

**US Food and Drug Administration***Specifications for eCTD Validation Criteria***Revision History**

<b>Date</b>	<b>Description</b>	<b>Version</b>
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
2022-03-15	Changes related to FDA ending support for DTD 2.01: <ul style="list-style-type: none"><li>• Removal of eCTD Validation Criteria that referenced ONLY US DTD Version 2.01. See Deleted Error Codes List at the end of Specification.</li><li>• Update to US DTD Version to remove reference to 2.01 for eCTD Validation Criteria: 2, 3, 4, 5, 6, 7, 1034, 1038, 1051, 1068, 1085, 1102, 1111, 1119, 1130, 1136, 1153, 1170, 1204, 1221, 1238, 1255, 1276, 1289, 1298, 1306, 1314, 1322, 1323, 1344, 1357, 1362, 1368, 1374, 1391, 1408, 1425, 1426, 1442, 1445, 1454, 1459, 1463, 1476, 1478, 1482, 1496, 1500, 1519, 1544, 1697, 1714, 1731, 1734, 1735, 1736, 1737, 1748, 1752, 1765, 1782, 1786, 1789, 1799, 1816,</li></ul>	4.3



## Revision History

Date	Description	Version
	<p>1850, 1867, 1884, 1901, 1918, 1935, 1953, 1969, 1981, 1985, 1990, 2001, 2002, 3001, 3015, 3029, 3036, 3050, 3078, 3102, 5005, 5020, 5029, 5030, 5032, 5034, 5035, 5038, 5040, 5045, 5050, 5055, 5057, 5100, 5101, 5102, 5103, 5105, 5110, 5115, 5117, 5200, 5201, 5202, 5203, 5205, 5210, 5215, 5217</p> <ul style="list-style-type: none"> <li>• Updates to Guidance Source for eCTD Validation Criteria: 1445, 1454, 1463, 1496, 1545, 1550, 1636, 1681, 1697, 2001, 2002, 2003, 2012, 2013, 2022, 2023, 2024, 2025, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2041, 2042, 2044, 2045, 3036, 3050, 3065, 5034</li> </ul> <p>Other changes:</p> <ul style="list-style-type: none"> <li>• Removal of eCTD Validation Criteria 3008. See Deleted Error Codes List at the end of Specification.</li> <li>• Update to Effective Date for eCTD Validation Criteria 1734, 1735, 1736, and 1737 to include CBER module 4 Effective Date.</li> <li>• Updates to Guidance Source for eCTD Validation Criteria: 6, 7, 1034, 1051, 1085, 1102, 1119, 1136, 1153, 1170, 1204, 1221, 1238, 1255, 1289, 1306, 1323, 1357, 1362, 1368, 1374, 1391, 1408, 1425, 1426, 1442, 1478, 1500, 1731, 1748, 1867, 1884, 1901, 1918, 1981, 3001, 3015, 5005, 5020, 5035, 5040, 5045, 5050, 5057, 5115, 5117, 5215, 5217</li> </ul>	
2022-05-11	Addition of the new validation error code 1738. Update to the problem for error code 1735. Update to the description and effective date for error code 1737.	4.4
2025-10-01	Addition of the new validation error code 2026. Update to the description for error code 1737, 1738, 2021, 2024, and 2025. Information added about the definition of “Effective Date.”	4.5



## 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
<b>High</b>	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.
<b>Medium</b>	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.
<b>Low</b>	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 commercial off-the-shelf product.*

### Effective Date

The effective date indicates the date FDA will begin or started validating submissions for each validation criteria. If an effective date is listed as TBD, this means that the effective date is “To Be Determined” and submissions will not be validated against the validation criteria.

## eCTD Validation Errors

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

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

<b>Number:</b>	1034
<b>Group:</b>	File checks
<b>Description:</b>	Invalid leaf element operation
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have submitted a leaf and did not include the operation attribute. The system substituted "New."
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; ICH eCTD Specification V3.2.2
<b>Number:</b>	1038
<b>Group:</b>	File checks
<b>Description:</b>	Application form and cover letter should be "New"
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a form or cover letter using an operator other than "New."
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	FDA Presentations

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

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



<b>Number:</b>	1119
<b>Group:</b>	File checks
<b>Description:</b>	Missing required file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	A required file in the UTIL folder is missing.
<b>Corrective Action:</b>	Corrective action may be necessary. Modify your SOPs to prevent this in the future.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; ICH Q&A 36 #2, 6, and 8
<b>Number:</b>	1130
<b>Group:</b>	File checks
<b>Description:</b>	Required file checksum value in the util folder must match the expected checksum
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a required file which has been altered (DTD or stylesheet in the UTIL folder).
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to prevent this in the future and ensure the required file is not altered.
<b>Guidance Source:</b>	ICH Q&A 36 #2, 6, and 8
<b>Number:</b>	1136
<b>Group:</b>	File checks
<b>Description:</b>	Omitted leaf element path
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have not provided the path to the file that should be referenced by the leaf.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; ICH Q&A 36 #13

<b>Number:</b>	1153
<b>Group:</b>	File checks
<b>Description:</b>	Missing modified file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The leaf referenced in the modified-file element cannot be found.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2
<b>Number:</b>	1154
<b>Group:</b>	File checks
<b>Description:</b>	A leaf referenced in the modified-file element was not originally submitted to all applications in the grouped submission
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	1170
<b>Group:</b>	File checks
<b>Description:</b>	Omitted leaf element modified file path
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The file path is not specified.
<b>Corrective Action:</b>	Resubmit the missing file path in a later submission referencing the original document using the operation attribute of "Replace."
<b>Guidance Source:</b>	ICH Q&A 36 #4; ICH eCTD Specification V3.2.2
<b>Number:</b>	1204
<b>Group:</b>	File checks
<b>Description:</b>	File name contains invalid characters: tilde(~), forward slash(/), backslash(\), colon(:), asterisk(*), question mark(?), single quote('), double quote(") less than(<), greater than(>), pipe( ), or space( )
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The file name contains invalid characters.
<b>Corrective Action:</b>	Modify your SOPs to ensure file names do not contain invalid characters.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2
<b>Number:</b>	1221
<b>Group:</b>	File checks
<b>Description:</b>	File name exceeds maximum length (64 characters) per eCTD specification
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The file name exceeds maximum length (64 characters).
<b>Corrective Action:</b>	Modify your SOPs to ensure files names do not exceed the maximum length (64 characters) per the eCTD Specification.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2

<b>Number:</b>	1238
<b>Group:</b>	File checks
<b>Description:</b>	File size exceeds maximum limit (400 MB) per eCTD specification
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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 Study Data Technical Conformance Guide for current information regarding dataset file sizes.
<b>Corrective Action:</b>	No corrective action is necessary. You should generally avoid sending files with sizes that exceed the eCTD Specification.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2
<b>Number:</b>	1255
<b>Group:</b>	File checks
<b>Description:</b>	Invalid file extension
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You provided a file extension that is not allowed in this section.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; Specifications for File Format Types Using eCTD Specifications

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

<b>Number:</b>	1306
<b>Group:</b>	File checks
<b>Description:</b>	No leaf element for file
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/1/2022
<b>Problem:</b>	You have submitted the file(s) listed in the validation report without a corresponding reference in the backbone.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH Q&A 36 #13; ICH eCTD Specification V3.2.2; eCTD Comprehensive Table of Contents Headings and Hierarchy
<b>Number:</b>	1314
<b>Group:</b>	File checks
<b>Description:</b>	Non-required file exists
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have submitted files in the UTIL folder that are not required.
<b>Corrective Action:</b>	Modify your SOPs to ensure that only required files are placed in the UTIL folder.
<b>Guidance Source:</b>	ICH Q&A #51

<b>Number:</b>	1322
<b>Group:</b>	File checks
<b>Description:</b>	Folder contains no files or sub folders
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	Your submission includes a file folder that contains no files or sub folders.
<b>Corrective Action:</b>	Modify your SOPs so that you do not submit empty folders in the future.
<b>Guidance Source:</b>	ICH Q&A #54
<b>Number:</b>	1323
<b>Group:</b>	File checks
<b>Description:</b>	No file for leaf element
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/1/2022
<b>Problem:</b>	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).
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH Q&A 36 #12; ICH eCTD Specification V3.2.2; eCTD Comprehensive Table of Contents Headings and Hierarchy

<b>Number:</b>	1344
<b>Group:</b>	General
<b>Description:</b>	Attribute value leads or ends with a space
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Attribute value leads or ends with a space.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure that attribute values do not lead or end with a space.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	1357
<b>Group:</b>	General
<b>Description:</b>	Required attribute value omitted in M2 - M5
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone File Specification for Study Tagging Files V2.6.1



<b>Number:</b>	1362
<b>Group:</b>	General
<b>Description:</b>	An attribute appears multiple times in the stf.xml file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1368
<b>Group:</b>	General
<b>Description:</b>	Extraneous attribute
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	No corrective action is currently possible. Modify your SOPs to ensure that attributes are used as described in the eCTD Specification.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1374
<b>Group:</b>	General
<b>Description:</b>	Checksum value must match the actual checksum
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your checksum value does not match the actual checksum.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2
<b>Number:</b>	1391
<b>Group:</b>	General
<b>Description:</b>	Invalid checksum formatting in index-md5.txt.
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure the proper MD5 checksum format is used.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2

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

<b>Number:</b>	1442
<b>Group:</b>	General
<b>Description:</b>	Omitted DTD version in index.xml file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have omitted the DTD version in the index.xml file.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1445
<b>Group:</b>	General
<b>Description:</b>	Omitted DTD version in us-regional.xml file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have omitted the DTD version in the us-regional.xml file.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	1454
<b>Group:</b>	M1
<b>Description:</b>	Company name is missing
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have omitted the company name in the us-regional.xml file.
<b>Corrective Action:</b>	No corrective action is necessary unless FDA notifies you that it is unable to process your submission.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	1459
<b>Group:</b>	General
<b>Description:</b>	Unsupported DTD version in index.xml file
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You are using an unsupported DTD version in the index.xml file.
<b>Corrective Action:</b>	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA eCTD Website
<b>Number:</b>	1463
<b>Group:</b>	General
<b>Description:</b>	Unsupported DTD version in us-regional.xml file
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You are using an unsupported DTD version in the us-regional.xml file.
<b>Corrective Action:</b>	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1; FDA eCTD and Module 1 Website
<b>Number:</b>	1476
<b>Group:</b>	General
<b>Description:</b>	Node-extension exists
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have included node extensions in your submissions. Node extensions are strongly discouraged by FDA.
<b>Corrective Action:</b>	Modify your SOPs to ensure that node extensions are not used in future submissions.
<b>Guidance Source:</b>	FDA Presentations

<b>Number:</b>	1478
<b>Group:</b>	General
<b>Description:</b>	Node-extension does not have a title
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Node extension is supplied without a title.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; General good practice to ensure reviewability.
<b>Number:</b>	1482
<b>Group:</b>	General
<b>Description:</b>	Node-extension title leads or ends with a space
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The node-extension title begins or ends with a space.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	1496
<b>Group:</b>	M1
<b>Description:</b>	Application type is invalid
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	The application type must match a valid, supported application type from the specification and/or attribute xml file if applicable.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	1500
<b>Group:</b>	General
<b>Description:</b>	Text data was truncated
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted data that exceed the maximum limits.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2

<b>Number:</b>	1519
<b>Group:</b>	M1
<b>Description:</b>	Application number does not match the folder name
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	Your application number and folder name must match; please correct one of them.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	1544
<b>Group:</b>	M1
<b>Description:</b>	Company name must remain constant
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The company name has changed.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.



<b>Number:</b>	1545
<b>Group:</b>	M1
<b>Description:</b>	Promotional labeling and advertising regulatory contact is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You did not provide the promotional labeling and advertising regulatory contact for a Promotional Labeling Advertising submission (submission-type=Promotional Labeling Advertising).
<b>Corrective Action:</b>	Ensure that a promotional labeling and advertising regulatory contact is provided for all future promotional labeling and advertising submissions.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	1550
<b>Group:</b>	M1
<b>Description:</b>	Material-id exceeds 30 characters
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided a material-id that exceeds the 30 character limitation.
<b>Corrective Action:</b>	Ensure each material-id is within character limitations in future submissions.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	1551
<b>Group:</b>	M1
<b>Description:</b>	2253 submission does not include Product Labeling
<b>Severity Description:</b>	High - CDER
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	10/18/2021
<b>Problem:</b>	Your 2253 submission did not include Product Labeling. Firms must submit the most current product labeling to section 1.14.6
<b>Corrective Action:</b>	Resubmit the 2253 submission with most current product labeling
<b>Guidance Source:</b>	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
<b>Number:</b>	1553
<b>Group:</b>	M1
<b>Description:</b>	The only valid FDA Form to include in a 2253 submission is FDA Form 2253
<b>Severity Description:</b>	High - CDER
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	10/18/2021
<b>Problem:</b>	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.
<b>Corrective Action:</b>	Resubmit without the non-2253 Form
<b>Guidance Source:</b>	Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs, Guidance for Industry

<b>Number:</b>	1554
<b>Group:</b>	M1
<b>Description:</b>	Promotional Material Issue Date Format is incorrect
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/15/2021
<b>Problem:</b>	The Promotional Material Issue Date in the submission does not match the proper format of YYYYMMDD
<b>Corrective Action:</b>	Resubmit following the date format YYYYMMDD
<b>Guidance Source:</b>	Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs, Guidance for Industry
<b>Number:</b>	1636
<b>Group:</b>	M1
<b>Description:</b>	The submission-id referenced has not been received and/or processed
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	The submission-id referenced has not been received and/or processed.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone Files Specification for Module 1; General good practice to ensure reviewability.

<b>Number:</b>	1681
<b>Group:</b>	M1
<b>Description:</b>	Issue-date attribute value is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You did not provide the issue-date for one or more promotional materials in a 2253 submission (promotional-material-doc-type=promotional 2253).
<b>Corrective Action:</b>	Ensure that an issue date is provided for each promotional material in future 2253 submissions.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	1697
<b>Group:</b>	M1
<b>Description:</b>	Sequence number was previously submitted
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	The sequence number used in your submission has already been submitted to the application.
<b>Corrective Action:</b>	Resubmit your submission ensuring that you use a 4 numeric digit sequence number that is unique within the application.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	1714
<b>Group:</b>	M1
<b>Description:</b>	Sequence number does not match the folder name
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The sequence number for the application containing files (application-containing-files="true") does not match the folder name.
<b>Corrective Action:</b>	Resubmit your submission ensuring that the sequence number for the application containing files (application-containing-files="true") matches the folder name for DTD V3.2.
<b>Guidance Source:</b>	ICH Q&A 36 #19

<b>Number:</b>	1731
<b>Group:</b>	STF
<b>Description:</b>	Cumulative STF files are not allowed
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	FDA only accepts the accumulative approach to STF.
<b>Corrective Action:</b>	Resubmit your submission ensuring that the STF files created follow the accumulative approach.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1734
<b>Group:</b>	General
<b>Description:</b>	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
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	9/15/2021 (CBER module 4 sections, 03/16/2023)
<b>Problem:</b>	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
<b>Corrective Action:</b>	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
<b>Guidance Source:</b>	Providing Regulatory Submissions in Electronic Format – Standardized Study Data; Study Data Technical Conformance Guide.

<b>Number:</b>	1735
<b>Group:</b>	STF
<b>Description:</b>	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
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	9/15/2021 (CBER module 4 sections, 03/16/2023)
<b>Problem:</b>	<p>You have submitted standardized XPT files or define.xml files without correct file tag.</p> <p>Valid file tags for XPT files are:  data-tabulation-dataset-sdtm  data-tabulation-dataset-send  analysis-dataset-adam</p> <p>Valid file tags for corresponding define.xml files are:  data-tabulation-data-definition  analysis-data-definition</p>
<b>Corrective Action:</b>	Resubmit using one of the valid file tags for all submitted datasets.
<b>Guidance Source:</b>	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.

<b>Number:</b>	1736
<b>Group:</b>	General
<b>Description:</b>	<p>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</p> <p>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</p> <p>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</p>
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	9/15/2021 (CBER module 4 sections, 03/16/2023)
<b>Problem:</b>	<p>You have not submitted SEND DM and corresponding define.xml for each study in Module 4, section 4.2.</p> <p>You have not submitted SDTM DM and corresponding define.xml for each study in Module 5, section 5.3.</p> <p>You have not submitted ADSL, and corresponding define.xml for each study in Module 5, section 5.3.</p>
<b>Corrective Action:</b>	<p>Resubmit the submission with the SEND DM and corresponding define.xml for each study in Module 4, section 4.2.</p> <p>Resubmit including SDTM DM and corresponding define.xml for each study in Module 5, section 5.3.</p> <p>Resubmit including ADSL and corresponding define.xml for each study in Module 5, section 5.3.</p>
<b>Guidance Source:</b>	Providing Regulatory Submissions in Electronic Format – Standardized Study Data; Study Data Technical Conformance Guide.

<b>Number:</b>	1737
<b>Group:</b>	General
<b>Description:</b>	For each study referenced by an STF file in Module 4 and Module 5, no more than one dataset of the same file name and leaf title should be submitted using the lifecycle operator “new.” STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/16/2023
<b>Problem:</b>	You have submitted more than one dataset of the same type using the lifecycle operator “new” for a study.
<b>Corrective Action:</b>	In future submissions, ensure that only one dataset of each type is marked using the lifecycle operator “new”.
<b>Guidance Source:</b>	Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specification; eCTD Technical Conformance Guide; Study Data Technical Conformance Guide.
<b>Number:</b>	1738
<b>Group:</b>	General
<b>Description:</b>	STF Study ID should match STUDYID or SPREFID listed in the referenced Trial Summary (ts.xpt) file. STFs are not required for 4.3 Literature references, 5.2 Tabular listings, 5.4 Literature references and 5.3.6 Postmarketing reports
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/16/2023
<b>Problem:</b>	The STF Study ID does not match the STUDYID or SPREFID listed in the referenced ts.xpt file (not an exact match).
<b>Corrective Action:</b>	Ensure ts.xpt is referenced under the correct STF. If ts.xpt is under the correct STF, update the STUDYID or SPREFID in the ts.xpt and other referenced study data files. Modify your SOPs to ensure that a consistent Study ID (exact match) is used.



<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files; Providing Regulatory Submissions in Electronic Format – Standardized Study Data; Study Data Technical Conformance Guide; General good practice to ensure reviewability.
<b>Number:</b>	1748
<b>Group:</b>	STF
<b>Description:</b>	Omitted STF DTD version in leaf element
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Omitted STF DTD version in leaf element.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1752
<b>Group:</b>	STF
<b>Description:</b>	Omitted STF DTD version in STF XML file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Omitted STF DTD version in the STF XML file.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1765
<b>Group:</b>	STF
<b>Description:</b>	STF DTD version must match the XML file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your STF DTD version listed in the leaf element does not match the DTD version in the STF XML file.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1782
<b>Group:</b>	STF
<b>Description:</b>	Unsupported STF DTD version in leaf element
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You are using an unsupported STF DTD version in a leaf element.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1786
<b>Group:</b>	STF
<b>Description:</b>	Unsupported STF DTD version in STF XML file
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You are using an unsupported STF DTD version in a STF XML file.
<b>Corrective Action:</b>	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1789
<b>Group:</b>	STF
<b>Description:</b>	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
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	9/15/2021
<b>Problem:</b>	All files in a study section must be referenced by an STF file.
<b>Corrective Action:</b>	Resubmit, referencing all files submitted in a required study section in an STF file.
<b>Guidance Source:</b>	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

<b>Number:</b>	1799
<b>Group:</b>	STF
<b>Description:</b>	STF cannot reference another STF
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The STF may not reference another STF.
<b>Corrective Action:</b>	Resubmit your submission ensuring that STFs do not reference other STFs. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	1816
<b>Group:</b>	STF
<b>Description:</b>	STF does not relate to any leaf elements
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	STF does not relate to any leaf elements.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1833
<b>Group:</b>	STF
<b>Description:</b>	STF relates to a non-existent leaf element
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	STF relates to a non-existent leaf element.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1850
<b>Group:</b>	STF
<b>Description:</b>	Study ID for STF must remain constant
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	"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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	1867
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF file extension
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have included an invalid STF file extension.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1884
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF file name
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have included an invalid STF file name.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1901
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF TOC location
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1918
<b>Group:</b>	STF
<b>Description:</b>	Omitted STF doc-content file tag
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have omitted the STF doc-content file tag which prevents the proper classification of the file within the submission.
<b>Corrective Action:</b>	In a future submission you should include an updated STF file that reflects the proper doc-content file tag using the "Replace" operator.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1935
<b>Group:</b>	STF
<b>Description:</b>	Multiple STF doc-content file tags
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have multiple STF doc-content file tags; processor will process the first tag but will ignore any additional tags.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; General good practice to ensure reviewability.
<b>Number:</b>	1953
<b>Group:</b>	STF
<b>Description:</b>	STF XML title and leaf element title do not match
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	Your STF study title and leaf element title do not match; viewer will show the title in the stf.xml file only.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure that STF titles match the provided leaf title.
<b>Guidance Source:</b>	General good practice to ensure reviewability.



<b>Number:</b>	1969
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF XML file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have submitted an invalid stf-xxxxxxx.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.
<b>Corrective Action:</b>	In a future submission, delete the leaves which were referenced in the previous invalid stf-xxxxxxx.xml file. Submit a new valid stf-xxxxxxx.xml files and use the "new" operator attribute to re-reference the previously submitted leaves in the STF files.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1981
<b>Group:</b>	STF
<b>Description:</b>	STF XML file is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have referenced an STF XML file in the xlink:xref attribute of a leaf and the system is unable to locate the file.
<b>Corrective Action:</b>	Resubmit the missing STF XML file in a new submission sequence and re-reference the appropriate leaves using the operation attribute of "Replace."
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1985
<b>Group:</b>	STF
<b>Description:</b>	The study title for the STF is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have omitted the title within the STF XML file. The title is required for STFs submitted using the version 2 specification.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1990
<b>Group:</b>	STF
<b>Description:</b>	The same STF XML is referenced more than once.
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted one STF XML file and referenced that STF XML file in more than one section.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH Q&A 60

<b>Number:</b>	2001
<b>Group:</b>	M1
<b>Description:</b>	An older version of the DTD has been used after a submission to the application used a higher version.
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2002
<b>Group:</b>	Schema Error
<b>Description:</b>	XML didn't pass validation with the schema (DTD) and attribute files
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided an index.xml, us-regional.xml or stf.xml file which does not conform to the schema (DTD) and/or attribute files.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; The eCTD Backbone Files Specification for Module 1; General good practice to ensure reviewability

<b>Number:</b>	2003
<b>Group:</b>	M1
<b>Description:</b>	us-regional.xml is not referencing the DTD and stylesheet at an approved valid location
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You submitted a submission with its us-regional.xml referencing incorrect DTD and stylesheet file locations.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2012
<b>Group:</b>	M1
<b>Description:</b>	A required attribute value in M1 is missing
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have failed to provide a required attribute value for an M1 element.
<b>Corrective Action:</b>	Resubmit the submission and ensure all required attribute values are provided. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	2013
<b>Group:</b>	M1
<b>Description:</b>	Invalid M1 attribute value
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	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.
<b>Corrective Action:</b>	Resubmit the submission and ensure all provided M1 attributes are valid. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2021
<b>Group:</b>	M1
<b>Description:</b>	A submission sub-type error occurred because this particular submission sub-type is only allowed once for each regulatory activity.
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	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, correspondence) can only be submitted once for each regulatory activity (e.g., original- application should only have one submission with a sub-type value "application").
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	2022
<b>Group:</b>	M1
<b>Description:</b>	Submission-sub-type is invalid for submission-type
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have used a submission-sub-type which is not allowed for the submission-type and/or type of application.
<b>Corrective Action:</b>	Resubmit the submission using a valid submission-sub-type. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2023
<b>Group:</b>	M1
<b>Description:</b>	All grouped submission submission-sub-type values must be the same
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have referenced more than one application and the submission sub-type values are not the same.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	2024
<b>Group:</b>	M1
<b>Description:</b>	For all sequences for a regulatory activity the submission type must be consistent.
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	TBD
<b>Problem:</b>	You have used a submission type that is different than the submission type of the parent regulatory activity.
<b>Corrective Action:</b>	Resubmit the submission with a submission type that matches the parent regulatory activity type.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2025
<b>Group:</b>	M1
<b>Description:</b>	The eCTD sequence number of the submission sub-type that starts a new regulatory activity and the submission-id must match.
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	TBD
<b>Problem:</b>	You have used a submission sub-type that begins a new regulatory activity and the eCTD sequence number does not match the submission-id.
<b>Corrective Action:</b>	Resubmit the submission where the eCTD sequence number matches the submission-id for the new regulatory activity.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2026
<b>Group:</b>	M1
<b>Description:</b>	The submission-id must reference the eCTD sequence number for the parent regulatory activity
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	TBD
<b>Problem:</b>	You have used a submission-id that matches the eCTD sequence number and the submission sub-type does not start a new regulatory activity.
<b>Corrective Action:</b>	You will be contacted if corrective action is necessary. Modify your SOPs to ensure that the submission-id references the sequence number that begins the regulatory activity.

<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
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<b>Number:</b>	2031
<b>Group:</b>	M1
<b>Description:</b>	All grouped submission application-type values must be the same
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have referenced more than one application and the application-type values are not the same.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2032
<b>Group:</b>	M1
<b>Description:</b>	All grouped submission submission-type values must be the same
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have referenced more than one application and the submission-type values are not the same.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1



<b>Number:</b>	2033
<b>Group:</b>	M1
<b>Description:</b>	Different sequence numbers are referenced for the same application number
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	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.
<b>Corrective Action:</b>	Resubmit, ensure the same sequence number is referenced for all regulatory activities to the same application number.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2034
<b>Group:</b>	M1
<b>Description:</b>	Submission-type is invalid for application-type
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have used a submission-type which is not allowed for the application type.
<b>Corrective Action:</b>	Resubmit the submission using a valid submission-type. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	2035
<b>Group:</b>	M1
<b>Description:</b>	Submission description exceeds 128 characters
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided a submission description that exceeds the 128 character limit.
<b>Corrective Action:</b>	Ensure future submissions do not have a submission-description that exceeds 128 characters.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2036
<b>Group:</b>	M1
<b>Description:</b>	No application element with application-containing-files value of "true"
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You did not provide an application-containing-files value="true" for any applications referenced in the us-regional.xml.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	2037
<b>Group:</b>	M1
<b>Description:</b>	More than one application-containing-files element has a value of "true"
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have reference more than one application with an application-containing-files value= "true."
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2038
<b>Group:</b>	M1
<b>Description:</b>	Cross-reference-application-number must contain 6 numeric digits only
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	Your cross-reference-application-number must be 6 numeric digits in length.
<b>Corrective Action:</b>	In a future submission, reference the correct six (6) digit application number.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	2041
<b>Group:</b>	M1
<b>Description:</b>	Supplement-effective-date-type attribute value is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You did not provide the supplement-effective-date-type for this first submission to the supplement.
<b>Corrective Action:</b>	Include a supplement-effective-date-type in the first submission to a new supplement.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2042
<b>Group:</b>	M1
<b>Description:</b>	Email address exceeds 64 characters
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided an email address that exceeds the 64 character limitation.
<b>Corrective Action:</b>	Ensure email addresses are within character limitations in future submissions.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2043
<b>Group:</b>	M1
<b>Description:</b>	id element has changed
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You are using an company id element that is different than the id used in previous submissions to the application.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	2044
<b>Group:</b>	M1
<b>Description:</b>	id element must contain 9 digits only
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided an id that is not 9 numeric digits.
<b>Corrective Action:</b>	Ensure future submissions include an id that is 9 numeric digits.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	2045
<b>Group:</b>	M1
<b>Description:</b>	Invalid form type for eCTD location
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have included an invalid form-type attribute value in the submission-information section.
<b>Corrective Action:</b>	Reference the form in the m1-1-forms section and not in submission-information in the admin section of the us-regional.xml.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	3001
<b>Group:</b>	STF
<b>Description:</b>	STF doc-content title used
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	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.
<b>Corrective Action:</b>	Corrective action may be necessary. In future submissions, ensure that doc-content titles for each document referenced in the STF XML are not included.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	3015
<b>Group:</b>	STF
<b>Description:</b>	The element 'file-tag' preceded the element 'property'
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	In the STF XML the 'property' element should come before its sibling element 'file-tag'.
<b>Corrective Action:</b>	Modify your SOPs to ensure your STF is in conformance with the ordering as described in the specification and the DTD.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	3029
<b>Group:</b>	STF
<b>Description:</b>	Use of content-block is not recommended
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Although content block is in both DTD versions, the specification does not refer to it; it is recommended that you do not use it.
<b>Corrective Action:</b>	Remove the content block element in the identified stf-xxxxxxx.xml and resubmit at time of next planned submission.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	3036
<b>Group:</b>	M1
<b>Description:</b>	Application number must contain 6 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The application number must be 6 numeric digits in length.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted application number. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	3050
<b>Group:</b>	M1
<b>Description:</b>	Submission sequence number must contain 4 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your submission's sequence number must be 4 numeric digits in length.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted sequence number.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1
<b>Number:</b>	3065
<b>Group:</b>	M1
<b>Description:</b>	Submission-id element must contain 4 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	Your submission-id must be 4 numeric digits in length.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted submission-id number. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	3078
<b>Group:</b>	General
<b>Description:</b>	eCTD element does not contain any leaf elements
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have included a lowest level element that does not contain any leaf elements.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure lowest level elements contain leaf elements.
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	3102
<b>Group:</b>	PDF
<b>Description:</b>	Failed to process PDF contents
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with contents that cannot be processed, e.g. a corrupted or invalid PDF document.
<b>Corrective Action:</b>	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated valid PDF file.
<b>Guidance Source:</b>	General good practice to ensure reviewability.



<b>Number:</b>	5005
<b>Group:</b>	PDF
<b>Description:</b>	Non standard font (not embedded)
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications
<b>Number:</b>	5020
<b>Group:</b>	PDF
<b>Description:</b>	PDF security used
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	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)
<b>Corrective Action:</b>	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated PDF file without restrictions.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2

<b>Number:</b>	5029
<b>Group:</b>	M1
<b>Description:</b>	Misnamed form
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.).
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	5030
<b>Group:</b>	M1
<b>Description:</b>	Application number in form does not match application number in us-regional.xml
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	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.
<b>Corrective Action:</b>	Resubmit, ensure the application number in the form matches the application number in the us-regional.xml.
<b>Guidance Source:</b>	FDA Presentations

<b>Number:</b>	5032
<b>Group:</b>	M1
<b>Description:</b>	Multiple application forms present for the same application
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted more than one application form for the same application.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	5034
<b>Group:</b>	M1
<b>Description:</b>	Application form placed in wrong TOC location
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted an application form that was not placed in the correct TOC location.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	FDA Presentations; The eCTD Backbone Files Specification for Module 1

<b>Number:</b>	5035
<b>Group:</b>	PDF
<b>Description:</b>	PDF version of document is incorrect
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document using a PDF version that is not consistent with ICH / regional guidance.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure that documents in future submissions conform to the published standards.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications
<b>Number:</b>	5038
<b>Group:</b>	M1
<b>Description:</b>	Wrong application form
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	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.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	FDA Presentations; FDA Form Instructions

<b>Number:</b>	5040
<b>Group:</b>	PDF
<b>Description:</b>	PDF does not have 'Fast Web Access' active
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a PDF that has been created without 'Fast Web Access' active.
<b>Corrective Action:</b>	Ensure that documents in future submissions are created with the 'Fast Web Access' option.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; ICH Q&A 36 #23
<b>Number:</b>	5045
<b>Group:</b>	PDF
<b>Description:</b>	PDF opening settings not optimal
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a PDF that does not open in the desired view.
<b>Corrective Action:</b>	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).
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications

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

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

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



<b>Number:</b>	5110
<b>Group:</b>	PDF
<b>Description:</b>	Inactive bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more inactive bookmarks.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5115
<b>Group:</b>	PDF
<b>Description:</b>	Non-relative bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more non-relative (absolute) bookmarks.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions have only relative bookmarks.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications; ICH Q&A 36 #23

<b>Number:</b>	5117
<b>Group:</b>	PDF
<b>Description:</b>	Bookmark does not 'Inherit Zoom'
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more bookmarks that are not set to 'Inherit Zoom'.
<b>Corrective Action:</b>	Ensure that all bookmarks are set to 'Inherit Zoom'.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications; Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications
<b>Number:</b>	5200
<b>Group:</b>	PDF
<b>Description:</b>	Broken hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more hyperlinks pointing to a file that does not exist.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	5201
<b>Group:</b>	PDF
<b>Description:</b>	Corrupt link
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more links pointing to a file that cannot be opened.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5202
<b>Group:</b>	PDF
<b>Description:</b>	Link has non-existent named destination or page
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more hyperlinks pointing to a named destination or page that does not exist.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

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

<b>Number:</b>	5215
<b>Group:</b>	PDF
<b>Description:</b>	Non-relative hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more non-relative (absolute) hyperlinks.
<b>Corrective Action:</b>	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.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications; ICH Q&A 36 #23
<b>Number:</b>	5217
<b>Group:</b>	PDF
<b>Description:</b>	Link does not 'Inherit Zoom'
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more links that are not set to 'Inherit Zoom'.
<b>Corrective Action:</b>	Ensure that all links in future submissions are set to 'Inherit Zoom'.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; FDA Portable Document Format Specifications; 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
1482	Low
1500	Low
1544	Low
1554	Low
1953	Low
2035	Low
2038	Low
2042	Low
2043	Low
3078	Low
5029	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
1476	Medium
1478	Medium
1519	Medium
1545	Medium
1550	Medium
1681	Medium
1737	Medium
1738	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
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
3065	High
5030	High
5038	High
1551	High - CDER
1553	High - CDER

## Validation Error Codes Removed

Number	1451
Severity	Medium
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1468
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1472
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1487
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1561
Severity	Medium
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1578
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1595
Severity	Medium
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1612
Severity	Medium
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1629
Severity	Medium
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1635
Severity	Medium
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1646
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1663
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	1680
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	3008
Severity	Medium
In Version	4.3
Reason For Deletion	Applies only to STF DTD v2.0

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Number	3064
Severity	High
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022

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Number	5031
Severity	Low
In Version	4.3
Reason For Deletion	DTD 2.01 not accepted after 3/1/2022