Content of Labeling/Product Data Elements SPL Technical Errors Training eBook

Interpretations & Solutions for
Technical Errors in Content of Labeling/Product Data Elements
SPL Documents
Submitted to FDA

Version 1.0

Purpose:

This SPL training eBook is to be utilized by SPL document authors as a reference to determine the source of and to locate the solution for technical errors in SPL documents submitted to FDA. This is a "living" document. More content will be included or revised as SPL validation procedures are added or refined.

How do you know when you have received an error message?

The receipt a second or third acknowledgment indicates that there is an error in your submission. At the time of the publication of this eBook, error messages (second or third acknowledgments) are transmitted within 24 – 48 hours (business days) of FDA's receipt of your SPL submission.

Technical Terms Glossary	
Term	**Definition**
Core ID	A unique identifier which the FDA Electronic Secure Gateway (ESG) (e.g. WebTrader) assigns to every submission. This core ID should be used to refer to your Gateway SPL submission.
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of an SPL document document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
Hyperlink ID	Used to cross reference sections in content of labeling. Allows reader of document to navigate to the cross referenced sections (Not used in
Observation Media ID	Identifier for the image file (doesn’t have to be a GUID)
Product data elements	The structured data about your product(s) (e.g. proprietary name, dosage form, route of administration, package description) (Table at the rendered near the end of the SPL document)
Section ID	GUID which is used to identify a section
SetID	GUID which is a unique identifier for the document that remains constant through all versions/revisions of the document.
UNII	Unique Ingredient Identifier (UNII) is a non- proprietary, free, unique, unambiguous, non semantic, alphanumeric identifier based on a substance’s molecular structure and/or descriptive information.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.

Document Tracking Information	
This section includes some of the error messages and solutions for document tracking information in Content of Labeling/Product Data Elements SPL files.	
Error	**Solution**
There is an id	Include a document root ID (GUID)
SPL file name must be the id root followed by ".xml"	Name the file with the document root ID. (**Do not** use creative names for the file name.) Include ".xml" after the document root ID
A submission contains only the SPL file whose name ends in '.xml' and associated image files whose names end in '.jpg'.	Remove any non-SPL files from the folder. Ensure the file extension (e.g. .xml (lower case letters) is included.
There is an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the **document's** effective time field using the YYYYMMDD format (e.g. Enter 20131221 for December 21, 2013)
The value '' of attribute 'value' on element 'effectiveTime' is not valid with respect to its type, 'ts'.	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20131221 for December 21, 2013)
id must be unique across all documents	Change the document root ID (GUID) to a GUID that is not in FDA system.
'' is not a valid value of union type 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
The value '' of attribute 'root' on element 'id' is not valid with respect to its type, 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
id root must be a Globally Unique Identifier (GUID).	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in (document) ID field.
id does not have an extension.	Do not include an extension for the ID (this is a coding extension)
id does not match any other id in the document.	Use each GUID one time and one time only.
id is unique across all documents, sections and any other ids	Use each **document root ID** one time and one time only – do not use that same **document root ID** in subsequent submissions
There is an id Include a document root ID (GUID) setId must be a GUID	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.

Document Tracking Information	
This section includes some of the error messages and solutions for document tracking information in Content of Labeling/Product Data Elements SPL files.	
Error	**Solution**
The value '' of attribute 'root' on element 'setId' is not valid with respect to its type, 'uid'.	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.
Value of version number must be a whole number > 0	Enter a version number which is a whole number that is greater than “0”
'' is not a valid value for 'integer'.	Use a whole number in the version number field.
The value '' of attribute 'value' on element 'versionNumber' is not valid with respect to its type, 'int'.	Use a whole number in the version number field.
Value of version number must be greater than the value of any previously submitted version for the same setId	Increase the document version number by one whole number.
There is an id Include a document root ID (GUID) setId must be a GUID	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.

Labeler, Registrant, and Establishment Information in Content of Labeling/Product Data Elements SPL	
Solutions for labeler, registrant, and establishment errors	
Error	**Solution**
There is one labeler	Include the name of the owner of the labeler code.
There is one id	In this instance, reference is made to the labeler's DUNS Number. Should be identical to labeler's DUNS Number that is associated with labeler code (first segment of NDC in this CoL/listing file) submitted in NDC Labeler Code SPL document.
There is one name	Include the name (owner of the labeler code)
First segment matches a Labeler Code associated with the Labeler id, except for parts.	Ensure that the labeler code and labeler's DUNS Number is **identical** to the labeler code and labeler's DUNS Number in your NDC Labeler Code SPL document with this labeler code.
The setId is not associated with any top level product with a different NDC Labeler Prefix	The labeler code in a previously submitted CoL/listing SPL document which has the same setID of this CoL/listing SPL document should be identical to the labeler code in this CoL/listing SPL document. (Enter one labeler code per CoL/listing SPL) This validation procedure does not apply to the labeler code of the NDC for products which are described as components of a kit (combination package)
There is 0 to 1 registrant	The registrant is included **if** the registrant is listing a drug made for a private label distributor. The information about the registrant would include the name and DUNS Number. Otherwise, the registrant fields should not exist in your file.
If there is a registrant, then there is one id.	If you enter the registrant information, you should include a DUNS Number (9-digit)
If there is a registrant, then there is one name	If you enter registrant information, you should include the registrant's name.
There is no other element besides id, name and establishments.	Do not include any other elements other those for the DUNS Number, name, & drug establishments.
If any of the products without a marketing completion date in this listing has no product source, then at least one establishment with a manufacture operation is included such as API manufacture (C82401), manufacture (C43360), or positron emission tomography drug production (C91403)	- If the products described in the SPL file are currently marketed and has no product source (source NDC product code) then an establishment with the following business operations is included: "manufacture," "API manufacture," or "positron emission tomography drug production. - If the products described in the SPL file all have a marketing end date (discontinued marketing) then no establishment data elements are needed (remove coding for the establishment data elements as well.

Labeler, Registrant, and Establishment Information in Content of Labeling/Product Data Elements SPL	
Solutions for labeler, registrant, and establishment errors	
Error	**Solution**
If the marketing status code for any of the products is **not** "completed," then there are one or more establishments.	If there is at least one drug product described in the listing document which is still marketed then include the information for one or more drug establishments. If all of the products in this CoL/listing SPL are discontinued then you do not have to include the information for any drug establishment in this CoL/listing file.
Each establishment has one id extension	Include the 9-digit DUNS Number (without hyphens) for each drug establishment.
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (establishment)	Include the 9-digit DUNS Number (without hyphens) for each drug establishment.
id not used for other establishments in the file	Do use the same DUNS Number for more than one drug establishment in the same file. DUNS Numbers are site-specific Obtain the other location's DUNS Number from D&B. If D&B will only assign one DUNS Number because the sites are located on the **same campus**, at the time of the publication of this eBook, you should enter information for one of the drug establishments.
There is one name (establishment)	Include the name of the drug establishment in the name "field."
Establishment ("assignedOrganization") has no other element besides id and name.	Do not include other element about the drug establishment (in this case the "assignedOrganization" element) other those for the DUNS Number and name
There are one or more business operations.	Include one or more business operations (e.g. manufacture) for each drug establishment
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, **DO NOT** add "import" or "united states agent" as a type of operation for an establishment.
Act definition code matches code for an establishment with same id previously submitted in documents of type "establishment registration" in the same or previous calendar year	If the drug establishment included in the establishment data elements section of your CoL/Listing SPL has been **electronically** registered via an Establishment Registration SPL, the type of operation included for the establishment in your CoL/Listing matches the type of operation in the previously submitted Establishment Registration SPL document. - Ensure that the DUNS Number for the drug establishment is correct. - Ensure that the type(s) of operation for each establishment is correct. - Ensure that the drug establishment has been registered this calendar year or at least the previous calendar year.

Labeler, Registrant, and Establishment Information in Content of Labeling/Product Data Elements SPL	
Solutions for labeler, registrant, and establishment errors	
Error	**Solution**
If there is no product source, then operation of API manufacture (C82401) and manufacture (C43360) are included	If the source NDC Product Code "field" is not populated then drug establishments with the types of operation "API manufacture" and "Manufacture" should be included. Do Not populate the source NDC Product Code field with an NDC Product Code which is identical to the NDC Product Code for this product just to bypass this validation procedure.

Product Names, Dosage Form, Route of Administration	
Solutions for errors related to the product name, dosage form, or route of administration.	
Error	**Solution**
There is a name, i.e., proprietary name of the product as used in product labeling or in the catalog	Include a proprietary/brand name. If no proprietary name is available, enter the generic name in this field.
Name contains no special symbols (e.g., no "®" or "™" etc) and no "USP"	Do not include symbols or "USP" in the proprietary name of the products in the product data elements section. **NOTE: Do not include the dosage, route or strength in the proprietary name field in the product data elements section.**
There is a generic medicine name	Include a generic (established) name for the product.
Generic medicine name contains no special symbols (e.g., no "®" or "™" etc) and no "USP"	Do not include symbols or "USP" in the generic/established name of the product in the product data elements section. **NOTE: Do not include the dosage, route or strength in the generic name field in the product data elements section.**
Generic medicine name contains no suffix.	The generic (established) name should not have a suffix field as the proprietary name could have.
Remove additional qualifiers (e.g. dosage form, route of administration, etc…) from product names in the product data elements section.	**Remove dosage form, route of administration, etc… from the product name(s) in the product data elements section of the SPL document.**

Product Names, Dosage Form, Route of Administration	
Solutions for errors related to the product name, dosage form, or route of administration.	
Error	**Solution**
There is a form code	Include a dosage form for the product
If the product has parts, then the form code is C47916	If this is a multi-component product, you should “Kit” as the “dosage form.”
If the document type is not for ‘bulk ingredient’ (53409-9) and product is not a top-level product whose form code is C47916, then there is one or more “consumed in” substance administration with route code.	Include one or more routes of administration unless the top level product is a kit (combination product)
If the document type is for ‘bulk ingredient’ (53409-9), then route code is “not applicable” or not present at all.	Enter “not applicable” as the route of administration for a bulk ingredient product.
The route code cannot be “not applicable” (C48623) for document types other than bulk ingredient (53409-9).	Enter “not applicable” as the route of administration for products only if the document type is “bulk ingredient.”

Product Codes	
Recommendations for fixing product code errors	
Error	**Solution**
Code has two segments separated by a hyphen	Insert a hyphen between the NDC Labeler Code (first segment of 3-segment, 10-digit NDC Package Code) and NDC Product Code (second segment of 3-segment, 10-digit NDC Package Code)
The first segment is numeric.	Ensure that the first segment (NDC Labeler Code) only consists of numbers.
The second segment is alpha-numeric (letters must be upper-case).	The second segment of the “NDC Product Code – first two segments of 3-segment, 10-digit NDC) is alphanumeric (with letters in uppercase if letters are utilized)

Product Codes	
Recommendations for fixing product code errors	
Error	**Solution**
Segments follow the pattern of 4-4, 5-4 or 5-3	Follow the pattern assigned if you received a labeler prior to June 1, 2009. Examples of the patterns of an NDC Product Code are: 4-4: 2222-5555, 5-4: 22222-2222, or 5-3: 22222-876) **DO NOT** use these exact numbers in your SPL document. Use your own labeler code, etc… Labelers with labeler codes assigned after June 1, 2009, can select pattern; however, once pattern is selected and used in an official CoL/Listing SPL submission, it can not be altered.
The first two segments of the NDC Package Code matches the NDC Product Code	The first two segments of the NDC Package Code (3-segment NDC) are identical to the first two segments of the NDC Product Code. (per product data elements table)
There is an Item Code, except for part products not requiring an Item Code.	Enter an NDC Product Code (An NDC Product Code are the first two segments of the 3-segment, 10-digit NDC Package Code) or NHRIC (first two segments of a 3-segment 10-digit NHRIC.
Defining material kind code matches an Item Code in an SPL file with a different setId	The source NDC product code should match an NDC product code/item code in the system in the original manufacturer's SPL file.
Code has the same labeler segment as the NDC Product Code of all other top-level products in this document.	All top-level products (products which are not considered as inner-component of a kit) should have the same labeler segment for the NDC Product Codes.
Code is not associated with another set id except under parts.	The NDC Package Code (3-segment NDC) may only be associated with one CoL/Listing document's setID except in the case where the 3-segment NDC is included as a component of a kit (combination package).
Code has the same length as the NDC Product Code of all other top-level products in this document (i.e., all NDC Product Codes have the same consistent length and hence all NDC Package Codes have the same consistent configuration.)	All NDC Product Codes have the same consistent length and hence all NDC Package Codes have the same consistent configuration.

Product Codes	
Recommendations for fixing product code errors	
Error	**Solution**
Code has the same length as all other NDC product/item codes with the same labeler segment in this document (i.e., all NDC product/item codes from one labeler have the same consistent length and hence all package item codes have the same consistent configuration.)	All NDC Product/Item Codes by the same labeler have the same consistent length and hence all NDC Package Codes have the same consistent configuration. (You should not change the configuration of your NDC number.)
There is only one product element for each NDC product/item code, i.e., the same product is not described more than once except under parts.	The same product is not described more than once except under parts.
If the NDC product/item code is mentioned elsewhere in the document, then the product and generic name, dosage form, UNII and strength of all ingredients are the same.	If the NDC product/item code is mentioned elsewhere in the document, then the product and generic name, dosage form, UNII and strength of all ingredients are the same.
If the NDC Package Code has been previously submitted, then the package form code and quantity value and unit are the same as in the most recent submission for this NDC code.	The package description associated with the NDC Package Code (3-segment NDC) of the incoming CoL/Listing SPL document should be identical to the package description for this NDC Package Code in the previously submitted CoL/Listing SPL document.
There is only one product element for each product code, i.e., the same product is not described more than once	The same product is not described more than once in the product data elements section.
Product source may be specified under a product	An source NDC Product Code may be included (for repackers and relabelers) (for top-level products and products which are components in a kit (combination product))
NDC Product Code for the source is not the same as the NDC Product Code for the product	Do not include the same NDC Product Code in both the NDC Product Code and source NDC Product Code “fields” in the same product data elements section.

Ingredients and Strength	
Solutions for ingredient or strength-related errors	
Error	**Solution**
Ingredients may be specified for products and parts	Include ingredients for the products (this also applies to products which are components of a kit)
If the product has parts, then the active ingredients are under parts	If this product is a combination product (kit) then the active ingredients are included in each in product component sections of the kit
There may be a strength with a numerator and denominator	For the active ingredient, include a strength and a denominator (e.g. 5 mg in 1 mL or 25 mg in 1 1) (strength is expressed as a ratio.) For cosmetics, there may be no strength for the ingredients
Numerator and denominator have a value greater than zero and a unit	The values (numerical amounts in the strength ratio) should be greater than zero. A unit should also be included for both the numerator and denominator for the strength ratio.
If the document type is for 'bulk ingredient' (53409-9), then numerator and denominator are the same.	The numerator and denominator strength for active ingredient in a bulk ingredient listing document should be identical (e.g. 1 kg in 1 kg).
There is no ingredient other than active ingredient (having class code ACTIM, ACTIR, ACTIB), and inactive ingredient (having class code IACT).	There can be no other ingredient classes other than those for the active ingredient, reference drug ingredient, active moiety or inactive ingredients.
If the document type is for 'bulk ingredient' (53409-9) with a marketing category of 'bulk ingredient' (C73626), then there is one and only one active ingredient.	In a bulk ingredient (API) listing SPL document, enter one and only one active ingredient.
If active ingredient code are on the list of active ingredients approved for vaccines, then the document type code is 53404-0 (Vaccine Label).	If an active ingredient UNII is on the list of active ingredients approved for vaccines, then the document type code is Vaccine Label.

Ingredients and Strength	
Solutions for ingredient or strength-related errors	
Error	**Solution**
If the document type code is 53404-0 (Vaccine Label), then there must be at least one active ingredient code on the list of active ingredients approved for vaccines.	If the document type is Vaccine Label, then there must be at least one active ingredient UNII on the list of active ingredients approved for vaccines.
If the product has no parts and is not a part, then there are one or more active ingredients.	If this is **not** a combination product (kit), then you should include one or more active ingredients in the product data elements section.
If the product has parts, then the active ingredients are under parts	If this is a combination product, the active ingredients should be entered in the component section of the product data elements section.
There is an ingredient code	Include an ingredient code
Name matches the code	Use the **preferred** name and UNII in the UNII list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
There are one or two active moieties	Include one or two active moieties for the active ingredient(s).
There is an active moiety code	Include the UNII for the active moiety
Active moiety name matches the code	Ensure that the active moiety code matches the corresponding preferred term
There is an active moiety name for each active moiety	For each active moiety include the preferred name for that active moiety. Use the **preferred** name and UNII in the UNII list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
Active moiety name does not include any of the names in the Active moiety validation (counter ion) list except if the word appears by itself optionally followed by “cation” or “anion” or “ion”.	Do not include names in the active moiety counter-ion list (labeled “counter-ion validation” located in the Additional Validation Files located on this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm unless word appears by itself optionally followed by “cation” or “anion” or “ion”.
If the class code is ACTIR, then there is an asEquivalentSubstance element with a defining substance	If the basis of strength is a reference drug then there should a name and code which represents the reference drug’s term and UNII.

Ingredients and Strength	
Solutions for ingredient or strength-related errors	
Error	**Solution**
If the class code is not ACTIR, then there is no asEquivalentSubstance element	If the basis of strength is NOT a reference drug then do not use the reference drug “field”
There is a reference ingredient code	Include a reference ingredient code (UNII)
There is a name (reference drug)	Include the name for the reference drug ingredient
The name matches the code	Add the UNII for the reference drug ingredient
There are zero to many inactive ingredients.	Include or do not include the inactive ingredients in the product data elements section.
There is a strength with a numerator and denominator (inactive ingredient)	For the inactive ingredient, include a strength and a denominator (e.g. 5 mg in 1 mL or 25 mg in 1 1) (strength is expressed as a ratio.)
If the document type is *human OTC drug label* (34390-5), then there is at least one inactive ingredient.	Include all inactive ingredients for a human OTC drug product. If there are no inactive ingredients in a human OTC drug product, request a manual loading of the submission by sending the core ID via e-mail to spl@fda.hhs.gov.
If the document type is *human OTC drug label* (34390-5), then there is no confidentiality code.	Do not mark inactive ingredients for a human OTC drug product as “confidential” since these ingredients are listed in the drug facts section.
If the product has parts, then the inactive ingredients are under parts	If this is a combination product, the inactive ingredients should be entered in the component section of the product data elements section.
For percentages numerator unit is not 1, instead use a volume unit for volume fractions and a mass unit for mass fractions.	For percentages numerator unit is not 1, instead use a volume unit for volume fractions and a mass unit for mass fractions.
The denominators values and units for all ingredients in this product are the same.	The unit of measure for each strength amount of a product should be the same in the product data elements section of a file.
There is an ingredient code with code and code system	Enter the ingredient name, UNII, and ingredient code system object ID.
The same ingredient substance code is not used more than once per product.	Do not repeat the ingredient name in the same product data elements section.
Numerator and denominator have a value greater than zero and a unit (inactive ingredient	The values (numerical amounts for the strength in the strength ratio) should be greater than zero. A unit should also be included for both the numerator and denominator for the strength ratio.

Ingredients and Strength	
Solutions for ingredient or strength-related errors	
Error	**Solution**
If the product has parts, then the inactive ingredients are under parts	If the combination products have inactive ingredients, include the names of the inactive ingredients in the product data element section for the component.
Unit comes from the UCUM units of measures list (strength of ingredients)	Units of measure (UCUM - Unified Codes for Units of Measure) should come from the UCUM list http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm168397.htm
There is an ingredient code	Include an ingredient code
Name matches the code (inactive ingredients)	Use the **preferred** name and UNII in the UNII list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
Unit comes from the UCUM units of measures list (strength of ingredients)	Units of measure (UCUM - Unified Codes for Units of Measure) should come from the UCUM list http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm168397.htm
If the products has parts, then the form code is C47916	If you are describing a combination product then use “kit” as the dosage form.
If the NDC product/item code was previously submitted, then the product and generic name, source, active ingredient UNII, dosage form, active ingredient strength, product characteristics of size, shape, color and imprint code are the same as in the most recent submission for this NDC product/item code.	- Ensure that the product information is the same in this subsequent submission. - If you are correcting an error or if you believe that the information you entered is correct, send an e-mail to spl@fda.hhs.gov with the **core ID** of the submission to request a manual override. If your request is granted, the file will be manually loaded. You will **ONLY** be notified via e-mail regarding your manual override request if your request is **NOT** granted.

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
There is one marketing category for each product and product part	Include a marketing category for each product (single component product) and each component of a combination product.
There is a marketing category code.	Select a code from the marketing category list (list of acceptable marketing category codes)
Code comes from the *Marketing category* list	Select a code from the marketing category list (list of acceptable marketing category codes)
If the code is C73583 (ANADA), then the id extension has the prefix "ANADA" followed by 6 digits	If the marketing category is "ANADA" then a six-digit application number should be preceded with "ANADA".
If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits	If the product is regulated by CDER as an ANDA, the six-digit application number should be preceded by "ANDA." If the product is regulated by CBER as an ANDA, the six-digit application number should be preceded by "BA"
If the code is C73585 (BLA), then the id extension has the prefix "BLA" followed by 6 digits	If the marketing category is "BLA" then the six-digit application number is preceded by "NADA".
If the code is C73593 (NADA) or C73588 (Conditional NADA), then the id extension has the prefix "NADA"	If the marketing category is "NADA" or "Conditional NADA" then the 6-digit application number is preceded by "NADA".
If the code is C73594 (NDA) or C73605 NDA authorized generic), then the id extension has the prefix "NDA" or "BN" followed by 6 digits	If the product is regulated by CDER as an NDA or NDA authorized generic, the six-digit application number should be preceded by "NDA" If the product is regulated by CBER as an NDA, the six-digit application number should be preceded by "BN"
If the code is C75302 (IND), then the id extension has the prefix "IND" followed by 6 digits	If the marketing category is "IND" then the 6-digit application number is preceded by "IND".
If the code is C92556 (Legally Marketed Unapproved New Animal Drugs for Minor Species), then the id extension has the prefix "MIF" followed by 6 digits.	If the marketing category is Legally Marketed Unapproved New Animal Drugs for Minor Species then the application number has the prefix "MIF" followed by 6 digits.

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the code is C73603 (OTC monograph final) or C73604 (OTC monograph not final), then the id extension must match a code in the OTC validation list.	If the marketing category is “OTC monograph final” or “OTC monograph not final” then the regulatory citation must match a code in the OTC validation list. The OTC validation list (otcval.xml) is located in the Additional Validation Files accessible via this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm
If the code is C80438 (Exempt device), then the id extension consists of 3 letters	If the marketing category is “Exempt device” then the product identifier consists of three letters.
If the code is C80440 (Humanitarian Device Exemption), then the id extension has a prefix “H” followed by 6 digits	If the marketing category is “Humanitarian Device Exemption” then the 6-digit application number is preceded by “H”.
If the code is C80441 (Premarket Application), then the id extension has a prefix “P” or “BP” followed by 6 digits	If the marketing category is “Premarket Application” then the 6-digit application number is preceded by a “P” or “BP”.
If the code is C80442 (Premarket Notification), then the id extension has a prefix “K” or “BK” followed by 6 digits.	If the marketing category is “Premarket Notification” then the 6-digit application number is preceded by “K” or “BK”.
If the code is C80438 (Exempt device), C80440 (Humanitarian Device Exemption), C80441 (Premarket Application), or C80442 (Premarket Notification), then there is at least one part.	If the marketing category is “Exempt Device,” “Humanitarian Device Exemption,” “Premarket Application,” or “Premarket Notification” then the product should be a combination product (kit)

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the code is not C73583 (ANADA), C73584 (ANDA), C73585 (BLA), C73588 (Conditional NADA), C73593 (NADA), C73594 (NDA), C73603 (OTC monograph final), C73604 (OTC monograph not final), C73605 (NDA authorized generic), C75302 (IND), C80438 (Exempt device), C80440 (Humanitarian Device Exemption), C80441 (Premarket Application), C80442 (Premarket Notification), C95600 (Approved drug product manufactured exclusively for private label distributor), or C92556 (Legally Marketed Unapproved New Animal Drugs for Minor Species), then there is no id.	If the marketing code is not ANADA, ANDA, BLA, Conditional NADA, NADA, NDA, OTC monograph final, OTC monograph not final, NDA authorized generic, IND, Exempt device, Humanitarian Device Exemption, Premarket application, Premarket Notification, Approved drug manufactured exclusively for a private label distributor, or Legally Marketed Unapproved New Animal Drugs for Minor Species then remove the application or citation number or application and citation number code system. Delete the empty application or citation number field. You may have to request to have the empty ID element removed if you still receive error after following above steps. Or you can delete all of the product information and re-enter.
If the marketing category is C95600 (Approved drug product manufactured exclusively for private label distributor), then there is an id.	If the marketing category is Approved drug product manufactured exclusively for private label distributor then there is an application number.

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the marketing category is C95600 (Approved drug product manufactured exclusively for private label distributor), C95601 (OTC monograph drug product manufactured exclusively for private label distributor), C95602 (Unapproved drug product manufactured exclusively for private label distributor), then the document type must be 34391-3 (Human prescription drug label) or 34390-5 (Human OTC drug label)	If the marketing category is Approved drug product manufactured exclusively for private label distributor, OTC monograph drug product manufactured exclusively for private label distributor, Unapproved drug product manufactured exclusively for private label distributor then the document type must be Human prescription drug label or Human OTC drug label. Do not use these marketing categories in SPL files for animal drugs or for drug products regulated by CBER.
If the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C), then there is no operation-product link.	If the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B, VFD type C, then there is no establishment-product relationship link.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA), then there exists a record of an application for the application number.	If the application number is associated with an ANDA, BLA, or NDA, that application number exists in the FDA's application number database.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the application number was already submitted, then the active ingredient UNIIs are the same as in any previous submission of a product with the same application number.	If the product is associated with the marketing categories "ANDA," "BLA," or "NDA," and the application number has been included in a previous SPL submission, the active ingredients' UNIIs have to be the same as those in any previous submission of an SPL for a product with the same application number.

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the code is C73603 (OTC monograph final) or C73604 (OTC monograph not final), then the id root is 2.16.840.1.113883.3.149 (Code of Federal Regulations)	If the marketing category is OTC monograph final or OTC monograph not final, then choose "Regulatory Citation" as the "Application or citation number code system." Include a monograph citation number using the correct format (e.g. "part352") OTC citations are in the otcval.xml file located in the Additional Validation Files located on this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm
If the code is C73583 (ANADA), C73584 (ANDA), C73585 (BLA), C73588 (conditional NADA), C73593 (NADA), C73594 (NDA), C73605 (NDA authorized generic), C75302 (IND), C80438 (Exempt device), C80440 (Humanitarian Device Exemption), C80441 (Premarket Application), or C80442 (Premarket Notification) or C92556 (Legally Marketed Unapproved New Animal Drugs for Minor Species), then the id root is 2.16.840.1.113883.3.150 (FDA application tracking system).	If the marketing category is ANADA, ANDA, BLA, Conditional NADA, NADA, NDA, NDA authorized generic, Exempt device, Humanitarian Device Exemption, IND, Premarket Application, Premarket Notification, or Legally Marketed Unapproved New Animal Drugs for Minor Species then choose "Application" as the "Application or citation number code system." Enter a six-digit application number preceded by the marketing category prefix (e.g. NDA013444)
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there is no id.	If the marketing category is bulk ingredient, medical gas, export only, unapproved drug other, unapproved homeopathic, or unapproved medical gas **DO NOT** enter an application number and **DO NOT** include an **"**application or citation number code system."

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C), then the marketing category is: C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), C92556 (legally marketed unapproved new animal drugs for minor species), C73614 (unapproved homeopathic), C73613 (unapproved medical gas) or C73627 (unapproved drug other).	If the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C, then the marketing category is: ANADA, Conditional NADA, NADA, unapproved homeopathic, unapproved medical gas, or unapproved drug other.
If the marketing category is C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), then the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C)	If the marketing category is ANADA, Conditional NADA, or NADA, then the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C
If the marketing category is C73626 (bulk ingredient), C94795 (drug for further processing), C96793 (bulk ingredient for human prescription compounding), or C98252 (bulk ingredient for animal drug compounding) then the document type is 53409-9 (bulk ingredient).	If the marketing category is bulk ingredient, drug for further processing, bulk ingredient for human prescription compounding, or bulk ingredient for animal drug compounding then the document type is bulk ingredient

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the document type is 53409-9 (bulk ingredient), then the marketing category is C73626 (bulk ingredient), C94795 (drug for further processing), C96793 (bulk ingredient for human prescription compounding), or C98252 (bulk ingredient for animal drug compounding).	If the document type is bulk ingredient, then the marketing category is bulk ingredient, drug for further processing, bulk ingredient for human prescription compounding, or bulk ingredient for animal drug compounding then the document type is bulk ingredient
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA), then there exists a record of an application for the application number.	If the application number is associated with an ANDA, BLA, or NDA, that application number exists in the FDA's application number database.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the marketing is active with a start date on or before the current date, then there exists a record of an approved application for the application number.	If the application number is associated with an ANDA, BLA, or NDA, the marketing status is "active" and the marketing start date is on or precedes the current date, there is a record of an approved application for that application number in the FDA's application number database.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the marketing status is completed, then there exists a record of an approved or withdrawn application for the application number.	If the application number is associated with an ANDA, BLA, or NDA and the marketing status is "completed" then there is a record of an approved or withdrawn application for that application number in the FDA's application number database.
If the marketing category is C86964 (Medical Food), then the document type is 58475-5 (Medical Food), except under parts.	If the document type is Medical Food, the marketing category should be Medical Food.
If the document type is 58475-5 (Medical Food), then the marketing category is C86964 (Medical Food).	If the document type is Medical Food, the marketing category should be Medical Food.

Marketing Category and Application/Citation Number	
Recommendations for resolving marketing category and application number issues.	
Error	**Solution**
If the marketing category is C86952 (Dietary Supplement), then the document type is 58476-3 (Dietary Supplement), except under parts.	If the document type is Dietary Supplement, the marketing category should be Dietary Supplement.
If the document type is 58476-3 (Dietary Supplement), then the marketing category is C86952 (Dietary Supplement).	If the document type is Dietary Supplement, the marketing category should be Dietary Supplement.

Marketing Status	
Solutions for fixing marketing status errors	
Error	**Solution**
Status code is “active” or “completed”	Include a marketing status of “active” (on the market) or “completed” (discontinued)
If the status code is active, then there is a low value and no high value	If the product is on the market then include a marketing start date.
If the code is completed, then there is a low and high value	If the product is discontinued then there is a marketing start date and a marketing end date.
The effective time low and high boundary have at least the precision of day in the format YYYYMMDD	The marketing start date and the marketing end date should have this date format: YYYYMMDD.
If there is a high value, then it is not less than the low value.	The marketing end date should be a date that is after the marketing start date.

Marketing Status	
Solutions for fixing marketing status errors	
Error	**Solution**
Invalid content was found starting with element 'ingredient'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	Delete all of the packaging description information and enter again. To avoid this error, enter all ingredient information and then add package description
Invalid content was found starting with element 'asEquivalentEntity'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	There is a problem with the source NDC Product Code. Delete the NDC Source Code from the file. Ensure that are using an up to date version of the listing SPL Xforms. If using version 1.02 or older then download a later version and create a completely new SPL document.
Invalid content was found starting with element 'effectiveTime'. One of '{"urn:hl7-org:v3":component}' is expected.	Create a section under content of labeling tab Qualify section from drop-down menu (i.e. Package.Label Principal Display Panel) Create and enter GUID for section (in section ID field) Open “add effective time” field and enter properly formatted data (YYYYMMDD) Open Observation Media fields (“add media”) and complete sections appropriately “Edit” section intended to reference (link to) jpeg image Before referencing image, replace “enter section text here” with appropriate text from label or, if creating a principal display panel section, enter text from principal display panel of carton or container. Ensure that there are no spaces before or after text. Save section and ensure to save document. Repeat above steps for all sections in which images will be referenced.
There must not be empty or incomplete elements except, in certain circumstances, code, state, title, text, and time (an id must have a root, a code must have a code system).	Ensure that there are no empty fields

Product Packaging	
Recommendations for solving product package errors	
Error	**Solution**
Every top-level product has an “as content” element (optional for parts)	Include a package description for each top-level product (product which is not the inner component of a kit (combination product))
Quantity includes a numerator and denominator	The quantity in the package description includes a numerator and denominator (e.g. 50 tablets (numerator) in 1 box (denominator) or 50 mL (numerator) in 1 vial (denominator))
Remove description of kit package from the parts	Delete the kit package description information from the component level (part) in the product data elements section.
Numerator has a value greater than zero and a unit	The value of the numerator is greater than zero and has a unit.
If the product has parts, then the initial numerator value and unit is “1”	If the product is a combination product (kit) then the initial numerator value and unit is “1”.
Unit of the numerator of the initial package is the same as the units for the denominators of all the ingredient quantities (strengths)	The unit of measure in the strength’s denominator field for all ingredients for a product should match the unit of measure in the initial package. For example, if the strength of the product is 5 mg in 1 mL then the initial package’s amount should be in “mL” (e.g. 10 mL)
Unit of the numerator of an outer package is the same as the unit for the denominator of the quantity of the inner package	The unit of the numerator of outer package should be the same as the unit for the denominator of the quantity of the inner package (e.g. inner level packaging: 50 tablets in 1 **bottle**/outer level of packaging 1 **bottle** in 1 box
If the numerator unit is “1” then it has a translation.	Include a translation if the numerator is “1” then use a translation element
If the numerator unit is not “1”, then there is no translation	If the numerator is not “1” then do not include a translation element
Translation code is from the *unit of presentation* list	The translation code is from the *unit of presentation* list.
Translation display name matches the translation code	Ensure that the display name for the translation matches the code for the translation.

Product Packaging	
Recommendations for solving product package errors	
Error	**Solution**
Translation code agrees with the contained item's form code. For example, if the form code is "blister pack" (C43168) the translation code is also "blister pack" (C61569) and not "blister".	Translation code agrees with the contained item's form code. For example, if the form code is "blister pack" (C43168) the translation code is also "blister pack" (C61569) and not "blister".
Denominator has value 1 and either no unit or unit "1"	Denominator has value 1 and either no unit or unit "1"
There is a form code and display name	Include a package type and code.
There is a Package Item Code with code and code system for outermost package except for parts.	Include the NDC Package Code (3-segment NDC) for outermost package except for the inner component of a combination product (kit)
If document type is 60684-8 (Cellular Therapy), 60683-0 (Plasma Derivative) and 53404-0 (Vaccine Label), then there is a package item code with code and code system for the inner, unit of use package.	If the document type is Cellular Therapy, Plasma Derivative, or Vaccine Label, then there is a package item code (NDC package code) for the inner, unit of use package.)
Container packaged product code is 10 digits (excluding any hyphens)	Include a ten digit NDC/Item code for the package.
NDC Package Code contains three segments divided by hyphens.	Include a 3-segment NDC Package Code the segments divided by hyphens.
The first two segments of the NDC Package Code matches the NDC Product Code	Ensure that the first two segments of the 3-segment NDC Package Code match the NDC Product Code.
Code is not associated with another set id except under parts	NDC Package Code (3-segment NDC) should not be associated with another setID unless it is for the inner component packaging in a combination product (kit)

Product Packaging	
Recommendations for solving product package errors	
Error	**Solution**
If the Package Item Code has been previously submitted, then the package form code and quantity value and unit are the same as in the most recent submission for this item code.	If the NDC/NHRIC package code (e.g. three-segment NDC) was submitted in a previous version of an SPL file, the packaging information (e.g. amount of product in package, package type) should be the same as in the most recent submission of the file with this item code.
If the Package Item Code is mentioned elsewhere in the document, then the package form code and quantity value and unit are the same and the content of both packages have an Item Code that is the same.	If the NDC Package Code is mentioned elsewhere in the document, then the package form code and quantity value and unit (package description information) are the same.
Package Item Code does not match any other Package Item Code in the same package hierarchy.	Each NDC Package/Item code is unique
Kits	
If the product form code is 'C47916' (KIT), then there must be one or more parts	If "Kit" is the "dosage form" (combination product) then there must be more than one inner component product.
If the product has parts, then at least one part has one or more active ingredients.	If this is a combination product then one of the products should have one or more active ingredients.
Each part has an overall quantity	Include an overall quantity for each product component in a kit (combination product)
If there is an "as content" data element in the part, then the numerator unit is the same as the numerator unit for the "as content" data element (combination product)	If there is packaging then the numerator unit is the same as the numerator unit for the packaging description
If there is no "as content" data element in the part, then the numerator unit is 1	If the inner component product for a combination product does not have packaging then the numerator is "1"

Product Characteristics	
Recommendations for solving product characteristic errors	
Error	**Solution**
If the dosage form is on the solid oral dosage form list, then there is a color.	Solid oral dosage form products should have a color
If the dosage form is on the solid oral dosage form list, then there is a shape	Solid oral dosage form products should have a shape
There is only one shape element	Solid oral dosage form products should only have one shape characteristic.
If the dosage form is on the solid oral dosage form list, then there is a size	Solid oral dosage form products should have a size
There is a unit and value	Include a unit (“mm”) and value (size of product)
Value units is mm	For size include “mm” as the unit (unit of measurement)
Value is a whole number greater than zero	Size of solid oral dosage form is greater than zero (do not use “0” as the size)
There is only one size element	Only include one size product characteristic per solid oral dosage from product
If the dosage form is on the solid oral dosage form list, then there is scoring	Indicate whether or not a solid oral dosage forms is scored.
The value is 1, 2, 3, 4 or nullFlavor=”OTH”	For scoring the value is “1” (no scoring) “2” (two even pieces) “3” (three even pieces) “4” (four even pieces) “OTH” (other)
There is only one score element	Solid oral dosage form products should each have one score characteristic.
Value has only letters and numbers separated by semicolon without spaces	Solid oral dosage form with an imprint code should have an imprint code that only consists of letters and numbers separated by semi-colon(s) without spaces.
There is only one imprint code element	Each solid oral dosage form should have only one imprint code characteristic.
The code list for the “contains” characteristic is pending	At this time of the publication of this eBook, do not use the “contains” characteristic.

Content of Labeling	
Solutions for fixing content of labeling errors.	
Error	**Solution**
Each section has zero to many subsections	Each section can have zero to many subsections.
Each section and subsection has an id root and no extension	Include a GUID for each section and subsection
Each section and subsection has a code	Each section and subsection should have the appropriate section heading and corresponding code for that section heading.
id does not match any other id in the document	Each section ID should be unique
There are no figures in the title for a section or subsection.	Do not enter figures in the title field for the sections or subsections.
id does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted	If you change the content of a section, the section root ID has to be changed. The ID for the section should not match any section ID, document root ID, set ID, etc…
Each section has an effective time with at least the precision of day in the format YYYYMMDD.	Include an effective time for each section. The effective time should have a date format of YYYYMMDD.

Content of Labeling	
Solutions for fixing content of labeling errors.	
Error	**Solution**
If the marketing category code is not C73626 (bulk ingredient), C94795 (drug for further processing), C73613 (unapproved medical gas), C95600 (approved drug product manufactured exclusively for private label distributor), C95601 (OTC monograph drug product manufactured exclusively for private label distributor), C95602 (unapproved drug product manufactured exclusively for private label distributor), C96793 (bulk ingredient for human prescription compounding) or C98252 (bulk ingredient for animal drug compounding), then there is at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	With the exception of SPL files with the marketing categories bulk ingredient, drug for further processing, approved drug product manufactured exclusively for private label distributor, OTC monograph drug product manufactured exclusively for private label distributor, unapproved drug product manufactured exclusively for private label distributor, bulk ingredient for human prescription compounding, bulk ingredient for animal drug compounding, or unapproved medical gas product SPL documents, include **each section** of the content of labeling (package insert or drug facts) in **each** appropriate SPL content of labeling section. Use the appropriate section header for each section. Add a section GUID, title, etc… This means that all other drug products should have a content of labeling sections. **DO NOT** include an image of the content of labeling. Enter the text or table from the package insert or drug facts in the appropriate sections SPL content of labeling.
If the document type is 34390-5 (Human OTC drug label) and the marketing category code is not C95601 or C95600 (OTC monograph or approved drug product manufactured exclusively for private label distributor) and the citation is not part352 (sunscreens), then there must be the following sections: 55106-9 (OTC- active ingredient section), 55105-1 (OTC – Purpose section), 50565-1 (OTC – keep out of reach of children section), 34067-9 (Indications & usage section), 34071-1 (Warnings section), 34068-7 (Dosage & administration section), and 51727-6 (Inactive ingredient section).	For human OTC drug products' SPL files, unless the monograph citation is "part352," and the marketing categories are not OTC monograph or approved drug product manufactured exclusively for private label include the following section headers for the content of labeling: OTC- active ingredient section, OTC – Purpose section, OTC – keep out of reach of children section, Indications & usage section, Warnings section, Dosage & administration section, and Inactive ingredient section

Content of Labeling	
Solutions for fixing content of labeling errors.	
Error	**Solution**
If the approval number is in the medication guide validation list and the marketing category is not C95600 (Approved drug product manufactured exclusively for private label distributor), then there must be such a Medication Guide section (42231-1).	Include the medication guide section header and LOINC code 42231-1 for SPL files which should have a medication guide.
There is a section with the code 51945-4 (principal display panel) with a jpg file (carton/container label). There is a section with the code 51945-4 (principal display panel) with an image of the carton/container label, except for files with only one establishment and this establishment having business operation 'C91403'.	Include each representative sample of a carton/container label in a **major** SPL section with section heading "Package.Label Principal Display Panel. (one carton/contain label image per section) unless the SPL file is for a Positron Emission Tomography drug product.
There are no figures in the title for a section or subsection.	Do not include figures in title for section or subsection.
There may be excerpts.	There may be highlights text sections for labeling in the **Physician's Labeling Rule** format.
Excerpts occur only in sections with the following codes: 34066-1 (Boxed Warning), 43683-2 (Recent Major Changes), 34067-9 (Indications and Usage), 34068-7 (Dosage and Administration), 43678-2 (Dosage Forms and Strengths), 34070-3 (Contraindications), 43685-7 (Warnings and Precautions), 34084-4 (Adverse Reactions), 34073-7 (Drug Interactions), 43684-0 (Use in Specific Populations), 49489-8 (Microbiology)	Include highlights text ONLY in these sections: Boxed Warning, Recent Major Changes, Indications and Usage, Dosage and Administration, Dosage Forms and Strengths, Contraindications, Warnings and Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations, or Microbiology.

Content of Labeling	
Solutions for fixing content of labeling errors.	
Error	**Solution**
If there is an excerpt, then it only has highlight text.	Include only highlights text in the excerpt
An excerpt in the adverse reactions section (34084-4) includes the statement: "to report suspected adverse reactions" and "1-800-FDA-1088" (different telephone number for documents of type 53404-0 – “Vaccine Label”).	The highlights text of the adverse reactions section includes the statement "to report suspected adverse reactions" and "1-800-FDA-1088" Use a different telephone number for documents of type “Vaccine Label”.
If there are highlights excerpts, then the title for the SPL file includes the text string (without the quotation marks): “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”	If there is highlights text then the SPL document title should include the following text string without quotation marks: “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”
Section for Medication Guide (42231-1) and Patient Package Insert (42230-3) is not a subsection.	Do not include the medication guide or patient package insert section as a subsection.
If the marketing category code is not C73626 (bulk ingredient) or C73613 (unapproved medical gas), then there is at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	If the marketing category for the product is NOT bulk ingredient or unapproved medical gas then there should be at least one other content of labeling section besides the Principal Display Panel and SPL Listing Data Elements sections.
Missing or insufficient content of labeling	**DO NOT** submit content of labeling as a jpeg. Add the text, tables and figures from the package insert or drug facts to each appropriate section of the SPL content of labeling. Include the content of labeling

Predecessor (Related Document)	
Solutions for errors related to “RelatedDocument” SPL Files	
Error	**Solution**
setId is different from the present document’s setId.	Ensure that the setID for the document that is to be replaced in the RelatedDocument section is not the same as the set ID of this file.
Document id, type, and versionNumber match the latest document previously submitted under that setId.	The document root ID, version number in the “relatedDocument” (a similar document with a different setID which is to be replaced) should match the previously submitted version of the document which is being replaced.

Images	
For issues with referencing images, see details below	
Error	**Solution**
Reference value must be the file name for the image	Ensure that you have referenced the image in the appropriate content of labeling section. Verify that you have use the same case of letters for the image file name and in the image file name field of the SPL file. - If you are using the Pragmatic Data Validator Lite tool, zip the image with the SPL document and upload the zip file. **HOWEVER, DO NOT** send a zip file to FDA. - Ensure that you have placed the image in the folder that has the SPL document.
File is a JPEG and the name has the extension “.jpg”	Image file should be a JPEG and should only have a file extension of “.jpg” (file name should be in lower case letters only)
Image components are referenced at least once in the text of any section.	Reference each image at least once in the text of any section
There is text	Include a text description of the image for the computer screen readers to provide the description of image to the visually impaired.

Images	
For issues with referencing images, see details below	
Error	**Solution**
All image files associated with the SPL document must be actually referenced from that SPL document.	Ensure that all files included in the folder are referenced in the SPL document.
Remove extra jpg extension	Do not include an extra jpg extension such as ".jpg.jpg" Use one instead ".jpg"
Size of image file is less than 1 MB	Reduce the size of each image file to under one megabyte (MB)
Media type is image/jpeg	Media type if image/jpeg
Image reference in text has an image "observationMedia" element with a matching ID in the same document.	Image reference in text has an image "observationMedia" element with a matching ID in the same document. The "ID" is the image ID.

Miscellaneous Errors	
Determine the source of and locate the solution for the errors in one's content of labeling/product data elements SPL document in the list below.	
Error/Comment	**Solution**
The document body contains two or more sections	Include more than one section in your content of labeling/listing (CoL/listing) document. However, do not include just one "content of labeling" section to "mislead" the validator. Include a content of labeling in the SPL document for each section in your content of labeling.
One section contains the product data elements	Include a section with product data elements
There is one or more products	Describe one or more products in the product data element section. Each product should its own product data elements section.
Product data element section has an id	In this instance, the "id" identifies a section. Include a GUID as the id for the section.
id root is a GUID and has no extension.	In this instance, the "id" identifies a section. Include a GUID as the id for the section. Do not include an extension.
There is an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the **section's** effective time field using the YYYYMMDD format (e.g. Enter 20131221 for December 21, 2013)

Transmission of an SPL Document	
One will receive these errors if one does not observe the proper procedures for packaging and sending an SPL document.	
Error Message	**Solution**
SPL document not enclosed within a directory (folder). See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Enclose the SPL document in a folder and **upload the folder** containing the file via the FDA Gateway **OC** portal. The path name in the Gateway field should end in the folder name, not the SPL file name.
<This submission ci1257520697672.5960@llntap02_te.1.zip is incorrectly packaged, it is a ZIP file, not a directory. See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Remove SPL file and, if applicable, image files from the **zip file** place in a **single folder** and resubmit via FDA Gateway **OC** portal.
Multiple SPL files or Submit one SPL file per folder	Include only one SPL document and, if applicable, associated image files per folder.
Extra folder layers	Send the SPL files and, if applicable, associated image files in a single folder.
A submission must contain only the SPL file whose name ends in '.xml' and associated image files whose names end in '.jpg'.	The file extension of the SPL document should be ".xml" (**lower case** letters only) The file extension of the JPEG image files should be ".jpg" (**lower case** letters only) **DO NOT** insert PDF, Excel or Word documents in the folder with the SPL or image files. **DO NOT** send PDF, Excel, or Word documents to the FDA **OC** Gateway portal.
Do not send zip files	**DO NOT** insert zip files in folder with SPL document. **DO NOT** send SPL document and, if applicable, associated image files in a zip file. You may zip SPL and image file to test submission via Pragmatic Data Validator Lite tool, but unzip submission prior to sending FDA.

Transmission of an SPL Document	
One will receive these errors if one does not observe the proper procedures for packaging and sending an SPL document.	
Error Message	**Solution**
Do not send SPL Xforms	Send the SPL documents, not the SPL Xforms used to create SPL document. You should not send any files which have this file extension: “xhtml” SPL documents have this file extension: “xml”
Do not send short cut file	Do not send the short cut file, send the actual file.

SPL Schema or Coding Errors	
The SPL documents must conform to the SPL schema. Basic schema-related errors are listed below.	
Error Message	**Solution**
There must not be empty or incomplete elements except, in certain circumstances, code, title, text, and time (an id must have a root, a code must have a code system).	Ensure that you have completed the appropriate fields
The value '' of attribute 'code' on element 'formCode' is not valid with respect to its type, 'cs'.	Ensure that you have completed the appropriate fields
Value '' with length = '0' is not facet-valid with respect to minLength '1' for type 'st'.	Ensure that you have completed the appropriate fields
If there is a confidentiality code, then the code is “B” and the codeSystem is “2.16.840.1.113883.5.25”	Add the code “B” and the Object Identifier (OID) “2.16.840.1.113883.5.25” if there is a confidentiality code.
Act definition display name matches code	Ensure that the display name for business operation matches the corresponding concept code for that business operation.
Code system is 2.16.840.1.113883.6.69	Use the code system (2.16.840.1.113883.6.69) for Food and Drug Administration Drug Registration and Listing System
Form code has the code system 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus

SPL Schema or Coding Errors	
The SPL documents must conform to the SPL schema. Basic schema-related errors are listed below.	
Error Message	**Solution**
Display name matches the code	Ensure that the display name matches the code. There is a code for each term. If you receive this error, the code may not have populated the field correctly or you did not use the correct code.
Class code for active ingredients are ACTIB, ACTIM or ACTIR	For the active ingredients, you can only use the following class codes “ACTIB,” “ACTIM,” or “ACTIR”
Code system is 2.16.840.1.113883.4.9	Use the code system (2.16.840.1.113883.4.9) for Food and Drug Administration Substance Registration System
Code system for the translation code is 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) National Cancer Institute Thesaurus
Display name matches form code	Ensure that the display name matches the code.
Code system for NDC Package Code is 2.16.840.1.113883.6.69	Use the code system (2.16.840.1.113883.6.69) for Food and Drug Administration Drug Registration and Listing System
Code is C53292 and code system is 2.16.840.1.113883.3.26.1.1.	Include the marketing status code and use the code system (2.16.840.1.113883.3.26.1.1) National Cancer Institute Thesaurus
If there is a DEA schedule, then the code system is 2.16.840.1.113883.3.26.1.1	If there is a DEA scheduled then use code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus
The policy element has a class code of ‘DEADrugSchedule’.	If there is a DEA schedule then the class code is DEADrugSchedule.
Value code system is 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus
Display name matches the value code	Ensure that the display name matches the value code
Route code system is 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus