US Food and Drug Administration

Specifications for eCTD Validation Criteria

Revision History

Date	Description	Version
2008-03-10	Initial Release of eCTD Validation Criteria	1.0
2010-12-10	eCTD Validation Criteria updated including additions and deletions of error codes **- DRAFT**	2.0
2011-12-20	eCTD Validation Criteria updated including clarifications and deletions of error codes **- FINAL**	2.1
2013-04-30	eCTD Validation Criteria effective dates updated **- FINAL**	2.2
2013-08-23	eCTD Validation Criteria added and existing criteria updated to incorporate changes for US eCTD Module 1 (using DTD version 3.2) **- FINAL**	3.0
2014-02-07	Updated DTD version 3.2 references to 3.3; DTD 2.01 added to the applicable DTD versions for error 2001; updated guidance sources where applicable **- FINAL** Note: On 2014-03-07, corrections were made to a date and the descriptions in the last two rows of this Revision History.	3.1
2016-09-21	eCTD Validation Criteria added to support Study Data Technical Conformance Guide	3.2
2016-11-07	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.3
2017-03-02	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.4
2017-03-29	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.5

Revision History

Date	Description	Version
2017-04-05	Update to the descriptions of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.5.1
2017-06-22	Updates to the description for PDF error 5055 and the STF description of the eCTD Validation Criteria which support the Study Data Technical Conformance Guide	3.6
2018-06-21	Added validation from FDA's submission acceptance process and deletion of low severity fillable form error 5025	3.7
2019-01-22	Update to the descriptions of the eCTD Validation Criteria (1734, 1735, and 1736) which support the Study Data Technical Conformance Guide, update to the severity of errors 1735 and 1789, and deletion of error codes 1 and 5033	3.8
2021-03-15	Update to the effective date of the eCTD Validation Criteria 1734, 1735, 1736 (see Technical Rejection Criteria for Study Data), 1737, and 1789, and new eCTD Validations (1551, 1553, 1554) which support the Promotional Labeling and Advertising Materials Guidance	3.9
2021-05-28	Update to the severity level to “High”, guidance source, and effective date for eCTD Validation Criteria 1306 and 1323. Update to the description for eCTD Validation 1553	4.0
2021-06-24	Update to the effective date of the eCTD Validation Criteria 1551 and 1553. Update to the description for eCTD Validation 1553	4.1
2021-08-16	Update of corrective action for eCTD Validation Criteria 1306, 1323, 1636, 1789, 2033 and 5030	4.2

Specifications for eCTD Validation Criteria

These specifications detail the validation criteria applied when FDA processes eCTD submissions. They provide a description of the error, an explanation of the error, the corrective steps necessary to correct the error and the severity level that has been assigned to the error.

Severity Levels

The severity levels outline the impact on the official receipt of your submissions.

Severity	Description
High	The error is a serious technical error which prevents the processing of the submission and will require resubmission. The submission is considered not received by FDA.
Medium	The error may impact the reviewability of the submission but cannot be determined without further inspection by the review staff. The submission might be considered received by FDA.
Low	The error is a technical error which may or may not impact the reviewability or the integrity of the submission. The submission will likely be considered received by FDA.

Note: The FDA utilizes a commercial off-the-shelf product to validate eCTD submissions. The vendor provides the error numbers, groups, and sections. These may be subject to change from time to time. Should they change, this document will be updated accordingly. Error codes 2-7 are not validated by a commerical off-the-shelf product.

eCTD Validation Errors

Number:	2
Group:	File Check
Description:	eCTD submission missing us-regional.xml file
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	4/2/2017
Problem:	You have submitted an eCTD submission without the required us-regional.xml file
Corrective Action:	Resubmit with us-regional.xml file
Guidance Source:	The eCTD Backbone Files Specification for Module 1, ICH eCTD Specification V3.2.2
Number:	3
Group:	File Check
Description:	Single file submission
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	5/31/2016
Problem:	You have a submitted a single file
Corrective Action:	Resubmit folder containing file(s)/subfolders
Guidance Source:	FDA Presentations
Number:	4
Group:	File Check
Description:	Submission containing no files
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	5/31/2016
Problem:	Submission does not contain files
Corrective Action:	Resubmit folder containing file(s)/subfolders
Guidance Source:	The eCTD Backbone Files Specification for Module 1, ICH eCTD Specification V3.2.2

Number:	5
Group:	M1
Description:	Application Mismatch
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	4/2/2017
Problem:	Application Type/Number in the FDA Form does not match Application Type/Number in us-regional.xml
Corrective Action:	Resubmit using consistent Application Type/Number between FDA Form and us-regional.xml
Guidance Source:	FDA Presentations
Number:	6
Group:	General
Description:	Submission is not in eCTD format
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	5/5/2017
Problem:	You are required to submit in eCTD format
Corrective Action:	Resubmit using eCTD format
Guidance Source:	eCTD Guidance
Number:	7
Group:	General
Description:	Fillable form not included
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	7/27/2018
Problem:	You have submitted without including the appropriate fillable form 356h, 2252, or 1571
Corrective Action:	Resubmit with the appropriate fillable form 356h, 2252, or 1571
Guidance Source:	eCTD Guidance

Number:	1034
Group:	File checks
Description:	Invalid leaf element operation
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have submitted a leaf and did not include the operation attribute. The system substituted "New."
Corrective Action:	If the operation attribute should not have been "New," submit two new leaves. The first leaf should delete the leaf submitted without the operation attribute. The second should associate the file referenced by the first leaf to the leaf you had originally intended to modify.
Guidance Source:	DTDs; ICH eCTD Specification V3.2.2 Appendix 6
Number:	1038
Group:	File checks
Description:	Application form and cover letter should be "New"
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a form or cover letter using an operator other than "New."
Corrective Action:	No corrective action is necessary as occasionally there is a need to replace an incorrect document. Modify your SOPs to ensure the "New" operator is used with forms and cover letters except for exception cases.
Guidance Source:	FDA Presentations

Number:	1051
Group:	File checks
Description:	Extraneous leaf element path
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have specified a hlink:xref path for an operation that does not require one, e.g., "Delete."
Corrective Action:	Modify your SOPs to ensure extraneous information is not submitted.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6
Number:	1068
Group:	File checks
Description:	Extraneous modified leaf element path
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have specified a modified-file path for an operation that does not require one, e.g., "New."
Corrective Action:	Modify your SOPs to ensure extraneous information is not submitted.
Guidance Source:	ICH Q&A 36 #4
Number:	1085
Group:	File checks
Description:	Leaf element path length exceeds maximum (230 characters)
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	There is a maximum path length of 230 characters. Internal processing adds additional characters to your paths which may invalidate your links.
Corrective Action:	Corrective action may be necessary. Examine your naming conventions to reduce the length of path statements.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2

Number:	1102
Group:	File checks
Description:	Leaf element path contains invalid characters: backslash(\), colon(:), asterisk(*), question mark(?), less than(<), greater than(>), pipe(|), or space ( )
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Your path statement contains invalid characters. Since the restriction on characters in the path is an operating system constraint there is likely to be an orphaned file caused by a mismatch between the path specified for the leaf and the actual path of the file referenced by the leaf.
Corrective Action:	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" to replace the original erroneous leaf.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2; FDA Portable Document Format Specifications V3.1
Number:	1111
Group:	File checks
Description:	More than one version of the us-regional.xml file exists
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	More than one us-regional.xml was found in the same sequence; the M1 element contains two leafs for regional files.
Corrective Action:	Resubmit with only one us-regional.xml and only one reference to a regional file per submission sequence.
Guidance Source:	General good practice to ensure reviewability.

Number:	1119
Group:	File checks
Description:	Missing required file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	A required file in the UTIL folder is missing.
Corrective Action:	Corrective action may be necessary. Modify your SOPs to prevent this in the future.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6; ICH Q&A 36 #2, 6, and 8

Number:	1130
Group:	File checks
Description:	Required file checksum value in the util folder must match the expected checksum
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a required file which has been altered (DTD or stylesheet in the UTIL folder).
Corrective Action:	No corrective action is necessary. Modify your SOPs to prevent this in the future and ensure the required file is not altered.
Guidance Source:	ICH Q&A 36 #2, 6, and 8

Number:	1136
Group:	File checks
Description:	Omitted leaf element path
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have not provided the path to the file that should be referenced by the leaf.
Corrective Action:	Resubmit the leaf specifying the file path to the original document in a later submission. Use the operational attribute of "Replace" to replace the original incorrect leaf.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6; ICH Q&A 36 #13

Number:	1153
Group:	File checks
Description:	Missing modified file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The leaf referenced in the modified-file element cannot be found.
Corrective Action:	In your next submission submit a leaf modifying the leaf that generated this error using the operation attribute of "Delete." In the same submission resubmit the leaf that generated this error correcting the modified-file reference.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6

Number:	1154
Group:	File checks
Description:	A leaf referenced in the modified-file element was not originally submitted to all applications in the grouped submission
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You are using an operator attribute on a leaf that has been found in a different application, but has not been submitted to this application.
Corrective Action:	In your next submission, submit a leaf modifying the leaf that generated this error using the operation attribute of "Delete." In the same submission, resubmit the leaf that generated this error correcting the modified-file reference.
Guidance Source:	General good practice to ensure reviewability.
Number:	1170
Group:	File checks
Description:	Omitted leaf element modified file path
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The file path is not specified.
Corrective Action:	Resubmit the missing file path in a later submission referencing the original document using the operation attribute of "Replace."
Guidance Source:	ICH Q&A 36 #4; ICH eCTD Specification V3.2.2 Appendix 6

Number:	1204
Group:	File checks
Description:	File name contains invalid characters: tilde(~), forward slash(/), backslash(\), colon(:), asterisk(*), question mark(?), single quote('), double quote(") less than(<), greater than(>), pipe(|), or space( )
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The file name contains invalid characters.
Corrective Action:	Modify your SOPs to ensure file names do not contain invalid characters.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2

Number:	1221
Group:	File checks
Description:	File name exceeds maximum length (64 characters) per eCTD specification
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The file name exceeds maximum length (64 characters).
Corrective Action:	Modify your SOPs to ensure files names do not exceed the maximum length (64 characters) per the eCTD Specification.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2

Number:	1238
Group:	File checks
Description:	File size exceeds maximum limit (400 MB) per eCTD specification
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The file size exceeds the maximum limit (400 MB). Note: This limit may not be applicable if your file is a dataset. Please refer to the FDA Study Data Specifications document for current information regarding dataset file sizes.
Corrective Action:	No corrective action is necessary. You should generally avoid sending files with sizes that exceed the eCTD Specification.
Guidance Source:	eCTD Backbone File Specification for Modules 2 through 5 V3.2.2; ICH eCTD Specification V3.2.2 Section 7
Number:	1255
Group:	File checks
Description:	Invalid file extension
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You provided a file extension that is not allowed in this section.
Corrective Action:	Only certain file extensions are valid in certain sections, therefore it is important to submit extensions only in the sections in which they are allowed. Corrective action may be necessary based on where the file with the invalid extension appears in the submission. You will be contacted if corrective action is necessary.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2; Specifications for File Format Types Using eCTD Specifications V1.0

Number:	1276
Group:	File checks
Description:	Leaf element title leads or ends with a space
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Leaf element title leads or ends with a space.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that leaf element titles do not lead or end with a space.
Guidance Source:	General good practice to ensure reviewability.
Number:	1289
Group:	File checks
Description:	Omitted leaf element title
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have omitted the title of a leaf element.
Corrective Action:	Resubmit a replacement leaf element in a later submission referencing the original leaf using the operation attribute of "Replace."
Guidance Source:	ICH Q&A 36 #20; ICH eCTD Specification V3.2.2 Appendix 6
Number:	1298
Group:	File checks
Description:	File does not contain a file extension
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have provided a file that does not have a file extension such as .pdf, .xpt, etc.
Corrective Action:	Resubmit a replacement leaf element in a later submission referencing the original leaf using the operation attribute of "Replace."
Guidance Source:	General good practice to ensure reviewability.

Number:	1306
Group:	File checks
Description:	No leaf element for file
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/1/2022
Problem:	You have submitted the file(s) listed in the validation report without a corresponding reference in the backbone.
Corrective Action:	Resubmit, corrective action is based on the underlying reason for the error. If the error is the result of a simple omission of a leaf element, then you should ensure the leaf element file is included in the submission before resubmitting. If the error occurred due to a difference between the name of the file in a leaf reference and the actual name of the file, then you should correct the leaf element before resubmitting.
Guidance Source:	ICH Q&A 36 #13; ICH eCTD Specification V3.2.2 Appendix 6; eCTD Comprehensive Table of Contents Headings and Hierarchy
Number:	1314
Group:	File checks
Description:	Non-required file exists
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have submitted files in the UTIL folder that are not required.
Corrective Action:	Modify your SOPs to ensure that only required files are placed in the UTIL folder.
Guidance Source:	ICH Q&A #51

Number:	1322
Group:	File checks
Description:	Folder contains no files or sub folders
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	Your submission includes a file folder that contains no files or sub folders.
Corrective Action:	Modify your SOPs so that you do not submit empty folders in the future.
Guidance Source:	ICH Q&A #54

Number:	1323
Group:	File checks
Description:	No file for leaf element
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/1/2022
Problem:	You have referenced the file(s) listed in the validation report from the us-regional.xml or index.xml files without providing the actual file(s).
Corrective Action:	Resubmit, corrective action is based on the underlying reason for the error. If the error is the result of a simple omission of the file, then you should ensure the file is included in the submission before resubmitting. If the error occurred due to a difference between the name of the file in a leaf reference and the actual name of a file, then you should correct the leaf element before resubmitting.
Guidance Source:	ICH Q&A 36 #12; ICH eCTD Specification V3.2.2 Appendix 6; eCTD Comprehensive Table of Contents Headings and Hierarchy

Number:	1344
Group:	General
Description:	Attribute value leads or ends with a space
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Attribute value leads or ends with a space.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that attribute values do not lead or end with a space.
Guidance Source:	General good practice to ensure reviewability.
Number:	1357
Group:	General
Description:	Required attribute value omitted in M2 - M5
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You did not specify a required attribute in a heading element or STF XML file in m2 through m5, e.g. 'indication' in the section 5.3.5 element or 'type of control' in the STF XML file for a study in section 5.3.5.1.
Corrective Action:	Corrective action may be necessary. If corrective action is necessary, you will be contacted by FDA. Modify your SOPs to ensure that attributes are used as described in the eCTD Specification.
Guidance Source:	DTDs; The eCTD Backbone File Specification for Study Tagging Files 2.6.1

Number:	1362
Group:	General
Description:	An attribute appears multiple times in the stf.xml file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have duplicated an attribute, e.g., two 'type-of-control' attributes in a STF XML file. Viewer will ignore duplicate attributes and display only the first attribute.
Corrective Action:	Corrective action may be necessary. If corrective action is necessary, you will be contacted by FDA. Modify your SOPs to ensure that attributes are used as described in the eCTD Specification.
Guidance Source:	DTDs; The eCTD Backbone File Specification for Study Tagging Files 2.6.1
Number:	1368
Group:	General
Description:	Extraneous attribute
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have submitted an attribute that is not called for in the specification, e.g. 'manufacturer' in a Module 4 or Module 5 heading element or 'species' in a Module 5 STF.
Corrective Action:	No corrective action is currently possible. Modify your SOPs to ensure that attributes are used as described in the eCTD Specification.
Guidance Source:	DTDs; The eCTD Backbone File Specification for Study Tagging Files 2.6.1

Number:	1374
Group:	General
Description:	Checksum value must match the actual checksum
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Your checksum value does not match the actual checksum.
Corrective Action:	Corrective action is based on the underlying reason for the error. You should determine if the issue is simply a miscalculation or misapplication of a checksum; if so, no corrective action is necessary. If you determine that the incorrect file was submitted you should submit the corrected file in a future submissions with a leaf element referencing the original leaf with an operation attribute of "Replace." If you believe that an error has occurred and that the file you have submitted may have become corrupt you should contact your appropriate Center representative.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2
Number:	1391
Group:	General
Description:	Invalid checksum formatting in index-md5.txt.
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You are using an invalid checksum format, i.e., you have not specified the 32 characters produced as part of generating the MD5 checksum, or you have included trailing spaces or carriage returns.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure the proper MD5 checksum format is used.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2

Number:	1408
Group:	General
Description:	Invalid checksum type
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have used an invalid checksum type.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure the use of MD5 checksums.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2
Number:	1425
Group:	General
Description:	Omitted checksum value
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have omitted the checksum value.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that the MD5 checksums are specified.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 2
Number:	1426
Group:	General
Description:	Unexpected checksum value
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have provided a checksum when the leaf operation is "Delete."
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that the checksums are not specified for delete operations.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6

Number:	1442
Group:	General
Description:	Omitted DTD version in index.xml file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have omitted the DTD version in the index.xml file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. Modify your SOPs to ensure that the DTD version is specified in the index.xml file.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section I

Number:	1445
Group:	General
Description:	Omitted DTD version in us-regional.xml file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have omitted the DTD version in the us-regional.xml file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. Modify your SOPs to ensure that the DTD version is specified in the us-regional.xml file.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3

Number:	1451
Group:	M1
Description:	Date format is missing
Severity Description:	Medium
US DTD Version	2.01
Effective Date:	4/30/2013
Problem:	You have omitted the date format in the us-regional.xml file.
Corrective Action:	Modify your SOPs to ensure the date format is specified in the us-regional.xml file.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II
Number:	1454
Group:	M1
Description:	Company name is missing
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have omitted the company name in the us-regional.xml file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II
Number:	1459
Group:	General
Description:	Unsupported DTD version in index.xml file
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You are using an unsupported DTD version in the index.xml file.
Corrective Action:	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
Guidance Source:	ICH eCTD Specification V3.2.2; FDA eCTD Website

Number:	1463
Group:	General
Description:	Unsupported DTD version in us-regional.xml file
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You are using an unsupported DTD version in the us-regional.xml file.
Corrective Action:	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3; FDA eCTD and Module 1 Website

Number:	1468
Group:	M1
Description:	Submission does not contain a prod-name element
Severity Description:	Low
US DTD Version	2.01
Effective Date:	4/30/2013
Problem:	You have omitted the prod-name element in the us-regional.xml file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II

Number:	1472
Group:	M1
Description:	Product name value is missing
Severity Description:	Low
US DTD Version	2.01
Effective Date:	4/30/2013
Problem:	You have omitted a value for the prod-name element in the us-regional.xml file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II
Number:	1476
Group:	General
Description:	Node-extension exists
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have included node extensions in your submissions. Node extensions are strongly discouraged by FDA.
Corrective Action:	Modify your SOPs to ensure that node extensions are not used in future submissions.
Guidance Source:	FDA Presentations

Number:	1478
Group:	General
Description:	Node-extension does not have a title
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Node extension is supplied without a title.
Corrective Action:	In a future submission, a leaf should be provided that references the original node-extension leaf specifying the "Delete" operation. A new leaf using an existing eCTD heading should be also submitted specifying the operation attribute of "New" taking care to include all required elements and attributes. The use of node extensions is strongly discouraged.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6; General good practice to ensure reviewability.
Number:	1482
Group:	General
Description:	Node-extension title leads or ends with a space
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The node-extension title begins or ends with a space.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that node extensions are not used in future submissions. The use of node extensions is strongly discouraged.
Guidance Source:	General good practice to ensure reviewability.

Number:	1487
Group:	M1
Description:	Product type is missing
Severity Description:	Low
US DTD Version	2.01
Effective Date:	4/30/2013
Problem:	You have omitted the type attribute or value from the prod-name element in the us-regional.xml file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II

Number:	1496
Group:	M1
Description:	Application type is invalid
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	The application type must match a valid, supported application type from the specification and/or attribute xml file if applicable.
Corrective Action:	Resubmit your application specifying a valid application type. Certain application types in the attribute file are used only for cross-referenced applications, and it's noted in the attribute file. You may resubmit using the original sequence number of the submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3

Number:	1500
Group:	General
Description:	Text data was truncated
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted data that exceed the maximum limits.
Corrective Action:	No corrective action is necessary. This is a warning to examine your naming conventions to reduce the size of the data values. Titles and keywords are limited to 512 characters.
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6
Number:	1519
Group:	M1
Description:	Application number does not match the folder name
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Your application number in the us-regional.xml file does not match the folder name or the application number referenced for application-containing-files="true" does not match the folder name.
Corrective Action:	Your application number and folder name must match; please correct one of them.
Guidance Source:	General good practice to ensure reviewability.

Number:	1544
Group:	M1
Description:	Company name must remain constant
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The company name has changed.
Corrective Action:	No corrective action is necessary since company names do change from time to time. Modify your SOPs to ensure that company name is used consistently from submission to submission. The company name should only change when there is an actual name change.
Guidance Source:	General good practice to ensure reviewability.
Number:	1545
Group:	M1
Description:	Promotional labeling and advertising regulatory contact is missing
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You did not provide the promotional labeling and advertising regulatory contact for a Promotional Labeling Advertising submission (submission-type=Promotional Labeling Advertising).
Corrective Action:	Ensure that a promotional labeling and advertising regulatory contact is provided for all future promotional labeling and advertising submissions.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	1550
Group:	M1
Description:	Material-id exceeds 30 characters
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You provided a material-id that exceeds the 30 character limitation.
Corrective Action:	Ensure each material-id is within character limitations in future submissions.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	1551
Group:	M1
Description:	2253 submission does not include Product Labeling
Severity Description:	High - CDER
US DTD Version	3.3
Effective Date:	10/18/2021
Problem:	Your 2253 submission did not include Product Labeling. Firms must submit the most current product labeling to section 1.14.6
Corrective Action:	Resubmit the 2253 submission with most current product labeling
Guidance Source:	FDA Form 2253 instructions; Firms must submit the most current product labeling, as required in 21 CFR 314.81(b)(3)(i), to section 1.14.6; Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs, Guidance for Industry

Number:	1553
Group:	M1
Description:	The only valid FDA Form to include in a 2253 submission is FDA Form 2253
Severity Description:	High - CDER
US DTD Version	3.3
Effective Date:	10/18/2021
Problem:	You have submitted an eCTD submission with an eCTD Submission Type of Promotional Labeling and included a Form which is not a 2253. Only 2253 Forms are allowed with a submission of this type.
Corrective Action:	Resubmit without the non-2253 Form
Guidance Source:	Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs, Guidance for Industry

Number:	1554
Group:	M1
Description:	Promotional Material Issue Date Format is incorrect
Severity Description:	Low
US DTD Version	3.3
Effective Date:	3/15/2021
Problem:	The Promotional Material Issue Date in the submission does not match the proper format of YYYYMMDD
Corrective Action:	Resubmit following the date format YYYYMMDD
Guidance Source:	Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs, Guidance for Industry

Number:	1561
Group:	M1
Description:	Circular relationship found in related sequences
Severity Description:	Medium
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	Sequences are referring to one another in a circular fashion. An example of this condition would be sequence 0001 relating to sequence 0002 and 0002 relating back to 0001. Another example would be a sequence that relates to itself.
Corrective Action:	Remove the circular relationship between sequences.
Guidance Source:	General good practice to ensure reviewability.

Number:	1578
Group:	M1
Description:	Multiple related sequences
Severity Description:	Low
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	You are relating the submission to multiple sequences, which is not typical.
Corrective Action:	No corrective action is necessary. Generally, a submission relates to one sequence only; although in rare cases valid, multiple related sequences are allowed, such as an amendment that relates to two supplements.
Guidance Source:	FDA Presentations

Number:	1595
Group:	M1
Description:	This related submission type cannot have a child submission
Severity Description:	Medium
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	You have specified an improper relationship between submission types. A second-level submission should never be related to another second-level submission, e.g. an 'amendment' related to another 'amendment'.
Corrective Action:	Modify your SOPs to ensure that submission types are properly related to one another.
Guidance Source:	FDA Presentations
Number:	1612
Group:	M1
Description:	This submission type cannot have a related sequence
Severity Description:	Medium
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	You have specified an improper relationship between submission types. The 'related-sequence-number' element should not be included for first-level submission types.
Corrective Action:	Remove the 'related-sequence-number' element.
Guidance Source:	FDA Presentations
Number:	1629
Group:	M1
Description:	This submission type requires a related sequence
Severity Description:	Medium
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	This submission type requires a related sequence. An example is submitting an amendment that is not related to anything.
Corrective Action:	Enter the correct related sequence.
Guidance Source:	FDA Presentations

Number:	1635
Group:	M1
Description:	The related sequence number referenced has not been received and/or processed
Severity Description:	Medium
US DTD Version	2.01
Effective Date:	4/30/2013
Problem:	You have submitted a sequence that references a related sequence number for a submission that has not been received and/or processed.
Corrective Action:	Submit the related submission sequence first before using it as a related sequence in future submissions.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3; General good practice to ensure reviewability.
Number:	1636
Group:	M1
Description:	The submission-id referenced has not been received and/or processed
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	The submission-id referenced has not been received and/or processed.
Corrective Action:	Resubmit, corrective action is based on the underlying reason for the error. If the incorrect submission-id was submitted, correct the submission-id before resubmitting. If the correct submission-id was submitted, ensure the sequence number matches the submission-id and the correct submission-type and submission sub-type are provided for the new regulatory activity.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3; General good practice to ensure reviewability.

Number:	1646
Group:	M1
Description:	Invalid date
Severity Description:	Low
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	Your date is invalid (e.g., December 32, 2011) or you did not provide the proper date format of YYYYMMDD.
Corrective Action:	Modify your SOPs to ensure that an actual date or date format is used in the preparation of your submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II
Number:	1663
Group:	M1
Description:	Invalid date format per eCTD specification
Severity Description:	Low
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	You have used an invalid date format.
Corrective Action:	Modify your SOPs to ensure that you are using the valid date format. The valid date format is YYYYMMDD, e.g., 20110615 for June 15, 2011.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II
Number:	1680
Group:	M1
Description:	Omitted date per eCTD specification
Severity Description:	Low
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	You have omitted the date.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that the date is specified in future submissions.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 Section II

Number:	1681
Group:	M1
Description:	Issue-date attribute value is missing
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You did not provide the issue-date for one or more promotional materials in a 2253 submission (promotional-material-doc-type=promotional 2253).
Corrective Action:	Ensure that an issue date is provided for each promotional material in future 2253 submissions.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	1697
Group:	M1
Description:	Sequence number was previously submitted
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	6/15/2015
Problem:	The sequence number used in your submission has already been submitted to the application.
Corrective Action:	Resubmit your submission ensuring that you use a 4 numeric digit sequence number that is unique within the application.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3

Number:	1714
Group:	M1
Description:	Sequence number does not match the folder name
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The sequence number used in your submission does not match the folder name or for DTD V3.2 the sequence number for the application containing files (application-containing-files="true") does not match the folder name.
Corrective Action:	Resubmit your submission ensuring that the sequence number used in your submission matches the folder name for DTD V2.01 or that the sequence number for the application containing files (application-containing-files=”true”) matches the folder name for DTD V3.2.
Guidance Source:	ICH Q&A 36 #19
Number:	1731
Group:	STF
Description:	Cumulative STF files are not allowed
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	FDA only accepts the accumulative approach to STF.
Corrective Action:	Resubmit your submission ensuring that the STF files created follow the accumulative approach.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section II

Number:	1734
Group:	General
Description:	A dataset named ts.xpt with information on study start date must be present for each study in Module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4, and in Module 5, sections 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
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	9/15/2021
Problem:	You have not submitted a dataset named ts.xpt with information on study start date for each study in Module 4, section 4.2, or in Module 5, section 5.3
Corrective Action:	Resubmit, including a dataset named ts.xpt with information on study start date for each study in Module 4, section 4.2, and Module 5, section 5.3
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study Data; Study Data Technical Conformance Guide.

Number:	1735
Group:	STF
Description:	The correct STF file-tags must be used for all standardized datasets and corresponding define.xml files in Module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4, and in Module 5, sections 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
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	9/15/2021
Problem:	You have submitted XPT files or define.xml files without correct file tag. Valid file tags for XPT files are: data-tabulation-dataset-sdtm data-tabulation-dataset-send analysis-dataset-adam Valid file tags for corresponding define.xml files are: data-tabulation-data-definition analysis-data-definition
Corrective Action:	Resubmit using one of the valid file tags for all submitted datasets.
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specification; Providing Regulatory Submissions in Electronic Format – Standardized Study Data; Study Data Technical Conformance Guide.

Number:	1736
Group:	General
Description:	For Standard for Exchange of Nonclinical Data (SEND) data, a Demographic (DM) dataset and define.xml must be submitted in Module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 For Study Data Tabulation Model (SDTM) data, a DM dataset and define.xml must be submitted in Module 5, sections 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 For Analysis Data Model (ADaM) data, an ADaM Subject level analysis dataset (ADSL) dataset and define.xml must be submitted in Module 5, sections 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
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	9/15/2021
Problem:	You have not submitted SEND DM and corresponding define.xml for each study in Module 4, section 4.2. You have not submitted SDTM DM and corresponding define.xml for each study in Module 5, section 5.3. You have not submitted ADSL, and corresponding define.xml for each study in Module 5, section 5.3.
Corrective Action:	Resubmit the submission with the SEND DM and corresponding define.xml for each study in Module 4, section 4.2. Resubmit including SDTM DM and corresponding define.xml for each study in Module 5, section 5.3. Resubmit including ADSL and corresponding define.xml for each study in Module 5, section 5.3.
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study Data; Study Data Technical Conformance Guide.

Number:	1737
Group:	General
Description:	For each study in Module 4, sections 4.2.3.1, 4.2.3.2, 4.2.3.4 and in Module 5, sections 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, no more than one dataset of the same name should be submitted as new
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	9/15/2021
Problem:	You have submitted more than one dataset of the same type as new for a study.
Corrective Action:	Corrective action may be necessary. In future submissions, ensure that only one dataset of each type is marked as new.
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Standardized Study; Study Data Technical Conformance Guide.

Number:	1748
Group:	STF
Description:	Omitted STF DTD version in leaf element
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Omitted STF DTD version in leaf element.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. Modify your SOPs to ensure that the DTD version is in the leaf element.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Page 4

Number:	1752
Group:	STF
Description:	Omitted STF DTD version in STF XML file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Omitted STF DTD version in the STF XML file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. Modify your SOPs to ensure that the DTD version is specified in the STF XML file.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
Number:	1765
Group:	STF
Description:	STF DTD version must match the XML file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Your STF DTD version listed in the leaf element does not match the DTD version in the STF XML file.
Corrective Action:	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. Modify your SOPs to ensure that the DTD version specified in the leaf matches that specified in the STF XML file.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1782
Group:	STF
Description:	Unsupported STF DTD version in leaf element
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You are using an unsupported STF DTD version in a leaf element.
Corrective Action:	Resubmit your submission using a version of the DTD that is supported. For STF Version 2.2 references, the version value should be indicated as "STF Version 2.2" exactly. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1786
Group:	STF
Description:	Unsupported STF DTD version in STF XML file
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You are using an unsupported STF DTD version in a STF XML file.
Corrective Action:	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1789
Group:	STF
Description:	A file has been submitted in a study section without providing an STF file. STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	9/15/2021
Problem:	All files in a study section must be referenced by an STF file.
Corrective Action:	Resubmit, referencing all files submitted in a required study section in an STF file.
Guidance Source:	Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specification; the eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1799
Group:	STF
Description:	STF cannot reference another STF
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The STF may not reference another STF.
Corrective Action:	Resubmit your submission ensuring that STFs do not reference other STFs. You may resubmit using the original sequence number of the submission.
Guidance Source:	General good practice to ensure reviewability.

Number:	1816
Group:	STF
Description:	STF does not relate to any leaf elements
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	STF does not relate to any leaf elements.
Corrective Action:	In a future submission, you should include an STF that includes references to appropriate leaf elements. Modify your SOPs to ensure that all STFs submitted reference leaf elements.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1833
Group:	STF
Description:	STF relates to a non-existent leaf element
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	STF relates to a non-existent leaf element.
Corrective Action:	In a future submission, you should include an STF that includes references to existing leaf elements. Modify your SOPs to ensure that all STFs submitted reference leaf elements.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1850
Group:	STF
Description:	Study ID for STF must remain constant
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have appended an STF with a second STF and the two Study IDs are different (not an exact match). The reviewer will see two studies instead of one.
Corrective Action:	"Delete" leaf references in the index.xml for the files with incorrect Study IDs and then add the leaf references as "New" to the index.xml and STF for the study that should remain. Modify your SOPs to ensure that a consistent Study ID (exact match) is used.
Guidance Source:	General good practice to ensure reviewability.
Number:	1867
Group:	STF
Description:	Invalid STF file extension
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have included an invalid STF file extension.
Corrective Action:	Corrective action may be necessary. If corrective action is necessary, you will be contacted. Modify your SOPs to ensure that the name for the STF XML file starts with the term "stf-" followed by the alphanumeric code used by the sponsor to unambiguously identify the study (i.e., study-id) and followed by ".xml" to complete the file name.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section I

Number:	1884
Group:	STF
Description:	Invalid STF file name
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have included an invalid STF file name.
Corrective Action:	Modify your SOPs to ensure that the name for the STF XML file starts with the term "stf-" followed by the alphanumeric code used by the sponsor to unambiguously identify the study (i.e., study-id) and followed by ".xml" as the file extension to complete the file name.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section I

Number:	1901
Group:	STF
Description:	Invalid STF TOC location
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Your leaf that points to the STF is under an invalid heading area or invalid module. For example, STFs can only be associated with certain headings under Modules 4 or 5.
Corrective Action:	In a future submission, place the STF under the correct module and heading element. Modify your SOPs to ensure that STFs are included only in Modules 4 and 5.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Intro

Number:	1918
Group:	STF
Description:	Omitted STF doc-content file tag
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have omitted the STF doc-content file tag which prevents the proper classification of the file within the submission.
Corrective Action:	In a future submission you should include an updated STF file that reflects the proper doc-content file tag using the "Replace" operator.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Intro

Number:	1935
Group:	STF
Description:	Multiple STF doc-content file tags
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have multiple STF doc-content file tags; processor will process the first tag but will ignore any additional tags.
Corrective Action:	No corrective action is possible due to current STF limitations. Modify your SOPs to ensure that only a single doc-content file tag is used.
Guidance Source:	DTDs; General good practice to ensure reviewability.

Number:	1953
Group:	STF
Description:	STF XML title and leaf element title do not match
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	Your STF study title and leaf element title do not match; viewer will show the title in the stf.xml file only.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that STF titles match the provided leaf title.
Guidance Source:	General good practice to ensure reviewability.

Number:	1969
Group:	STF
Description:	Invalid STF XML file
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have submitted an invalid stf-xxxxxxxx.xml file. This error will occur when: no Study ID is defined, there are no child nodes in the XML document, or the XML document fails to load.
Corrective Action:	In a future submission, delete the leaves which were referenced in the previous invalid stf-xxxxxxx.xml file. Submit a new valid stf-xxxxxxxx.xml files and use the "new" operator attribute to re-reference the previously submitted leaves in the STF files.
Guidance Source:	DTDs; The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1981
Group:	STF
Description:	STF XML file is missing
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have referenced an STF XML file in the hlink:xref attribute of a leaf and the system is unable to locate the file.
Corrective Action:	Resubmit the missing STF XML file in a new submission sequence and re-reference the appropriate leaves using the operation attribute of "Replace."
Guidance Source:	ICH eCTD Specification V3.2.2 Appendix 6; The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1985
Group:	STF
Description:	The study title for the STF is missing
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have omitted the title within the STF XML file. The title is required for STFs submitted using the version 2 specification.
Corrective Action:	In a new submission sequence, resubmit the STF file which includes the corrected study title (it is not necessary to resubmit files or regenerate leaves). Ensure that your Study ID is identical to what you previously submitted.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	1990
Group:	STF
Description:	The same STF XML is referenced more than once.
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted one STF XML file and referenced that STF XML file in more than one section.
Corrective Action:	Only the first study will appear when an STF XML file is referenced more than once. Add a new study STF XML file and one PDF file that states the study is located in another section and provides a link to the study.
Guidance Source:	ICH Q&A 60
Number:	2001
Group:	M1
Description:	An older version of the DTD has been used after a submission to the application used a higher version.
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	6/15/2015
Problem:	You referenced a version of the DTD that can no longer be used for the application because a previous submission(s) to the same application referenced a higher, more recent version.
Corrective Action:	Resubmit your submission using the same or higher version of the DTD referenced in previous submissions. You may resubmit using the original sequence number of the submission.
Guidance Source:	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3

Number:	2002
Group:	Schema Error
Description:	XML didn't pass validation with the schema (DTD) and attribute files
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	6/15/2015
Problem:	You provided an index.xml, us-regional.xml or stf.xml file which does not conform to the schema (DTD) and/or attribute files.
Corrective Action:	Resubmit your submission ensuring that you use xml files valid with the schema (DTD) and attribute files as applicable. You may resubmit using the original sequence number of the submission.
Guidance Source:	ICH eCTD Specification V3.2.2; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3; General good practice to ensure reviewability
Number:	2003
Group:	M1
Description:	us-regional.xml is not referencing the DTD and stylesheet at an approved valid location
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You submitted a submission with its us-regional.xml referencing incorrect DTD and stylesheet file locations.
Corrective Action:	Resubmit your submission that contains a us-regional.xml that references the valid, correct versions of the DTD and stylesheet. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2012
Group:	M1
Description:	A required attribute value in M1 is missing
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have failed to provide a required attribute value for an M1 element.
Corrective Action:	Resubmit the submission and ensure all required attribute values are provided. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3
Number:	2013
Group:	M1
Description:	Invalid M1 attribute value
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You submitted a submission that refers to an M1 attribute value that has a status of invalid or the value itself is not allowed according to the corresponding referenced attribute type list.
Corrective Action:	Resubmit the submission and ensure all provided M1 attributes are valid. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2021
Group:	M1
Description:	A submission sub-type error occurred because this particular submission sub-type is only allowed once for each regulatory activity.
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You used a submission sub-type that was provided in a previous submission to the same regulatory activity. Certain submission sub-types (application, original, report) can only be submitted once for each regulatory activity. (e.g., original-application should only have one submission with a sub-type value "application").
Corrective Action:	You will be contacted if corrective action is necessary. Modify your SOPs to ensure that the submission sub-types which should only be used once for each regulatory activity, are not used again for subsequent submissions to the same regulatory activity.
Guidance Source:	General good practice to ensure reviewability.
Number:	2022
Group:	M1
Description:	Submission-sub-type is invalid for submission-type
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have used a submission-sub-type which is not allowed for the submission-type and/or type of application.
Corrective Action:	Resubmit the submission using a valid submission-sub-type. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2023
Group:	M1
Description:	All grouped submission submission-sub-type values must be the same
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have referenced more than one application and the submission sub-type values are not the same.
Corrective Action:	Resubmit the submission and provide the same submission sub-type for all applications referenced in the us-regional.xml. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2024
Group:	M1
Description:	For all sequences for a regulatory activity the submission type must be consistent, and the submission sub-type must be valid for the submission type.
Severity Description:	High
US DTD Version	3.3
Effective Date:	TBD
Problem:	You have used a submission sub-type that is invalid for the submission type of the parent regulatory activity type or the submission type is different than the submission type of the parent regulatory activity.
Corrective Action:	Resubmit the submission with a valid submission sub-type that is allowed for the submission type of the parent regulatory activity and include the submission type that matches the parent regulatory activity type.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3.

Number:	2025
Group:	M1
Description:	The eCTD sequence number of the submission sub-type that starts a new regulatory activity and the submission id must match.
Severity Description:	High
US DTD Version	3.3
Effective Date:	TBD
Problem:	You have used a submission sub-type where the eCTD sequence number does not match the Submission ID.
Corrective Action:	Resubmit the submission where the eCTD sequence number matches the Submission ID for the new regulatory activity.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3.
Number:	2031
Group:	M1
Description:	All grouped submission application-type values must be the same
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have referenced more than one application and the application-type values are not the same.
Corrective Action:	Resubmit the submission and provide the same application-type for all applications referenced in the us-regional.xml. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2032
Group:	M1
Description:	All grouped submission submission-type values must be the same
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have referenced more than one application and the submission-type values are not the same.
Corrective Action:	Resubmit the submission and provide the same submission-type for all applications referenced in the us-regional.xml. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2033
Group:	M1
Description:	Different sequence numbers are referenced for the same application number
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You referenced different sequence numbers to the same application in a grouped submission. When submitting to different regulatory activities in the same application, use the same sequence number for each submission.
Corrective Action:	Resubmit, ensure the same sequence number is referenced for all regulatory activities to the same application number.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2034
Group:	M1
Description:	Submission-type is invalid for application-type
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have used a submission-type which is not allowed for the application type.
Corrective Action:	Resubmit the submission using a valid submission-type. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2035
Group:	M1
Description:	Submission description exceeds 128 characters
Severity Description:	Low
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You provided a submission description that exceeds the 128 character limit.
Corrective Action:	Ensure future submissions do not have a submission-description that exceeds 128 characters.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2036
Group:	M1
Description:	No application element with application-containing-files value of “true”
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You did not provide an application-containing-files value="true" for any applications referenced in the us-regional.xml.
Corrective Action:	Resubmit the submission indicating which application contains the files by ensuring the application's application-containing-files element has a value="true." You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2037
Group:	M1
Description:	More than one application-containing-files element has a value of "true"
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have reference more than one application with an application-containing-files value= "true."
Corrective Action:	Resubmit the submission indicating which application contains the files by ensuring the application's application-containing-files element has a value="true." You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2038
Group:	M1
Description:	Cross-reference-application-number must contain 6 numeric digits only
Severity Description:	Low
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	Your cross-reference-application-number must be 6 numeric digits in length.
Corrective Action:	In a future submission, reference the correct six (6) digit application number.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2041
Group:	M1
Description:	Supplement-effective-date-type attribute value is missing
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You did not provide the supplement-effective-date-type for this first submission to the supplement.
Corrective Action:	Include a supplement-effective-date-type in the first submission to a new supplement.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2042
Group:	M1
Description:	Email address exceeds 64 characters
Severity Description:	Low
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You provided an email address that exceeds the 64 character limitation.
Corrective Action:	Ensure email addresses are within character limitations in future submissions.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	2043
Group:	M1
Description:	id element has changed
Severity Description:	Low
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You are using an company id element that is different than the id used in previous submissions to the application.
Corrective Action:	No corrective action is necessary since id can change from time to time. Modify your SOPs to ensure that same id is used consistently in future submissions to the application. The id should change only when there is a change in ownership of the application.
Guidance Source:	General good practice to ensure reviewability.
Number:	2044
Group:	M1
Description:	id element must contain 9 digits only
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You provided an id that is not 9 numeric digits.
Corrective Action:	Ensure future submissions include an id that is 9 numeric digits.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	2045
Group:	M1
Description:	Invalid form type for eCTD location
Severity Description:	Medium
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	You have included an invalid form-type attribute value in the submission-information section.
Corrective Action:	Reference the form in the m1-1-forms section and not in submission-information in the admin section of the us-regional.xml.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3

Number:	3001
Group:	STF
Description:	STF doc-content title used
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	You have included a STF doc-content title. This title is not visible to the reviewer and should not be used. The leaf title is visible to reviewers.
Corrective Action:	Corrective action may be necessary. In future submissions, ensure that doc-content titles for each document referenced in the STF XML are not included.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Page 14

Number:	3008
Group:	STF
Description:	Use of the property element is required in STF DTD V2.0; the xlink:href attribute of the doc-content element is not used
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Use of the property element is required. The xlink:href attribute of the doc-content element is not used. Note: Only applies to the STF 2.0 specification.
Corrective Action:	Modify your SOPs to use the most current STF DTD indicated on the FDA eCTD Website.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V1.1 Section III

Number:	3015
Group:	STF
Description:	The element 'file-tag' preceded the element 'property'
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	In the STF XML the 'property' element should come before its sibling element 'file-tag'.
Corrective Action:	Modify your SOPs to ensure your STF is in conformance with the ordering as described in the specification and the DTD.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section III

Number:	3029
Group:	STF
Description:	Use of content-block is not recommended
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Although content block is in both DTD versions, the specification does not refer to it; it is recommended that you do not use it.
Corrective Action:	Remove the content block element in the identified stf-xxxxxxxx.xml and resubmit at time of next planned submission.
Guidance Source:	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

Number:	3036
Group:	M1
Description:	Application number must contain 6 numeric digits only
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	The application number must be 6 numeric digits in length.
Corrective Action:	Resubmit your submission specifying a properly formatted application number. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 Section II

Number:	3050
Group:	M1
Description:	Submission sequence number must contain 4 numeric digits only
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	3/10/2008
Problem:	Your submission's sequence number must be 4 numeric digits in length.
Corrective Action:	Resubmit your submission specifying a properly formatted sequence number.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 Section II

Number:	3064
Group:	M1
Description:	Related sequence number must contain 4 numeric digits only
Severity Description:	High
US DTD Version	2.01
Effective Date:	3/10/2008
Problem:	Your submission's related sequence number element must only contain 4 numeric digits or the element should not appear in the us-regional.xml file.
Corrective Action:	Resubmit your submission specifying a properly formatted related sequence number. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V1.3 Section II
Number:	3065
Group:	M1
Description:	Submission-id element must contain 4 numeric digits only
Severity Description:	High
US DTD Version	3.3
Effective Date:	6/15/2015
Problem:	Your submission-id must be 4 numeric digits in length.
Corrective Action:	Resubmit your submission specifying a properly formatted submission-id number. You may resubmit using the original sequence number of the submission.
Guidance Source:	The eCTD Backbone Files Specification for Module 1 V2.3
Number:	3078
Group:	General
Description:	eCTD element does not contain any leaf elements
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have included a lowest level element that does not contain any leaf elements.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure lowest level elements contain leaf elements.
Guidance Source:	FDA Presentations

Number:	3102
Group:	PDF
Description:	Failed to process PDF contents
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with contents that cannot be processed, e.g. a corrupted or invalid PDF document.
Corrective Action:	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated valid PDF file.
Guidance Source:	General good practice to ensure reviewability.

Number:	5005
Group:	PDF
Description:	Non standard font (not embedded)
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have used a non-standard font and failed to fully embed the font. You should limit fonts to standard fonts. If you use non-standard fonts you should fully embed them in the PDF file.
Corrective Action:	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated PDF file with all non standard fonts embedded.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; FDA Portable Document Format Specifications V3.1

Number:	5020
Group:	PDF
Description:	PDF security used
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a PDF file with security settings that limit the ability to select text or graphics, or make other changes. This prevents agencies from copying text and taking other actions with submitted documents. (Not applicable for FDA Forms)
Corrective Action:	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated PDF file without restrictions.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7
Number:	5029
Group:	M1
Description:	Misnamed form
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You may have submitted an application form that is not named correctly (a 1571 form missing 1571 in its filename or 356 form with missing 356h in its file name). If so, this will prevent automated processing of the form.
Corrective Action:	In the future, ensure that your application form is named 356h.pdf or 1571.pdf. It is also good practice to follow a similar approach when submitting other FDA forms (e.g., 2252, 3674, etc.).
Guidance Source:	FDA Presentations

Number:	5030
Group:	M1
Description:	Application number in form does not match application number in us-regional.xml
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	The application number in your application form does not match the application number supplied in your us-regional.xml file. Note: This error can be ignored for trans BLAs.
Corrective Action:	Resubmit, ensure the application number in the form matches the application number in the us-regional.xml.
Guidance Source:	FDA Presentations
Number:	5031
Group:	M1
Description:	Submission date in form does not match submission date in us-regional.xml
Severity Description:	Low
US DTD Version	2.01
Effective Date:	4/30/2013
Problem:	The submission date in your application form does not match the submission date supplied in your us-regional.xml file.
Corrective Action:	In future submissions, ensure that these dates match. You may need to resubmit with consistent information.
Guidance Source:	FDA Presentations

Number:	5032
Group:	M1
Description:	Multiple application forms present for the same application
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted more than one application form for the same application. Note: This error can be ignored for trans-BLAs submitted with DTD version 2.01.
Corrective Action:	In future submissions, include only one file with the form number as part of the file name. For example, only include one file named 356h.pdf for an NDA, and do not include 356h in the file names of other ancillary documents.
Guidance Source:	FDA Presentations
Number:	5034
Group:	M1
Description:	Application form placed in wrong TOC location
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted an application form that was not placed in the correct TOC location.
Corrective Action:	If corrective action is necessary, you will be contacted. You should provide forms in the correct Module 1 location as specified in the applicable eCTD Backbone Files Specification for Module 1.
Guidance Source:	FDA Presentations; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3

Number:	5035
Group:	PDF
Description:	PDF version of document is incorrect
Severity Description:	Low
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document using a PDF version that is not consistent with ICH / regional guidance.
Corrective Action:	No corrective action is necessary. Modify your SOPs to ensure that documents in future submissions conform to the published standards.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; FDA Portable Document Format Specifications V3.1
Number:	5038
Group:	M1
Description:	Wrong application form
Severity Description:	High
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted the wrong application form based on your application type, that is, you have submitted a form named 1571.pdf for an NDA/ANDA/BLA, a form named 356h.pdf for an IND or a form named 2252.pdf for a sequence that is not an annual report.
Corrective Action:	Resubmit your submission with the correct application form. You may resubmit using the original sequence number of the submission. Modify your SOPs to ensure that your submission has a the correct type of form correctly named 356h.pdf or 1571.pdf and referenced in the correct eCTD location.
Guidance Source:	FDA Presentations; FDA Form Instructions

Number:	5040
Group:	PDF
Description:	PDF does not have 'Fast Web Access' active
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a PDF that has been created without 'Fast Web Access' active.
Corrective Action:	Ensure that documents in future submissions are created with the 'Fast Web Access' option.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; ICH Q&A 36 #23
Number:	5045
Group:	PDF
Description:	PDF opening settings not optimal
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a PDF that does not open in the desired view.
Corrective Action:	Ensure that PDF Opening settings are correct for all future submissions. The initial view of the PDF files should be set as Bookmarks and Pages in the Navigation Panel. If there are no bookmarks, the initial view should be set to Pages only. PDFs should open in 'most recent view' (i.e. 'inherit zoom' for bookmarks and links, and 'default' in open dialogue box).
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; FDA Portable Document Format Specifications V3.1

Number:	5050
Group:	PDF
Description:	Document has password protection
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that has password protection and cannot be opened. (Not applicable for FDA Forms)
Corrective Action:	Resubmit the protected file in a later submission referencing the original leaf using the operation attribute of "Replace."
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; ICH Q&A 36 #21
Number:	5055
Group:	PDF
Description:	Document has annotations, only PDFs in module 1, section 1.15 are permitted to have annotations.
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	9/14/2016
Problem:	You have submitted a document that has PDF annotations, only PDFs in module 1, section 1.15 are permitted to have annotations.
Corrective Action:	Ensure that documents in future submissions do not have annotations, only PDFs in module 1, section 1.15 are permitted to have annotations..
Guidance Source:	General good practice to ensure reviewability.

Number:	5057
Group:	PDF
Description:	Document contains no text
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that is a scanned image only and is not text searchable.
Corrective Action:	Ensure that documents in future submissions are text searchable whenever possible (minimize the use of scanned documents).
Guidance Source:	FDA Portable Document Format Specifications V3.1
Number:	5100
Group:	PDF
Description:	Broken bookmark
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more bookmarks pointing to a file that does not exist.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have broken bookmarks.
Guidance Source:	General good practice to ensure reviewability.
Number:	5101
Group:	PDF
Description:	Corrupt bookmark
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more bookmarks pointing to a file that cannot be opened.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have corrupt bookmarks.
Guidance Source:	General good practice to ensure reviewability.

Number:	5102
Group:	PDF
Description:	Bookmark has non-existent named destination or page
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more bookmarks pointing to a named destination or page that does not exist.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have bookmarks linking to non-existent pages or named destinations.
Guidance Source:	General good practice to ensure reviewability.
Number:	5103
Group:	PDF
Description:	Multiple action bookmark
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more bookmarks containing multiple actions.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have bookmarks triggering multiple actions.
Guidance Source:	General good practice to ensure reviewability.
Number:	5105
Group:	PDF
Description:	External bookmark
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that makes reference to one or more external bookmarks (e.g. web links, email links).
Corrective Action:	Ensure that documents in future submissions do not have bookmarks that are external to the application.
Guidance Source:	ICH Q&A 64

Number:	5110
Group:	PDF
Description:	Inactive bookmark
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that has one or more inactive bookmarks.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have inactive bookmarks.
Guidance Source:	General good practice to ensure reviewability.
Number:	5115
Group:	PDF
Description:	Non-relative bookmark
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that has one or more non-relative (absolute) bookmarks.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions have only relative bookmarks.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 6; FDA Portable Document Format Specifications V3.1; ICH Q&A 36 #23

Number:	5117
Group:	PDF
Description:	Bookmark does not 'Inherit Zoom'
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more bookmarks that are not set to 'Inherit Zoom'.
Corrective Action:	Ensure that all bookmarks are set to 'Inherit Zoom'.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; FDA PDF Specifications V2.0; Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications
Number:	5200
Group:	PDF
Description:	Broken hyperlink
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more hyperlinks pointing to a file that does not exist.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have broken hyperlinks.
Guidance Source:	General good practice to ensure reviewability.

Number:	5201
Group:	PDF
Description:	Corrupt link
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more links pointing to a file that cannot be opened.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have corrupt links.
Guidance Source:	General good practice to ensure reviewability.
Number:	5202
Group:	PDF
Description:	Link has non-existent named destination or page
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more hyperlinks pointing to a named destination or page that does not exist.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have links pointing to non-existent pages or named destinations.
Guidance Source:	General good practice to ensure reviewability.

Number:	5203
Group:	PDF
Description:	Multiple action hyperlink
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more hyperlinks containing multiple actions.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have links triggering multiple actions.
Guidance Source:	General good practice to ensure reviewability.
Number:	5205
Group:	PDF
Description:	External hyperlink
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that makes reference to one or more web references in a hyperlink (e.g. web links, email links).
Corrective Action:	Ensure that documents in future submissions do not have hyperlinks that are external to the application.
Guidance Source:	ICH Q&A 64
Number:	5210
Group:	PDF
Description:	Inactive hyperlink
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that has one or more inactive hyperlinks.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have inactive hyperlinks.
Guidance Source:	General good practice to ensure reviewability.

Number:	5215
Group:	PDF
Description:	Non-relative hyperlink
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document that has one or more non-relative (absolute) hyperlinks.
Corrective Action:	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have non-relative hyperlinks.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 6; FDA Portable Document Format Specifications V3.1; ICH Q&A 36 #23

Number:	5217
Group:	PDF
Description:	Link does not 'Inherit Zoom'
Severity Description:	Medium
US DTD Version	2.01 and 3.3
Effective Date:	4/30/2013
Problem:	You have submitted a document with one or more links that are not set to 'Inherit Zoom'.
Corrective Action:	Ensure that all links in future submissions are set to 'Inherit Zoom'.
Guidance Source:	ICH eCTD Specification V3.2.2 Section 7; FDA PDF Specifications V2.0; Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications

Validation Error Codes (sorted by severity)

Error Number	Severity Level
1038	Low
1130	Low
1204	Low
1221	Low
1238	Low
1276	Low
1322	Low
1344	Low
1368	Low
1374	Low
1391	Low
1408	Low
1425	Low
1426	Low
1454	Low
1468	Low
1472	Low
1482	Low
1487	Low
1500	Low
1544	Low
1554	Low
1578	Low
1646	Low
1663	Low
1680	Low
1953	Low
2035	Low
2038	Low
2042	Low
2043	Low

3078	Low
5029	Low
5031	Low
5032	Low
5034	Low
5035	Low
1034	Medium
1051	Medium
1068	Medium
1085	Medium
1102	Medium
1119	Medium
1136	Medium
1153	Medium
1154	Medium
1170	Medium
1255	Medium
1289	Medium
1298	Medium
1314	Medium
1357	Medium
1362	Medium
1442	Medium
1445	Medium
1451	Medium
1476	Medium
1478	Medium
1519	Medium
1545	Medium
1550	Medium
1561	Medium
1595	Medium
1612	Medium
1629	Medium

1635	Medium
1681	Medium
1737	Medium
1748	Medium
1752	Medium
1765	Medium
1816	Medium
1833	Medium
1850	Medium
1867	Medium
1884	Medium
1901	Medium
1918	Medium
1935	Medium
1969	Medium
1981	Medium
1985	Medium
1990	Medium
2021	Medium
2041	Medium
2044	Medium
2045	Medium
3001	Medium
3008	Medium
3015	Medium
3029	Medium
3102	Medium
5005	Medium
5020	Medium
5040	Medium
5045	Medium
5050	Medium
5055	Medium
5057	Medium

5100	Medium
5101	Medium
5102	Medium
5103	Medium
5105	Medium
5110	Medium
5115	Medium
5117	Medium
5200	Medium
5201	Medium
5202	Medium
5203	Medium
5205	Medium
5210	Medium
5215	Medium
5217	Medium
2	High
3	High
4	High
5	High
6	High
7	High
1111	High
1306	High
1323	High
1459	High
1463	High
1496	High
1636	High
1697	High
1714	High
1731	High
1734	High
1735	High

1736	High
1782	High
1786	High
1789	High
1799	High
2001	High
2002	High
2003	High
2012	High
2013	High
2022	High
2023	High
2024	High
2025	High
2031	High
2032	High
2033	High
2034	High
2036	High
2037	High
3036	High
3050	High
3064	High
3065	High
5030	High
5038	High
1551	High - CDER
1553	High - CDER

Validation Error Codes Removed

Number	1128
Severity	Low
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1314.

Number	1161
Severity	Low
In Version	2.1
Reason For Deletion	A title may be provided, however, providing anything other than the original title may impact reviewability.

Number	1272
Severity	Low
In Version	2.0
Reason For Deletion	There are no invalid characters for leaf titles, only for file names.

Number	1340
Severity	Low
In Version	2.0
Reason For Deletion	There are no invalid characters for attributes.

Number	1480
Severity	Low
In Version	2.0
Reason For Deletion	There are no invalid characters for node extension titles.

Number	1952
Severity	Low
In Version	2.0
Reason For Deletion	Retired and replaced by Error 3001.

Number	5025
Severity	Low
In Version	Replaced by new code
Reason For Deletion	Replaced by new ASR error code

Number	5300
Severity	Low
In Version	2.1
Reason For Deletion	Error functionality removed by FDA eCTD tool vendor.

Number	1017
Severity	Medium
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1153.

Number	1187
Severity	Medium
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1153.

Number	1630
Severity	Medium
In Version	2.1
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3064.

Number	3022
Severity	Medium
In Version	2.1
Reason For Deletion	Error provided redundant functionality. Replaced by Erorr 1362 and Error 1368.

Number	5000
Severity	Medium
In Version	2.1
Reason For Deletion	Non-standard fonts may be used if they are fully embedded in the PDF file (not just an embedded subset).

Number	5033
Severity	Medium
In Version	3.8
Reason For Deletion	duplicate

Number	5080
Severity	Medium
In Version	2.1
Reason For Deletion	Error provided redundant functionality. Replaced by Error 5040.

Number	1
Severity	High
In Version	3.8
Reason For Deletion	duplicate

Number	1493
Severity	High
In Version	2.0
Reason For Deletion	Fatal XML errors will prevent the validation of the sequence. No validation report would be created.

Number	1510
Severity	High
In Version	2.0
Reason For Deletion	Fatal XML errors will prevent the validation of the sequence. No validation report would be created.

Number	1527
Severity	High
In Version	2.0
Reason For Deletion	This error would never occur. A change in application number would cause the sequence to be associated with a different application.

Number	1697
Severity	High
In Version	2.0
Reason For Deletion	This error would never occur. The duplicate sequence would be rejected by the FDA.

Number	3043
Severity	High
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3036.

Number	3057
Severity	High
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3050.

Number	3071
Severity	High
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3064.