eCTD Submissions

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FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Poll

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

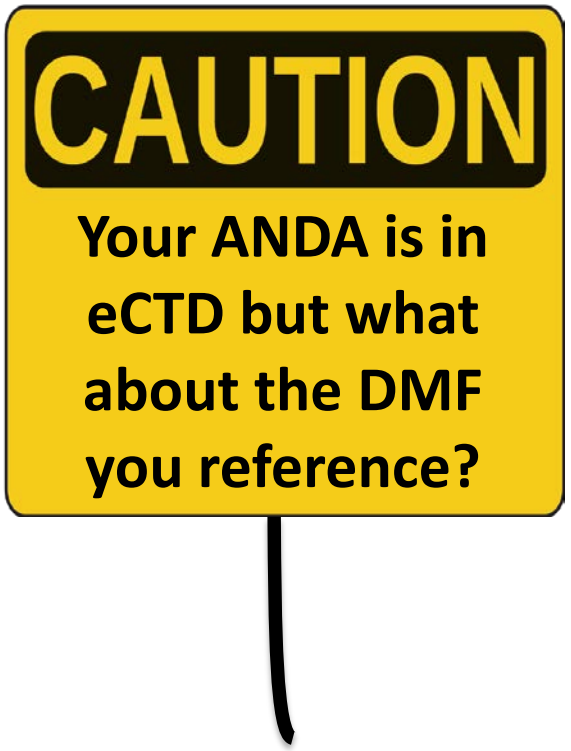
- ❑ I'm an experienced expert
- ❑ I'm pretty good at it
- ❑ Somebody else in my company handles the eCTD
- ❑ I am a beginner
- ❑ Wait. What is eCTD?

Topics Covered

- Important Submission Deadlines
- Preparing to Submit Electronically and Points to Consider
- Gateway Notifications and Submission Issues

Deadlines for Required eCTD Submission

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



Deadlines for Required eCTD Submission

- Exemptions are outlined in the guidance
- Submissions that do not adhere to the requirements stated in the eCTD Guidance will be **not be filed or received**
- Please see the eCTD web page www.fda.gov/ectd for further information
- DMF submission information available at www.fda.gov/cder/dmf

What Else?

- ✓ Must use Fillable Forms
- ✓ Must use Gateway for submissions 10GB or less
- ✓ Must use correct Lifecycle operators

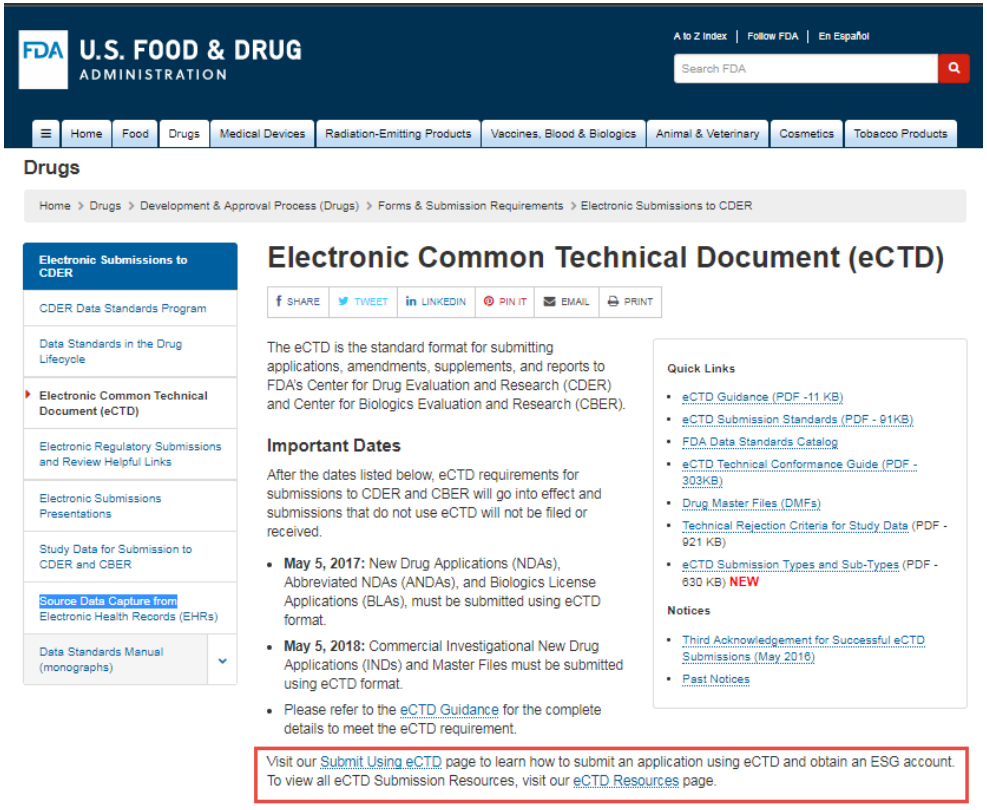
  Use the “Replace” lifecycle operator when updating content

Standardized Study Data in Electronic Format

- **What** is the requirement?
  - Studies that start after **December 17, 2016** must be in standardized format for ANDA submissions
  - See the Study Data Standards Resources page for more information
- **How** will it be enforced?
  - Technical Rejection Criteria for Study Data
  - Specifications for eCTD Validation Criteria
- **Where** can I find *The Guidance*?
- Have Questions? Contact eData@fda.hhs.gov

Preparing to Submit Electronically and Points to Consider

Become familiar with the eCTD website



Important Dates

Quick Links

- eCTD Guidance (PDF -11 KB)
- eCTD Submission Standards (PDF - 91KB)
- FDA Data Standards Catalog

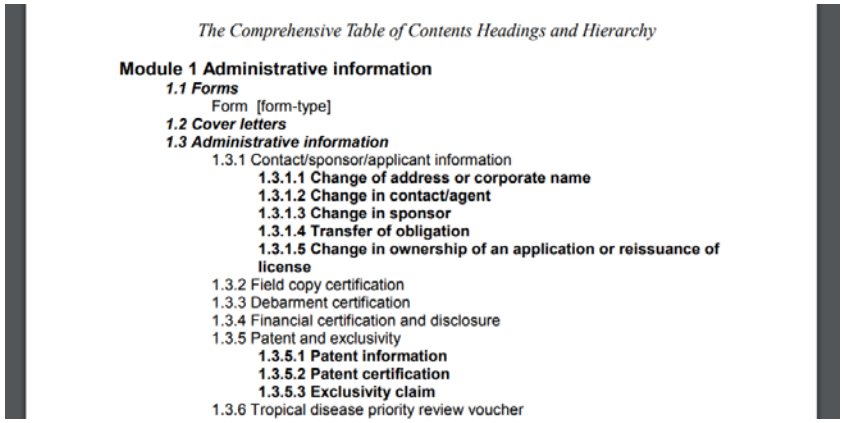
Notices

- Third Acknowledgement for Successful eCTD Submissions (May 2016)
- Past Notices

Visit our Submit Using eCTD page to learn how to submit an application using eCTD and obtain an ESG account.

Submission Hierarchy

- Organize content to follow Common Technical Document (CTD) structure
- 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



The Comprehensive Table of Contents Headings and Hierarchy

Module 1 Administrative information
1.1 Forms
Form [form-type]
1.2 Cover letters
1.3 Administrative information
1.3.1 Contact/sponsor/applicant information
1.3.1.1 Change of address or corporate name
1.3.1.2 Change in contact/agent
1.3.1.3 Change in sponsor
1.3.1.4 Transfer of obligation
1.3.1.5 Change in ownership of an application or reissuance of license
1.3.2 Field copy certification
1.3.3 Debarment certification
1.3.4 Financial certification and disclosure
1.3.5 Patent and exclusivity
1.3.5.1 Patent information
1.3.5.2 Patent certification
1.3.5.3 Exclusivity claim
1.3.6 Tropical disease priority review voucher

File Format and PDF Specifications

- 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

- Follow FDA's PDF Specifications and communicate to vendors the need to follow these specifications

Study Data

- If submitting study data, please see the Study Data for Submission to CDER and CBER website.
- Key Study Data Resources:
  - Providing Regulatory Submissions In Electronic Format — Standardized Study Data Guidance for Industry
  - Technical Rejection Criteria for Study Data
  - Study Data Technical Conformance Guide
  - ANDA Forms and Submission Requirements Website

Prepare for Submission to FDA

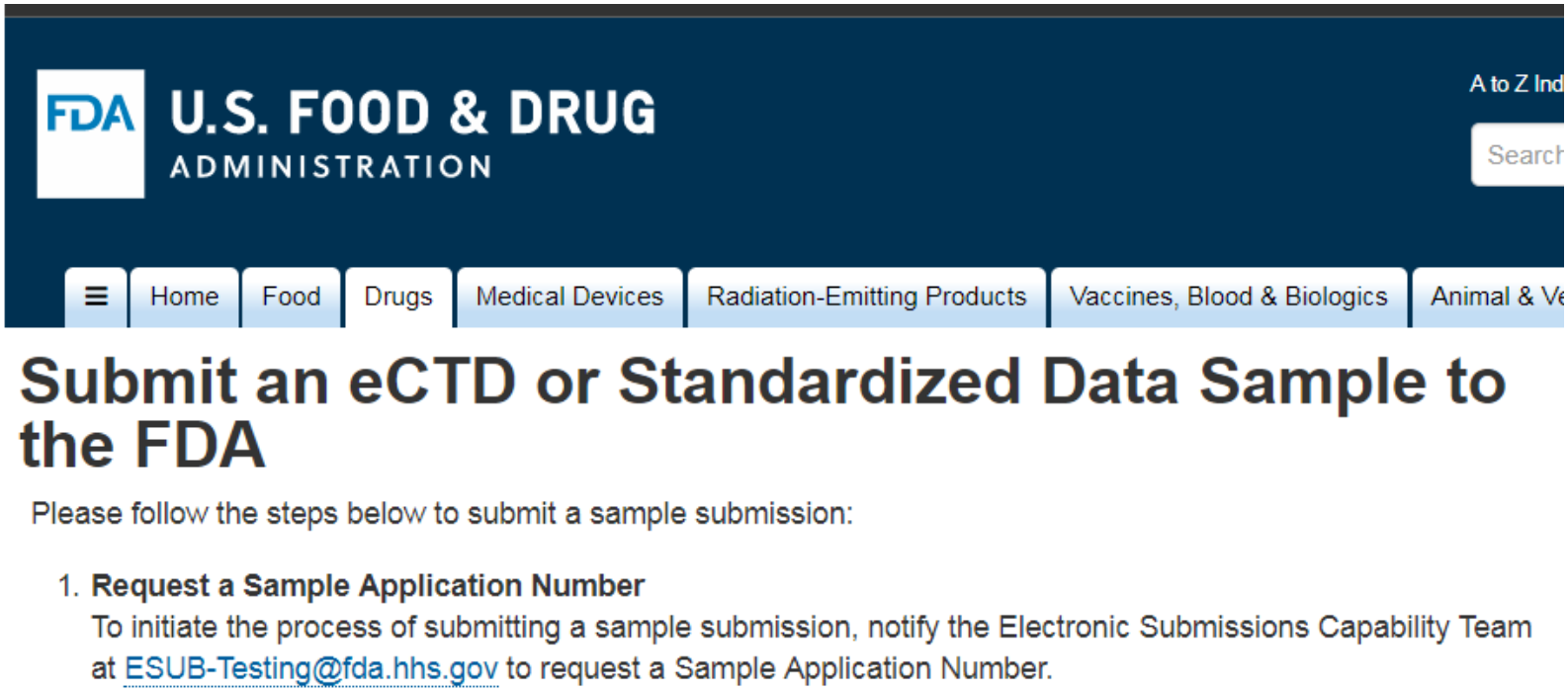
- Request an Application Number from FDA
- Register for an Electronic Submission Gateway

Generate the eCTD for Submission to FDA

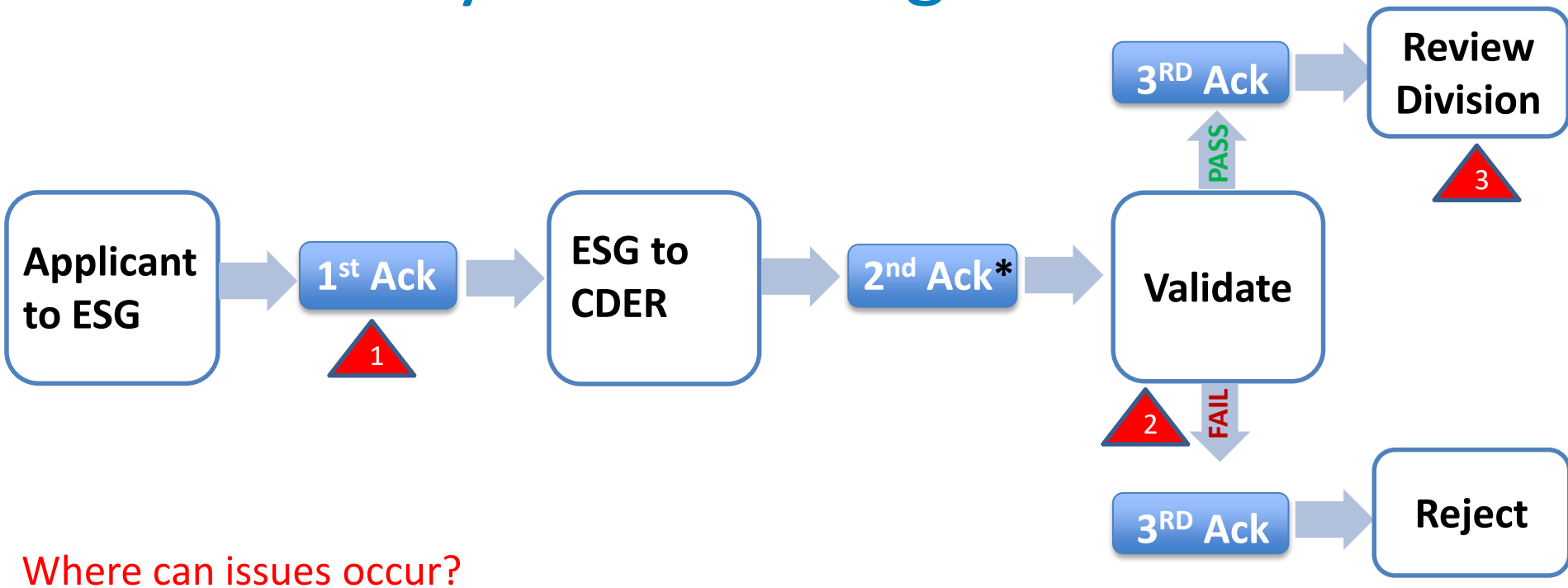
- Publish content into eCTD format via eCTD Publishing Tool or eCTD Tool Vendor
  - Utilize eCTD publishing tool to:
    - Capture administrative information
    - Map submission content to CTD section headings
    - Generate final submission in eCTD format including all required technical files/folder structure

Validate eCTD (Optional) and/or Request eSub Feedback

- (Optional) Validate via eCTD Validation Tool
- (Optional) Ask ESUB-Testing@fda.hhs.gov for technical feedback via Sample Submission Process



Submit eCTD via ESG and Receive Gateway Acknowledgements



Where can issues occur?

1 Transmission to FDA

2 CDER Validation

3 Division of Filing Review

*Per FDA Receipt Date Guidance, 2nd Ack (Center Acknowledgement) is used to calculate receipt date. See guidance for details and exceptions.

Summary

- Important Submission Deadlines
  - **ANDAs Must be Submitted in eCTD Format May 5, 2017**
  - **DMFs Must be in Submitted in eCTD Format May 5, 2018**
- Preparing to Submit Electronically and Points to Consider
  - **Utilize FDA's eCTD Website**
  - **Align Content with CTD**
  - **Get ESG Account Early**
- Where Submission Issues Occur
  - **Transmission to FDA. Validation. Division of Filing Review.**

Thank You

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www.fda.gov/ectd


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