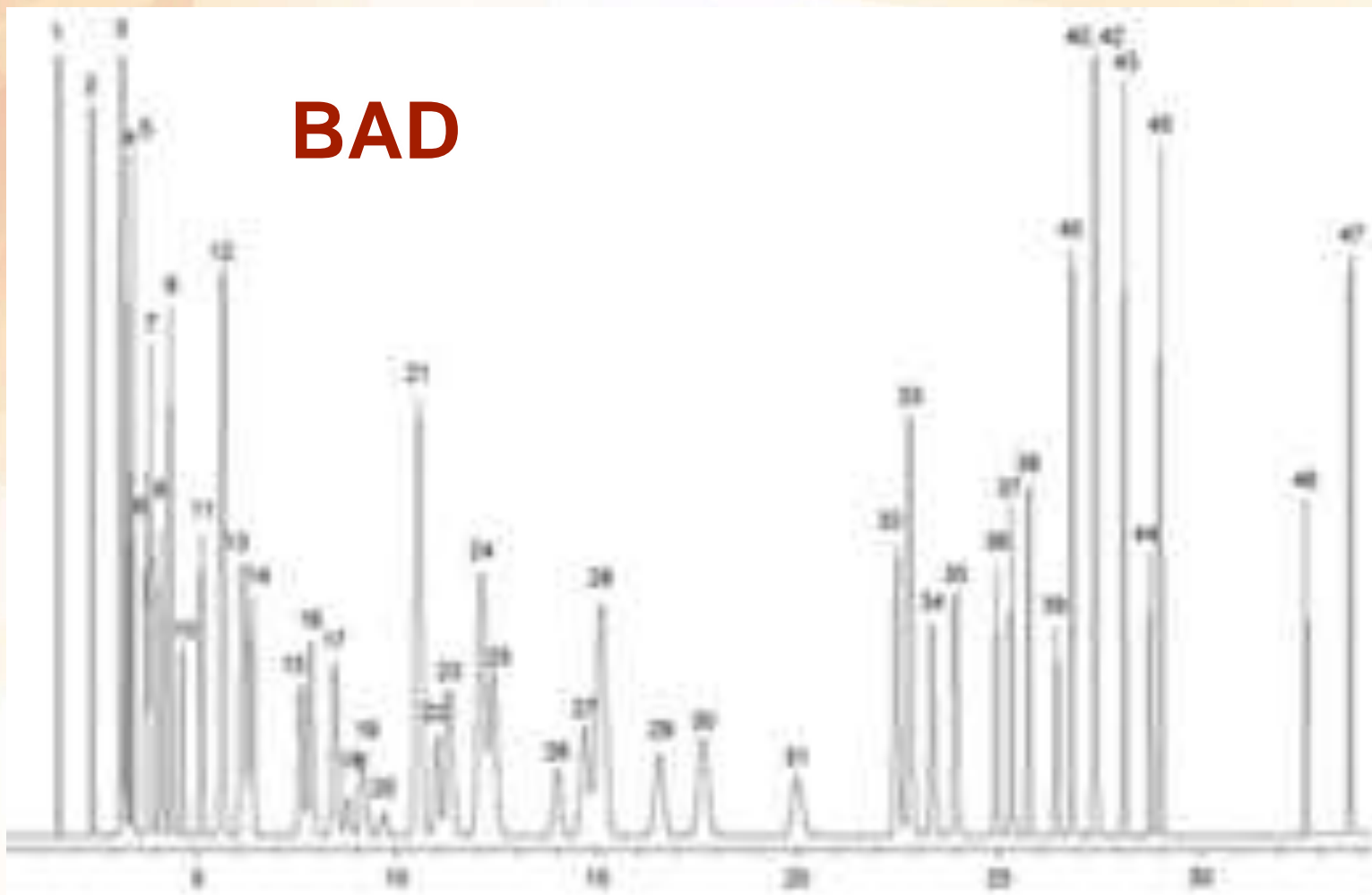
## Legibility and Font Size

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

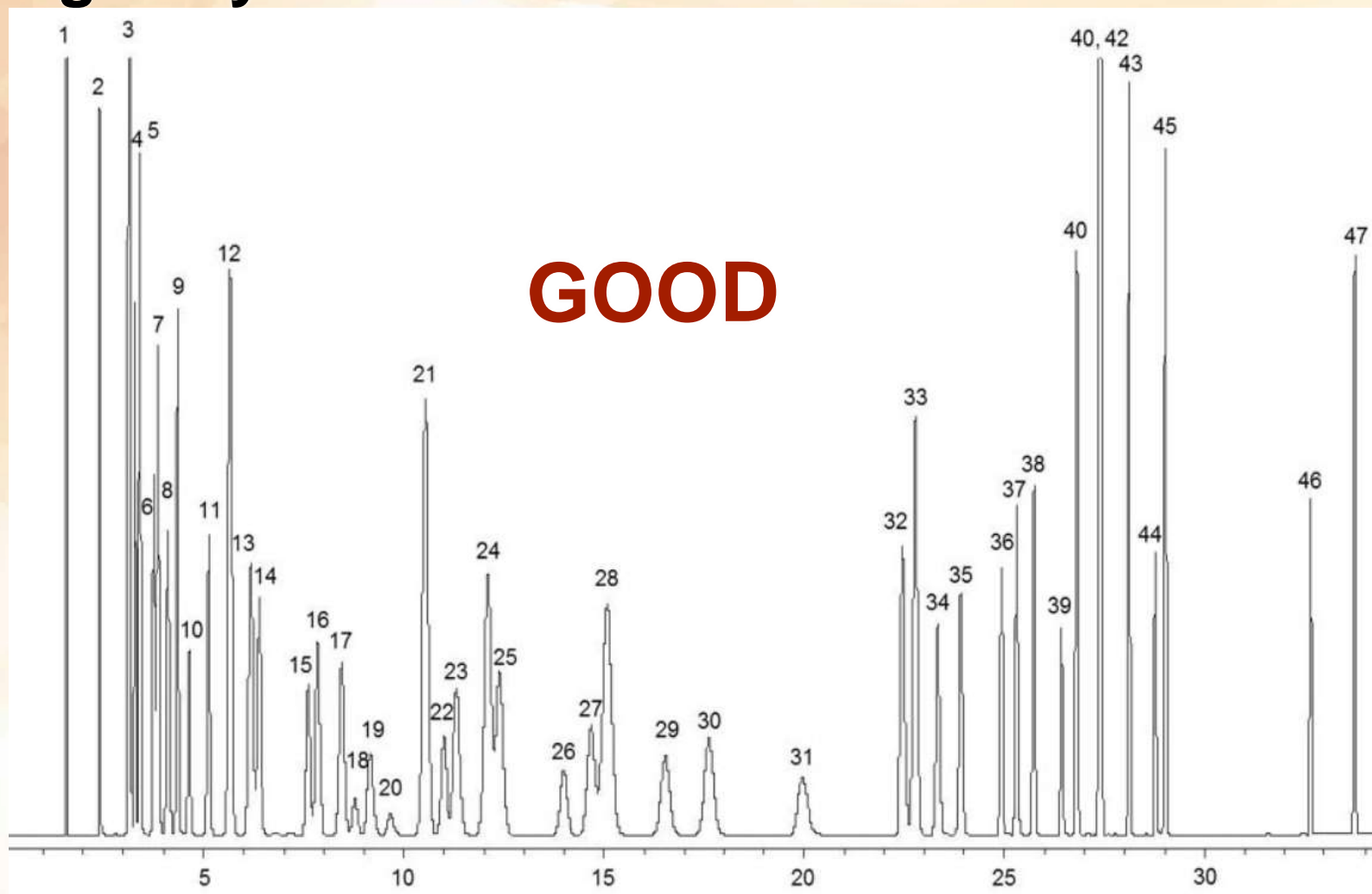
## Legibility and Font Size





# Common eCTD Deficiencies

## Legibility and Font Size

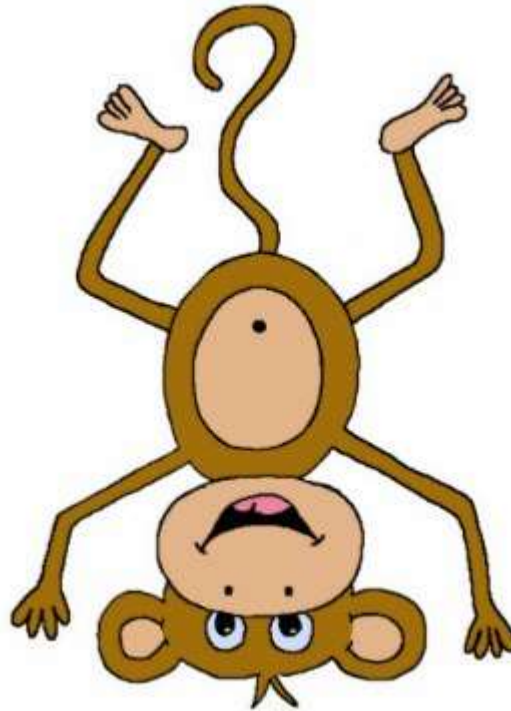




# Common eCTD Deficiencies

## Orientation

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

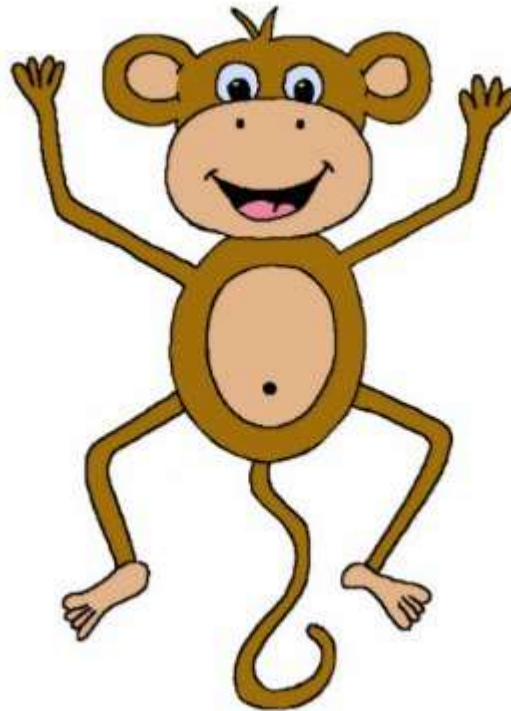




# Common eCTD Deficiencies

## Orientation

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





# Common eCTD Deficiencies

## Hypertext Table of Contents and Bookmarks

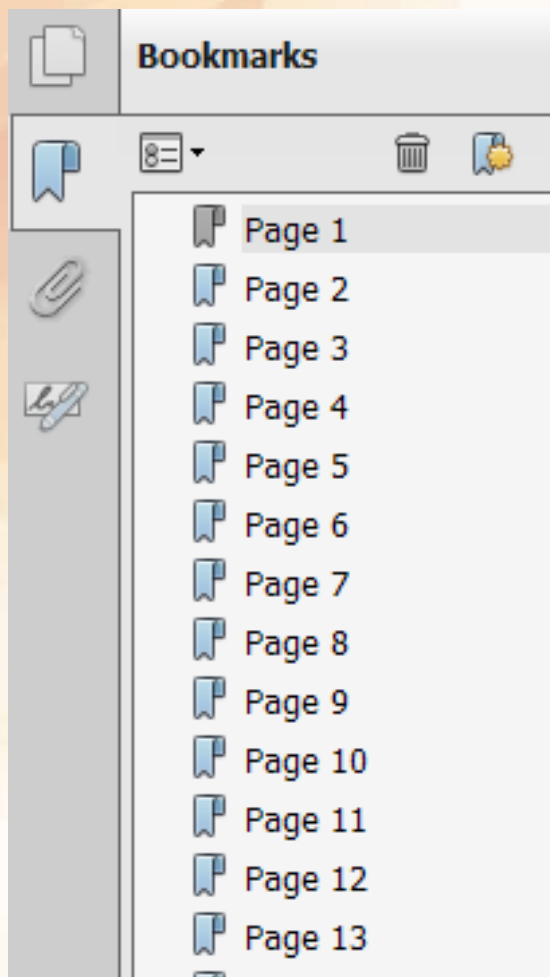
- Should be the same
- For documents **5 pages or longer**
- Up to **4 levels deep** in hierarchy
- **Each item** listed in the table of contents, which should include all tables, figures, publications, other references, and appendices that are essential for navigation
- Set magnification to **Inherit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



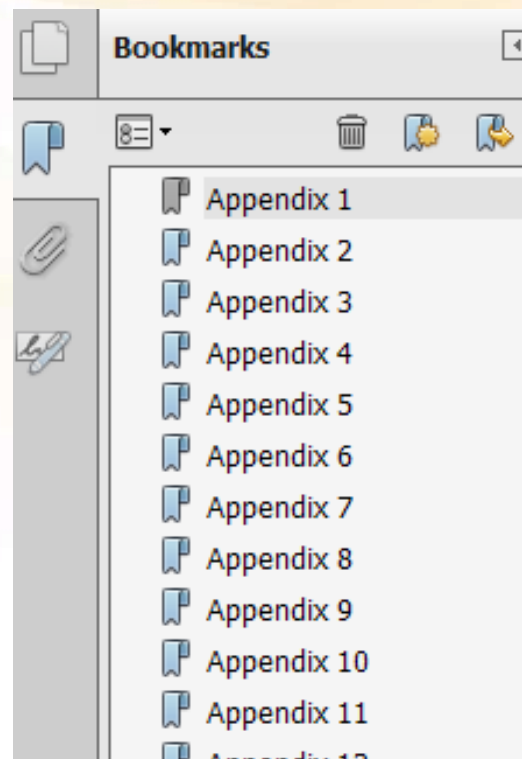


# Common eCTD Deficiencies

## Bookmarks



**Really  
Bad**



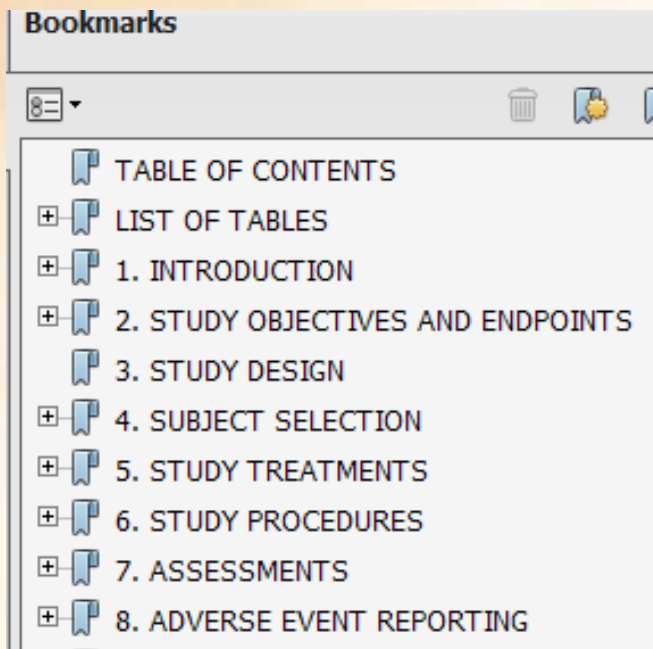
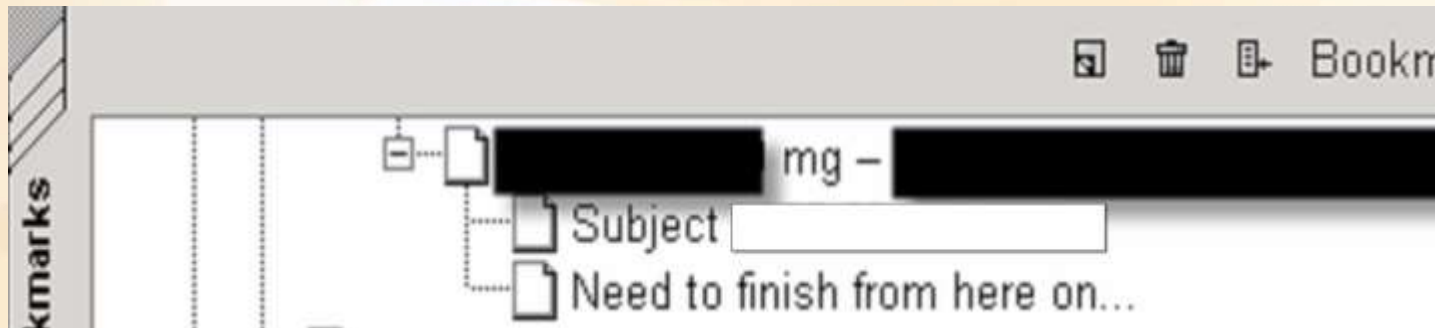
**Bad**



# Common eCTD Deficiencies

## Bookmarks

**BAD**



**GOOD**



# Common eCTD Deficiencies

**BAD**

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# Common eCTD Deficiencies

Bookmarks

- And Consent
- 6.0 Investigators And Study Administrative Structure
- 6.1 Facilities
- 7.0 Introduction
- 8.0 Study Objectives
- 9.0 Investigational Plan
  - 9.1 Overall Study Design And Plan-Description
  - 9.2 Discussion Of Study Design, Including The Choice Of
  - 9.3 Selection Of Study Population
    - 9.3.1 Inclusion Criteria

INTEGR

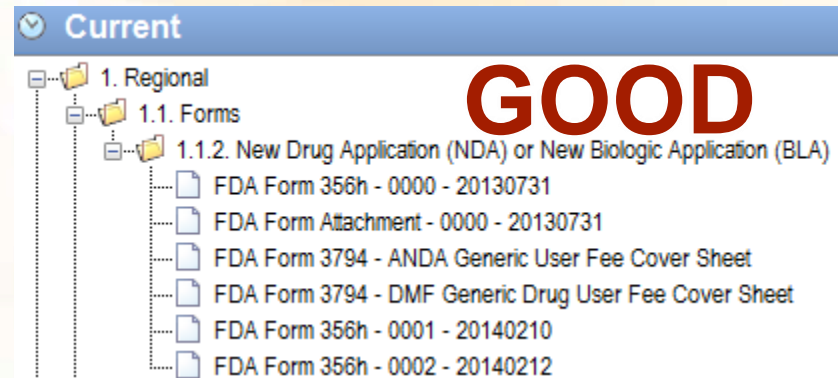
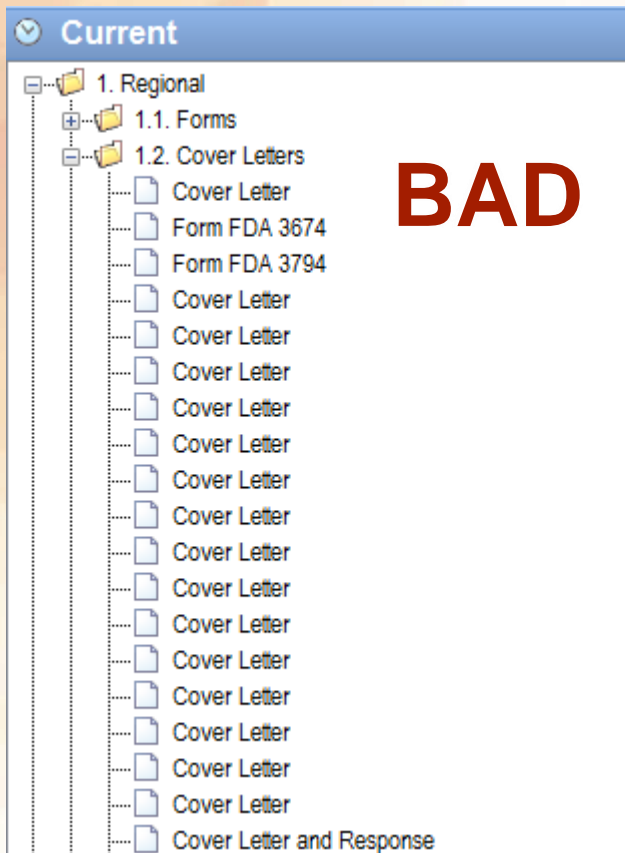
GOOD

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# Common eCTD Deficiencies

## Leaf Titles



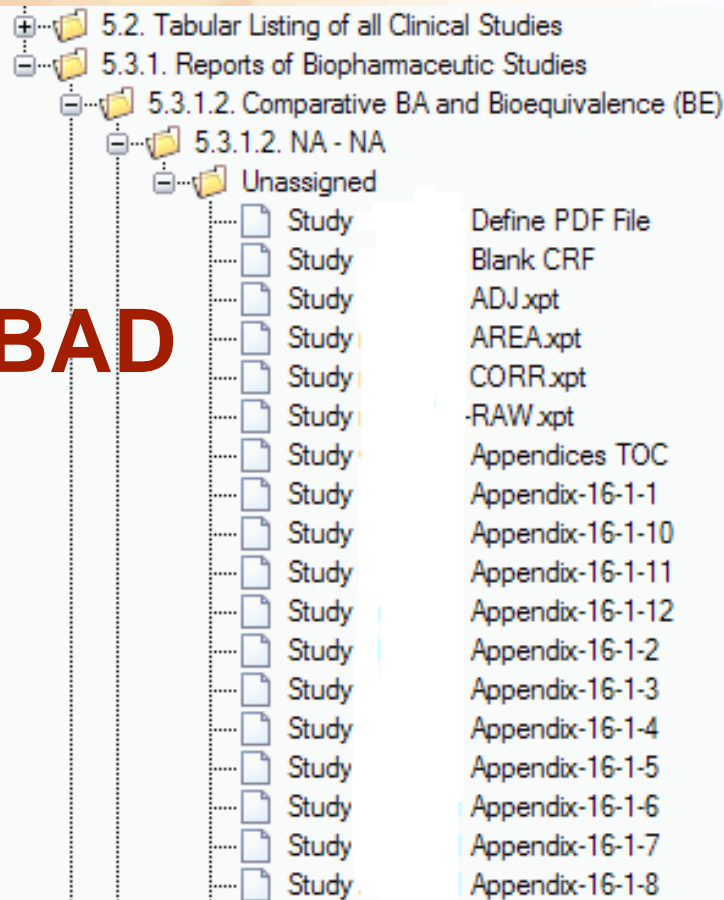




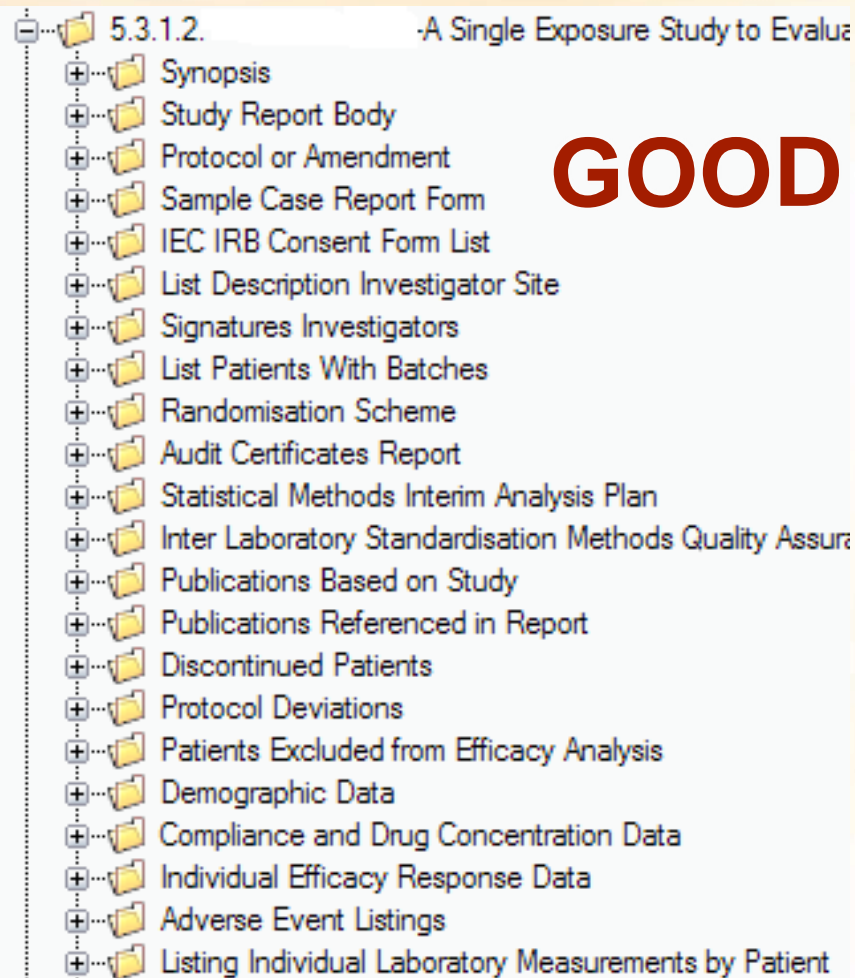
# Common eCTD Deficiencies

## STF .xml Study Information

**BAD**



**GOOD**





# Summary

- Any documents submitted to the Agency should follow eCTD specifications, including contracted documents
- Currently if deficiencies are not corrected within 7 calendar days, you lose your goal date

**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 \(Presentation 09/11/13\)](#)



# Questions?

**Johnny Young, M.A.**  
**Julia Lee, Pharm.D.**

eCTD questions should be sent directly to  
CDER ESUB at, [ESUB@fda.hhs.gov](mailto:ESUB@fda.hhs.gov)

General Questions: [CDERSBIA@fda.hhs.gov](mailto:CDERSBIA@fda.hhs.gov)

Evaluation: [surveymonkey.com/r/GDF-D2S3](https://surveymonkey.com/r/GDF-D2S3)