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| DRAFT Guidance Document: Preparation of Product Monographs in the Extensible Markup Language Format  Appendix 1: Validation Rules |
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Health Products and Food Branch



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# Introduction

This document serves as an appendix to the *Guidance Document: Preparation of Product Monographs in the Extensible Markup Language Format.*

This document provides detailed guidance on how to build and validate a product monograph based on Extensible Markup Language (XML) and Health Level 7’s (HL7) Structured Product Label (SPL) standard.

# Purpose

To provide sponsors with detailed technical guidance on the XML hierarchy, technical conformance rules and technical validation rules needed to prepare a valid XML product monograph in compliance with the HL7 SPL standard.

# General Technical Conformance Requirements

## Identifiers

Unless stated otherwise (e.g., Hyperlink ID or Observation Media ID), identifiers shall be Globally Unique Identifiers (GUID). This includes but is not limited to the following:

* Document Root ID
* ID
* SetId
* Section ID

GUID’s should follow the canonical structure, content and formatting rules; e.g., displayed in five groups separated by hyphens, in the form 8-4-4-4-12 for a total of 36 characters (32 alphanumeric characters and four hyphens).

It is the sponsor’s responsibility to ensure that there are no collisions between identifiers.

## Content Changes and Versioning

Any change to content requires an update to the effectiveTime and/or the identifier.

In the case where the content change occurs in an element that does not have an identifier or effectiveTime then the closest version-able parent element must be versioned. Examples of versioning:

1. Changing an image would require the observationMedia@ID to be versioned.
2. Changing the content of a section would require both the section@ID and the effectiveTime@value of the section to be versioned.
3. Changing the content of a section would require both the section@ID and the effectiveTime@value of the section to be versioned.
4. Changing the content of a subsection would require both the section@ID and the effectiveTime@value of the subsection to be versioned, however the parent section would not be versioned as the child contains both an ID and an effectiveTime element.

## File Type

Only file formats detailed in the table below are permitted in the SPL output:

**Table 1 List of acceptable file types**

| **File Format** | **Description** | **Specifications** | **Extension** |
| --- | --- | --- | --- |
| JPEG/JFIF | Joint Photographic Experts Group (JPEG) / JPEG File Interchange Format (JFIF) is a compression standard for encoding and exchanging still digital raster files. | ISO 10918-1 | jpg |
| PDF/A-1 | Portable Document Format Archive version 1, is an archival format designed for long term preservation of digital files based on Adobe PDF v1.4 | ISO 19005-1 | pdf |
| PDF/A-2 | Portable Document Format Archive version 2, is an archival format designed for long term preservation of digital files based on Adobe PDF v1.7 | ISO 19005-2 | pdf |
| XML | Extensible Markup Language (XML) is a markup language that defines document encoding rules. | W3C XML 1.0 | xml |

## SPL File name

The SPL content (e.g., xml and images) must always be placed in a single SPL folder.

The .xml file must be named with GUID from the documentID.

It is the sponsor’s responsibility to ensure there are no content naming collisions between any of the files in the SPL folder.

## External File References

All files associated with the SPL document are referenced in the .xml.

## Codes

There are no spaces in codes.

## Case Sensitivity

There is no general case sensitivity rule.

## Display Name

All display names are language specific. When derived from a controlled vocabulary the display name shall match the language of the document; e.g., French display name for a French document and English display names for English documents.

## Image Quality

All images will be displayed as is without transformation or modification. Therefore, images shall be of sufficient quality and size to be legible by end users.

## Date and Time

Time values (such as effectiveTime@value, [effectiveTime.low@value](mailto:effectiveTime.low@value) and effectiveTime.high@value) are based on ISO-8601. They use the following format YYYYMMDDHHMMSS+”GMT offset”.

All values other than the + symbol are integers; the time aspect is based on a 24hr notation; and, unless specified otherwise, use the Time Zone offset assumed to be GMT time.

YYYY represents the year and is 4 digits; MM represents the month and is 2 digits; DD represents the day and is 2 digits; HH represents the hour and is 2 digits; MM represents the minutes and is 2 digits; SS represents the seconds and is 2 digits.

The time may be followed by a + (plus) or a - (minus) symbol and a Time Zone offset from GMT expressed as 4 digits. While the ISO standard provides many options the HPFB only allows for the following three permutations on time values:

1. Date Only: in this model the string is limited to YYYYMMDD
2. Date and GMT Time: in this model the string is limited to YYYYMMDDHHMMSS
3. Date and Local Time: in this model the GMT offset is added as an example YYYYMMDDHHMMSS-0500 represents EST. The offset is static and therefore must be manually adjusted for Daylight Saving Time as appropriate.

## Narrative Text

No text (i.e., <text><paragraph></paragraph></text>) is to appear immediately under the following major section headings.

* Title Page
* Part I: Health Professional Information
* Part II: Scientific Information
* Part III : Patient Medication Information

With respect to the above mentioned section headings, text can only appear under the sub-headings; e.g., text cannot appear immediately under Part I but text is meant to appear under section 1 Indications.

Text is meant to appear directly under the Recent Major Changes section heading.

## General Validation Rules

1. XML is well formed and valid against the schema
2. There are no data elements and attributes in addition to those described in this document
3. There are no spaces in codes
4. Codes must have a codeSystem name attribute
5. Display names are case insensitive
6. There are no spaces in id extensions
7. Letters in Globally Unique Identifiers (GUID) are lower case
8. There are no empty or incomplete elements except
9. Characteristics have no class code at all
10. There are no confidentiality codes

# XML Prolog

## Description

The XML version, character encoding, the schema and the location of the schema.

## XML Sample

<?xml version="1.0" encoding="UTF-8"?>

<?xml-stylesheet href="https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/current/hpfb-spm-core.xsl"?>

<?xml-stylesheet href="https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/current/hpfb-spm.css"?>

<document xmlns="urn:hl7-org:v3"

xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"

xsi:schemaLocation="https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd">

## Validation Rules

1. XML reference is for version 1.0 and encoding “UTF-8”.
2. There is an xml-stylesheet reference to <https://github.com/HealthCanada/HPFB/blob/master/Structured-Product-Labeling-(SPL)/Style-Sheets/current/hpfb-spm.xsl>
3. The schemaLocation of the urn:hl7-org:v3 namespace is provided as “<https://github.com/HealthCanada/HPFB/blob/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd>”
4. There are no processing instructions other than the xml and xml-stylesheet declarations
5. There are no comments
6. SPL file name is the document id GUID followed by “.xml”
7. A submission contains only the SPL file whose name ends in ‘.xml’ and, if appropriate, associated image files whose names end in '.jpg'
8. All image files associated with the SPL document are referenced in the .xml

# Document

## Description

Provides general information about the overall document:

* The templateId extension specifies the regulatory activity associated with this version of the product monograph
* The <id root> is a GUID and is unique for each version of the document. Letters used in a GUID are lower case.
* The <code> is the HPFB code that specifies the document type.
* The <title> data element is used for the title for the product monograph.
  + Images are not included in the title.
  + Multiple lines may be used in the title with each line separated by a line break <br/> tag.
* The <effectiveTime> specifies the Date of Last Revision for this version.
* The <originalText description> specifies the Date of Initial Approval.
* The <languageCode> is the HPFB code that specifies the language of the document.
* The <setId> is a GUID and is a unique identifier for the document that remains constant through all versions/revisions of the document.
* The <versionNumber> is an integer greater than zero that specifies the version of the document.

## XML Sample

<document>

<templateId extension="regulatory activity code" root="2.16.840.1.113883.2.20.6.11"/>

<id root="7f363dae-0612-4be7-bb92-a8381fa1da35"/>

<code code="1"

codeSystem="2.16.840.1.113883.2.20.6.10"

displayName="product monograph type"/>

<title>"Scheduling <sub>Symbol</sub>" "Brand Name" "Proper name" "Dosage Form(s), Strength(s) and Route(s) of Administration" "Pharmaceutical Standard, "Pharmaceutical Standard, "Pharmaceutical Standard" "Therapeutic Classification"

</title>

<effectiveTime value="20180101"><!-- Date of Last Revision -->

<originalText description="Date of Initial Approval">20170101</originalText>

</effectiveTime>

<languageCode code="1" codeSystem="2.16.840.1.113883.2.20.6.29" displayName="english"/>

<setId root="4eb4ec67-8764-4b72-b7a5-0bae88db11a3"/>

<versionNumber value="2"/>

## Validation Rules

1. There is a document id
2. id root is a Globally Unique Identifier (GUID).
3. id does not have an extension.
4. id does not match any other id in the document.
5. There is a code for document type from the code system is 2.16.840.1.113883.2.20.6.10 and the display name matches the code
6. There are no images in the title.
7. There is an effective time with at least the precision of day in the format YYYYMMDD.
8. There is an original text description with at least the precision of day in the format YYYYMMDD.
9. There is a code for language from the code system 2.16.840.1.113883.2.20.6.29 and the display name matches the code
10. There is a set id
11. The set id is a GUID
12. There is a version number
13. Value of version number is a whole number > 0

# Market Authorization Holder and Importer or Distributor

## Description

Provides the company name, address and contact information for the market authorization holder associated with this document. If applicable, the company name, address and contact information for the Canadian importer or distributor will be specified as well.

* The <representedOrganization> is the HPFB code that specifies the company ID for the market authorization holder.
* <assignedOrganization> is the HPFB code that specifies the company ID for the Canadian importer or distributor.

## XML Sample

<document>

…

<author><!--Organization Information-->

<time/>

<assignedEntity>

<representedOrganization><!--Market Authorization Holder-->

<id extension="1111" root="2.16.840.1.113883.2.20.6.31"/>

<name>Market Authorization Holder Inc</name>

<contactParty>

<addr>

<streetAddressLine>256 Lanark Drive</streetAddressLine>

<city>Ottawa</city>

<state>Ontario</state>

<postalCode>a1a 2a2</postalCode>

<country code="1" codeSystem="2.16.840.1.113883.2.20.6.17" displayName="CANADA"/>

</addr>

<telecom value="tel:+1-613-123-4567"/>

<telecom value="mailto:test@canada.ca"/>

<contactPerson>

<name>Market Authorization Holder Inc</name>

</contactPerson>

</contactParty>

<assignedEntity>

<assignedOrganization><!-- Importer/Distributor -->

<id extension="0000" root="2.16.840.1.113883.2.20.6.31"/>

<name>Importer Inc</name>

<contactParty>

<addr>

<streetAddressLine>257 Lanark Ave</streetAddressLine>

<city>Ottawa</city>

<state>Ontario</state>

<postalCode>a2a 1a1</postalCode>

<country code="1" codeSystem="2.16.840.1.113883.2.20.6.17"/>

</addr>

<telecom value="tel:+1-613-123-4598"/>

<telecom value="mailto:test.2@canada.ca"/>

<contactPerson>

<name>Importer Inc</name>

</contactPerson>

</contactParty>

</assignedOrganization>

</assignedEntity>

</representedOrganization>

</assignedEntity>

</author>

## Validation Rules

1. One id is a company code from the code system 2.16.840.1.113883.2.20.6.31 and the display name matches the code.
2. There is a name.
3. There is an address with street address line, city, province and country.
4. The country code is from the code system 2.16.840.1.113883.2.20.6.17 and the display name matches the code. Country is a full country name.
5. If the country is “Canada”, then the contact party’s address has a province (2-letter abbreviation) and has a postal code
6. If the country is “Canada”, then there is a postal code as a 6 digit alpha numeric number in the format “A1A 1A1” with a space separating the third and fourth characters. There is no hyphen.
7. There is a postal code
8. There are two <telecom> elements
9. One telecom value begins with “tel:” and is a telephone number based on the following rules:
   1. telephone numbers are global telephone numbers;
   2. telephone numbers contain no letters or spaces;
   3. telephone numbers begin with “+”;
   4. include hyphens to separate the country code, area codes and subscriber number;
   5. have any telephone number extensions separated by “;ext=”.
   6. If there is a semicolon in the telephone number, then it is followed by ext.
10. One telecom value begins with “mailto:” and encodes an email address in the format <username>@<dns-name>
11. The <contactperson> value matches the <name> value; i.e., the contact person value and the company name value are the same.

# SPL Body

## Description

The body of the SPL document includes structured components for the manufactured product(s) and the narrative text sections of the product monograph (e.g., Title Page, Part I: Health Professional Information, Part II: Scientific Information and Part III: Patient Medication Information).

Sections and subsections have id, title, and code. HPFB codes are used for sections and subsections codes.

The <title> of the sections and subsections and order of the sections and subsections in the SPL are used to render the product monograph contents. The numbering for the sections and subsections are included in the display name of each section or subsection.

In the SPL schema, the <structuredBody> element contains multiple <component>s, and each <component> contains a <section>.

Sections are used to aggregate paragraphs into logical groupings. The order in which sections appear in an SPL document is the order the sections will appear when displayed (rendered) using the standard HPFB stylesheet. Major sections are defined by the *Guidance Document Product Monograph* and the product monograph templates associated with the relevant product type; e.g., the 2016 Product Monograph Template – Schedule D defines the major product monograph section headings for a biologic.

Sections that have not been assigned a specific HPFB code are assigned the HPFB code for “SPL Unclassified Section”.

Each section has a unique identifier (<id>), an <effectiveTime>, and a HPFB code (i.e., the <code> element). A section may or may not contain a <title>.

The human readable content of the product monograph is contained within the <text> element in the <section>. The <section> can be nested to form sub-sections. The schema for subsections in SPL requires that the nested <section> tag first be nested inside a <component> tag. Use nested sections to relate paragraphs. The section tag applies to all of the nested sections. By nesting sections, computer systems can use the section tags in SPL to display information useful for the care of patients. If information is not associated with the tag, it will not be displayed.

Using the following principles for markup of text information improves access to information in the product monograph:

* Capture the section heading using the <title> element rather than placing the text of the title within the <text> element. This allows computer systems to use and display this information properly.
* Link different parts of the product monograph using the ID attribute to the <section> element. For example, <section ID=" 4.1 Dosing Considerations”> serves as the target of a <linkHtml> element. Linking to the ID attribute of a section allows the link to 'reference' the section entirely, e.g., for retrieval of a whole section in a non-browser interface.
* Separate the text and images for each concept using <paragraph> tags.

## XML Sample – Manufactured Product Section

<document>

…

<component>

<structuredBody>

<component><!—SPL Body -->

<section ID="f6ac9de5-be91-442c-9579-5bc9ebd36902">

<id root="bdeefc11-4315-41e3-8c56-83e8bf4f770b"/>

<code code="MP"

codeSystem="2.16.840.1.113883.2.20.6.8"

displayName="Manufactured Product"/>

<effectiveTime value="20170101"/>

<subject>

## XML Sample – Narrative Text Section

<document>

…

<component><!--Title Page section-->

<section ID="Ld8d30d86-e343-48f4-9cec-524834b3803b">

<id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208"/>

<code code="TP" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="title page"/>

<title>Title Page</title>

<text>

<paragraph>"Scheduling <sub>Symbol</sub>" "Brand Name" "Proper name" "Dosage Form(s),

Strength(s) and Route(s) of Administration" "Pharmaceutical Standard, "Pharmaceutical

Standard, "Pharmaceutical Standard" "Therapeutic Classification"

</paragraph>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

## Validation Rules

1. Each section has zero to many subsections
2. Each section and subsection has an id root and no extension
3. id root (section id) is a GUID
4. id does not match any other id in the document
5. id (section id) does not match any other id across all sections
6. Each section and subsection has a code from the code system 2.16.840.1.113883.2.20.6.8 and the display name matches the code
7. Each section has an effective time with at least the precision of day in the format YYYYMMDD
8. There are no figures in the title for a section or subsection.

# Manufactured Product

## Description – Manufactured Product Code and Name

Provides information about the manufactured product(s) associated with this product monograph. This includes:

* The <code> is the Drug Identification Number (DIN) for this manufactured product
* The <name> is the proprietary name or brand name for this manufactured product
* The <formCode> is the manufactured dosage form of the manufactured product
* The <asEntityWithGeneric><genericmedicine><name> is the non-proprietary name for this manufactured product

### XML Sample – Manufactured Product

<document>

<component>

<structuredBody>

<component><!-- Manufactured Product Information -->

<section ID="f6ac9de5-be91-442c-9579-5bc9ebd36902">

<id root="bdeefc11-4315-41e3-8c56-83e8bf4f770b"/>

<code code="MP" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="Manufactured Product"/>

<effectiveTime value="20170101"/>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<code code="123456" codeSystem="2.16.840.1.113883.2.20.6.42" displayName="display name"/><!-- DIN Number -->

<name>Product#1</name>

<formCode code="85"

codeSystem="2.16.840.1.113883.2.20.6.3"

displayName="Tablet"/>

<asEntityWithGeneric>

<genericMedicine>

<name>International Nonproprietary Name</name>

</genericMedicine>

</asEntityWithGeneric>

<ingredient classCode="ACTIR">

<quantity>

<numerator value="5" unit="mg"/>

<denominator value="1" unit="1"/>

</quantity>

<ingredientSubstance>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#1"/>

<name>ingredient#1 - base</name>

<activeMoiety>

<activeMoiety>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#2"/>

<name>ingredient#2 - moiety</name>

</activeMoiety>

</activeMoiety>

<asEquivalentSubstance>

<definingSubstance>

<code code="3" codeSystem="2.16.840.1.113883.4.9" displayName="ingredient#3"/>

<name>ingredient#3 - referenced as basis of strength</name>

</definingSubstance>

</asEquivalentSubstance>

</ingredientSubstance>

</ingredient>

<ingredient classCode="IACT">

<ingredientSubstance>

<code code="4" codeSystem="2.16.840.1.113883.2.20.6.14"displayName="ingredient#4"/>

<name>ingredient#4</name>

</ingredientSubstance>

</ingredient>

<asContent><!-- Packaging -->

<quantity>

<numerator value="1" unit="1"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="123-456" codeSystem="2.16.840.1.113883.2.20.6.56"/><!--company defined pack code-->

<formCode code="5" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="bottle"/>

</containerPackagedProduct>

<subjectOf>

<marketingAct>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.37" displayName="approved"/>

<statusCode code="active"/>

<effectiveTime><!-- regulatory status of this package -->

<low value="20170101"/><!-- Date of Initial Approval -->

<high value="20180101"/><!-- Date of DIN cancellation -->

</effectiveTime>

</marketingAct>

</subjectOf>

</asContent>

</manufacturedProduct>

<subjectOf><!--Regulatory Activity associated with this products status-->

<approval>

<id extension="123456" root="2.16.840.1.113883.2.20.6.49"/><!-- Control Number -->

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="SNDS"/>

<author>

<territorialAuthority>P

<territory>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.17" displayName="canada"/>

</territory>

</territorialAuthority>

</author>

</approval>

</subjectOf>

<subjectOf><!--Regulatory status of this product-->

<marketingAct>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.37" displayName="approved"/>

<statusCode code="active"/>

<effectiveTime>

<low value="20170101"/>

</effectiveTime>

</marketingAct>

</subjectOf>

<!--Characteristics of this product-->

<subjectOf>

<characteristic>

<code code="0" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="product class"/>

<value code="2" codeSystem="2.16.840.1.113883.2.20.6.53" displayName="product class display name"

xsi:type="CE">

<originalText>biologic</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="colour" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="colour"/>

<value code="2" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="blue display name"

xsi:type="CE">

<originalText>light blue</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="shape" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="shape"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.25" displayName="shape diplay name"

xsi:type="CE">

<originalText>shape</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="size" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="size"/>

<value unit="mm" value="10" xsi:type="PQ"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="score" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="score"/>

<value value="1" xsi:type="INT"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="imprint" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="imprint"/>

<value xsi:type="ST">value</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="flavour" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="flavour"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.26" xsi:type="CE">

<originalText>new almond</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="image" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="image"/>

<value xsi:type="ED" mediaType="image/jpeg">

<reference value="filename.jpg"/>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="13" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Pharmaceutical Standard"/>

<value code="7" codeSystem="2.16.840.1.113883.2.20.6.5" displayName="display name" xsi:type="CV"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="14" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="scheduling symbol"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.2" displayName="Pr"

xsi:type="CV"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="15" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="therapeutic class"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.6" displayName="display name"

xsi:type="CV"/>

</characteristic>

</subjectOf>

<consumedIn>

<substanceAdministration>

<routeCode code="56" codeSystem="2.16.840.1.113883.2.20.6.7" displayName="oral"/>

</substanceAdministration>

</consumedIn>

</manufacturedProduct>

</subject>

</section>

</component>

### Validation Rules

1. There is a code representing the DIN with the code system 2.16.840.1.113883.2.20.6.42
2. There is a proprietary name
3. There is a formCode with the code system 2.16.840.1.113883.2.20.6.3. Display name matches the code
4. There is a non-proprietary name
5. There is a approval with the code system 2.16.840.1.113883.2.20.6.11. Display name matches the code

## Description – Manufactured Product Ingredients

Information about the ingredients in this manufactured product.

* <ingredient> is the ingredient information based on role (active, inactive or adjuvant), strength, ingredient code and ingredient name
* The <ascontent> is the packaging information based on pack code, quantity, pack type and regulatory status of the packaging
* The <subjectof><approval> is the regulatory activity associated with this manufactured product based on the control number, regulatory activity type and country
* The <subjectof><marketingact> is the regulatory status for this manufactured product
* The <subjectof><characteristic> are the characteristics of this manufactured product; i.e., Shape, size, score, imprint, flavour, image, pharmaceutical standard, scheduling symbol, therapeutic class
* The <consumedin><substanceAdministration><routecode> is the route of administration for this product

### XML Sample – Active Ingredient Base (ACTIB)

<ingredient classCode="ACTIB">

<quantity>

<numerator value="5" unit="mg"/>

<denominator value="1" unit="1"/>

</quantity>

<ingredientSubstance>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#1"/>

<name>ingredient#1 - base</name>

<activeMoiety>

<activeMoiety>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#2"/>

<name>ingredient#2 - moiety</name>

</activeMoiety>

</activeMoiety>

</ingredientSubstance>

</ingredient>

### XML Sample – Active Ingredient Moiety (ACTIM)

<ingredient classCode="ACTIM">

<quantity>

<numerator value="5" unit="mg"/>

<denominator value="1" unit="1"/>

</quantity>

<ingredientSubstance>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#1"/>

<name>ingredient#1 - base</name>

<activeMoiety>

<activeMoiety>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#2"/>

<name>ingredient#2 - moiety</name>

</activeMoiety>

</activeMoiety>

</ingredientSubstance>

</ingredient>

### XML Sample – Active Ingredient Reference (ACTIR)

<ingredient classCode="ACTIR">

<quantity>

<numerator value="5" unit="mg"/>

<denominator value="1" unit="1"/>

</quantity>

<ingredientSubstance>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.14"

displayName="ingredient#1"/>

<name>ingredient#1 - base</name>

<activeMoiety>

<activeMoiety>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.14"

displayName="ingredient#2"/>

<name>ingredient#2 - moiety</name>

</activeMoiety>

</activeMoiety>

<asEquivalentSubstance>

<definingSubstance>

<code code="3" codeSystem="2.16.840.1.113883.4.9" displayName="ingredient#3"/>

<name>ingredient#3 - referenced as basis of strength</name>

</definingSubstance>

</asEquivalentSubstance>

</ingredientSubstance>

</ingredient>

### XML Sample – Inactive Ingredient (IACT)

<ingredient classCode="IACT">

<ingredientSubstance>

<code code="4" codeSystem="2.16.840.1.113883.2.20.6.14"

displayName="ingredient#4"/>

<name>ingredient#4</name>

</ingredientSubstance>

</ingredient>

### XML Sample – Adjuvant (ADJV)

<ingredient classCode="ADJV">

<ingredientSubstance>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ingredient#1"/>

<name>ingredient#1 - base</name>

</ingredientSubstance>

</ingredient>

### Validation Rules

1. There is a class code with the code system 2.16.840.1.113883.2.20.6.39 (ingredient role). Display name matches the code
2. There is a strength with a numerator and denominator if the ingredient role is ACTIB, ACTIM or ACTIR
3. Numerator and denominator have a value greater than zero and a unit
4. Unit comes from the code system 2.16.840.1.113883.2.20.6.15 (units of measure)
5. For percentages numerator unit is not 1, instead use a volume unit for volume fractions and a mass unit for mass fractions.
6. The denominators values and units for all ingredients in this product are the same.
7. There is an ingredient code from the code system 2.16.840.1.113883.2.20.6.14 (ingredient id)
8. The same ingredient code is not used more than once per product.
9. There is an ingredient name. Name matches the code display name.

## Packaging

### Description – General Packaging

The packaging includes the quantity of product in the package and the package type, along with all packaging aspect that make up the package (such as inner packages).

Packaging is represented as a quantity, a product ID if applicable and a package type. The quantity aspect is represented as a numerator and denominator along with a unit of measure and packaging type. The Units of Presentation code (the numerator) is derived from OID: 2.16.840.1.113883.2.20.6.15, while the Packaging Type code (the denominator) is derived from OID: 2.16.840.1.113883.2.20.6.32.

### XML Sample – General Packaging

<asContent><!-- Packaging -->

<quantity>

<numerator value="1" unit="1"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="123-456" codeSystem="2.16.840.1.113883.2.20.6.56"/><!--company defined pack code-->

<formCode code="5" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="bottle"/>

</containerPackagedProduct>

<subjectOf>

<marketingAct>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.37" displayName="approved"/>

<statusCode code="active"/>

<effectiveTime><!-- regulatory status of this package -->

<low value="20170101"/><!-- Date of Initial Approval -->

<high value="20180101"/><!-- Date of DIN cancellation -->

</effectiveTime>

</marketingAct>

</subjectOf>

</asContent>

### Validation Rules – General Packaging

1. A product may have an “as content” (package information) element.
2. Quantity (for package information) includes a numerator and denominator
3. Numerator (for package amount) has a value greater than zero and a unit
4. If the product has parts, then the initial numerator value and unit is “1”
5. Unit of the numerator (for package amount) of the initial package is the same as the units for the denominators of all the ingredient quantities (strengths)
6. Unit of the numerator (for package amount) of an outer package is the same as the unit for the denominator of the quantity of the inner package
7. Denominator has value 1 and either no unit or unit “1”
8. There is a pack type code from the code system 2.16.840.1.113883.2.20.6.32 and the display name matches the code
9. There is a package item code with code and code system 2.16.840.1.113883.2.20.6.56.
10. If the package item code is mentioned elsewhere in the document, then the package type code and quantity value and unit are the same.
11. Package type code does not match any other package item code in the same package hierarchy.

### Description - Kit

When products have more than one part, each part is described under <partProduct>. Currently, when a drug product has parts, it is considered a Kit indicated by the formCode for KIT. Products may be combined in various ways such as:

* Drug kit with a device part
* Drug in a delivery device

### XML Sample – Kit

<manufacturedProduct>

<manufacturedProduct>

<code code="Company pack code for kit" codeSystem="2.16.840.1.113883.2.20.6.56"/>

<name>name of kit</name>

<formCode code="36" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="KIT"/>

<asEntityWithGeneric .../>

<part>

<quantity>

<numerator value="amount of this part’s content in one kit" unit="unit for amount"/>

<denominator value="1"/>

</quantity>

<partProduct>

<code code="DIN code of drug part" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>name of drug part</name>

<formCode code="dosage form code of drug part" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="display name"/>

<ingredient ... />

<asContent>

<quantity>

<numerator value="amount of this part in its package" unit="unit of amount"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="Company code of part’s package" codeSystem="2.16.840.1.113883.2.20.6.56"/>

<formCode code="package type" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="display name"/>

</containerPackagedProduct>

</asContent>

</partProduct>

</part>

<part>

<quantity>

<numerator value="amount of this device part in one kit"/>

<denominator value="1"/>

</quantity>

<partProduct>

<code code="Company pack code for this part" codeSystem="2.16.840.1.113883.2.20.6.56"/>

<name>name of part</name>

<desc>description of device part</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="00" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="PRE-FILLED SYRINGE"/>

</generalizedMaterialKind>

</asSpecializedKind>

</partProduct>

</part>

### Validation Rules – Kit

1. If the pack type is Kit, then there is one or more parts
2. Each part has an overall quantity
3. If there is an “as content” (packaging) data element in the part, then the numerator unit is the same as the numerator unit for the “as content” data element
4. If there is no “as content” (packaging) data element in the part, then the numerator unit is 1
5. There is a code and code system is 2.16.840.1.113883.2.20.6.56.
6. There is a name.
7. Procedures for ingredients, characteristics and packaging are the same as for products without parts.

## Regulatory Status of Packaging

### Description

The marketing status provides information on when the product is on or off the market.

The <code> indicates the regulatory status. The status of the product is described in the <statusCode> using the appropriate HPFB status code. The status specifies when the product is available on the market or no longer available on the market.

The <effectiveTime> is used to capture the Date of Initial Approval and the date the DIN was cancelled. Effective time low value is the date when the original Notice of Compliance was issued. Effective time high is the date when the DIN was cancelled.

### XML Sample

<asContent><!-- Packaging -->

<quantity>

<numerator value="1" unit="1"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="123-456" codeSystem="2.16.840.1.113883.2.20.6.56"/><!--company defined pack code-->

<formCode code="5" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="bottle"/>

</containerPackagedProduct>

<subjectOf>

<marketingAct>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.37" displayName="approved"/>

<statusCode code="active"/>

<effectiveTime><!-- regulatory status of this package -->

<low value="20170101"/><!-- Date of Initial Approval -->

<high value="20180101"/><!-- Date of DIN cancellation -->

</effectiveTime>

</marketingAct>

</subjectOf>

</asContent>

### Validation Rules

1. There is not more than one regulatory status on any one item.
2. Regulatory status code is from the code system 2.16.840.1.113883.2.20.6.37 and the display name matches the code.
3. If the status code is Approved, then there is a low value (marketing start date) and no high value (marketing end date)
4. If the marketing status code is Cancelled, then there is a low and high value.
5. The effective time low and effective time high have at least the precision of day in the format YYYYMMDD
6. If there is an effective time high value, then it is not less than the low value.

## Regulatory Activity and Control Number

### Description

The <approval> structure specifies the regulatory activity and, if applicable, the control number under which the product is approved. The control number is captured in the <id extension>.

### XML Sample

<subjectOf><!--Regulatory Activity associated with this products status-->

<approval>

<id extension="123456" root="2.16.840.1.113883.2.20.6.49"/><!-- Control Number -->

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="SNDS"/>

<author>

<territorialAuthority>P

<territory>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.17" displayName="canada"/>

</territory>

</territorialAuthority>

</author>

</approval>

</subjectOf>

### Validation Rules

1. There is one marketing category for every product and product part.
2. There is a regulatory activity code from the code system 2.16.840.1.113883.2.20.6.11 and the display name matches the code.
3. Territorial authority is the code for Canada from the code system 2.16.840.1.113883.2.20.6.17 and the display name matches the code.

## Regulatory Status of the Manufactured Product

### Description

The <code> indicates the activity of “marketing” (or in cases of some packages as “marketing of sample packages not for sale”). The status of the product is described in the <statusCode> as either “active” for being on the market or “completed” when marketing is done the product is no longer going to be available on the market, or “new” to indicate that the product item code is being reserved for future use. If the status of the product is cancelled, the NDC reservation is being cancelled. The date when the product is on or off the market is included in the <effectiveTime>. The date when the product is on the market is characterized by the <low value>.

The date off the market such as the expiration date of the last lot released to the market is characterized by the <high value>.

### XML Sample

<subjectOf><!--Regulatory status of this product-->

<marketingAct>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.37" displayName="approved"/>

<statusCode code="active"/>

<effectiveTime>

<low value="20170101"/>

</effectiveTime>

</marketingAct>

</subjectOf>

### Validation

1. There is not more than one regulatory status on any one item.
2. Regulatory status code is from the code system 2.16.840.1.113883.2.20.6.37 and the display name matches the code.
3. If the status code is active or new, then there is a low value (marketing start date) and no high value (marketing end date)
4. The effective time low value (Notice of Compliance date) and high value (DIN Cancellation date) have at least the precision of day in the format YYYYMMDD
5. If the regulatory status code is approved, dormant or marketed, there is only a low value.
6. If the regulatory status code is cancelled, then there is a low and high value.

## Product characteristics

Product characteristics include a range of items that includes: the scheduling symbol, the therapeutic class, pharmaceutical standard, colour, score, shape, size, imprint and image flavour.

Characteristic value types are as follows:

* **Physical Quantity (PQ)**: A dimensioned quantity expressing the result of measuring.
* **Integer Number (INT)**: Integer numbers (-1,0,1,2, 100, 3398129, etc.) are precise numbers that are results of counting and enumerating. Integer numbers are discrete, the set of integers is infinite but countable. No arbitrary limit is imposed on the range of integer numbers. Two NULL flavors are defined for the positive and negative infinity.
* **Interval (IVL)**: A set of consecutive values of an ordered base data type.
* **Interval Of Physical Quantities (IVL\_PQ):** A range of physical quantity can either be expressed using "low" and "high" child elements to define the bounds of the interval (if only one of these is sent, then the other is assumed to be unbounded), or by sending the "center" element to express a single quantity instead of a range. The IVL\_PQ flavour is used when there is a single value in an attribute that is able to contain an interval of quantity values. This is equivalent to Quantity in Standard Units.
* **Coded Value (CV)**: Coded data, specifying only a code, code system, and optionally display name and original text. Used only as the type of properties of other data types.
* **Coded with Equivalents (CE)**: Coded data that consists of a coded value and, optionally, coded value(s) from other coding systems that identify the same concept. Used when alternative codes may exist.
* **Character String (ST)**: The character string data type stands for text data, primarily intended for machine processing (e.g., sorting, querying, indexing, etc.) Used for names, symbols, and formal expressions.
* **Encapsulated Data (ED)**: Data that is primarily intended for human interpretation or for further machine processing outside the scope of HL7. This includes unformatted or formatted written language, multimedia data, or structured information in as defined by a different standard (e.g., XML-signatures.) Instead of the data itself, an ED may contain only a reference (see TEL.) Note that ST is a specialization of the ED where the mediaType is fixed to text/plain.
* **Boolean (BL)**: BL stands for the values of two-valued logic. A BL value can be either true or false, or, as any other value may be NULL.

### XML Sample – Characteristics

<subjectOf>

<characteristic>

<code code="0" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="product class"/>

<value code="2" codeSystem="2.16.840.1.113883.2.20.6.53" displayName="product class display name"

xsi:type="CE">

<originalText>biologic</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="colour" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="colour"/>

<value code="2" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="blue display name"

xsi:type="CE">

<originalText>light blue</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="shape" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="shape"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.25" displayName="shape diplay name"

xsi:type="CE">

<originalText>shape</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="size" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="size"/>

<value unit="mm" value="10" xsi:type="PQ"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="score" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="score"/>

<value value="1" xsi:type="INT"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="imprint" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="imprint"/>

<value xsi:type="ST">value</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="flavour" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="flavour"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.26" xsi:type="CE">

<originalText>new almond</originalText>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="image" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="image"/>

<value xsi:type="ED" mediaType="image/jpeg">

<reference value="filename.jpg"/>

</value>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="13" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Pharmaceutical Standard"/>

<value code="7" codeSystem="2.16.840.1.113883.2.20.6.5" displayName="display name" xsi:type="CV"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="14" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="scheduling symbol"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.2" displayName="Pr"

xsi:type="CV"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="15" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="therapeutic class"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.6" displayName="display name"

xsi:type="CV"/>

</characteristic>

</subjectOf>

### Validation

1. There is a characteristic code from the code system 2.16.840.1.113883.2.20.6.23 and the display name matches the code.
2. There is a characteristic value code from the corresponding code system and the display name matches the code.
3. The characteristic value code is compliant with the specified value typev.
4. Value type is PQ, INT, IVL\_PQ, CV, CE, ST, ED, or BL

## Route of Administration

### Description

The route of administration for the product.

### XML Sample

<consumedIn>

<substanceAdministration>

<routeCode code="56" codeSystem="2.16.840.1.113883.2.20.6.7" displayName="oral"/>

</substanceAdministration>

</consumedIn>

### Validation

1. There is a route of administration code from the code system 2.16.840.1.113883.2.20.6.7 and the display name matches the code.

# Narrative Text Sections

## General

The narrative text that makes up the Title Page, Part I: Health Professional Information, Part II: Scientific Information and Part III: Patient Medication Information.

The human readable text content of the document is contained within the <text> element. The actual content is contained within a <paragraph>, <table>, and/or <list>.

* If a section consists only of nested sections, the <text> tag is not included.
* Elements that can be used within the <text> element to capture the human readable content include paragraphs (<paragraph>), lists (<list>), tables (<table>) and images (<renderMultimedia>).
* Elements permitted as children of the <text> element, used as children of the <paragraph> element or within <table> and <list> include superscripts (<sup>), subscripts (<sub>), links (<linkHtml>), line breaks (<br>), footnotes (<footnote>), footnote references (<footnoteRef>).
* Images may be included in the content of labeling using the <renderMultiMedia> tag. This tag may be used as a direct child of <text> for ‘block’ images or as a child of <paragraph> for inline images.

### Formatting

There are certain aspects of the content that must be specified in the source to insure that the content of labeling is formatted correctly when rendered, as an example:

<text>

<paragraph>

The next snippet <content styleCode="bold italics">will appear as bold italics</content> in the rendering.

</paragraph>

</text>

Will be rendered as: The next snippet ***will appear as bold italics*** in the rendering.

The <content styleCode=””> can be nested, for example:

<text>

<paragraph>

<content styleCode="bold italics">bold italics</content>

But it can also be represented as:

<text>

<paragraph>

<content styleCode="bold”>

<content styleCode="italics”> bold italics.</content>

</content>

Both of the above will appear as ***bold italics***

The values for <styleCode> for font effect are bold, italics and underline. To assist people who are visually impaired, the <styleCode=”emphasis”> is used to prompt computer screen reader programs to emphasize text such as a box warning. The bold, italics and underline font effects may be used together with each other and the emphasis styleCode. For example:

<content styleCode=”bold”>

<content styleCode=”emphasis”>

</content>

</content>

Will appear as bold and be emphasized by screen reader programs.

### Symbols and special characters

Special characters can be included in the text. Superscripts and subscripts are accomplished using the <sup> and <sub> tags.

Since the SPL encoding is UTF-8, any Unicode character can be included as is. Unicode references may also be inserted as either &#dddd; where dddd is the Unicode value in decimal notation or &#xdddd; where dddd is the Unicode value in hexadecimal notation. The font used in the standard HPFB stylesheet is a Unicode font assuring that most Unicode characters will be rendered correctly if viewed by a browser supporting this font.

The only prohibited characters in XML that cannot be directly used are less-than “<” (because SPL XML tags begin with it) and ampersand “&” (because XML entity references begin with it). Use of these two symbols must be replaced by the XML entity references &lt; and &amp.

### Footnotes

The SPL schema includes a specific footnote element <footnote>. Footnotes are rendered automatically by the standard HPFB stylesheet. <footnoteRef> is used to refer to another (usually earlier) footnote. For example,

<footnote ID=”testNote”>This is the footnote content</footnote>

will generate the following footnote at the appropriate end of a section. “This is footnote content”

The <footnoteRef> element with the appropriate IDREF attribute, e.g., <footnoteRefIDREF=”testNote”/> will display the footnote reference in the text corresponding to the footnote with the same ID.

Footnotes are rendered by the standard HPFB stylesheet using Arabic numbers; e.g., 1,2 3. Footnotes within tables are rendered at the bottom of the table.

### Lists

All lists are marked up using the <list> tag, and each item in a list is marked with an <item> tag. The ‘listType’ attribute identifies the list as ordered (numbered) or unordered (bulleted). The default numbering and bulleting are controlled by the standard HPFB stylesheet.

<text>

<paragraph>Fist Para ...</paragraph>

<list listType="ordered" styleCode="BigRoman">

<item>Fist Item</item>

<item>Second Item</item>

</list>

<paragraph>2nd Para ...</paragraph>

</text>

Lists featuring a standard set of specialized markers (standard specialized lists) can be created using the styleCode attribute with the <list> element. Options available for ordered lists are:

* Arabic (List is ordered using Arabic numerals: 1, 2, 3)
* LittleRoman (List is ordered using little Roman numerals: i, ii, iii)
* BigRoman (List is ordered using big Roman numerals: I, II, III)
* LittleAlpha (List is order using little alpha characters: a, b, c)
* BigAlpha (List is ordered using big alpha characters: A, B, C)

For example: <list listType="ordered" styleCode="LittleRoman">

For unordered lists the following options exist:

* Disc (List bullets are simple solid discs: ●)
* Circle (List bullets are hollow discs: ○)
* Square (List bullets are solid squares: ■)

For example: <list listType=”unordered” styleCode=”Disc”>

In addition to the standard specialized lists, user-defined characters are also permitted as markers by nesting <caption> within the <item> tag. Note that any character, XML entity, or Unicode symbol, may be used in the <caption>, and that the <caption> for each <item> are not restricted to the same character. For example: <item><caption>\*</caption> the asterisk is used as item marker here.<item>

### Tables

Tables can be created with the full structure (header (e.g. for column names), body (e.g. for the rows of the table) and footer e.g. for table footnotes)). The element <tbody> is required for an SPL table while the elements <thead> and <tfoot> are optional in the SPL schema. The structure will display a standard typographical table with rules between the caption (table title) and head, the head and body, and the body and <tfoot>. If a <tfoot> element is included and footnotes are present in a table, then footnotes are rendered after the existing content of the <tfoot> element.

It is recommended to always start with a standard table (i.e. <thead> and <tbody> elements) and test to see whether the rendering is unambiguous and interpretable. In the unusual situation where additional formatting is needed, the rule styleCode specified or certain attributes may be used to modify the table.

The rule codes are as follows (note that the control names are case sensitive):

* Rule on left side of cell is Lrule
* Rule on right side of cell is Rrule
* Rule on top of cell is Toprule
* Rule on bottom of cell is Botrule

Note: More than one rule control may be used in a cell, e.g., <td styleCode code=”Botrule Lrule”>Cell content</td>

Rule control codes should be used only when necessary for the interpretability of the table. Use of these codes may result in overriding the default rules for tables. Rather than setting the rule for each cell, table rules may also be controlled according to entire rows or columns by use of the styleCode attributes with <col>, <colgroup>, <thead>, <tfoot>, <tbody> and <tr> elements.

To make rowgroups appear with horizontal rules, use the styleCode attribute "Botrule" with the appropriate <tr> element. The Botrule value is rarely needed on the <td> element.

The preferred method for using vertical rules is to define colgroup with styleCode="Lrule” or “Rrule" (or both). Only if this does not yield the desired vertical rule should the Lrule or Rrule code value with styleCode attributes on the <td> or <th> element itself be used. Note: In general, vertical rules should not be used. Good typography for tables means using few vertical rules.

To merge cells vertically and horizontally, the rowspan and colspan attributes should be used on the <td>element.

To determine the width of a table, the width attribute may be used on the <table> element and to determine the width of a table column, the width attribute may be used on the <col> and <colgroup> elements. Note: best practice is to omit the width aspect. This ensures the rendering is done to the width. The only time the width should be specified is when the information is to be smaller than the standard width and in those cases a relative size (%) should be used.

For horizontal alignment, the preferred method for aligning cell content within the margins is to use <col align=”.. ”/> in the <colgroup> element, though this can be used in the <colgroup> element as well. Valid values for align are “left”, “center”, “right”, “justify” (for full justification of contents within the cells), and “char” (for character alignment within the cells). Using the <col align=”.. ”/> markup ensures that the contents for all cells in the column share the same alignment.

For vertical alignment, the valign attribute can be used within cells. For cases in which the cell alignment must be different from other cells in the column, align is also available as an attribute on the other table elements, including <td>.

Markup for table footnote is rendered in the <tfoot> tag. This element does not need to be included in SPL; the standard stylesheet will include a <tfoot> tag if a <footnote> element is present within either the <thead> or <tbody> sections. A <tfoot> section should be included in SPL only if there is additional information other than footnotes that needs to be rendered in this section.

For table text spacing, in some instances, the use of a “tab” or text indentation is desirable in a given table cell. In an SPL document, this effect is achieved by using the nonbreaking space (&#160;) as if it were a “tab” space. As the following snippet of XML shows, two nonbreaking spaces were used to offset the word “Male” from the margin: <td>&#160;&#160;Male</td>. The nonbreaking space can also be used to keep text in a table from breaking inappropriately due to browser resizing.

### Hypertext links

SPL offers hypertext linking capabilities generally similar to those found in the HTML specification.

Links are specified by the <linkHtml> construct, where the value for the href attribute of <linkHtml> (the target of the link) is the ID attribute value of a <section>, <paragraph>, <table>, <list>, <content>,<renderMultimedia> element. The stylesheet does not support the styleCode attribute of the <linkHtml> element; if a styleCode is needed for a link, this should be coded via the <content> element within the link as with other text.

### Recent major label changes

SPL offers a notation to identify recent major changes in the product monograph text including table elements <table> and table data <td>. The recent major text is tagged using the <content styleCode=“xmChange”>, for example:

<text>This is an example of text that is not changed.

<content styleCode=“xmChange”>

This is an example of text that is a recent major change

</content>

This is an example of changed text that is not considered a recent major change

</text>

### XML Sample

<component><!-- Part I: Health Professional Information -->

<section ID="L16a947eb-e2be-45c0-8b2e-15d0d0eebea8">

<id root="e6bb83b9-2602-4f96-9077-b8b9535c254e"/>

<code code="P1" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="Part I: Health Professional Information"/>

<title>Part I: Health Professional Information</title>

<effectiveTime value="20180101"/>

<component>

<section ID="L52ea4fad-2b79-4dbc-8d99-6843adc2dec8">

<id root="9a3f869a-7734-425a-85d8-b8bd4d3500a5"/>

<code code="P1-1" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="1 Indications"/>

<title>1 Indications</title>

<text>

<paragraph>

sample text

</paragraph>

</text>

<effectiveTime value="20180101"/>

<component>

<section ID="f2aa7e0e-2042-4a4c-a783-9ad4e8717a32">

<id root="b9db4be0-3f46-437a-bd7b-4a3e010adaad"/>

<code code="P1-1.1" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="1.1 Pediatrics"/>

<title>1.1 Pediatrics</title>

<text>

<paragraph>

sample text

</paragraph>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

### Validation Rules – Narrative Text

1. Text is enclosed under <paragraph>, <list>, or <table> elements.

## Images

### Description

The SPL schema uses <observationMedia> elements to identify graphic files to be rendered at the locations where they are referenced by <renderMultiMedia> elements in the <section>. An image in a SPL will be rendered wherever it is referenced by the renderMultimedia markup, no matter where the observationMedia markup appears.

The referencedObject attribute of the renderMultiMedia element identifies the corresponding observationMedia instance by means of its ID identifier such as <renderMultiMedia referencedObject="MM1"/>. For example,

<section>

<text>

<paragraph>...</paragraph>

<renderMultiMedia referencedObject="MM1"/>

<paragraph>...</paragraph>

</text>

<component>

<observationMedia ID="MM1">

<text>descriptive text</text>

<value xsi:type="ED" mediaType="image/jpeg">

<reference value="filename.jpg"/>

</value>

</observationMedia>

</component>

</section>

The <observationMedia> element does not contain the graphics file, but instead points at the file.

For image placement, if an image is a block image (i.e., should appear in its own space), insert the renderMultimedia tag between <paragraph> elements. If an image is inline (i.e., should appear alongside text), insert the renderMultimedia tag in the text of a <paragraph> as appropriate. Inline images are expected to be uncommon and basically represent symbols that cannot be represented by Unicode characters. In addition, <caption> are not applicable for inline images since these are not offset from the surrounding text.

The standard HPFB stylesheet does not perform any resizing of graphics or changing the resolution of graphics files. Thus, all images are rendered in the browser as-is, with all characteristics of the actual graphic file itself. To ensure that a graphic will appear as desired, it is important that the graphic file is edited to a dimension appropriate for its presentation within the browser. If this is not done, the appearance of the graphic may reduce the readability of the file. JPEG image file type using appropriate pixels per inch for images for viewing in a browser using the standard HPFB style sheet.

Only file formats detailed in **Table 1** are permitted

### Validation Rules

1. There is text
2. Value xsi:type is as above
3. Media type is image/jpeg
4. Reference value is the file name for a valid image
5. Size of image file is less than 1 MB
6. File is a JPEG image and the name has the extension “.jpg”
7. Image components are referenced at least once in the text of any section.
8. Image reference in text has an image “observationMedia” element with a matching ID in the same document.

## Title Page

### Description

### XML Sample

<component><!--Title Page section-->

<section ID="Ld8d30d86-e343-48f4-9cec-524834b3803b">

<id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208"/>

<code code="TP" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="title page"/>

<title>Title Page</title>

<effectiveTime value="20180101"/>

<component>

<section ID="Lbe75cfb9-3131-4903-800b-267427388a13">

<id root="b9db4be0-3f46-437a-bd7b-4a3e010adaad"/>

<code code="TP-1.1" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="TITLE"/>

<title>title</title>

<text>

<paragraph>

Scheduling Symbol, Brand Name, Proper name, Dosage Form(s), Strength(s) and

Route(s) of Administration, Pharmaceutical Standard, Pharmaceutical Standard, Pharmaceutical

Standard, Therapeutic Classification

</paragraph>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

<component>

<section ID="f187daf9-5e75-425a-9de6-f6ce1af2a965">

<id root="ac26f58c-721a-4c51-8bbc-c9dddb1f1233"/>

<code code="TP-1.2" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="Company Name and address"/>

<title>Company Name and Address</title>

<text>

<paragraph>

Company Name and Address

</paragraph>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

<component>

<section ID="bf2dab4e-fd04-4ec9-9cdc-247188622d0f">

<id root="v5f1dea3-d907-4664-b46f-e1d9736d47af"/>

<code code="TP-1.3" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="DATE OF INITIAL APPROVAL"/>

<title>Date of Initial Approval</title>

<text>

<effectivetime>

<low value="20170101"/>

</effectivetime>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

<component>

<section ID="k0184119-8fd7-4378-af77-b227c39e8445">

<id root="ad78301c-29a9-41af-96f8-d58815fed296"/>

<code code="TP-1.4" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="DATE OF REVISION"/>

<title>Date of Revision</title>

<text>

<effectivetime>

<high value="20180101"/>

</effectivetime>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

<component>

<section ID="ebc3f3dc-71be-424f-91ef-8aca8c138b21">

<id root="efd8c4c1-d0dd-434d-b1c2-4daa18752fa8"/>

<code code="TP-1.5" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="CONTROL NUMBER"/>

<title>Control Number</title>

<text>

<paragraph>

123456

</paragraph>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

</section>

</component>

### Validation Rules

1. Date of initial approval and date of revision are encoded with an effective time low value and high value
2. The control number is a six digit integer with no other text

## Recent Major Changes

### Description

### XML Sample

<component><!-- Recent Major Changes -->

<section ID="l7cee5c8-7ee9-4fd2-884e-7a50c06b27e1">

<id root="dd1e1c43-f0d3-4ba8-b1f5-ad009a5dd5a8"/>

<code code="RMLC" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="RECENT MAJOR LABEL CHANGES"/>

<title>Recent Major Label Changes</title>

<text>

<paragraph>

Section Heading, Subsection heading (Section or Subsection number), yyyymmdd

</paragraph>

</text>

<effectiveTime value="20180101"/>

</section>

</component>

### Validation Rules

No specific validation rules other than what is described in Section 9.1.9.