

## Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing

This document describes computer instructions for automating the validation of Structured Product Labeling (SPL) release 4 files for the drug establishment registration and drug listing process at FDA. Information on electronic submission may be found in guidance entitled *Providing Regulatory Submissions in Electronic Format – Establishment Registration and Drug Listing*. A link to the latest SPL schema and controlled terminology used in SPL and other technical documents may be found on the FDA Data Standards Council web site at: [www.fda.gov/oc/datacouncil/spl.html](http://www.fda.gov/oc/datacouncil/spl.html).

1	SPL Header .....	2
1.1	General .....	2
1.2	XML references .....	2
1.3	Document information .....	2
1.4	Labeler and manufacturing information- NDC Labeler Code Request .....	4
1.4.1	Document type .....	4
1.4.2	Labeler information .....	4
1.4.3	Labeler contact party.....	4
1.5	Labeler and manufacturing information – Establishment registration .....	5
1.5.1	Document type .....	5
1.5.2	Registrant information .....	5
1.5.3	Establishment information .....	5
1.5.4	Establishment US agent .....	6
1.5.5	Import business .....	7
1.5.6	Establishment operation.....	7
1.6	Labeler and manufacturing information – Drug Listing.....	7
1.6.1	Labeler information .....	7
1.6.2	Registrant information .....	8
1.6.3	Establishment information .....	8
2	SPL Body .....	9
2.1	Product data elements .....	9
2.1.1	Product .....	9
2.1.2	Product source.....	10
2.1.3	Active ingredient.....	10
2.1.4	Inactive ingredient .....	11
2.1.5	Packaging.....	12
2.1.6	Parts.....	13
2.1.7	Marketing category .....	14
2.1.8	Marketing date .....	14
2.1.9	DEA schedule .....	15
2.1.10	Color .....	15
2.1.11	Shape.....	15
2.1.12	Size.....	15
2.1.13	Scoring .....	16
2.1.14	Imprint code .....	16

2.1.15	Flavor .....	16
2.1.16	Contains .....	17
2.1.17	Image.....	17
2.1.18	Route of administration.....	17
2.2	Content of labeling.....	18
2.2.1	Sections.....	18
2.2.2	Images.....	18
2.2.3	Highlights.....	18

## 1 SPL Header

### 1.1 General

General procedures

- Procedures
  - XML is well formed and valid against the schema
  - There are no data elements and attributes in addition to those described in this document
  - There are no spaces in codes or id extensions
  - Letters in Globally Unique Identifiers (GUID) are lower case
  - Display names are case insensitive
  - SPL file name is the id root followed by “.xml”

### 1.2 XML references

This is the reference to the character set, stylesheet, name space and schema

- `<?xml version="1.0" encoding="UTF-8"?>`
- `<?xml-stylesheet href="http://www.accessdata.fda.gov/spl/stylesheet/spl.xml" type="text/xsl"?>`
- `<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd">`
- Procedures
  - XML references are as in the example above

### 1.3 Document information

This contains information on the type of document and versioning

- `<id root="50606941-3e5d-465c-b4e0-0f5a19eb41d4"/>`
- Procedures

## Structured Product Labeling Release 4 validation procedures v1.0

- There is an id root
- id root is a Globally Unique Identifier (GUID).
- id root does not match any other id root
- id root is unique in the database
  
- `<code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName="Establishment registration"/>`
- Procedures
  - There is a code
  - Code system is 2.16.840.1.113883.6.1
  - Code comes from the *Document type* list
  - Display name matches the code
  
- `<title/>`
- Procedures
  - If there are highlights excerpts, the title for the SPL file includes the text string (without the quotation marks):
    - “These highlights do not include all of the information needed to use”
    - "see full prescribing information for"
    - “Initial U.S. Approval:”
  - If there are highlights excerpts, the excerpt in the adverse reactions section (34084-4) includes the statement: "to report suspected adverse reactions" and "1-800-FDA-1088".
  - No figures allowed in the title
  
- `<effectiveTime value="20070424"/>`
- Procedures
  - There is an effective time with at least the precision of day in the format `yyyymmdd`
  
- `<setId root="a30acceff437-4136-808c-9ed4ada5fcf8"/>`
- Procedures
  - There is a setId
  - setId is a GUID
  
- `<versionNumber value="1"/>`
- Procedures
  - There is a version number
  - Value is a whole number > 0
  - Value is greater than the value of any previously submitted version for the same setId

## 1.4 *Labeler and manufacturing information- NDC Labeler Code Request*

### 1.4.1 Document type

- `<code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC Labeler Code request"/>`
- Procedures
  - Document type as above
  - Display name matches code

### 1.4.2 Labeler information

- `<author><assignedEntity>`
  - `<representedOrganization>`
    - `<id extension="100000002" root="1.3.6.1.4.1.519.1"/>`
    - `<id extension="0001" root="2.16.840.1.113883.6.69"/>`
    - `<name>Mann's drug Store</name>`
- Procedures
  - There are two id extensions
  - One id extension has the root 1.3.6.1.4.1.519.1
  - Name matches id extension with the root 1.3.6.1.4.1.519.1 in the database
  - One id extension has the root 2.16.840.1.113883.6.69
  - id extension with the root 2.16.840.1.113883.6.69 is not associated with any other setId

### 1.4.3 Labeler contact party

- `<contactParty>`
  - `<addr>`
    - `<streetAddressLine>1625 29th street</streetAddressLine>`
    - `<city>Camden</city>`
    - `<state>NJ</state>`
    - `<postalCode>08101</postalCode>`
    - `<country>USA</country>`
  - `</addr>`
  - `<telecom value="tel:+1-800-555-1213;ext=112"/>`
  - `<telecom value="mailto:Bob.Jones@acme.com"/>`
  - `<contactPerson> <name>Bob Jones</name></contactPerson>`
- `</contactParty>`
- Procedures
  - There is one contact party
  - Contact party has a street address line, city, and country
  - If the country is USA, then the contact party has a state and postal code
  - There are two or more `<telecom>` elements
  - One telecom value begins with "tel:"
  - Telephone numbers are: global telephone numbers; no letters; begin with "+"; include hyphens to separate the country code, area codes and

subscriber number; extensions are separated by “;ext=” (see Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966)

- One telecom value begins with “mailto:”
- There is one contact person name

## ***1.5 Labeler and manufacturing information – Establishment registration***

### **1.5.1 Document type**

- `<code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName="Establishment registration"/>`
- Procedures
  - Document type is as above, “No change notification” or “Out of business notification”
  - Display name matches code

### **1.5.2 Registrant information**

- `<author><assignedEntity>`
  - `<representedOrganization>`
    - `<assignedEntity>`
      - `<assignedOrganization>`
        - `<id extension="100000001" root="1.3.6.1.4.1.519.1"/>`
        - `<name>Acme drug company</name>`
        - `<contactParty>`
- Procedures
  - If the document type is “No change notification” or “Out of business notification”, there is no registrant information, otherwise there is registrant information
  - There is one id extension
  - id extension has the root 1.3.6.1.4.1.519.1
  - There is one name
  - Name matches the id extension in database
  - id is not associated with any other setId for document type “Establishment registration”
  - There is one contact party (see the procedures for contact party above)

### **1.5.3 Establishment information**

- `<assignedEntity>`
  - `<assignedOrganization>`
    - `<id extension="100000001" root="1.3.6.1.4.1.519.1"/>`
    - `<id extension="123456"/>`
    - `<name>Middleton Manufacturing company</name>`
    - `<addr>`
      - `<streetAddressLine>123 Burl Road</streetAddressLine>`

- <city> Dublin</city>
  - <state></state>
  - <postalCode></postalCode>
  - <country>IRL</country>
- </addr>
- <contactParty>
- Procedures
  - If the document type is “No change notification” or “Out of business notification”, there is no establishment information, otherwise there is establishment information
  - There are one or more establishments if the document type is “establishment registration”
  - Each establishment has one or two id extensions
  - One id extension has the root 1.3.6.1.4.1.519.1
  - There is one name for each establishment
  - Each establishment has a street address line, city, and country
  - If the country is USA, then the establishment has a state and postal code
  - Name matches id extension with the root 1.3.6.1.4.1.519.1 in the database
  - There is one contact party (see the procedures for contact party above)

#### 1.5.4 Establishment US agent

- <assignedEntity>
  - <assignedOrganization>
    - <id extension="100000001" root="1.3.6.1.4.1.519.1"/>
    - <name>Simmons Reps Company</name>
    - <telecom value="tel:+1-800-555-1212"/>
    - <telecom value="mailto:contact@USagent.com"/>
  - </assignedOrganization>
  - <performance>
    - <actDefinition>
      - <code code="C73330" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="United States agent"/>
- Procedures
  - If the country code for the establishment is not USA, then there is a US agent
  - If the country code for the establishment is USA, then there is no US agent
  - US agent element has an id extension
  - id extension has the root 1.3.6.1.4.1.519.1
  - There is one name
  - Name matches id extension in database
  - There are two or more <telecom> elements
  - One telecom value begins with “tel:”
  - One telecom value begins with “mailto:”

- Code, code system and display name are as above

### 1.5.5 Import business

- <assignedEntity>
  - <assignedOrganization>
    - <id extension="100000005" root="1.3.6.1.4.1.519.1"/>
    - <name>Waytogo importers</name>
    - <telecom value="tel:+1-800-555-1214"/>
    - <telecom value="mailto:contact@waytogo.com"/>
  - </assignedOrganization>
  - <performance>
    - <actDefinition>
      - <code code=" C73599" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="import"/>
- Procedures
  - If the country code for the establishment is not USA, then there may be one or more import businesses each with an id extension
  - If the country code for the establishment is USA, then there are no import businesses
  - Each business has one id extension
  - id extension has the root 1.3.6.1.4.1.519.1
  - There is one name for each business
  - Name matches id extension in database
  - There are two or more telecom
  - One telecom value begins with “tel:
  - One telecom value begins with “mailto:
  - Code, code system and display name as above

### 1.5.6 Establishment operation

- <performance>
  - <actDefinition>
    - <code code="C43360" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="manufacture"/>
- Procedures
  - There are one or more codes
  - Code system is 2.16.840.1.113883.3.26.1.1
  - Display name matches the code

## 1.6 Labeler and manufacturing information – Drug Listing

### 1.6.1 Labeler information

- <assignedEntity>

- <representedOrganization>
  - <id extension="100000007" root="1.3.6.1.4.1.519.1"/>
  - <name>Acme drug company</name>
- Procedures
  - There is one labeler
  - There is one id extension
  - id extension has the root 1.3.6.1.4.1.519.1
  - id extension match the NDC Labeler Code portion of the NDC Product Code in the database
  - There is one name
  - Name matches id extension in database

### 1.6.2 Registrant information

- <assignedEntity>
  - <assignedOrganization>
    - <id extension="100000008" root="1.3.6.1.4.1.519.1"/>
    - <name>Acme drug company</name>
- Procedures
  - There is 0 to 1 registrant
  - If there is a <confidentialityCode>, the code is “B”
  - If there is a registrant, there is one id extension
  - id extension has the root 1.3.6.1.4.1.519.1
  - If there is a registrant, there is one name
  - Name matches id extension in database

### 1.6.3 Establishment information

- <assignedEntity>
  - <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
  - <assignedOrganization>
    - <id extension="1000000019" root="1.3.6.1.4.1.519.1"/>
    - <name>Middleton Manufacturing company</name>
  - </assignedOrganization>
  - <performance>
    - <actDefinition>
      - <code code="C43360" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="manufacture"/>
- Procedures
  - There are one or more establishments
  - If there is a <confidentialityCode>, the code is “B”
  - Each establishment has one id extension
  - id extension has the root 1.3.6.1.4.1.519.1
  - There is one name
  - Name matches id extension in database



- Display name matches code
- Act definition code matches code for establishment with same id extension in document type “establishment registration”

## 2 SPL Body

The beginning of the SPL body

`<component><structuredBody>`

### 2.1 Product data elements

The beginning of the product data elements

- `<component>`
  - `<section>`
    - `<id root="e13a985b-f706-a5c8-e8ef-73891eb1c697"/>`
    - `<code code="48780-1" codeSystem="2.16.840.1.113883.6.1" displayName="SPL listing data elements section"/>`
    - `<effectiveTime value="20070424"/>`
  - Procedures
    - Product data element section has an id root
    - id root is a GUID
    - Code, code system and display name are as above
    - There is an effective time with at least the precision of day in the format `yyyymmdd`

#### 2.1.1 Product

- `<subject>`
  - `<manufacturedProduct>`
    - `<manufacturedProduct>`
      - `<code code="0001-0001" codeSystem="2.16.840.1.113883.6.69"/>`
      - `<name>Tazmin <suffix>XR</suffix></name>`
      - `<formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="tablet"/>`
      - `<asEntityWithGeneric>`
        - `<genericMedicine>`
      - `<name>tazminate hydrochloride</name>`
        - `</genericMedicine>`
    - Procedures
      - Code system is 2.16.840.1.113883.6.69
      - Code has two segments separated by a hyphen

- Segments follow the pattern of 4-4, 5-4 or 5-3 except when the document type is for minimally manipulated cell products or non standardized allergenic products where the pattern may be 5-5
- Code is not associated with another setId
- First segment matches an NDC Labeler Code associated with the Labeler id in the Labeler and Manufacturing section
- There is a name
- There is a form code
- Form code has the code system 2.16.840.1.113883.3.26.1.1
- If the product has parts, the form code is C47916
- Display name matches the code
- There is a generic medicine name
- If the NDC Product Code is in the database with a marketing status date the same or later than the current date, then the product and generic name, active ingredient UNII, dosage form, active ingredient strength, product characteristics of size, shape, color and imprint code are the same

### 2.1.2 Product source

- `<asEquivalentEntity classCode="EQUIV">`
  - `<code code="C64637" codeSystem="2.16.840.1.113883.3.26.1.1">`
  - `<definingMaterialKind>`
    - `<code code="source NDC Product Code" codeSystem="2.16.840.1.113883.6.69"/>`
- Procedures
  - As equivalent entity class code, code and code system are as above
  - Defining material kind code matches a NDC Product Code in a SPL file with a different setId

### 2.1.3 Active ingredient

- `<ingredient classCode="ACTIR">`
  - `<quantity>`
    - `<numerator value="10" unit="mg"/>`
    - `<denominator value="1" unit="1"/>`
  - `</quantity>`
  - `<ingredientSubstance>`
    - `<code code="1234567890" codeSystem="2.16.840.1.113883.4.9"/>`
    - `<name>tazminate malate</name>`
    - `<activeMoiety>`
      - `<activeMoiety>`
        - `<code code="0987654321" codeSystem="2.16.840.1.113883.4.9"/>`
        - `<name>tazminic acid</name>`

- `</activeMoiety>`
  - `</activeMoiety>`
  - `<asEquivalentSubstance>`
    - `<definingSubstance>`
      - `<code code="A123455678" codeSystem="2.16.840.1.113883.4.9"/>`
      - `<name>tazemate formate</name>`
- Procedures
  - There are zero to many active ingredients
  - If the product has parts, the active ingredients are under parts
  - Class code for active ingredients are ACTIB, ACTIM or ACTIR
  - There is a strength with a numerator and denominator
  - Numerator and denominator have a value and unit
  - Unit comes from the *UCUM units of measures* list
  - There is an ingredient code
  - Code system is 2.16.840.1.113883.4.9
  - There is an ingredient name
  - Ingredient name matches the code
  - There are one or two active moieties
  - There is an active moiety code for each active moiety
  - Code system is 2.16.840.1.113883.4.9
  - There is an active moiety name for each active moiety
  - Active moiety name does not include any of the names in the *Active moiety validation* list
  - Active moiety name matches the code
  - If the class code is ACTIR, there is an `<asEquivalentSubstance>` data element with a code and name
  - Code system is 2.16.840.1.113883.4.9

#### 2.1.4 Inactive ingredient

- `<ingredient classCode="IACT">`
  - `<confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>`
  - `<quantity>`
    - `<numerator value="50" unit="mg"/>`
    - `<denominator value="1" unit="1"/>`
  - `</quantity>`
  - `<ingredientSubstance>`
    - `<code code="010202020" codeSystem="2.16.840.1.113883.4.9"/>`
    - `<name>secret dioxide</name>`
- Procedures
  - There are zero to many inactive ingredients
  - If the product has parts, the inactive ingredients are under parts
  - Class code is IACT
  - If there is a `<confidentialityCode>`, the code is “B”
  - There may be a strength with a numerator and denominator

- If there is a strength, then numerator and denominator have a value and unit
- Unit comes from the *UCUM units of measures* list
- There is an ingredient code
- Code system is always 2.16.840.1.113883.4.9
- There is an ingredient name
- Ingredient name matches the code

## 2.1.5 Packaging

- <asContent>
  - <quantity>
    - <numerator value="100" unit="1">
      - <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="tablet"/>
    - </numerator>
    - <denominator value="1"/>
  - </quantity>
  - <containerPackagedProduct>
    - <code code="0001-0001-05" codeSystem="2.16.840.1.113883.6.69"/>
    - <formCode code="C43169" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="bottle"/>
- Procedures
  - There is an “as content” data element
  - Quantity includes a numerator and denominator
  - Numerator has a value and unit
  - If the product has parts, the initial numerator’s value and unit is “1”
  - Unit of the initial package is the same as the unit for the denominator of the strength
  - There is a translation of the numerator unit if the unit is “1”
  - If the numerator unit is not “1”, there is no translation
  - Translation code is from the *unit of presentation* list
  - Code system for the translation code is 2.16.840.1.113883.3.26.1.1
  - Translation display name matches the translation code
  - If a product has parts, the translation code for the initial numerator is “C48504”
  - Denominator is as above
  - There is a form code and display name
  - Code system for form code is 2.16.840.1.113883.3.26.1.1
  - Display name matches form code
  - There is a container packaged product code for outermost package
  - Container packaged product code is 10 characters

- Code system for NDC Package Code is 2.16.840.1.113883.6.69
- NDC Package Code contains three segments divided by hyphens except for SPL files with document types for minimally manipulated cell products and non standardized allergenic products where the package code may only have two segments
- The first two segments of the NDC Package Code matches the NDC Product Code
- If the NDC Package Code is in the database with a marketing status date the same or later than the current date, then the package form code and quantity value and unit are the same

## 2.1.6 Parts

Products with one or more parts

- <part>
  - <quantity>
    - <numerator value="1" unit="1"/>
    - <denominator value="1"/>
  - </quantity>
  - <partProduct>
    - <code code="0001-0001" codeSystem="2.16.840.1.113883.6.69"/>
    - <name>Tazmin <suffix>XR</suffix></name>
    - <formCode code="C42916" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="capsule, extended release"/>
    - <asEntityWithGeneric>
      - <genericMedicine>
        - <name>tazminate hydrochloride</name>
- Procedures
  - Each part has an overall quantity
  - 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
  - If there is no “as content” data element in the part, then the numerator unit is 1
  - If there is a code, the code has two segments (first segment is numeric) separated by a hyphen
  - Segments follow the pattern of 4-4, 5-4 or 5-3 except when the document type is for minimally manipulated cell products or non standardized allergenic products where the pattern may be 5-5
  - If there is a code, the code system is 2.16.840.1.113883.6.69
  - There is a name
  - There is a form code
  - Form code has the code system 2.16.840.1.113883.3.26.1.1
  - Display name matches the code

- There is a generic medicine name
- Procedures for source, ingredients, characteristics and packaging are the same as for products without parts

### 2.1.7 Marketing category

- <subjectOf>
  - <approval>
    - <id extension="NDA123456" root="2.16.840.1.113883.3.150"/>
    - <code code="C70882" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="NDA"/>
    - <author>
      - <territorialAuthority>
      - <territory>
        - <code code="USA" codeSystem="2.16.840.1.113883.5.28"/>
- Procedures
  - If the code is C73583, C73584, C73585, C73588, C73593, C73594, C73605 then the id root is 2.16.840.1.113883.3.150
  - If the code is C73603 or C73604, then the id root is 2.16.840.1.113883.3.149
  - If the code display is neither of the above, the id null flavor is "OTH"
  - There is a code for each product and product part
  - Code comes from the *Marketing category* list
  - Display name matches the code
  - Code system is 2.16.840.1.113883.3.26.1.1
  - Territorial authority is as above

### 2.1.8 Marketing date

- <subjectOf>
  - <marketingAct>
    - <code code="C53292" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    - <statusCode code="active"/>
    - <effectiveTime>
      - <low value="20040120"/>
- Procedures
  - There is a marketing status code for each product
  - Code is as above
  - Status code is *active* or *completed*
  - If the status code is *active*, there is a low value and no high value
  - If the code is *completed*, there is a low and high value
  - There is an effective time with at least the precision of day in the format *yyyymmdd*

## 2.1.9 DEA schedule

- <subjectOf>
  - <policy classCode="DEADrugSchedule">
    - <code code="C48675" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="CII"/>
- Procedures
  - If there is a DEA schedule, the code system is 2.16.840.1.113883.3.26.1.1
  - Display name matches the code

## 2.1.10 Color

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLCOLOR" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value code="C48333" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="blue" xsi:type="CE">
  - <originalText>LIGHT BLUE</originalText>
- Procedures
  - If the dosage form is on the *solid oral dosage form* list, then there is a color, otherwise color is optional
  - Class code, code and code system is as above
  - Value code system is 2.16.840.1.113883.3.26.1.1
  - Display name matches the value code

## 2.1.11 Shape

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLSHAPE" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value code="C48336" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="capsule" xsi:type="CE"/>
  - <originalText>"capsule like"</originalText>
- Procedures
  - If the dosage form is on the *solid oral dosage form* list, then there is a shape
  - Class code, code and code system is as above
  - Value code system is 2.16.840.1.113883.3.26.1.1
  - Display name matches the value code

## 2.1.12 Size

- <subjectOf>

- <characteristic classCode="OBS">
  - <code code="SPLSIZE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  - <value unit="mm" value="18" xsi:type="PQ"/>
- Procedures
  - If the dosage form is on the *solid oral dosage form* list, then there is a size
  - Class code, code and code system is as above
  - There is a unit and value
  - Value units is mm
  - Display name matches the value code

### 2.1.13 Scoring

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLSCORE" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value value="1" xsi:type="INT"/>
- Procedures
  - If the dosage form is on the *solid oral dosage form* list, then there is scoring
  - Code and code system is as above
  - The value is 1, 2, 3, 4 or nullFlavor="OTH"

### 2.1.14 Imprint code

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLIMPRINT" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value xsi:type="ST">05</value>
- Procedures
  - Class code, code and code system is as above
  - Value has only letters and numbers separated by semicolon without spaces

### 2.1.15 Flavor

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLFLAVOR" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value code="C73391" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="grape" xsi:type="CE">
  - <originalText>wild grape</originalText>
- Procedures
  - If there is a flavor, class code, code and code system is as above
  - Value code system is 2.16.840.1.113883.3.26.1.1



- Display name matches the value code

### 2.1.16 Contains

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLCONTAINS" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value code="C00000" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="example" xsi:type="CE">
  - <originalText>contains peanuts</originalText>
- Procedures
  - If there is contains, then class code, code and code system is as above
  - Value code system is 2.16.840.1.113883.3.26.1.1
  - Display name matches the value code
  - Code pending

### 2.1.17 Image

- <subjectOf>
  - <characteristic classCode="OBS">
    - <code code="SPLIMAGE" codeSystem="2.16.840.1.113883.1.11.19255"/>
    - <value xsi:type="ED" mediaType="image/jpeg"><reference value=" 8837a946-1912-4c1f-8035-e313fdd11ef2.jpg"/>
- Procedures
  - If there is SPL image, class code, code and code system is as above
  - Value xsi:type is as above
  - Reference value is the file name for the image
  - Image file obtained from FDA has the file name assigned by FDA and is submitted together with the SPL file

### 2.1.18 Route of administration

- <consumedIn>
  - <substanceAdministration>
    - <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="oral"/>
- Procedures
  - There is one or more “consumed in”
  - Route code system is 2.16.840.1.113883.3.26.1.1
  - Display name matches the code

## 2.2 Content of labeling

### 2.2.1 Sections

- <component>
  - <section>
    - <id root="62abedf9-6bde-4787-beb0-abd214307427"/>
    - <code code="34067-9" codeSystem="2.16.840.1.113883.6.1" displayName="Indications and Usage"/>
    - <title>Indications and Usage</title>
    - <text>labeling text</text>
    - <effectiveTime value="20070822"/>
  - Procedures
    - Each section has zero to many subsections
    - Each section has an id root
    - id root is a GUID
    - Each section has a code
    - Code system is 2.16.840.1.113883.6.1
    - Display name matches the value code
    - There is an effective time with at least the precision of day in the format yyyyymmdd

### 2.2.2 Images

- <component>
  - <observationMedia ID="MM1">
    - <text>descriptive text</text>
    - <value xsi:type="ED" mediaType="image/jpeg">
      - <reference value="04056a1a-cadb-48d8-b7c5-17d4cda3924b.jpg"/>
    - </value>
  - Procedure
    - There is text
    - Media type is image/jpeg
    - Reference value is the file name for the image
    - File name has the extension “.jpg”

### 2.2.3 Highlights

- <excerpt>
  - <highlight>
    - <text></text>
- Procedures
  - Excerpts are optional

## Structured Product Labeling Release 4 validation procedures v1.0

- Excerpts only occur 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)
- If there is an excerpt, it only has highlights text data elements