



**U.S. FOOD & DRUG
ADMINISTRATION**

Center for Drug Evaluation and Research



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Center for Drug Evaluation and Research

Update on eCTD Submissions

Heather Crandall
Operations Research Analyst
CDER/OSP/OBI

February 4, 2025

Agenda

- What's New?
- Common Errors for eCTD submissions



What's New?

What's New?

eCTD Submission Standards for eCTD v3.2.2 and Regional M1

- 03/20/2024 – Updates to [File Format Specification](#)
 - **Removed recommendation to include PDF archive format copy** when submitting .doc/.docx, .xls/.xlsx
 - Updated file format added:
 - Modeling & Simulation file types: .pumascp, .jmd, .qmd
- 09/09/2024 – Updates to
 - Version of Lorenz tool
 - [eCTD Technical Conformance Guide](#)
 - As of April 1, 2024, FDA published final guidance "[Providing Regulatory Submissions in Electronic Format: IND Safety Reports Guidance for Industry](#)", which provides a new method to submit these reports
 - [Comprehensive Table of Contents Headings and Hierarchy](#)
 - adding Valid-Values.xml v6.0 (support date TBD)

Module 5 Clinical Study Reports

- 5.2 *Tabular listing of all clinical studies*
- 5.3 *Clinical study reports and related information*
- ...
- Pharmacogenomics*
- Pharmacokinetics*
- Quality of life*
- Hepatic Impairment Study* (TBD)
- Renal Impairment Study* (TBD)
- Drug-drug Interaction Study* (TBD)
- Mass Balance Study* (TBD)
- Population PK Report* (TBD)

What's New?

4. Send a Sample Submission to FDA

Submitting a sample eCTD or standardized data sample is optional and can provide valuable feedback. This is separate from the test submissions made as part of the ESG account signup process.

Please refer to the following pages:

- [Submitting standardized study data](#)
- [Submitting eCTD v4.0 \(may include standardized study data sample\)](#)

Tip: Submit the sample early to allow time to make adjustments prior to final submission.

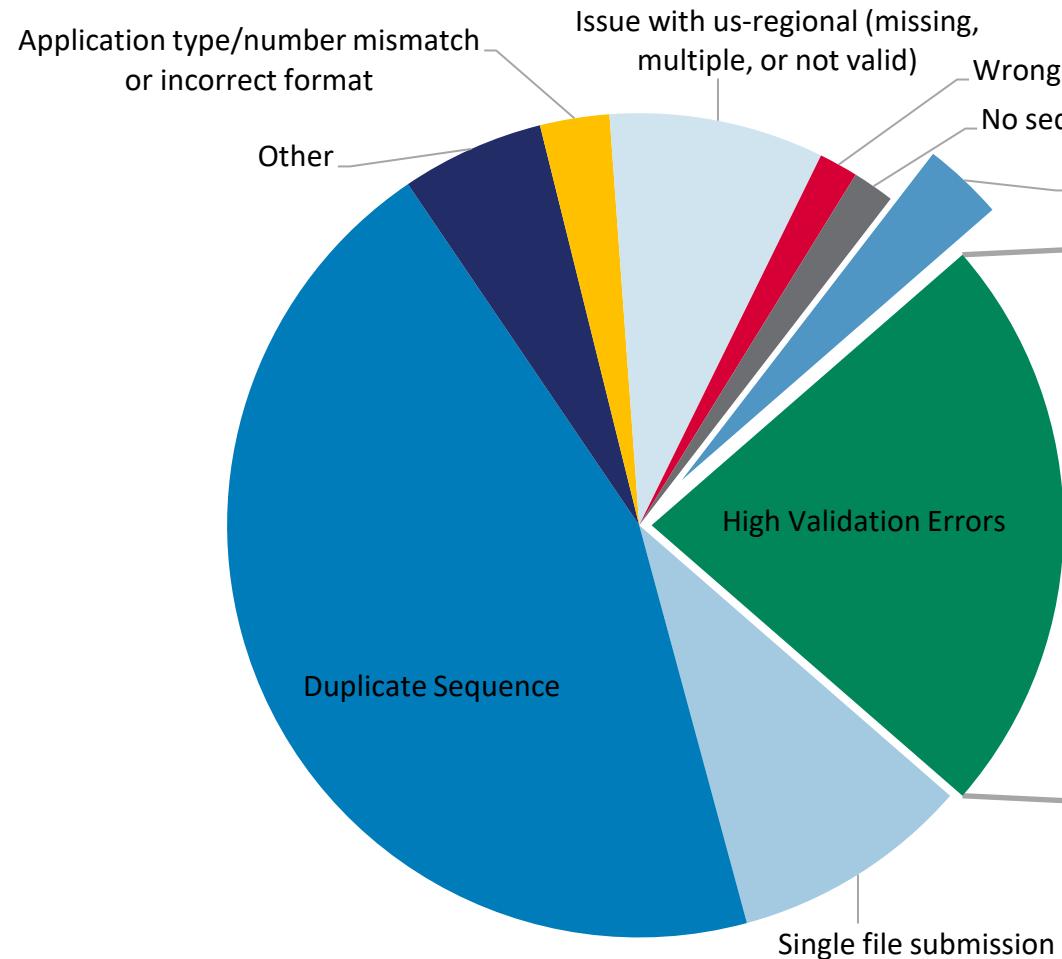
Submit a Standardized Data Sample to FDA

Formerly “Submit an eCTD or Standardized Data Sample to FDA”

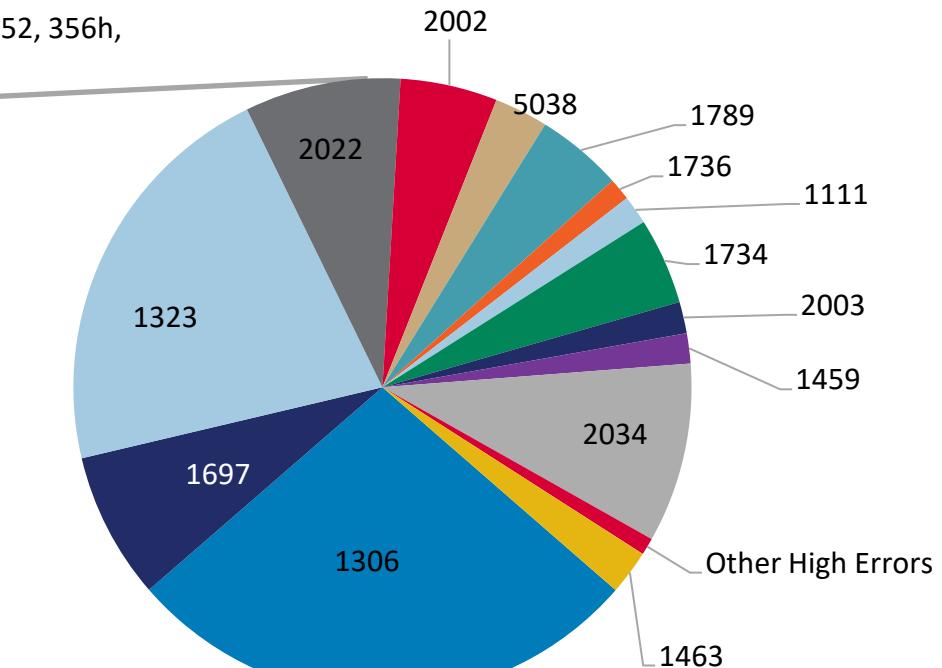
- FDA now encourages all eCTD samples to be in v4.0 format
- Standardized data samples can be submitted for sample evaluation and feedback utilizing **either** v3.2.2 or v4.0 format

Common Errors for eCTD submissions

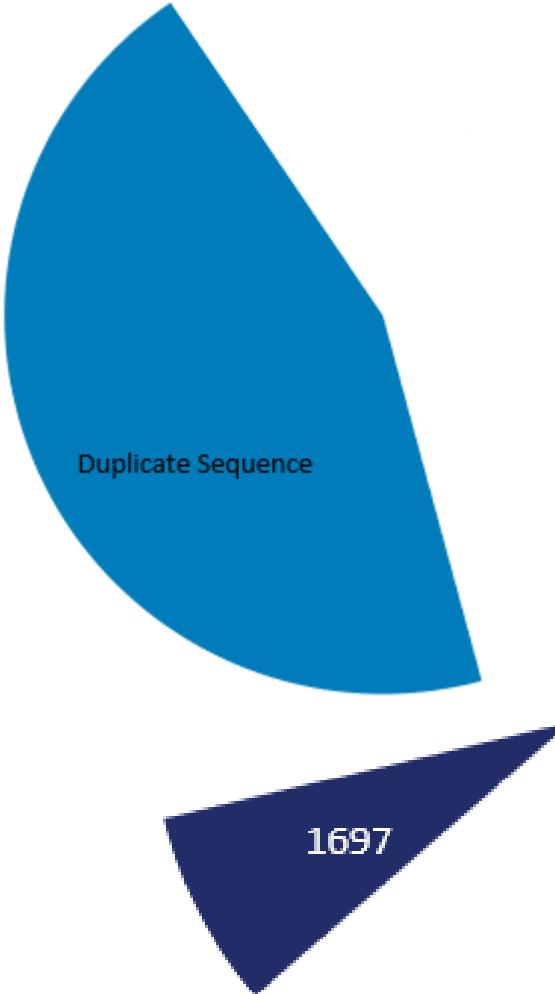
Top Reasons for eCTD Rejection



January 1, 2023 through December 31, 2023

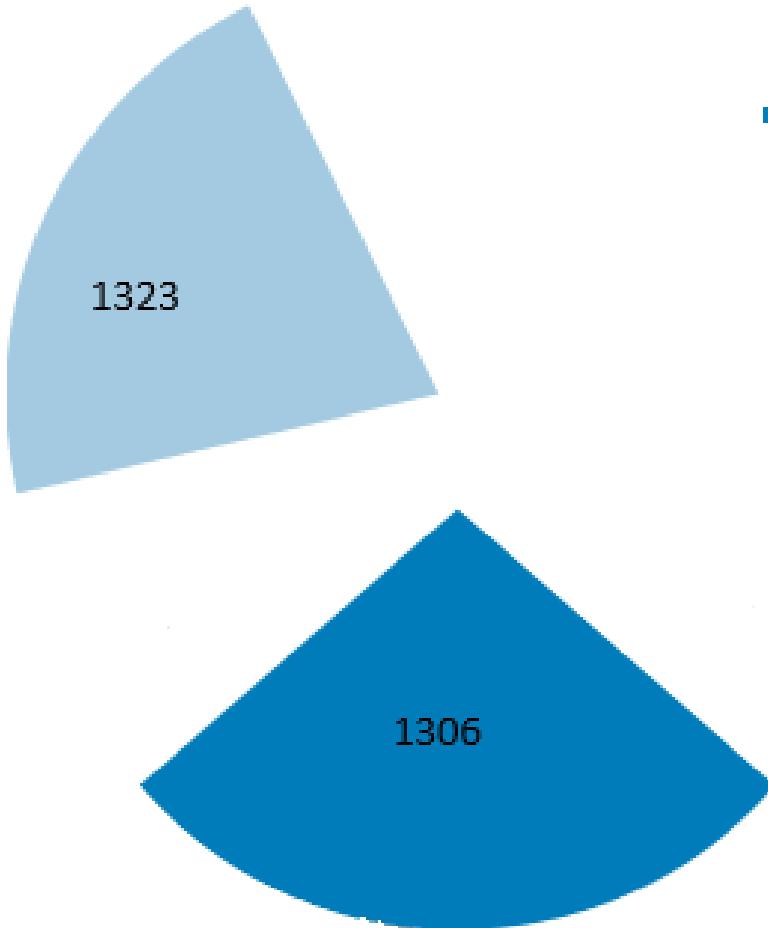


Duplicate Sequence Numbers



- From January 1 through August 1, 2023, 2973 applications were rejected for duplicate sequence numbers
 - All sequence numbers, including sequence numbers for child applications in a grouped submission must be unique
- Sequence numbers for a given application must be unique
 - The sequence-number element is used to uniquely identify each individual submission to an application. It must be a unique number with a maximum of four (4)-numeric digits – The eCTD Backbone Files Specification for Module 1

Leaf element errors



- From January 1 through August 1, 2023, **710 applications were rejected** for leaf element errors
 - A leaf element is “Information for an individual document is contained in the leaf element, its attributes, and its title element.”
– [The eCTD Backbone Files Specification for Module 1](#)
 - Validation Code 1306 - No leaf element for file
 - Validation Code 1323 – No file for leaf element

us-regional.xml errors

Issue with us-regional (missing, multiple, or not valid)

- From January 1 through December 31, 2023, **595 applications were rejected** for errors with the us-regional.xml backbone file
 - **469 submissions had no us-regional.xml file**
 - **58 submissions had more than one us-regional.xml file**
 - **58 submissions had an invalid or unsupported version of the us-regional.xml file**

1463

111

The eCTD Backbone Files Specification for Module 1

INTRODUCTION

This document provides specifications for creating the electronic common technical document (eCTD) backbone file for Module 1 for submission to the FDA. It should be used in conjunction with the guidance to industry: *Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.

Font formatting conventions are used in this document to enhance its readability and emphasize items such as heading elements, attributes, titles, and file names:

- ***Bold italic*** font is used for elements and attributes.
- *Italic* font is used for links, leaf titles, publication titles, file names, and folder names.

The Module 1 eCTD Backbone File (*us-regional.xml*) includes administrative information and information for each file submitted in Module 1. The backbone file contains an XML element named *fda-regional:fda-regional*, which contains both the *admin* and *m1-regional* elements. The individual file information is provided within an XML element called the *leaf* element. The *leaf* elements are organized using the Module 1 section headings. The Module 1 section headings are named and organized according to the subject matter of the information contained in the files. Section headings are provided as XML elements in the *m1-regional* element of the backbone file. Administrative information about each submission is provided in the *admin* element of the backbone file.

The Module 1 eCTD Backbone File may be used in a wide range of applications and related submission types; therefore, a specific submission may not use all of the possible section heading elements. Only include the section headings that reference files in the submission. Empty section headings should not be included. The *admin* element should always be included, and it contains two elements named: *applicant-info* and *application-set*. These elements should be included in order as listed in [section III Admin Elements](#).

The *us-regional-v3-3.ddl* file (refer to [Appendix 1](#)) provides the organization for each element used in the *us-regional.xml* file.

I. USE OF ATTRIBUTES

Certain *admin* and *m1-regional* heading elements require an attribute to provide information that is pertinent to the application and submission. The attribute lists are maintained as separate XML files, and each contains a standard set of codes and display names for each defined attribute type. The attribute files contain a version number, version date and coded values and display names for each value. Each coded value has a status of "active" or "inactive" to accommodate future changes; only coded values with a status of "active" should be submitted. Only the code should be provided as the attribute value in the appropriate element in the *us-regional.xml* file. The display name is shown to the reviewers in the review tool.

The following table contains the names of the attribute type lists and their respective file names.

Version 2.5

1

Submission-type errors

2022

- From January 1 through December 31, 2023, **256 applications were rejected** for errors with submission-type attributes
 - Validation Code 2034 – Submission-type is invalid for application-type
 - Validation Code 2022 – Submission-sub-type is invalid for submission-type

2034

Table 2: Submission Types and Descriptions of Use

Submission Type	Submission Sub-Type	Supplement Effective Date Type (if applicable and <i>submission-sub-type</i> = "application")	Valid For Application Types
Original Application	Presubmission Application Amendment Resubmission		IND, NDA, ANDA, BLA, DMF, EUA
Efficacy Supplement	Presubmission		NDA, BLA
	Application	Prior Approval Supplement (PAS)	
	Amendment Resubmission		
Chemistry Manufacturing Controls Supplement	Presubmission		NDA, ANDA, BLA
	Application	Prior Approval Supplement (PAS), Changes Being Effectuated (CBE-0), or Changes Being Effectuated 30 (CBE-30)	
	Amendment Resubmission		
Labeling Supplement	Presubmission		NDA, ANDA, BLA
	Application	Prior Approval Supplement (PAS) or Changes Being Effectuated (CBE-0)	
	Amendment Resubmission		
REMS Supplement	Application	Prior Approval Supplement (PAS) or Changes Being Effectuated (CBE-30)	NDA, ANDA, BLA
	Amendment Resubmission		
Annual Report	Report Amendment		IND, NDA, ANDA, BLA, DMF
Product Correspondence	Correspondence Amendment		IND, NDA, ANDA, BLA, DMF
Postmarketing Requirements or Postmarketing Commitments	Original Amendment		NDA, BLA
Promotional Labeling Advertising	Original Resubmission Amendment		NDA, ANDA, BLA
IND Safety Reports	Report Amendment		IND
Periodic Safety Reports (Periodic Adverse Drug Experience Report)	Report Amendment		NDA, ANDA, BLA

No fillable form

Missing fillable form (2252, 356h,
1571)

503B

- From January 1 through December 31, 2023, **243 applications were rejected** for fillable form errors
 - Annual Report submissions must have a fillable 2252 form
 - All other NDA, ANDA, and BLA submissions must have a fillable 356h form
 - All other IND submissions must have a fillable 1571 form

APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE		Form Approved: OMB No. 0910-0338 Expiration Date: March 31, 2026 See PRA Statement on page 4	
1. Date of Submission (mm/dd/yyyy)		Next Page	
APPLICANT INFORMATION 2. Name of Applicant 3. Telephone Number (Include country code if applicable and area code) 4. Facsimile (FAX) Number (Include country code if applicable and area code) 5. Applicant Address Address 1 (Street address, P.O. box, company name c/o) Email Address Address 2 (Apartment, suite, unit, building, floor, etc.) Applicant DUNS City Country			
TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS AND BIOLOGICS FOR HUMAN USE (21 CFR 314.81)			
NOTE: This report is required by law (21 U.S.C. 355, 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug or Biologics License Application.			
INSTRUCTIONS Complete a transmittal for each application for which an annual report is being submitted. If submitting electronically, submit one copy of the form and annual report to FDA. If submitting in paper, submit two copies of the transmittal form along with two copies of the annual report to FDA.			
If any part of the annual report applies to more than one application, list in item 8 all other applications to which such parts apply.			
4. APPLICANT U.S. Agent Company Prefix <input checked="" type="checkbox"/> First Name Address 1 (Street address, P.O. box, company name c/o) Address 2 (Apartment, suite, unit, building, floor, etc.) City Country			
5. PHONE NUMBER (For FDA Use Only) 6. TYPE OF REPORT (Check one) <input type="checkbox"/> ANNUAL <input type="checkbox"/> OTHER			
7. DRUG/BIOLOGIC NAME 7. NDA, ANDA, or BLA Application Number 8. OTHER APPLICATION NUMBERS (List numbers of any other applications for which report applies to more than one number.) 9. Established Name (e.g., proper name, USP/USAN name) 10. Proprietary Name (Trade Name) (If any) 11. Chemical/Biochemical/Blood Product Name (If any) 12. Dosage Form 13. Strengths 15A. Proposed Indication for Use 15B. SNOMED CT Indication Disease Term (Use continuation p)			
9. PERIOD COVERED BY REPORT FROM TO YEAR MONTH YEAR MONTH			
10. BLA REPORT INFORMATION REQUIRED (See § 314.81 for description) (Enter type of information attached under "Identification" if you have more than one, enter None.) INFORMATION IN "10" AND "11" IS ALREADY REQUIRED IDENTIFICATION (Electronically or CTD location or Volume No. (s) / Tab(s) / Page(s) of Report)			
11. BLA USE INFORMATION REQUIRED (See § 301.70 for description) TYPE OF INFORMATION CONTENTS (Check one) 12. ANNUAL PROGRESS REPORTS OF POSTMARKETING STUDIES 13. APPLICANT'S RETURN ADDRESS NAME 14. SIGNATURE TITLE			
15. DATE OF RECEIPT City State ZIP or Postal Code			

FORM FDA 2252 (07/22) Previous Edition Is Obsolete

Page 1 of 2

FDA Publishing Services (301)435-4760

Fillable Form Expiration Dates

Form Approved: OMB No. 0910-0338
 Expiration Date: March 31, 2026
 See PRA Statement on page 4

Form Approved: OMB No. 0910-0338
 Expiration Date: March 31, 2026
 See PRA Statement on page 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration

APPLICATION TO MARKET A NEW
 OR ABBREVIATED NEW DRUG OR
 BIOLOGIC FOR HUMAN USE
 (Title 21, Code of Federal Regulations, Parts 314 & 601)

APPLICANT INFORMATION

2. Name of Applicant

3. Telephone Number
 (Include country code if applicable and area code)

4. Facsimile (FAX) Number (Include country code if applicable and area code)

5. Applicant Address

Address 1 (Street address, P.O. box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Country

6. Authorized U.S. Agent (Required for non-U.S. applicants)

U.S. Agent Company Prefix First Name

Address 1 (Street address, P.O. box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

7. DRUG/BIOLOGIC NAME

7. NDA, ANDA, or BLA Application Number

9. Established Name (e.g., proper name, USP/USAN name)

10. Proprietary Name (Trade Name) (if any)

11. Chemical/Biochemical/Blood Product Name (if any)

12. Dosage Form

13. Strengths

15A. Proposed Indication for Use

15B. SNOMED CT Indication Disease Term (Use continuation p)

Form FDA 356h (07/23) (PREVIOUS EDITION OBSOLETE)

TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS AND BIOLOGICS FOR HUMAN USE
 (21 CFR 314.81)

DATE SUBMITTED

Form Approved: OMB No. 0910-0338
 Expiration Date: March 31, 2026
 See PRA Statement on page 4

NOTE: This report is required by law (21 U.S.C. 356; 21 CFR 314.81). Failure to report can result in withdrawal of approval of the New Drug or Biologics License Application.

INSTRUCTIONS

Complete a transmittal for each application for which an annual report is being submitted. If submitting electronically, submit one copy of the form and annual report to FDA. If submitting in paper, submit two copies of the transmittal form along with two copies of the annual report to FDA.

If any part of the annual report applies to more than one application, list in item 8 all other applications to which such parts apply.

1. Center (Select One)
 CDER CBER

2. Application Type
 CdeR One

3. Application Number
 /

Report No. (For FDA Use Only) ANNUAL OTHER

4. APPLICANT ()

5. PHONE NUMBER ()

6. TYPE OF REPORT (Check one)
 ANNUAL OTHER

7. DRUG/BIOLOGIC NAME

8. OTHER APPLICATION NUMBERS (List numbers of any other application that applies to more than one number)
 Choose One Application Type Application Number Add Row Remove Row

9. PERIOD COVERED BY REPORT
 FROM TO
 YEAR MONTH YEAR MONTH

10. NDA REPORT INFORMATION REQUIRED (See § 314.81 for description) (Enter type of information attached under "Identification" if you have more than one NDA)
 (INFORMATION IN "10b" AND "10c" IS ALREADY REQUIRED IN "11")
 IDENTIFICATION (Electronically Name or ECTD location or Volume Item No. (s) / Table / Pages of Report)

TYPE OF INFORMATION

a. SUMMARY OF SIGNIFICANT NEW INFORMATION

b. DISTRIBUTION DATA Authorized Generic Info

c. LABELING (Whether or not previously submitted)

d. CHEMICAL MANUFACTURING AND CONTROLS CHANGES SUPAC

e. NONCLINICAL LABORATORY STUDIES

f. CLINICAL DATA

g. STATUS REPORTS OF OPEN PMR/UPMC (Enter None if no open PMR/UPMC to report)
 a. STATUS OF OTHER OPEN POSTMARKETING STUDIES (Enter None if no other open postmarketing studies, and product stability studies)
 b. STATUS OF OTHER OPEN POSTMARKETING STUDIES (Enter None if no other open postmarketing studies, and product stability studies)

11. BLA REPORT INFORMATION REQUIRED (See § 301.70 for description)
 TYPE OF INFORMATION CONTENTS (Check one)

12. ANNUAL PROGRESS REPORTS OF POSTMARKETING STUDIES

13. APPLICANT'S RETURN ADDRESS
 Name of Sponsor / Applicant / Submitter NDA OR ANDA NUMBER

14. SIGNATURE Sign

FDA USE ONLY
 NDA OR ANDA NUMBER

15. DATE OF RECEIPT

FORM FDA 356 (07/22) Previous Edition Is Obsolete Page 1 of 2

Common Questions for eSub



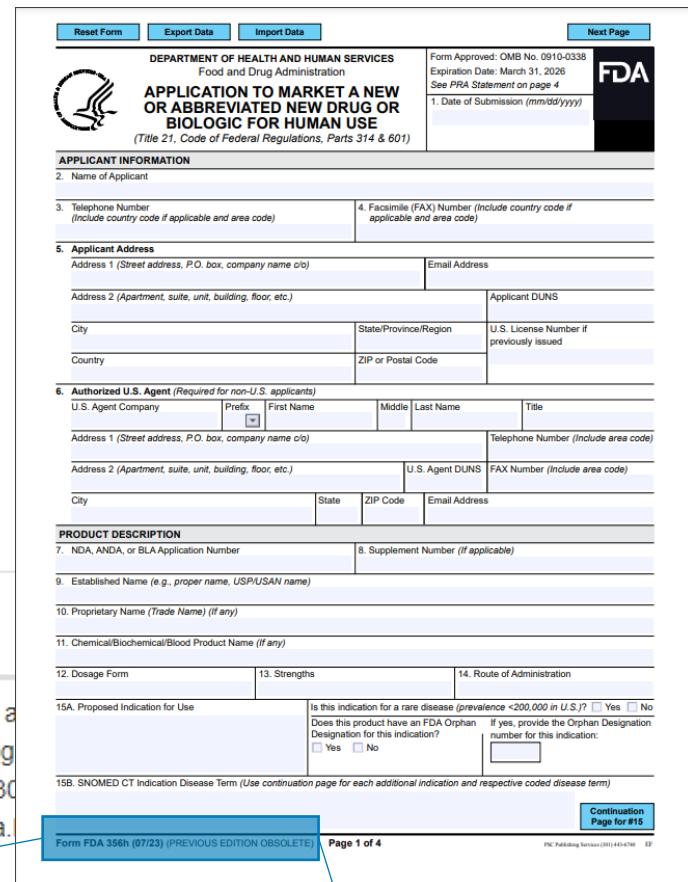
How do I confirm the latest version of the form?

FDA

Resources:

- ✓ [FDA Forms webpage](#)
- ✓ druginfo@fda.hhs.gov
- ✓ esub@fda.hhs.gov

Form Number	Title	Edition Date	Format	Contact
0356h	Application to Market a New or Abbreviated New Drug or Biologic for Human Use (PDF)	07/2023	FDA-356h_AcroForm_Sec_07-07-2023_0.pdf3.37 MB	CBER MATT a industry.biolog Drug Info at 30 druginfo@fda.



Reset Form Export Data Import Data Next Page

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2026
See PRA Statement on page 4

1. Date of Submission: (mm/dd/yyyy)

APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE
(Title 21, Code of Federal Regulations, Parts 314 & 601)

APPLICANT INFORMATION

2. Name of Applicant

3. Telephone Number (Include country code if applicable and area code) 4. Facsimile (FAX) Number (Include country code if applicable and area code)

5. Applicant Address

Address 1 (Street address, P.O. box, company name c/o) Email Address

Address 2 (Apartment, suite, unit, building, floor, etc.) Applicant DUNS

City State/Province/Region U.S. License Number if previously issued

Country ZIP or Postal Code

6. Authorized U.S. Agent (Required for non-U.S. applicants)

U.S. Agent Company Prefix First Name Middle Last Name Title

Address 1 (Street address, P.O. box, company name c/o) Telephone Number (Include area code)

Address 2 (Apartment, suite, unit, building, floor, etc.) U.S. Agent DUNS FAX Number (Include area code)

City State ZIP Code Email Address

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number 8. Supplement Number (If applicable)

9. Established Name (e.g. proper name, USP/USAN name)

10. Proprietary Name (Trade Name) (If any)

11. Chemical/Biochemical/Blood Product Name (If any)

12. Dosage Form 13. Strengths 14. Route of Administration

15A. Proposed Indication for Use

Is this indication for a rare disease (prevalence <20,000 in U.S.)? Yes No

Does this product have an FDA Orphan Designation for this indication? Yes No If yes, provide the Orphan Designation number for this indication:

15B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)

Continuation Page for #15

Form FDA 356h (07/23) (PREVIOUS EDITION OBSOLETE) Page 1 of 4

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Form FDA 356h (07/23) (PREVIOUS EDITION OBSOLETE)

Where do I place 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
- ✓ esub@fda.hhs.gov

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

1.4 References

1.4.1 Letter of authorization

1.4.2 Statement of right of reference

1.4.3 List of authorized persons to incorporate by reference

What file types can I submit?

Specifications for File Format Types Using eCTD Specifications

Resources:

- ✓ [Specifications for File Format Types Using eCTD Specifications](#)
- ✓ [eCTD Technical Conformance Guide](#)
- ✓ [FDA Regulatory Project Manager](#)
- ✓ esub@fda.hhs.gov

Specifications for File Format Types Using eCTD Specifications

This document provides specifications for submitting file format types using eCTD specifications. It is a list of accepted file types and the eCTD locations in which those file types should be provided.

I. General Information

Documents should be provided in PDF searchable format. Images and other document types should be rendered into PDF format and retain searchable text whenever possible. Additional information related to PDF documents is available in the FDA technical specification FDA Portable Document Format (PDF) Specifications.

II. Acceptable File Formats for Use in eCTD

In most cases, files submitted in formats below should also be provided in PDF format for archival purposes, please reference the "Archive Format Copy" column to see if an alternative version of the document should also be provided.

File Type	File Format	Format Name	Accepted location in eCTD	Archive Format Copy	Permissible Uses
<i>Documents</i>					
	.pdf	Portable Document Format	M1 – M5		
	.doc	Microsoft Word document	M1.14, 1.16 M2.3, M2.7	PDF	ANDA
	.docx	Microsoft Word Open XML document	M1.14, 1.16 M2.3 M2.7	PDF	ANDA ANDA, BLA, NDA
	.txt	Text file	M3 - M5		
	.xls	Microsoft Excel document	M3 – M5	PDF	
	.xlsx	Microsoft Excel Open XML document	M3 – M5	PDF	
<i>Images</i>					
	.bmp	Bitmap Graphics	M1.15		
	.gif	Graphics Interchange Format	M1 - M5		Package Insert in draft labeling

I received a 1734 error. How can I make sure I pass validation?



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ADMINISTRATION

Contains Nonbinding Recommendations

Table 6: eCTD Technical Rejection Criteria for Study Data Expectations⁹²

Data Type	Modules & Submodules	Center	Application Type	Study Start Date	Requirement
Non-clinical	4.2.3.1, 4.2.3.2, 4.2.3.4	CDER	NDA, BLA, ANDA	On/Prior to December 17, 2016	Submit simplified ts.xpt*
				After December 17, 2016	Comply with CDISC standards
		CBER	Commercial IND	On/Prior to December 17, 2017	Submit simplified ts.xpt*
				After December 17, 2017	Comply with CDISC standards
	5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, 5.3.5.2	CBER & CDER	NDA, BLA, ANDA, Commercial IND	On/Prior to March 15, 2023	Submit simplified ts.xpt*
				After March 15, 2023	Comply with CDISC standards
			Commercial IND	On/Prior to December 17, 2016	Submit simplified ts.xpt if study contains an xpt dataset (other than ts.xpt)
				After December 17, 2016	Comply with CDISC standards
Rejection criteria not applied					

⁹²Rejection criteria will be applied if a study report with one of the three file tags, 'pre-clinical-study-report', 'legacy-clinical-study-report', or 'study-report-body' is included, and/or an xpt file (other than the ts.xpt) is submitted.

⁹² This table only applies to eCTD validation 1734, 1735, and 1736. An STF must be provided for all applications and data types for both CDER and CBER (eCTD validation 1789). For more information, see the *Specifications for eCTD Validation Criteria* found here: <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ecd>

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

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December 2023

What file-tag should I use?

INTERNATIONAL CONFERENCE ON HARMONISATION OF
TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

Resources:

✓ [Valid-Values.xml](#)

✓ [The eCTD Backbone File Specification for Study Tagging Files](#)

✓ [Study Data Technical Conformance Guide](#)

✓ [eCTD Technical Conformance Guide](#)

✓ esub@fda.hhs.gov

ICH M2 EWG

The eCTD Backbone File Specification for Study Tag

This specification has been developed by the ICH M2 Expert Group and maintained by the eCTD Implementation Working Group in accordance with the ICH Process as pertains to the M2 EWG. Change control as it pertains to the eCTD IWG

```
<ectd:study-values xmlns:ectd="http://www.ich.org/ectd" dtd-version="2.2">
  <!-- valid-values v3.0 - November 10, 2010 -->
  <category name="species">
    <valid-value realm="ich" value="mouse"/>
    <valid-value realm="ich" value="rat"/>
    <valid-value realm="ich" value="hamster"/>
    <valid-value realm="ich" value="other-rodent"/>
    <valid-value realm="ich" value="rabbit"/>
    <valid-value realm="ich" value="dog"/>
    <valid-value realm="ich" value="non-human-primate"/>
    <valid-value realm="ich" value="other-non-rodent-mammal"/>
    <valid-value realm="ich" value="non-mammals"/>
  </category>
  <category name="route-of-admin">
    <valid-value realm="ich" value="oral"/>
    <valid-value realm="ich" value="intravenous"/>
    <valid-value realm="ich" value="intramuscular"/>
    <valid-value realm="ich" value="intraperitoneal"/>
    <valid-value realm="ich" value="subcutaneous"/>
    <valid-value realm="ich" value="inhalation"/>
    <valid-value realm="ich" value="topical"/>
    <valid-value realm="ich" value="other"/>
  </category>
  <category name="duration">
    <valid-value realm="us" value="short"/>
    <valid-value realm="us" value="medium"/>
    <valid-value realm="us" value="long"/>
  </category>
  <category name="type-of-control">
    <valid-value realm="ich" value="placebo"/>
    <valid-value realm="ich" value="no-treatment"/>
    <valid-value realm="ich" value="dose-response-without-placebo"/>
    <valid-value realm="ich" value="active-control-without-placebo"/>
    <valid-value realm="ich" value="external"/>
  </category>
  <property>
    <valid-value realm="us" value="site-identifier"/>
  </property>
  <file-tag>
    <valid-value realm="ich" value="pre-clinical-study-report"/>
    <valid-value realm="ich" value="legacy-clinical-study-report"/>
    <valid-value realm="ich" value="synopsis"/>
    <valid-value realm="ich" value="study-report-body"/>
    <valid-value realm="ich" value="protocol-or-amendment"/>
    <valid-value realm="ich" value="sample-case-report-form"/>
    <valid-value realm="ich" value="iec-irb-consent-form-list"/>
    <valid-value realm="ich" value="list-description-investigator-site"/>
    <valid-value realm="ich" value="signatures-investigators"/>
    <valid-value realm="ich" value="list-patients-with-batches"/>
    <valid-value realm="ich" value="randomisation-scheme"/>
    <valid-value realm="ich" value="audit-certificates-report"/>
    <valid-value realm="ich" value="statistical-methods-interim-analysis-plan"/>
    <valid-value realm="ich" value="inter-laboratory-standardisation-methods-quality-assurance"/>
    <valid-value realm="ich" value="publications-based-on-study"/>
    <valid-value realm="ich" value="publications-referenced-in-report"/>
  </file-tag>
</ectd:study-values>
```

Resources

- eCTD
 - [Web page for latest version of eCTD guidance, specifications, and validations](#)
 - [eCTD Comprehensive Table of Contents Headings and Hierarchy](#)
 - [eCTD Technical Conformance Guide](#)
 - [The eCTD Backbone Files Specification for Module 1](#)
 - [Specifications for File Format Types](#)
- Standards
 - [M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry](#)
 - [Interdisciplinary Review Team for Cardiac Safety Studies \(formerly QT-IRT\)](#)
- eCTD 4
 - [FDA's eCTD v4 implementation page](#)