eCTD

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May 29, 2019

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 NDA/BLA in proper eCTD format?

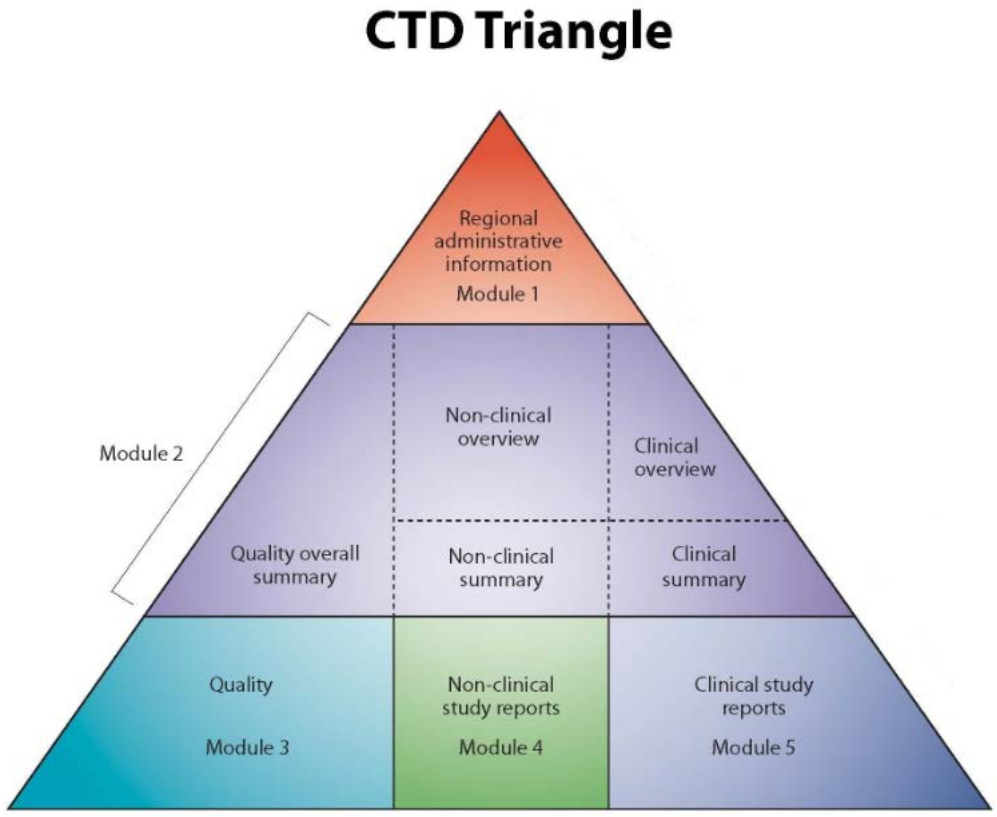
- ❑ I'm an experienced expert
- ❑ I'm pretty good at it
- ❑ Somebody else in my company handles the eCTD
- ❑ I am a beginner
- ❑ Wait. What is eCTD?

Topics Covered

- eCTD Background, Guidance, and Metrics
- Preparing to Submit Electronically and Points to Consider
- Electronic Submission Processing

eCTD Background

eCTD is the electronic version of the Common Technical Document (CTD). The eCTD contains an electronic table of contents, also referred to as a “backbone”, that manages all the metadata for an application.



The CTD triangle. The Common Technical Document is organized into five modules. Module 1is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

Guidance – eCTD Required

- **NDAs, BLAs, DMFs*, ANDAs** and **Commercial INDs** must be in eCTD format

- Paper and/or non-eCTD submissions are no longer accepted for above application types

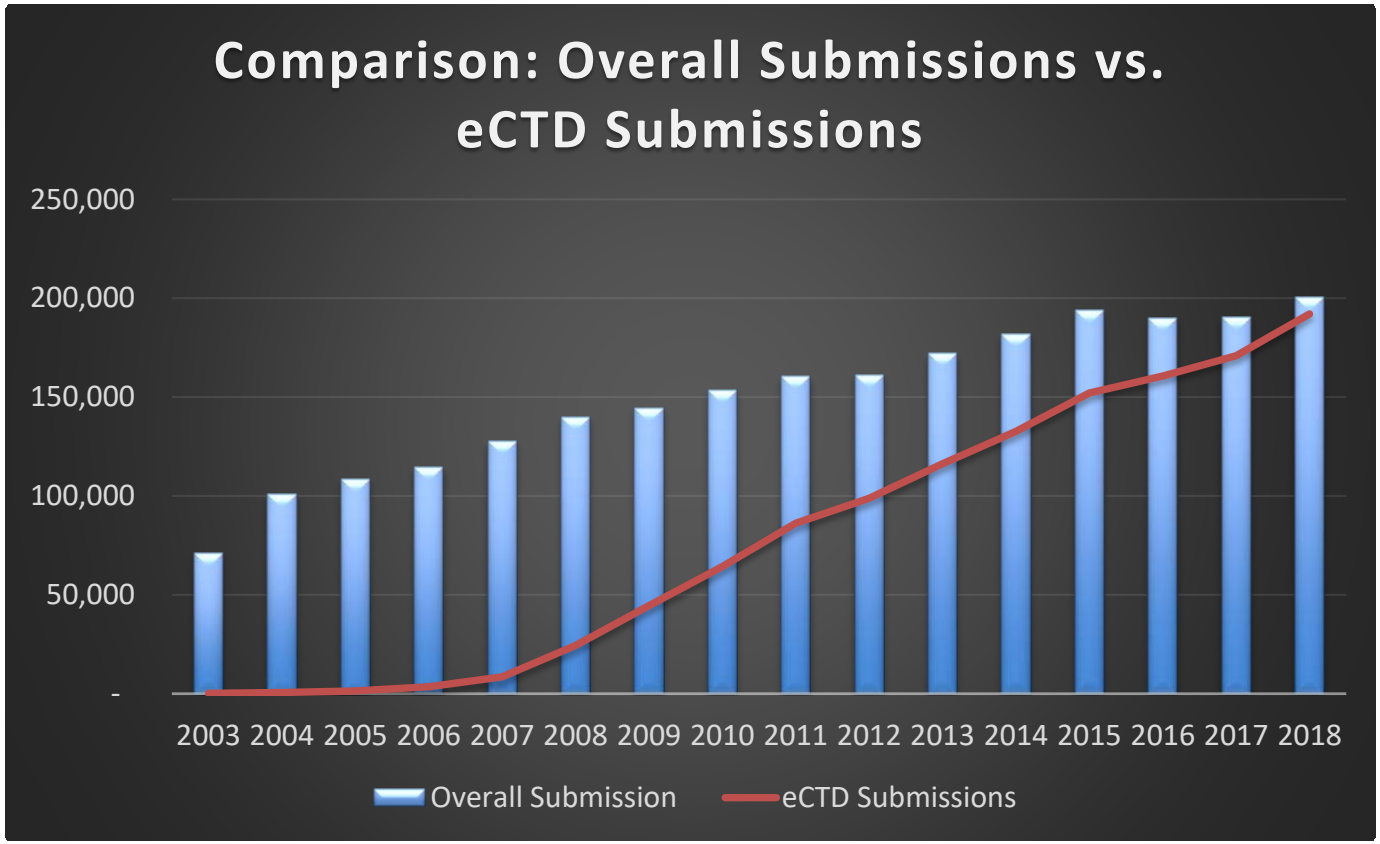
- Study information in modules 4 or 5 must include the Study Tagging File (STF)

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

*Type III DMFs deadline extended to May 5, 2020

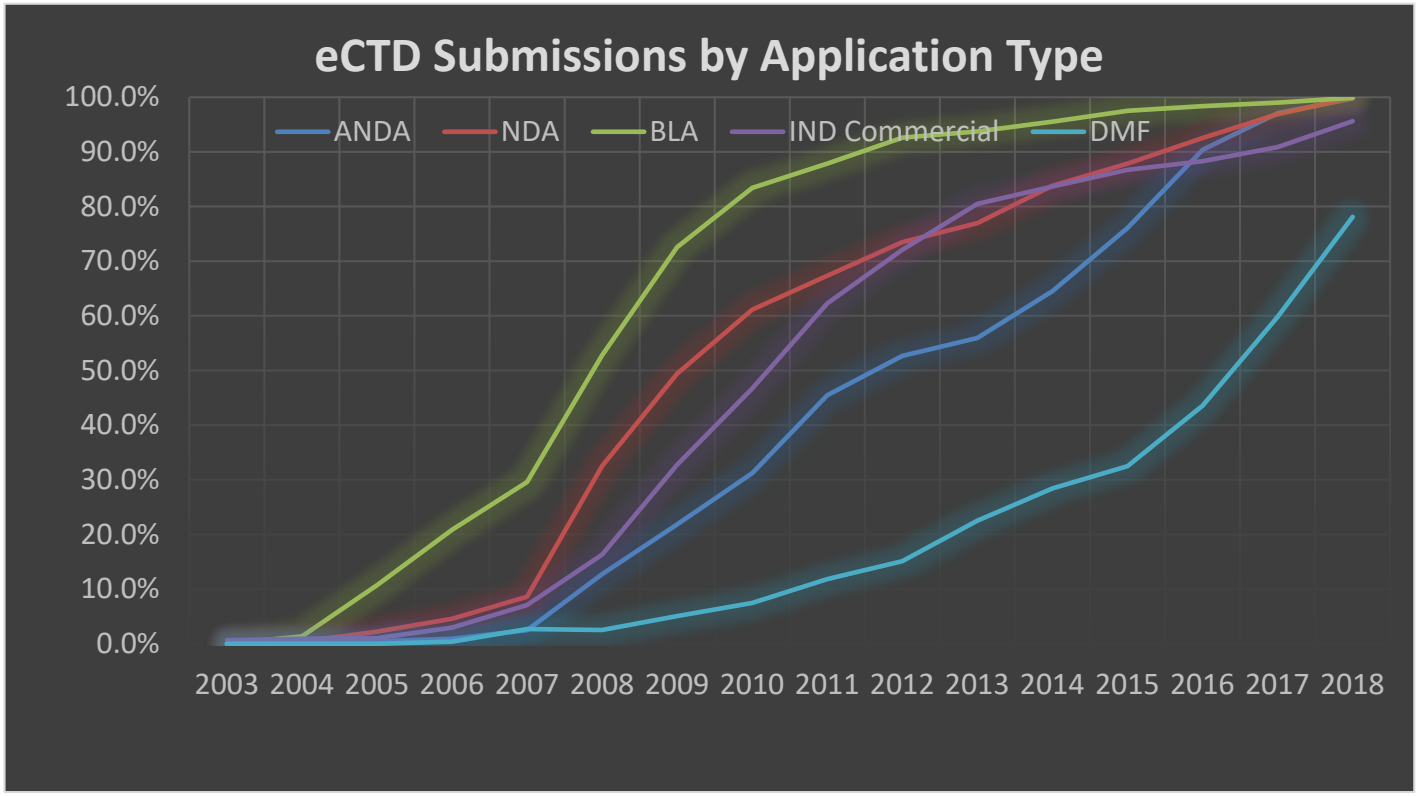
eCTD Submission Metrics

CDER receives approximately 200,000 electronic submissions via ESG annually. Nearly 192,000 were in eCTD in FY 2018.



eCTD Submission Metrics

In FY 2018, nearly 100% of the regulatory submissions for NDA, BLA, and ANDA were in eCTD. For Commercial IND and DMF, 96% and 78% (Type II, IV, V).



Preparing to Submit Electronically and Points to Consider

Become familiar with the eCTD website

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Drugs

Home > Drugs > Development & Approval Process (Drugs) > Forms & Submission Requirements > Electronic Submissions to CDER

- **Electronic Submissions to CDER**
- CDER Data Standards Program
- Data Standards in the Drug Lifecycle
- **Electronic Common Technical Document (eCTD)**
- Electronic Regulatory Submissions and Review Helpful Links
- Electronic Submissions Presentations
- Study Data for Submission to CDER and CBER
- Source Data Capture from Electronic Health Records (EHRs)
- Data Standards Manual (monographs)

Electronic Common Technical Document (eCTD)

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

The eCTD is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

Important Dates

After the dates listed below, eCTD requirements for submissions to CDER and CBER will go into effect and submissions that do not use eCTD will not be filed or received.

- **May 5, 2017:** New Drug Applications (NDAs), Abbreviated NDAs (ANDAs), and Biologics License Applications (BLAs), must be submitted using eCTD format.
- **May 5, 2018:** Commercial Investigational New Drug Applications (INDs) and Master Files must be submitted using eCTD format.
- Please refer to the eCTD Guidance for the complete details to meet the eCTD requirement.

Quick Links

- eCTD Guidance (PDF -11 KB)
- eCTD Submission Standards (PDF - 91KB)
- FDA Data Standards Catalog
- eCTD Technical Conformance Guide (PDF - 303KB)
- Drug Master Files (DMFs)
- Technical Rejection Criteria for Study Data (PDF - 921 KB)
- eCTD Submission Types and Sub-Types (PDF - 630 KB) **NEW**

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. To view all eCTD Submission Resources, visit our eCTD Resources page.

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Submission Hierarchy

"Where should I place my documents?"

- 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

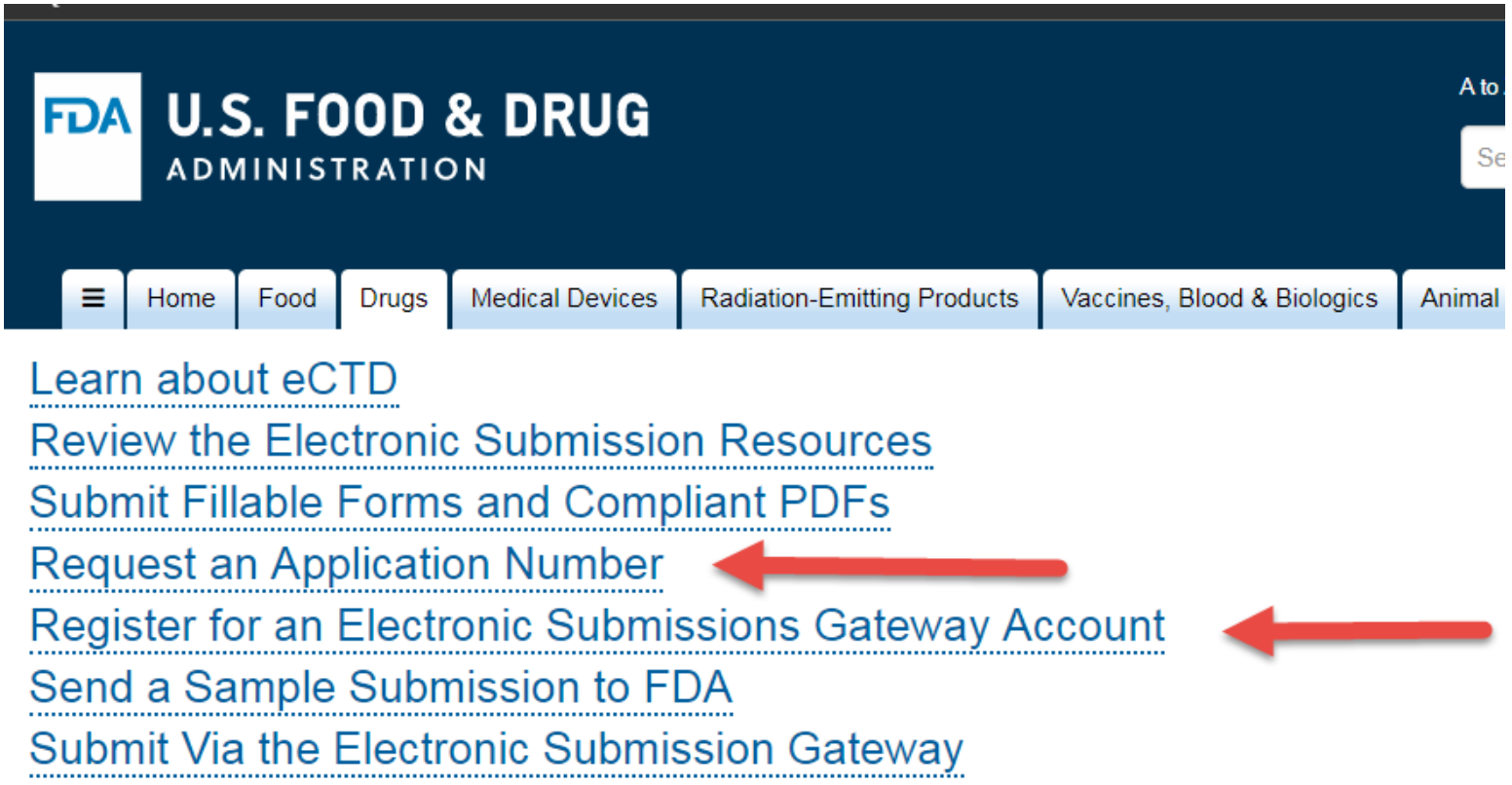
Learn about FDA requirements for submission of study data at the Study Data for Submission to CDER and CBER website.

- 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

Have Questions? Contact eData@fda.hhs.gov

Prepare for Submission to FDA

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

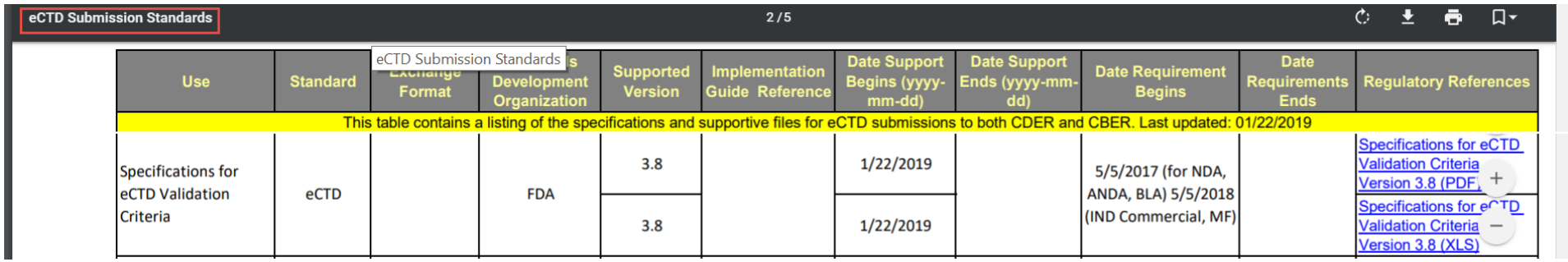


Generate the eCTD for Submission to FDA

- 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
- eCTD Validation Criteria is posted on www.fda.gov/ectd in the eCTD Submission Standards


eCTD Submission Standards 2 / 5

eCTD Submission Standards

Use	Standard	Exchange Format	Development Organization	Supported Version	Implementation Guide Reference	Date Support Begins (yyyy-mm-dd)	Date Support Ends (yyyy-mm-dd)	Date Requirement Begins	Date Requirements Ends	Regulatory References
This table contains a listing of the specifications and supportive files for eCTD submissions to both CDER and CBER. Last updated: 01/22/2019										
Specifications for eCTD Validation Criteria	eCTD		FDA	3.8		1/22/2019		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Specifications for eCTD Validation Criteria Version 3.8 (PDF)
				3.8		1/22/2019				Specifications for eCTD Validation Criteria Version 3.8 (XLS)

Electronic Submission Processing: Increasing Automation

Submission Processing: 2018

All CDER regulatory submissions received are processed by Document Room

Document Room Process:

Staff reads the Cover Page of every submission (Approx. 850 per day) to categorize and route to correct Review Divisions

Submission Processing: 2019

Automate process to identify Submission Category

Process:

1. Determine Submission Category based on structured data in eCTD sequence
2. Route to Review Division based on Submission Category

Benefit:

Reviewer gets submission faster

Submission Processing Challenges

- Data submitted in eCTD backbone file (e.g. us-regional.xml) and regulatory form (e.g., Form 356h) sometimes contradict each other

eCTD Data Discrepancy Example

Can you guess the correct regulatory activity in this submission?

us-regional.xml (DTD V3.3)

```
<submission-information>
  <submission-id submission-type="fdast3" supplement-effective-date-type="fdasedt2">[redacted]</submission-id>
  <sequence-number submission-sub-type="fdasst3">[redacted]</sequence-number>
```

Indicating "CBE"

Form 356h

21. Submission *(See instructions)*	☐ Original	☐ Labeling Supplement	☑ CMC Supplement	☐ Efficacy Supplement	☐ Annual Report
☐ Product Correspondence	☐ REMS Supplement	☐ Postmarketing Requirements or Commitments	☐ Periodic Safety Report		
☐ Request for Proprietary Name Review	☐ Other *(Specify)*: _____				
22. Submission Sub-Type	☐ Presubmission	☐ Amendment	23. If a supplement, identify the appropriate category.	☐ CBE	☑ Prior Approval (PA)
	☑ Initial Submission	☐ Resubmission		☐ CBE-30	

Indicating "Prior Approval"

This submission was an Initial CMC Supplement CBE.
The appropriate "**Supplement Category**" on Form 356h would have been "**CBE**"

eCTD Data Discrepancy Impact

- When data is submitted correctly in eCTD backbone files (e.g. us-regional.xml file) and regulatory form (e.g., Form 356h), submission can be efficiently routed to the assigned review division and/or reviewer(s)

- Indicating information in us-regional.xml that contradicts Form 356h could:
  - Impact FDA's ability to automate the submission process
  - Require additional effort to read the Cover Letter in order to resolve the discrepancy
  - May require Request(s) for Information that may otherwise not be necessary

Summary

- Important Guidance Requirements
  - **NDAs, BLAs, DMFs, ANDAs, and Commercial INDs must be submitted in eCTD**
  - **Study information in modules 4 or 5 must include the Study Tagging File (STF)**
- Preparing to Submit Electronically and Points to Consider
  - **Utilize FDA's eCTD Website**
  - **Align Content with CTD**
  - **Technical Rejection Criteria for Study Data**
- Confirm eCTD metadata does not contradict FDA Form
  - **eCTD Submission Type/Subtype and Supplement Category align with values on FDA Form 356h**

Thank You

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CDER Electronic Submission Support Team

eSub@fda.hhs.gov

www.fda.gov/ectd


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