Specifications for eCTD Validation Criteria

Revision History

Date	Description	Version
2008-03-10	Initial release of eCTD Validation Criteria	1.0

Specifications for eCTD Validation Criteria

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

Severity Levels

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

Severity	Description
High	The error is a serious technical error which prevents the processing of the submission and will require resubmission. The submission is considered not received by FDA.
Medium	The error may impact the reviewability of the submission but cannot be determined without further inspection by the review staff. The submission might be considered received by FDA.
Low	The error is a technical error which may or may not impact the reviewability or the integrity of the submission. The submission will likely be considered received by FDA.
Ignore	Error is a technical error which has no impact on the processing of the submission or the integrity of the submission. The submission will 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.

eCTD Validation Errors

Number	1017
Group	File checks
Section	File Operation
Description	Leaf element already replaced or deleted
Severity	Medium
Effective Date	03/10/2008
Problem	You have replaced or deleted a leaf that you had previously performed the operation on
Corrective Action	You should review your submission and ensure that the leaf you referenced was the intended link. If yes, no corrective action is necessary. If not, resubmit referring the correct leaf.

Number	1034
Group	File checks
Section	File Operation
Description	Invalid leaf element operation
Severity	Medium
Effective Date	03/10/2008
Problem	You have submitted a leaf and did not include the operation attribute. The system substituted "new"
Corrective Action	If the operation attribute should not have been new, submit two new leaves. The first leaf should delete the leaf submitted without the operation attribute. The second should associate the file referenced by the first leaf to the leaf you had originally intended to modify.

Number	1051
Group	File checks
Section	File References
Description	Extraneous leaf element path
Severity	Medium
Effective Date	03/10/2008
Problem	You have specified a hlink:xref path for an operation that does not require one, e.g., "delete"
Corrective Action	No corrective action is required. The validator ignored the extraneous path information.

Number	1068
Group	File checks
Section	File References
Description	Extraneous modified leaf element path
Severity	Medium
Effective Date	03/10/2008
Problem	You have specified a modified-file path for an operation that does not require one, i.e., "new"
Corrective Action	No repair is necessary

Number	1085
Group	File checks
Section	File References
Description	Leaf element path length exceeds maximum (230 characters)
Severity	Low
Effective Date	03/10/2008
Problem	There is a maximum path length of 255 characters. Internal processing may add additional characters to your paths resulting in path lengths which exceed 255 characters which will invalidate your links.
Corrective Action	No corrective action is necessary. This is simply a warning that you may want to examine your naming conventions to reduce the size of the path statements.

Number	1102
Group	File checks
Section	File References
Description	Leaf element path contains invalid characters: backslash(\), colon(:), asterisk(*), question mark(?), less than(<), greater than(>), pipe(|)
Severity	Medium
Effective Date	03/10/2008
Problem	Your path statement contains invalid characters. Since the restriction on characters in the path is an operating system constraint there is likely to be an orphaned file caused by a mismatch between the path specified for the leaf and the actual path of the file referenced by the leaf.
Corrective Action	Resubmit a corrected leaf in a future submission with the operation attribute of "replace" to replace the original erroneous leaf.

Number	1119
Group	File checks
Section	File References
Description	Missing file
Severity	Medium
Effective Date	03/10/2008
Problem	You have referenced a file in the hlink:xref attribute of a leaf and the system is unable to locate the file.
Corrective Action	Resubmit the missing file in a later submission referencing the original leaf using the operation attribute of "replace"

Number	1128
Group	File checks
Section	File References
Description	More than one version of the required file exists
Severity	Low
Effective Date	03/10/2008
Problem	You have submitted a required file, e.g., us-regional.dtd, more than once in the submission
Corrective Action	No corrective action is necessary. You should update your SOPs to prevent this in the future.

Number	1136
Group	File checks
Section	File References
Description	Omitted leaf element path
Severity	Medium
Effective Date	03/10/2008
Problem	You have not provided the path to the file that should be referenced by the leaf.
Corrective Action	Resubmit the leaf specifying the file path to the original document in a later submission. Use the operational attribute of "replace" to replace the original incorrect leaf.

Number	1153
Group	File checks
Section	File References
Description	Missing modified file
Severity	Medium
Effective Date	03/10/2008
Problem	The leaf referenced in the *modify-file* element cannot be found.
Corrective Action	In your next submission submit a leaf modifying the leaf that generated this error using the operation attribute of "delete". In the same submission resubmit the leaf that generated this error correcting the *modified-file* reference.

Number	1170
Group	File checks
Section	File References
Description	Omitted leaf element modified file path
Severity	Medium
Effective Date	03/10/2008
Problem	The file path is not specified.
Corrective Action	Resubmit the missing file path in a later submission referencing the original document using the operation attribute of "replace"

Number	1187
Group	File checks
Section	File References
Description	Modified leaf element path references a sequence that has not been validated
Severity	Medium
Effective Date	03/10/2008
Problem	A sequence is being processed that references another sequence that has not yet been processed.
Corrective Action	Generally, no corrective action is necessary. This situation can occur if the earlier sequence is received by FDA after the later sequence. You should verify that the earlier sequence was actually submitted and received.

Number	1204
Group	File checks
Section	File Rules
Description	File name contains invalid characters per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	The file name contains invalid characters.
Corrective Action	No corrective action is required. You should modify your SOPs to bring future submissions in conformance with specifications.

Number	1221
Group	File checks
Section	File Rules
Description	File name exceeds maximum length (64 characters) per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	The file name exceeds maximum length (64 characters).
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure files names do not exceed the maximum length (64 characters) per eCTD Specification

Number	1238
Group	File checks
Section	File Rules
Description	File size exceeds maximum (100 MB) per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	File size exceeds maximum (100 MB) per eCTD Specification.
Corrective Action	No corrective action is necessary. However, generally try not sending in files this large if it can be avoided.

Number	1255
Group	File checks
Section	File Rules
Description	Invalid file extension
Severity	Medium
Effective Date	03/10/2008
Problem	The only valid file extensions are: .pdf, .xpt, .doc, .xml, .xsl, and .txt.
Corrective Action	Corrective action may be necessary based on where the file with the invalid extension appears in the submission. You will be contacted by FDA if corrective action is necessary.

Number	1272
Group	File checks
Section	File Rules
Description	Leaf element title contains an invalid character per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	Leaf element title contains an invalid character per eCTD Specification
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that that leaf element titles do not contain invalid characters, per the eCTD Specification.

Number	1276
Group	File checks
Section	File Rules
Description	Leaf element title leads or ends with a space per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	Leaf element title leads or ends with a space.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that leaf element titles do not lead or end with a space, per the eCTD Specification.

Number	1289
Group	File checks
Section	File Rules
Description	Omitted leaf element title
Severity	Medium
Effective Date	03/10/2008
Problem	You have omitted the title of a leaf element.
Corrective Action	Resubmit a replacement leaf element including the leaf element title in a later submission referencing the original leaf using the operation attribute of "replace".

Number	1306
Group	File checks
Section	Orphaned File
Description	No leaf element for file
Severity	Medium
Effective Date	03/10/2008
Problem	You have submitted the file(s) listed in the validation report without a corresponding reference in the backbone
Corrective Action	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 submit a leaf element referencing the file in a future submission using the operation attribute of replace. 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 submit a corrected leaf element in a future submission that references the original leaf with an operation attribute of "replace"

Number	1314
Group	File checks
Section	Orphaned File
Description	Non-Required File Exists
Severity	Medium
Effective Date	03/10/2008
Problem	You have submitted files in the UTIL folder that are not required.
Corrective Action	No corrective action is required. You should modify your SOPs to ensure that only required files are placed in the UTIL folder.

Number	1323
Group	File checks
Section	Orphaned Leaf
Description	No file for leaf element
Severity	Medium
Effective Date	03/10/2008
Problem	You have referenced the file(s) listed in the validation report from the us-regional.xml or index.xml files without providing the actual file(s).
Corrective Action	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 submit the file and a leaf element referencing the original leaf using the operation attribute of "replace" in a future submission. 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 submitted then you should submit a corrected leaf element in a future submission that references the original leaf with an operation attribute of "replace"

Number	1340
Group	General
Section	Attribute Values (Repeat Groups)
Description	Attribute value contains an invalid character per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	Attribute value contains an invalid character.
Corrective Action	Correct attribute values so that they do not contain invalid characters, per the eCTD Specification.

Number	1344
Group	General
Section	Attribute Values (Repeat Groups)
Description	Attribute value leads or ends with a space per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	Attribute value leads or ends with a space per eCTD Specification
Corrective Action	Correct attribute values so that they do not lead or end with a space, per the eCTD Specification.

Number	1357
Group	General
Section	Attribute Values (Repeat Groups)
Description	Omitted attribute value
Severity	Medium
Effective Date	03/10/2008
Problem	You did not specify a required attribute such as Manufacturer.
Corrective Action	No corrective action is currently possible. You should modify your SOPs to ensure that attributes are used as described in the eCTD Specifications.

Number	1362
Group	General
Section	Attribute Values (Repeat Groups)
Description	The attribute appears multiple times
Severity	Medium
Effective Date	03/10/2008
Problem	Yu have duplicated an attribute, e.g., two manufacturer attributes in a single element.
Corrective Action	No corrective action is currently possible. You should modify your SOPs to ensure that attributes are used as described in the eCTD Specifications.

Number	1368
Group	General
Section	Attribute Values (Repeat Groups)
Description	Extraneous attribute
Severity	Low
Effective Date	06/29/06
Problem	You have submitted an attribute that is not called for in the specification, e.g. manufacturer in Module 4 or Module 5.
Corrective Action	No corrective action is currently possible. You should modify your SOPs to ensure that attributes are used as described in the eCTD Specifications.

Number	1374
Group	General
Section	Checksum
Description	Checksum value must match the actual checksum
Severity	Low
Effective Date	03/10/2008
Problem	Your checksum value does not match the actual checksum.
Corrective Action	Corrective action is based on the underlying reason for the error. You should determine if the issue is simply a miscalculation or misapplication of a checksum; if so, no corrective action is necessary. If you determine that the incorrect file was submitted you should submit the corrected file in a future submissions with a leaf element referencing the original leaf with an operation attribute of "replace". If you believe that an error has occurred and that the file you have submitted may have become corrupt you should contact your appropriate Center representative.

Number	1391
Group	General
Section	Checksum
Description	Invalid checksum format
Severity	Low
Effective Date	03/10/2008
Problem	You are using an invalid checksum file format, i.e., you have not specified the 32 characters produced as part of generating the MD5 checksum
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure the proper MD5 checksum format is used.

Number	1408
Group	General
Section	Checksum
Description	Invalid checksum type
Severity	Low
Effective Date	03/10/2008
Problem	You have used an invalid checksum type.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure the use of MD5 checksums.

Number	1425
Group	General
Section	Checksum
Description	Omitted checksum value
Severity	Low
Effective Date	03/10/2008
Problem	You have omitted the checksum value.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that the MD5 checksums are specified.

Number	1442
Group	General
Section	DTD Version
Description	Omitted DTD version in backbone XML file
Severity	Medium
Effective Date	03/10/2008
Problem	You have omitted the DTD version in the backbone XML file
Corrective Action	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. You should modify your SOPs to ensure that the DTD version is specified in the backbone XML file.

Number	1445
Group	General
Section	DTD Version
Description	Omitted DTD version in regional XML file
Severity	Medium
Effective Date	03/10/2008
Problem	You have omitted DTD version in the regional XML file
Corrective Action	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. You should modify your SOPs to ensure that the DTD version is specified in the regional XML file.

Number	1459
Group	General
Section	DTD Version
Description	Unsupported DTD version in backbone XML file
Severity	High
Effective Date	03/10/2008
Problem	You are using an unsupported DTD version in the backbone XML file.
Corrective Action	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.

Number	1463
Group	General
Section	DTD Version
Description	Unsupported DTD version in regional XML file
Severity	High
Effective Date	03/10/2008
Problem	You are using an unsupported DTD version in the regional XML file.
Corrective Action	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.

Number	1476
Group	General
Section	Node Extension
Description	Node-extension exists
Severity	Medium
Effective Date	03/10/2008
Problem	You have included node extensions in your submissions. Node extensions are strongly discouraged by FDA.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that node extensions are not used in future submissions.

Number	1478
Group	General
Section	Node Extension
Description	Node-extension does not have a title
Severity	Medium
Effective Date	03/10/2008
Problem	Node extension is supplied without a title.
Corrective Action	In a future submission, a leaf should be provided that references the original node-extension leaf specifying the "delete" operation. A new leaf using an existing eCTD heading should be also submitted specifying the operation attribute of "new" taking care to include all required elements and attributes. The use of node extensions is strongly discouraged.

Number	1480
Group	General
Section	Node Extension
Description	Node-extension title contains an invalid character
Severity	Low
Effective Date	03/10/2008
Problem	There is an invalid character in the node-extension title.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that node extensions are not used in future submissions. The use of node extensions is strongly discouraged.

Number	1482
Group	General
Section	Node Extension
Description	Node-extension title leads or ends with a space
Severity	Low
Effective Date	03/10/2008
Problem	The node-extension title begins or ends with a space.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that node extensions are not used in future submissions. The use of node extensions is strongly discouraged.

Number	1493
Group	General
Section	XML Validation
Description	Invalid XML file
Severity	High
Effective Date	03/10/2008
Problem	You have submitted an invalid index.xml or us-regional.xml file.
Corrective Action	Resubmit your submission ensuring that you use valid index.xml and us-regional.xml files. You may resubmit using the original sequence number of the submission.

Number	1510
Group	General
Section	XML Validation
Description	XML file error
Severity	High
Effective Date	03/10/2008
Problem	Your XML file contains an error.
Corrective Action	Resubmit your submission ensuring that you use valid index.xml and us-regional.xml files. You may resubmit using the original sequence number of the submission.

Number	1519
Group	M1
Section	Application Number
Description	Application Number does not match the folder name
Severity	High
Effective Date	03/10/2008
Problem	Your application Number does not match the folder name.
Corrective Action	Your application Number and folder name must match; please correct one of them.

Number	1527
Group	M1
Section	Application Number
Description	Application Number must remain constant
Severity	High
Effective Date	03/10/2008
Problem	Your application Number has changed and must remain constant.
Corrective Action	Resubmit your submission ensuring that you use the same application number as in your original submission. You may resubmit using the original sequence number of the submission.

Number	1544
Group	M1
Section	Company Name
Description	Company name must remain constant
Severity	Low
Effective Date	03/10/2008
Problem	The company name has changed.
Corrective Action	No corrective action is necessary since company names do changed from time to time. You should review 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.

Number	1561
Group	M1
Section	Related Sequence
Description	Circular relationship found in related sequences
Severity	Medium
Effective Date	03/10/2008
Problem	Sequences are referring to one another in a circular fashion.
Corrective Action	Remove the circular relationship between sequences.

Number	1578
Group	M1
Section	Related Sequence
Description	Multiple related sequences are not allowed
Severity	Low
Effective Date	03/10/2008
Problem	You are relating the submission to multiple sequences.
Corrective Action	No corrective action is necessary. Generally, a submission relates to one sequence only; although in rare cases where valid, multiple related sequences are allowed, such as an amendment that related to two supplements.

Number	1595
Group	M1
Section	Related Sequence
Description	This submission type cannot have a child submission
Severity	Medium
Effective Date	03/10/2008
Problem	You have specified an improper relationship between submission types. Submissions types are divided into high level and second level submission types. Only second level submission types should use a related sequence. A second level submission should never be related to another second-level submission. • High-level submission types are: – "original-application" – "annual-report" – "efficacy-supplement" – "labeling-supplement" – "chemistry-manufacturing-controls-supplement" – "other" • Second-level submission types are: – "amendment" – "resubmission"
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that submission types are properly related to one another.

Number	1612
Group	M1
Section	Related Sequence
Description	This submission type cannot have a related sequence
Severity	Medium
Effective Date	03/10/2008

Problem	You have specified an improper relationship between submission types. Submissions types are divided into high level and second level submission types. Only second level submission types should use a related sequence. A high level submission should never be related to another submission.
	
	• High-level submission types are:
	   – "original-application"
	   – "annual-report"
	   – "efficacy-supplement"
	   – "labeling-supplement"
	   – "chemistry-manufacturing-controls-supplement"
	   – "other"
	
	• Second-level submission types are:
	   – "amendment"
	   – "resubmission"
	.

Corrective Action	Remove the invalid relationship.

Number	1629
Group	M1
Section	Related Sequence
Description	This submission type requires a related sequence
Severity	Medium
Effective Date	03/10/2008
Problem	For example, an amendment that is not related to anything.
Corrective Action	Make the proper relationship.

Number	1646
Group	M1
Section	Submission Date
Description	Invalid date
Severity	Low
Effective Date	03/10/2008
Problem	Your date or date format is invalid
Corrective Action	No corrective action is necessary for this error. You should modify your SOPs to ensure that a proper date or date format is used in the preparation of your submission.

Number	1663
Group	M1
Section	Submission Date
Description	Invalid date format per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	You have used an invalid date format.
Corrective Action	No corrective action is required. You should modify your SOPs to ensure that you are using the valid date format. The valid date format is YYYYMMDD, e.g., 20070615 for June 15, 2007.

Number	1680
Group	M1
Section	Submission Date
Description	Omitted date per eCTD Specification
Severity	Low
Effective Date	03/10/2008
Problem	You have omitted the date.
Corrective Action	No corrective action is required. You should modify your SOPs to ensure that the date is specified in future submissions.

Number	1697
Group	M1
Section	Submission Number
Description	Sequence Number is not unique
Severity	High
Effective Date	03/10/2008
Problem	The Sequence Number identified in your submission has already been submitted to the application. The Sequence Number must be unique for each submission
Corrective Action	Resubmit your submission ensuring that you use a unique Sequence Number.

Number	1714
Group	M1
Section	Submission Number
Description	Sequence Number does not match the folder name
Severity	High
Effective Date	03/10/2008
Problem	The Sequence Number used in your submission does not match the folder name in which the submission is contained.
Corrective Action	Resubmit your submission ensuring that the Sequence Number used in your submission matches the name of the folder.

Number	1731
Group	STF
Section	STF Cumulative Approach
Description	Cumulative STF files are not allowed
Severity	High
Effective Date	03/10/2008
Problem	FDA only accepts the accumulative approach to STF.
Corrective Action	Resubmit your submission ensuring that the STF files created follow the accumulative approach.

Number	1748
Group	STF
Section	STF DTD Version
Description	Omitted STF DTD version in leaf element
Severity	Medium
Effective Date	03/10/2008
Problem	Omitted STF DTD version in leaf element
Corrective Action	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. You should modify your SOPs to ensure that the DTD version is the leaf element.

Number	1752
Group	STF
Section	STF DTD Version
Description	Omitted STF DTD version in STF XML file
Severity	Medium
Effective Date	03/10/2008
Problem	Omitted STF DTD version in the STF XML file
Corrective Action	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. You should modify your SOPs to ensure that the DTD version is specified in the backbone XML file.

Number	1765
Group	STF
Section	STF DTD Version
Description	STF DTD version must match the XML file
Severity	Medium
Effective Date	03/10/2008
Problem	Your STF DTD version listed in the leaf element does not match the DTD version in the XML file.
Corrective Action	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. You should modify your SOPs to ensure that the DTD version specified in the backbone XML file matches that specified in the leaf.

Number	1782
Group	STF
Section	STF DTD Version
Description	Unsupported STF DTD version in leaf element
Severity	High
Effective Date	03/10/2008
Problem	You are using an unsupported STF DTD version in leaf element.
Corrective Action	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.

Number	1786
Group	STF
Section	STF DTD Version
Description	Unsupported STF DTD version in STF XML file
Severity	High
Effective Date	03/10/2008
Problem	You are using an unsupported STF DTD version in STF XML file.
Corrective Action	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.

Number	1799
Group	STF
Section	STF File References
Description	STF cannot reference another STF
Severity	High
Effective Date	03/10/2008
Problem	The STF may not reference another STF.
Corrective Action	Resubmit your submission ensuring that STFs do not reference other STFs. You may resubmit using the original sequence number of the submission.

Number	1816
Group	STF
Section	STF File References
Description	STF does not relate to any leaf elements
Severity	Medium
Effective Date	03/10/2008
Problem	STF does not relate to any leaf elements
Corrective Action	In a future submission you should include an STF that includes references to appropriate leaf elements. You should modify your SOPs to ensure that all STFs submitted reference leaf elements.

Number	1833
Group	STF
Section	STF File References
Description	STF relates to a non-existent leaf element
Severity	Medium
Effective Date	03/10/2008
Problem	STF relates to a non-existent leaf element
Corrective Action	In a future submission you should include an STF that includes references to existing leaf elements. You should modify your SOPs to ensure that all STFs submitted reference leaf elements.

Number	1850
Group	STF
Section	STF File Rules
Description	Document ID for STF must remain constant
Severity	Medium
Effective Date	03/10/2008
Problem	Document ID for STF must remain constant; if not constant, viewer will reflect 2 studies where there is only 1 study; reviewer will see duplicates where there is only one study.
Corrective Action	No corrective action is possible due to current STF limitations. You should modify your SOPs to ensure that a consistent Document ID is used.

Number	1867
Group	STF
Section	STF File Rules
Description	Invalid STF file extension
Severity	Medium
Effective Date	03/10/2008
Problem	You have included an invalid STF file extension.
Corrective Action	No corrective action is necessary. You should 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.

Number	1884
Group	STF
Section	STF File Rules
Description	Invalid STF file name
Severity	Medium
Effective Date	03/10/2008
Problem	You have included an invalid STF file name.
Corrective Action	No corrective action is necessary. You should 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.

Number	1901
Group	STF
Section	STF File Rules
Description	Invalid STF TOC location
Severity	Medium
Effective Date	03/10/2008
Problem	Your leaf that points to the STF is in under an invalid heading area or invalid module. For example, STF can only be associated with certain headings under Modules 4 or 5.
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure that STFs are only included in Modules 4 and 5.

Number	1918
Group	STF
Section	STF File Rules
Description	Omitted STF doc-content file tag
Severity	Medium
Effective Date	03/10/2008
Problem	You have omitted the STF doc-content file tag which prevents the proper classification of the file within the submission.
Corrective Action	In a future submission you should include an updated STF file that reflects the proper doc-content file tag.

Number	1935
Group	STF
Section	STF File Rules
Description	Multiple STF doc-content file tags
Severity	Medium
Effective Date	03/10/2008
Problem	You have multiple STF doc-content file tags; processor will process the first tag but will ignore any additional flags.
Corrective Action	No corrective action is possible due to current STF limitations. You should modify your SOPs to ensure that only a single doc-content file tag is used.

Number	1952
Group	STF
Section	STF File Rules
Description	STF doc-content title and leaf element title do not match
Severity	Low
Effective Date	03/10/2008
Problem	Your STF doc-content title and leaf element title do not match; viewer will show the title of the leaf only.
Corrective Action	No corrective action is necessary. In a future submission you may consider updating the STF file to reflect the proper title.

Number	1969
Group	STF
Section	STF XML Validation
Description	Invalid XML STF file
Severity	Medium
Effective Date	03/10/2008
Problem	You have submitted an stf-xxxxxxxx.xml file.
Corrective Action	Resubmit your submission ensuring that you use valid stf-xxxxxxxx.xml files. You may resubmit using the original sequence number of the submission.

Number	3001
Group	STF
Section	STF XML Validation
Description	Use of the element title is not recommended" Description="Element 'title' is unexpected according to content model of parent element 'doc-content'
Severity	Medium
Effective Date	03/10/2008
Problem	Use of the element title is not recommended" Description="Element 'title' is unexpected according to content model of parent element 'doc-content'. Only applies to the STF 2.0 specification.
Corrective Action	No corrective action is necessary. You should modify your SOPs to use the STF 2.2 specification.

Number	3008
Group	STF
Section	STF XML Validation
Description	Use of the property element is required. The xlink:href attribute of the doc-content element is not used" Description="The attribute '{http://www.w3c.org/1999/xlink}href' on the element 'doc-content' is not defined in the DTD/Schema.
Severity	Medium
Effective Date	03/10/2008
Problem	Use of the property element is required. The xlink:href attribute of the doc-content element is not used" Description="The attribute '{http://www.w3c.org/1999/xlink}href' on the element 'doc-content' is not defined in the DTD/Schema. Only applies to STF 2.0 Specification
Corrective Action	No corrective action is necessary. You should modify your SOPs to use the STF 2.2 specification.

Number	3015
Group	STF
Section	STF XML Validation
Description	Preceding the element file-tag with the element property is recommended" Description="Element 'file-tag' is unexpected according to content model of parent element 'doc-content'. Expecting: property.
Severity	Medium
Effective Date	03/10/2008
Problem	the STF xml the <file-tag> element should come before its sibling element <property>
Corrective Action	No corrective action is necessary. You should modify your SOPs to ensure your STF is in conformance with the ordering as described in the specification.

Number	3022
Group	STF
Section	STF XML Validation
Description	The maximum occurrences of the category element is three" Description="Element 'category' is unexpected according to content model of parent element 'document-identifier'
Severity	Medium
Effective Date	03/10/2008
Problem	You have exceeded the maximum occurrences of the category element. Additional occurrences will be ignored by viewer.
Corrective Action	No corrective action is possible due to STF limitations. You should modify your SOPs to ensure that your STF is in conformance with the number of category elements as described in the specification.

Number	3029
Group	STF
Section	STF XML Validation
Description	Use of content-block is not recommended" Description="Element 'content-block' is unexpected according to content model of parent element 'document'.
Severity	Medium
Effective Date	03/10/2008
Problem	Although content block is in both DTD versions, the Specification does not refer to it; recommended that you do not use it.
Corrective Action	Remove the content block element in the identified stf-xxxxxxxx.xml and resubmit at time of next planned submission.

Number	3036
Group	M1
Section	Application Number
Description	Application Number must contain 6 characters" Description="violates pattern constraint of '[0-9][0-9][0-9][0-9][0-9][0-9]'.The element 'application-Number' with value
Severity	High
Effective Date	03/10/2008
Problem	The *application-number* must be 6 numeric characters in length.
Corrective Action	Resubmit your submission specifying a properly formatted *application-number*. You may resubmit using the original sequence number of the submission.

Number	3043
Group	M1
Section	Application Number
Description	Application Number can only contain numeric characters" Description="as integer datatype. The element 'application-number' with value
Severity	High
Effective Date	03/10/2008
Problem	Your *application-number* contained non-numeric characters.
Corrective Action	Resubmit your submission specifying a properly formatted *application-number*. You may resubmit using the original sequence number of the submission.

Number	3050
Group	M1
Section	Submission Number
Description	Submission Number (ed. Sequence number) must contain 4 characters" Description="violates pattern constraint of '[0-9][0-9][0-9][0-9]'.The element 'sequence-Number' with value
Severity	High
Effective Date	
Problem	Your submission's *sequence-number* must be 4 numeric characters in length.
Corrective Action	Resubmit your submission specifying a properly formatted *sequence-number*.

Number	3057
Group	M1
Section	Submission Number
Description	Submission Number (ed. Sequence number) can only contain numeric characters" Description="as integer datatype.
Severity	High
Effective Date	03/10/2008
Problem	Your submission's *sequence-number* contained non-numeric characters.
Corrective Action	Resubmit your submission specifying a properly formatted *sequence-number*.

Number	3064
Group	M1
Section	Related Sequence
Description	Related Sequence Number must contain 4 characters" Description="violates pattern constraint of '[0-9][0-9][0-9][0-9]'.The element 'related-sequence-Number' with value
Severity	High
Effective Date	03/10/2008
Problem	Your submission's *related-sequence-number* must be 4 numeric characters in length.
Corrective Action	Resubmit your submission specifying a properly formatted *related-sequence-number*. You may resubmit using the original sequence number of the submission.

Number	3071
Group	M1
Section	Related Sequence
Description	Related submission Number (ed. Sequence number) can only contain numeric characters" Description="as integer datatype. The element 'related-sequence-Number' with value
Severity	High
Effective Date	03/10/2008
Problem	Your submission's *related-sequence-number* contained non-numeric characters.
Corrective Action	Resubmit your submission specifying a properly formatted *related-sequence-number*. You may resubmit using the original sequence number of the submission.

Validation Report

The validation process [produces a validation report which identifies the errors and the source of the errors. The following is an excerpt from the report and its matching explanation.

TOC: fda-regional:fda-regional/m1-regional/m1-14-labeling/m1-14-1-draft-labeling/m1-14-1-3-draft-labeling-text/
Leaf ID: a436a9642064e
Relative File Path: 0002/m1/us/spl/inderal-la-capsules.xml
Error(s):   Error# 1187 (Medium): Leaf modified XML path is invalid or references a leaf that has not been validated;

Number	1187
Group	File checks
Section	File References
Description	Modified leaf element path references a sequence that has not been validated
Severity	Medium
Effective Date	03/10/2008
Problem	A sequence is being processed that references another sequence that has not yet been processed.
Corrective Action	Generally, no corrective action is necessary. This situation can occur if the earlier sequence is received by FDA after the later sequence. You should verify that the earlier sequence was actually submitted and received.

Error Number	Severity Level
1017	Medium
1034	Medium
1051	Medium
1068	Medium
1085	Low
1102	Medium
1119	Medium
1128	Low
1136	Medium
1153	Medium
1170	Medium
1187	Medium
1187	Medium
1204	Low
1221	Low
1238	Low
1255	Medium
1272	Low
1276	Low
1289	Medium
1306	Medium
1314	Medium
1323	Medium
1340	Low
1344	Low
1357	Medium
1362	Medium
1368	Low
1374	Low
1391	Low
1408	Low
1425	Low
1442	Medium
1445	Medium
1459	High
1463	High
1476	Medium
1478	Medium
1480	Low
1482	Low
1493	High
1510	High
1519	High

1527	High
1544	Low
1561	Medium
1578	Low
1595	Medium
1612	Medium
1629	Medium
1646	Low
1663	Low
1680	Low
1697	High
1714	High
1731	High
1748	Medium
1752	Medium
1765	Medium
1782	High
1786	High
1799	High
1816	Medium
1833	Medium
1850	Medium
1867	Medium
1884	Medium
1901	Medium
1918	Medium
1935	Medium
1952	Low
1969	Medium
3001	Medium
3008	Medium
3015	Medium
3022	Medium
3029	Medium
3036	High
3043	High
3050	High
3057	High
3064	High
3071	High