

WORKING DRAFT

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Technical Guidance Document

Structured Product Labelling (SPL) – General Validation Rules for all Document Types

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Published by authority of the

Minister of Health

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| --- | --- |
| Adopted Date | ??? |
| Effective Date | ??? |

Health Products and Food Branch



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| Our mission is to help the people of Canada maintain and improve their health.    Health Canada | The Health Products and Food Branch (HPFB)’s mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:   * Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, * Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.   Health Products and Food Branch |

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Également disponible en français sous le titre : Ligne directrice: ???

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance’s.

DOCUMENT REVISION HISTORY

|  |  |  |  |
| --- | --- | --- | --- |
| File name | Structured Product Labeling (SPL) Document Validation | Replaces | N/A |
| Date Adopted  Effective Date | ???  ??? | Date Adopted  Effective Date | N/A  N/A |

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Location of Change | Change Made | Effective Date |
| 1 | Not Applicable | Initial Issuance of Guidance | ??? |
|  |  |  |  |

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# Introduction & General Information

This section will outline the intent of guidance document along with general information on the guidance document.

## Purpose

The purpose of this guidance document is to assist with the overall technical validation of the Structured Product Labeling (SPL) documents.

This document details how the Health Products and Food Branch (HPFB) implements the technical validation of the Structured Product Labeling (SPL) document. In this context technical validation includes ensuring that the business rules are adhered to however the content itself is not validated.

Additionally there is a detailed document per document type instance that provides document type specific details.

The guidance document is limited to the technical aspects of validating the overall SPL document and is a companion to the business related guidance document for the specific document type.

## Inquiries

Questions should be emailed to [hc.hpr-rps.sc@canada.ca](mailto:hc.hpr-rps.sc@canada.ca)

## Content Related

The content along with all associated material such as images, of the SPL labeling files should be placed in a single folder. The file naming conventions for all content shall be adhered to and it is the sponsors responsibility to ensure that there are no content naming collisions.

## GUID Related

The GUID rules shall be adhered to and it is the sponsors responsibility to ensure that there are no GUID collisions.

## Visual Aids within the Document

There are several visual aids used in this document, they are designed to assist the user:

* The blue shaded text boxes in this document are illustrative samples; they are not intended to be complete document snippets but rather to assist the reader to understand a specific concept.
* The element tables identify the rules related to a specific xml element.
* Numbers (1) are used to detail technical conformance requirements; validation rules are detailed directly below the requirements and are organized using letters (a).
* Comments are used to denote sections or content that is under development.

# General

This section will outline general validation rules that apply to the overall document.

1. When the validation rules are context sensitive (e.g. an element can appear in multiple places within the document) then a dot (.) notation has been used to provide the context. For example, contactParty (representedOrganization.contactParty and assignedOrganization.contactParty respectively).

a) Informational only (no validation aspect).

1. Elements that neither contain content nor attributes are not directly validated. Rather, they are validated by the lack of a required child element. Therefore they are omitted from this document, an example is assignedEntity.

a) Informational only (no validation aspect).

1. SPL file name is the document id (the value of id@root in the document information section) followed by “.xml”
2. A SPL labeling file contains only the SPL file and associated files.
3. All files associated with the SPL document are referenced from that SPL document.
4. XML is well formed and valid against the schema.

a) SPL Rule 22 identifies the outcome of the validation for both well formedness and validity of the document, this includes both the status and the details.

1. There are no elements and/or attributes in addition to those described in the schema.

a) SPL Rule 22 identifies the outcome of the validation for both well formedness and validity of the document, this includes both the status and the details.

1. There are no spaces in codes.

a) There are several rules that, when combined, validate the codes, however the main one used to validate against the Controlled Vocabulary (CV) is SPL Rule’s 7 and 8.

1. The case sensitivity rules for display names are document specific.

a) All validation is case sensitive, however there is no general case sensitivity rule.

1. All displayNames are language specific and when derived from a CV they shall be based on the language of the document.

a) CV validation rules are responsible for ensuring the applicability, however there is no general case sensitivity rule.

1. There are no spaces in id extensions.
2. Letters in Globally Unique Identifiers (GUID) are lower case.
3. There are no empty or incomplete elements except where the element can be empty.
4. The maximum file size limit is 500MB per individual file.
5. The overall SPL labeling file is limited to 5GB in size, should a SPL labeling file exceed 5GB then it must be divided into subsets with a clear explanation of how the data set has been split.
6. There are no Processing Instructions included in the SPL file.
7. The Schema and Style sheet are a pure adaptation of the HL7 schema.

a) Informational only (no validation aspect).

1. Images shall be of sufficient quality and size to be legible in the intended context by a user.

a) Informational only (no validation aspect).

1. Any element not explicitly mentioned in the validation rules is to be left empty where permitted and when it cannot be left empty is to be removed.
2. ???
3. The title for labeling section will be the same as the <code@displayName> value when the Title column states Fixed, when it states Manual then the title is free form, in cases when it states N/A then there is no title for the section.
   1. ???

# Controlled Vocabularies

A listing of the CV’s used in the context of HPFB SPL is provided below, the usage and validation aspects are detailed throughout the document as appropriate.

| **OID** | **Symbolic Name** | **Usage** |
| --- | --- | --- |
| 2.16.840.1.113883.2.20.6 | hc-hpfb | Root OID for the Health Products and Food Branch (HPFB) |
| 2.16.840.1.113883.2.20.6.2 | scheduling-symbol | Short form version of the product schedule; e.g., Pr, N, CT  This OID is currently used only for doctype specific aspects. |
| 2.16.840.1.113883.2.20.6.3 | dosage-form | List of dosage forms; e.g., Aerosol, Drops, Tablet |
| 2.16.840.1.113883.2.20.6.4 | telecom-use | Defines the type of contact information; e.g., Home, Office, Private.  This OID is currently not used by the SPM. |
| 2.16.840.1.113883.2.20.6.5 | pharmaceutical-standard | List of pharmaceopias; e.g., BP, MFR, PH EUR, USP  This OID is currently used only for doctype specific aspects. |
| 2.16.840.1.113883.2.20.6.6 | therapeutic-class | List of therapeutic classes; e.g., Chlorhexidine, Cimetidine, Silicones  This OID is currently used only for doctype specific aspects. |
| 2.16.840.1.113883.2.20.6.7 | route-of-administration | List of routes of administration; e.g.,  Dental, Epidural, Intracardiac |
| 2.16.840.1.113883.2.20.6.8 | section-id | List of all document section headings; e.g., Indications and Clinical Use, Psychiatric, Geriatrics |
| 2.16.840.1.113883.2.20.6.9 | template-id | List of identifier for each template; e.g., 2004 Product Monograph Template – Standard, 2016 Product Monograph Template - Schedule D |
| 2.16.840.1.113883.2.20.6.10 | document-id | Lists the type of document; e.g., CPID, PM, QOS |
| 2.16.840.1.113883.2.20.6.11 | marketing-category | The regulatory activity the approved PM is associated with; e.g., NDS, SNDS |
| 2.16.840.1.113883.2.20.6.12 | equivalence-codes | Can be used to link a generic to its reference product. |
| 2.16.840.1.113883.2.20.6.13 | identifier-type | All non HPFB assigned part and product ID’s; e.g., sponsor assigned part ID’s for kit components. |
| 2.16.840.1.113883.2.20.6.14 | ingredient-id | List of HPFB substances |
| 2.16.840.1.113883.2.20.6.15 | units-of-measure | List of units of measure; e.g., mg, mm, ml |
| 2.16.840.1.113883.2.20.6.16 | form-code | Use is to be determined |
| 2.16.840.1.113883.2.20.6.17 | country-code | List of countries; e.g., CAN, US |
| 2.16.840.1.113883.2.20.6.18 | marketing-status | Status of products; e.g., approved, marketed cancelled |
| 2.16.840.1.113883.2.20.6.19 | telecom-capability | Type of telecommunication; e.g., phone, fax or email.  This OID is currently not used by the SPM. |
| 2.16.840.1.113883.2.20.6.20 | product-item-code | List of HPFB products |
| 2.16.840.1.113883.2.20.6.21 | information-disclosure | List of terms related to confidentiality and privacy; e.g., |
| 2.16.840.1.113883.2.20.6.22 | schedule | List of product schedules (Spelled out version), Ethical, Schedule G (CDSA IV, CDSA Recommended |
| 2.16.840.1.113883.2.20.6.23 | product-characteristics | List of physical characteristics; e.g., colour and shape |
| 2.16.840.1.113883.2.20.6.24 | color | List of colours; e.g., white, yellow, red |
| 2.16.840.1.113883.2.20.6.25 | shape | List of shapes; e.g., oval, square, capsule, triangle |
| 2.16.840.1.113883.2.20.6.26 | flavor | List of flavours; e.g., rose, pepper, sweet, honey |
| 2.16.840.1.113883.2.20.6.27 | product-classification | List of HPFB product classes |
| 2.16.840.1.113883.2.20.6.28 | submission-tracking-system | This OID is currently not used by the SPM. Description to be added at a later date |
| 2.16.840.1.113883.2.20.6.29 | language-code | List of languages; e.g., ENG, FRA |
| 2.16.840.1.113883.2.20.6.30 | combination-product-type | List of combination products, ; e.g., ??? |
| 2.16.840.1.113883.2.20.6.31 | company-id | List of companies; e.g., Mylan, Pfizer |
| 2.16.840.1.113883.2.20.6.32 | pack-type | List of packaging types |
| 2.16.840.1.113883.2.20.6.33 | organization-role | List of company roles; e.g., DIN Owner, Agent, Importer, |
| 2.16.840.1.113883.2.20.6.34 | product-source | This OID is currently not used by the SPM. |
| 2.16.840.1.113883.2.20.6.35 | derived-source | This OID is currently not used by the SPM. Description to be added at a later date |
| 2.16.840.1.113883.2.20.6.36 | structure-aspects | Not used as a CV. This OID is a table concept used to facilitate validation and publishing. |
| 2.16.840.1.113883.2.20.6.37 | term-status | List of status' used to describe what terms can be usede.g., approved, superseded, legacy |
| 2.16.840.1.113883.2.20.6.38 | units-of-presentation | List of units of presentation ; e.g., bag, cup, implant |
| 2.16.840.1.113883.2.20.6.39 | ingredient-role | The role an ingredient plays in a product; e.g., CNTM, ACTIB, IACT |
| 2.16.840.1.113883.2.20.6.40 | notice-type | This OID is currently not used by the SPM. Description to be added at a later date |
| 2.16.840.1.113883.2.20.6.41 | related-documents | This OID is currently not used by the SPM. Description to be added at a later date |
| 2.16.840.1.113883.2.20.6.42 | din | List of Drug Identification Numbers (DIN); |

# SPL Documents

This section details the technical and validation aspects for HPFB SPL documents.

## Prolog/Declaration

This section will outline the XML prolog, it must be the first part of the SPL file.

### XML

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

<?xml-stylesheet type="text/xsl" href=" https://raw.githubusercontent.com/HealthCanada/Structured-Content-Information/master/Structured%20Product%20Labeling%20(SPL)/Style%20Sheets/SPM/current/spl.xsl"?>

<?xml-stylesheet type="text/css" https://raw.githubusercontent.com/HealthCanada/Structured-Content-Information/master/Structured%20Product%20Labeling%20(SPL)/Style%20Sheets/SPM/current/spl.css"?>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ?xml | N/A | 1:1 |  | The XML declaration aspects |
| Version | 1:1 |  |  |
| Encoding | 1:1 |  |  |
| Conformance | 1. The version must be 1.0 2. The encoding must be UTF-8 3. There are no comments or annotations | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ?xml-stylesheet | N/A | 1:n | N/A | The formatting related aspects are captured in this PI to ensure consistency. |
| Conformance | Both the XSL and CSS stylesheet definitions are required but they are document type specific. | | | |

## Document Information

Outlined in this section are all aspects relating to the Document Information (applicable to the overall document). The Document Information provides the identity of the particular document, its type, template, title, date and versioning as a member of a document set.

### XML

<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 https://raw.githubusercontent.com/HealthCanada/Structured-Content-Information/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd">

<typeId assigningAuthorityName=” Health Products and Food Branch”/>

<templateId extension="1" root="2.16.840.1.113883.2.20.6.9"/>

<id root="a6c469cf-5820-48a8-b140-f8f4d63f5600"/>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.10"

displayName="Product Monograph"/>

<title=”Lipitor”/title>

<effectiveTirme value="20070424"/>

<languageCode code="ENG" codeSystem="2.16.840.1.113883.2.20.6.29" displayName="English”/>

<setId root="a30accef-f437-4136-808c-9ed4ada5fcf8"/>

<versionNumber value=“1”/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| document | N/A | 1:1 |  |  |
| xmlns | 1:1 |  |  |
| xmlns:xsi | 1:1 |  |  |
| xsi:schemaLocation | 1:1 |  |  |
| Conformance | 1. There is a document element 2. There is a name space 3. The name space is urn:hl7-org:v3 4. There is a name space for the schema 5. The name space for the schema is: <http://www.w3.org/2001/XMLSchema-instance> 6. The schema location is identified 7. The schemaLocation of the urn:hl7-org:v3 namespace is provided as: https://raw.githubusercontent.com/HealthCanada/Structured-Content-Information/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd 8. There are no processing instructions other than the xml and xml-stylesheet declarations 9. There are no comments | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| typeId | N/A | 1:1 |  | Identifies that the document is a HPFB specified document |
| assigningAuthorityName | 1:1 |  |  |
|  |  |  |  |  |
| Conformance | 1. There is a typeId element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a assigningAuthorityName attribute with a value of: Health Products and Food Branch 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The assigningAuthorityName SPL Rule 10 identifies that the attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| templateId | N/A | 1:1 |  | Provides an ID for the document template.  It is used to document the specific template (e.g. 2004 Standard Product Monograph) |
| root | 1:1 |  |  |
|  | extension | 1:1 |  |  |
| Conformance | 1. There is a templateId element 2. SPL Rule 3 identifies that the element has not been defined. 3. There is an root attribute with a value of: 2.16.840.1.113883.2.20.6.9 4. SPL Rule 5 identifies that the attribute has not been defined. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. There is an extension attribute derived from the OID. 7. SPL Rule 5 identifies that the attribute has not been defined. 8. SPL Rule 8 identifies that the code is not in the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:1 |  | Provides a globally unique ID for the document. |
| root | 1:1 |  |  |
| Formation Conformance | 1. There is an id element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is an root attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The id@root is a GUID 7. The id@root is unique for each version of the document 8. Currently this is not validated. 9. The id@root does not have an extension 10. The id@root does not match any other id in the document 11. The id@root is unique across all documents, sections and any other ids 12. Currently this is not validated. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| code | N/A | 1:1 |  | Details the Document Type (i.e. what is the content of the document).  It is used to document the business document type not the specific template (ie. PM not the 2004 Standard temple) |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code attribute whose value is derived from the OID. 5. SPL Rule 5 identifies that the attribute has not been defined. 6. SPL Rule 8 identifies that the code is not in the CV. 7. The code value is document specific 8. Informational only (no validation aspect). 9. There is a codeSystem attribute with a value of: 2.16.840.1.113883.2.20.6.10 10. SPL Rule 5 identifies that the attribute has not been defined. 11. SPL Rule 2 identifies that the OID value is incorrect. 12. There is a displayName attribute that shall display the appropriate label. 13. SPL Rule 5 identifies that the attribute has not been defined. 14. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| title | N/A | 0:1 |  | Provides the title for the document. |
| Conformance | 1. There may be a title, unless specified otherwise in the document specific validation guidance. 2. Informational only (no validation aspect). 3. The title is free form 4. Informational only (no validation aspect). 5. There are no figures in the title. 6. There are no images in the title. 7. Multiple lines may be used in the title with each line separated by a line break <br/> tag. (note: titles can also be as follows: <title mediaType="text/x-hl7-title+xml">). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| effectiveTime | N/A | 1:1 |  | Used to capture relevant time and date information:   * Document effective date = Date of preparation (or date of Revision if more current than date of preparation) * Section effective date = Date of preparation (or date of Revision if more current than date of preparation) |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is an value attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The effectiveTime@value has as a minimum precision of day. 7. The format is year, month and day (yyyymmdd). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| languageCode | N/A | 1:1 |  | Specifies the language of the document |
| code | 1:1 |  |  |
|  | codeSystem | 1:1 |  |  |
|  | displayName | 1:1 |  |  |
| Conformance | 1. There is a languageCode element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code attribute whose value can either be ENG or FRA. 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The code SPL Rule 10 identifies that the attribute value is incorrect. 7. There is a codeSystem attribute with a value of: 2.16.840.1.113883.2.20.6.29 8. SPL Rule 5 identifies that the attribute has not been defined. 9. SPL Rule 2 identifies that the OID value is incorrect. 10. There is a displayName attribute that shall display the appropriate label. 11. SPL Rule 5 identifies that the attribute has not been defined. 12. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| setId | N/A | 1:1 |  | Unique identifier for the document that remains constant through all versions/revisions of the document. |
| root | 1:1 |  |  |
| Conformance | 1. There is a setID element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a root attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The setId@root is a GUID 7. The setId@root does not have an extension. 8. The setId@root does not match any other id in the document | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| versionNumber | N/A | 1:1 |  | The version of the document. |
| value | 1:1 |  |  |
| Conformance | 1. There is a versionNumber element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a value attribute which is an integer greater than zero that provides a sequence to the versions of the document 5. SPL Rule 5 identifies that the attribute has not been defined. 6. SPL Rule 30 identifies that the versionNumber@value is 0. 7. SPL Rule 31 identifies that the versionNumber@value is not an integer. 8. The value of value must be incremented by 1 for each version of a document with the same setID@root 9. Currently not validated. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| author | N/A | 1:1 |  | The version of the document. |
| Conformance | 1. There is an author element 2. Due to the complexity of this element it has been detailed in the Author Information section | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component | N/A | 1:1 |  | The version of the document. |
| Conformance | 1. There is an component element 2. Due to the complexity of this element it has been detailed in several sections primarily the Labeling Content Section Information and Product Data Information – Product in General sections. | | | |

## Author Information

Outlined in this section are all aspects relating to the author aspects for the document

### XML

<document>

<author>

<assignedEntity>

<representedOrganization> <!—DIN Owner -->

<assignedEntity>

<assignedOrganization> <!—Other parties as required-->

The following is a representative coding of the author aspect:

<author>

<time/>

<assignedEntity>

<representedOrganization>

<id root="2.16.840.1.113883.2.20.6.31" extension="999999999"/>

<id root="2.16.840.1.113883.2.20.6.33" extension="1"/>

<name>Acme Inc.</name>

<contactParty>

<addr>

<streetAddressLine>12 ApplewoodAve</streetAddressLine>

<city>Ottawa</city>

<state>Ontario</state>

<postalCode>K1S 0B5</postalCode>

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

</addr>

<telecom value="tel:+1-613-239-9919"/>

<telecom value="mailto:a@b.com"/>

<contactPerson>

<name>Smith, Joe</name>

</contactPerson>

</contactParty>

<assignedEntity>

<assignedOrganization>

<assignedEntity>

<assignedOrganization>

<id root="2.16.840.1.113883.2.20.6.31" extension="999999999"/>

<id root="2.16.840.1.113883.2.20.6.33" extension="3"/>

<name>Bell Canada</name>

<telecom value="tel:+1-613-239-9009"/>

<telecom value="mailto:c@b.com"/>

<addr>

<streetAddressLine>122 ApplewoodAve</streetAddressLine>

<city>Ottawa</city>

<state>Ontario</state>

<postalCode>K1S 0B3</postalCode>

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

</addr>

<contactParty>

<contactPerson>

<name>Fred, Last</name>

</contactPerson>

</contactParty>

</assignedOrganization>

</assignedEntity>

</assignedOrganization>

</assignedEntity>

</representedOrganization>

</assignedEntity>

</author>

Organizations are identified using HPFB Company IDs. These are identifiers with the root 2.16.840.1.113883.2.20.6.31 and an extension.

<representedOrganization>

<id extension=“Company ID” root="2.16.840.1.113883.2.20.6.31"/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| Author | N/A | 1:1 |  |  |
| Conformance | 1. There is an author element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| Time | N/A | 0:1 |  |  |
| Conformance | 1. There may be a time element 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedEntity | N/A | 0:1 |  |  |
| Conformance | 1. There is an assignedEntity element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is an representedOrganization element 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization | N/A | 1:1 |  |  |
| Conformance | 1. There is a representedOrganization element. 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. The representedOrganization will contain one or more id elements. 5. SPL Rule 3 identifies that the element has not been defined. 6. The representedOrganization must contain an id element that has an root value of 2.16.840.1.113883.2.20.6.33, and an extension value of 1 7. SPL Rule 5 identifies that the extension attribute has not been defined. 8. SPL Rule 2 identifies that the OID value is incorrect. 9. SPL Rule 10 identifies that no role has been assigned. 10. SPL Rule 10 identifies that more than one role has been assigned. 11. SPL Rule 10 identifies that no DIN owner is identified. 12. SPL Rule 10 identifies that the role is not DIN owner. 13. The representedOrganization must contain an id element that has an id@root value of 2.16.840.1.113883.2.20.6.31, and an extension value containing a valid Company ID number derived from OID: 2.16.840.1.113883.2.20.6.31 or a value of 999999999 to indicate that the Company ID is Not Available. 14. SPL Rule 5 identifies that the extension attribute has not been defined. 15. SPL Rule 2 identifies that the OID value is incorrect. 16. SPL Rule 10 identifies that no company ID has been assigned. 17. SPL Rule 10 identifies that more than one company ID has been assigned 18. SPL Rule 10 identifies that the company ID is not in the CV or 999999999. 19. The representedOrganization will contain a name element. 20. SPL Rule 3 identifies that the element has not been defined. 21. SPL Rule 8 identifies that the code is not in the CV. 22. SPL Rule 6 identifies that the name is empty. 23. The representedOrganization will contain a contactParty element. 24. SPL Rule 3 identifies that the element has not been defined. 25. The representedOrganization may contain one or more assignedEntity elements as per the Doctype specifics 26. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedEntity | N/A | 0:1 |  |  |
| Conformance | 1. There may be an assignedEntity element 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization | N/A | 0:1 |  |  |
| Conformance | 1. There may be an assignedOrganizationelement 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedEntity | N/A | 0:1 |  |  |
| Conformance | 1. There may be an assignedEntity element 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization | N/A | 0:n |  |  |
| Conformance | 1. The assignedOrganization must contain one or more id elements. 2. SPL Rule 3 identifies that the element has not been defined. 3. The assignedOrganization must contain an id element that has an id@root value of 2.16.840.1.113883.2.20.6.33, and an extension value other than 1. 4. SPL Rule 2 identifies that the OID value is incorrect. 5. SPL Rule 8 identifies that the code is not in the CV 6. SPL Rule 10 identifies that the role is the DIN Owner. 7. The assignedOrganization must contain an id element that has an id@root value of 2.16.840.1.113883.2.20.6.31, and an extension value containing a valid Company ID number derived from OID: 2.16.840.1.113883.2.20.6.31 or a value of 999999999 to indicate that the Company ID is Not Available. 8. SPL Rule 2 identifies that the OID value is incorrect. 9. SPL Rule 10 identifies that there is no company ID. 10. SPL Rule 10 identifies that more than one company ID is identified. 11. SPL Rule 8 identifies that the company ID is not in the CV or 999999999. 12. The assignedOrganization shall contain a name element. 13. Informational only (no validation aspect). 14. The assignedOrganization may contain a telecom element. 15. Informational only (no validation aspect). 16. The assignedOrganization may contain a contactParty element. 17. Informational only (no validation aspect). 18. The assignedOrganization may contain one or more assignedOrganization elements. 19. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:n |  |  |
| extension |  |  |  |
| Root |  |  |  |
| Conformance | This is validated as part of representedOrganization and assignedOrganization | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| name | N/A | 1:1 |  |  |
| Conformance | 1. There must be a name element. 2. SPL Rule 3 identifies that the element has not been defined. 3. The name shall contain the business name that was assigned the id@extension value. 4. SPL Rule 8 identifies that the code is not in the CV 5. SPL Rule 6 identifies that the name is empty. 6. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.contactParty | N/A | 0:n |  |  |
| Conformance | 1. There shall be a contactParty element 2. SPL Rule 3 identifies that the element has not been defined. 3. The contactParty shall contain an addr element 4. SPL Rule 3 identifies that the element has not been defined. 5. The contactParty may contain a telecom element 6. Informational only (no validation aspect). 7. The contactParty may contain a contactPerson element 8. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization.contactParty | N/A | 0:n |  |  |
| Conformance | 1. There may be a contactParty element 2. Informational only (no validation aspect). 3. The contactParty may contain an addr element 4. Informational only (no validation aspect). 5. The contactParty may contain a telecom element 6. Informational only (no validation aspect). 7. The contactParty may contain a contactPerson element 8. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.addr | N/A | 0:1 |  | The address for the Sponsor |
| Conformance | 1. There shall be a complete address 2. SPL Rule 9 identifies that there are not 5 elements in the address, therefore some aspect is missing. 3. The addr shall contain a streetAddressLine. 4. SPL Rule 3 identifies that the element has not been defined. 5. SPL Rule 6 identifies that the element is empty. 6. The addr shall contain a city. 7. SPL Rule 3 identifies that the element has not been defined. 8. SPL Rule 6 identifies that the element is empty. 9. The addr shall contain a state. 10. SPL Rule 3 identifies that the element has not been defined. 11. SPL Rule 6 identifies that the element is empty. 12. The addr shall contain a postalCode. 13. SPL Rule 3 identifies that the element has not been defined. 14. SPL Rule 6 identifies that the element is empty. 15. The addr shall contain a country. 16. SPL Rule 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization .addr | N/A | 0:1 |  | The address for any other party |
| Conformance | 1. There may be an address element 2. Informational only (no validation aspect). 3. The addr element may contain a streetAddressLine element. 4. Informational only (no validation aspect). 5. The addr element may contain a city element. 6. Informational only (no validation aspect). 7. The addr element may contain a state element. 8. Informational only (no validation aspect). 9. The addr element may contain a postalCode element. 10. Informational only (no validation aspect). 11. The addr element may contain a country element. 12. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| streetAddressLine | N/A | 0:1 |  | The streetAddressLine is used for capturing the number, apartment, unit, P.O Box as well as the street name or number. |
| Conformance | 1. There may be a streetAddressLine element. 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| city | N/A | 0:1 |  | The city element is used for capturing city or area information. |
| Conformance | 1. There may be a city element. 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| state | N/A | 0:1 |  | The state element is used for capturing state, province, region |
| Conformance | 1. There may be a state element. 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| postalCode | N/A | 0:1 |  | The postalCode element is used for capturing Postal Codes and Zip Codes |
| Conformance | 1. There may be a postalCode element. 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| country | N/A | 0:1 |  | The country element is used for capturing the country code |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There may be a country element 2. Informational only (no validation aspect). 3. The country has no content. 4. SPL Rule 11 identifies that the element is not empty. 5. The country@codeSystem value is: 2.16.840.1.113883.2.20.6.17 6. SPL Rule 2 identifies that the OID value is incorrect. 7. SPL Rule 8 identifies that the code is not in the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| telecom | N/A | 0:n |  |  |
| value | 1:1 |  |  |
|  | use | 0:1 |  |  |
|  | capability | 0:1 |  |  |
| Conformance | 1. There may be one or more telecom. 2. The telecom shall have no content. 3. The telecom@value attribute shall have contain an type id followed by : then a string 4. The telecom@value type ids are: mailto, tel, fax, cel 5. A telecom with a telecom@value that has a type id of a mailto, tel or cel is required. 6. When the telecom string shall be in ITU-T E.123 notation, as an example: +1 613 960 7510 or +1 613 960 7510 ;ext. 343 7. The number is a global number and therefore must include the country and area code. 8. A + prepends the number. 9. Only white space is used to delineate numbers. 10. Number groups should be separated using white space. 11. The string “;ext” shall preface all extensions 12. The only alpha string permitted is “;ext” all other content shall be + white space or numeric. 13. The telecom@use attribute shall only contain values from OID: 2.16.840.1.113883.2.20.6.4 14. The telecom@capability attribute shall only contain values from OID: 2.16.840.1.113883.2.20.6.??? 15. When the telecom@value type id is mailto then the string shall be of the simple form <username>@<dns-name> | | | |

Outlined below is an example of the contactPerson element.

<contactPerson>

<name>contact person name for DIN Owner/Regulatory Contact</name>

</contactPerson>

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| contactPerson | N/A | 1:1 |  |  |
| Conformance | 1. There may be a contactPerson 2. Informational only (no validation aspect). 3. The contactPerson shall contain a name 4. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| name | N/A | 1:1 |  |  |
| Conformance | 1. There may be a name 2. Informational only (no validation aspect). 3. The name shall be in the form last name, first name. 4. Informational only (no validation aspect). | | | |

## Core Document Reference

For some SPL documents it is permitted to specify a “core document” reference. A document with a core document reference “inherits” all the sections from the referenced core document and may override certain top-level sections with its own sections. A core document reference is specified as follows:

### XML

<document> ...

<author .../>

<relatedDocument typeCode="APND">

<relatedDocument>

<setId root="20d9b74e-e3d8-4511-9df9-cec2087372fc"/>

<versionNumber value="1"/>

</relatedDocument>

</relatedDocument>

<component .../>

</document>

The reference contains the setId of the referenced core-document. The document and the core-document can develop independently. The core-document may be updated, but the reference remains to the latest core-document with the same setId. The version number in the reference may be provided to indicate which version of the core-document was used when at the time the referencing document was created or modified.

### Validation

Currently out of scope for the HPFB implementation therefore not validated.

## Predecessor Document

Other documents may be merged into this document by providing a reference to the other predecessor documents that are replaced by this document.

### XML

<document>

...

<author .../>

<relatedDocument typeCode="RPLC">

<relatedDocument>

<id root="464239de-45c7-4d2f-a89a-45d303f428bd"/>

<setId root=“9ea75e1e-84ef-4605-89ff-dd08a4c94f40”/>

<versionNumber value=“3”/>

</relatedDocument>

</relatedDocument>

<component .../>

</document>

### Validation

Currently out of scope for the HPFB implementation therefore not validated.

## Document Body

The body of the document includes the structured text such as Warnings and Precautions (see section *4.7 Labeling Content Section Information*) and specific data elements such as ingredients (see section *4.10 Product Data Information*).

### XML

<document>

<author .../>

<component>

<structuredBody>

## Labeling Content Section Information

Outlined in this section are all aspects relating to the SPL documents content.

### XML

<section>

<id root="62abedf9-6bde-4787-beb0-abd214307427"/>

<code code="60" codeSystem="2.16.840.1.113883.2.20.6.8" displayName=" Scheduling Symbol"/>

<title>Scheduling Symbol</title>

<text>labeling text</text>

<excerpt>excerpt text</excerpt>

<effectiveTime value="20070822"/>

<component/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| section | N/A | 0:n |  |  |
| Conformance | 1. Each section has zero to many subsections 2. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:1 |  | Provides a globally unique ID for a specific section. |
| root | 1:1 |  |  |
| Conformance | 1. There is an id element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a root attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The id@root is a GUID 7. The id@root is unique for each section 8. The id@root does not have an extension 9. The id@root does not match any other id in the document 10. The id@root is unique across all documents, sections and any other ids | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| code | N/A | 1:1 |  | The section type/label. It is used to identify the content of the section. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a codeSystem attribute with a value of: 2.16.840.1.113883.2.20.6.8 5. SPL Rule 5 identifies that the attribute has not been defined. 6. SPL Rule 2 identifies that the OID value is incorrect. 7. There is a code attribute that is derived from the OID 8. SPL Rule 5 identifies that the attribute has not been defined. 9. SPL Rule 8 identifies that the code is not in the CV. 10. The code value is document specific 11. Informational only (no validation aspect). 12. There is a displayName attribute that shall display the appropriate label. 13. SPL Rule 5 identifies that the attribute has not been defined. 14. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| title | N/A | 0:1 |  | Provides the title for the document. |
| Conformance | 1. There may be a title, unless specified otherwise in the document specific validation guidance 2. Informational only (no validation aspect). 3. The title is free form. 4. Informational only (no validation aspect). 5. There are no figures in the title. 6. There are no images in the title. 7. Multiple lines may be used in the title with each line separated by a line break <br/> tag. (note: titles can also be as follows: <title mediaType="text/x-hl7-title+xml">). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| text | N/A | 0:1 |  | Provides the content for the document. |
| Conformance | 1. There may be text, unless specified otherwise in the document specific validation guidance. 2. Informational only (no validation aspect). 3. The text is free form, however the text content may consist of paragraph elements, table elements, and/or list elements. Due to the complexity of this element it has been detailed in section 4.8 Text Information. 4. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| renderMultiMedia | N/A | 0:n |  |  |
|  | referencedObject | 1:1 |  |  |
| Conformance | 1. There is a renderMultiMedia element. 2. SPL Rule 11 identifies that the element is not empty. 3. There is a referencedObject attribute. 4. SPL Rule 5 identifies that the attribute has not been defined. 5. SPL Rule 6 identifies that the attribute is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| observationMedia | N/A | 0:n |  |  |
|  | ID | 1:1 |  |  |
| Conformance | 1. There is a observationMedia element 2. Informational only (no validation aspect). 3. There is an ID attribute. 4. SPL Rule 5 identifies that the attribute has not been defined. 5. SPL Rule 6 identifies that the attribute is empty. 6. There is a text element 7. SPL Rule 3 identifies that the element has not been defined. 8. SPL Rule 6 identifies that the element is empty. 9. There is a value element 10. SPL Rule 3 identifies that the element has not been defined. 11. SPL Rule 11 identifies that the attribute has content. 12. There is a value@mediaType attribute 13. SPL Rule 5 identifies that the attribute has not been defined. 14. SPL Rule 6 identifies that the attribute is empty. 15. There is a value. reference element 16. SPL Rule 3 identifies that the element has not been defined. 17. There is a value. reference@value attribute, with the following characteristics:  * File name followed by a 3 character file extension. * The file name shall not exceed 59 characters * The file name and file extension shall be all lower case. * Only file formats detailed in the table are permitted:  1. SPL Rule 3 identifies that the element has not been defined. 2. SPL Rule 11 identifies that the attribute has content. 3. The file name contained in the value attribute of the <reference> child element of the <observationMedia> element may not contain spaces. 4. The file name must refer to an accessible file and include the file extension. 5. The <observationMedia> element must identify the graphic media type (i.e., jpg). 6. The <observationMedia> element must include a textual description of the image within the <text> child element of the <observationMedia> element. 7. The type value of the <observationMedia> element shall be xsi:type. 8. Image referenced in text must have an image <observationMedia> element with a matching ID in the same document. 9. The <observationMedia> element is always contained within a <component>. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| excerpt | N/A | 0:1 |  | Provides the content for the document. |
| Conformance | 1. There may be excerpts, unless specified otherwise in the document specific validation guidance. 2. Informational only (no validation aspect). 3. The text is free form, however the text content may consist of paragraph elements, table elements, and/or list elements. Due to the complexity of this element it has been detailed in section 4.9 Excerpt Information. 4. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| effectiveTime | N/A | 1:1 |  |  |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a value attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The effectiveTime@value has as a minimum precision of day. 7. The format is year, month and day (yyyymmdd) if the precision is a date if the precision is greater than date the format is year, month and day (yyyymmdd) space hour, minute, second (hhmmss) | | | |

### Labeling Content Section Details

Sections are the basic building blocks of the document and may contain content or nested sections (subsections) and so forth. All sections have the XML structure outlined above (id, title, code, etc…).

Document element contains a single component element, which in turn contains a single <structuredBody> element. The <structuredBody> contains one or more <component> elements, each <component> element in turn contains 0 (Zero) to N (unbounded) <section> elements. Sections are used to aggregate paragraphs into logical groupings. The order in which the sections appear in the document is the order the sections will appear when displayed (rendered) unless otherwise specified in the document specific information.

Sections may also link to other sections rather than including the content directly.

<section>

<!-- this section’s id, codes -->

<text>

<!-- actual text content in “narrative block” markup -->

</text>

</section>

When applicable as per the doctype, sections shall be nested to form sub-sections. The SPL schema requires that the nested <section> element be nested inside a <component> element.

Use nested sections to relate paragraphs. The <section> element 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 as illustrated below:

<section>

<!-- this section’s id, codes -->

<text>

<!-- actual text content in “narrative block” markup -->

</text>

<component>

<section>

<!-- subsection content -->

</section>

</component>

<component>

<section>

<!-- subsection content -->

</section>

</component>

</section>

The title (if present) and the order of the sections and subsections are used to render the document. An example showing multilevel nesting is included below:

<section ID="Ld8d30d86-e343-48f4-9cec-524834b3803b">  
 <id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208"/>

<code code="450" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="Title Page"/>  
 <title>Title Page</title>  
 <effectiveTime value="20160629"/>  
 <component>  
 <section ID="Ld8d30d86-e343-48f4-9cec-524834b3403b">  
 <id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208"/>

<code code="60" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="Scheduling Symbol"/>  
<title>Scheduling Symbol</title>  
<effectiveTime value="20160629"/>  
<component>  
 <section ID="L79d35375-0da3-429d-b858-bba36a4252e7">  
 <id root="a67b4df8-26d6-42b5-bb29-9920553bbbb6"/>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.2" displayName="Pr"/>  
 <effectiveTime value="20160629"/>  
 </section>

</component>

</section>

The human readable content is contained within the <text> element in the <section>. Using the following principles for markup of text information improves access to information in labeling:

* Capture the section using the <section> element rather than within a <text> element. This allows computer systems to use and display this information properly.
* Capture the section title 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 labeling using the ID attribute to the <section> element. For example, <section ID="Clin\_Pharm\_Section”> 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.
* In general separate content by concept using <paragraph> tags.

## Text Information

Outlined in this section are all aspects relating to the SPL documents textual content.

### XML

<section>

<text>

<paragraph>

The first paragraph in a section.

</paragraph>

<paragraph>

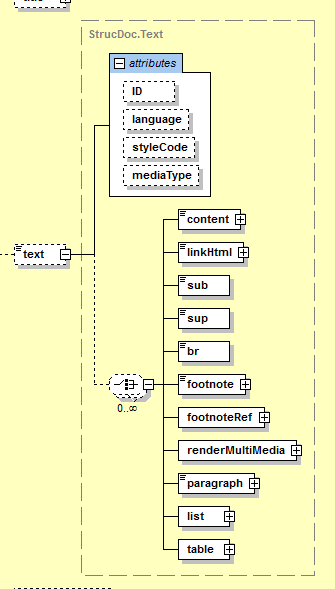
The first paragraph in a section.

</paragraph>

</text>

</section>

The diagram below shows the complete XML structure for the <text> element.



### Text Details

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 Details

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. For example:

<text>

<paragraph>

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

</paragraph>

</text>

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

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

<text>

<paragraph>

<content styleCode="bold italics"> will appear as bold italics</content>

Can also be represented as:

<text>

<paragraph>

<content styleCode="bold”>

<content styleCode="italics”>will appear as bold italics.</content>

</content>

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>

This will appear as bold and will be emphasized by the 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.

Because 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 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; respectively, as an example:

“<paragraph>The mean for group 1 was &lt; 13. </paragraph>”

This will render as “The mean for group 1 was <13.” and

“D&amp;C Yellow #10”

will render as “D&C Yellow #10”.

### Footnote Details

The SPL schema includes a specific footnote element <footnote>. Footnotes are rendered automatically by the SPL 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. “6 This is footnote content”

The <footnoteRef> element with the appropriate IDREF attribute, e.g., <footnoteRef IDREF=”testNote”/> will display the footnote reference in the text corresponding to the footnote with the same ID, e.g., in this example footnote 6.

Footnotes are rendered by the default stylesheet using Arabic numbers (e.g., 1,2 3,). Within tables, footnotes are rendered using footnote marks in the series: \* † ‡ § ¶ # ♠ ♥ ♦ ♣, effectively separating numbered footnotes within general text and footnotes within tables. Footnotes within tables are rendered at the bottom of the table.

### List Details

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 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>

### Table Details

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. It is important that the table communicate labeling content not that it duplicates the presentation in word processed or typeset versions of the package insert. 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 changes in labeling text

SPL offers a notation to identify recent major changes in the labeling 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>

### Images

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>. In other words, an image in an 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"/>

<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="drug-01.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 SPL stylesheet does not perform any resizing 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 very 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 not be consistent with the narrative content reducing the readability of the file. JPEG image file type using appropriate pixels per inch for images for viewing in a browser using the standard style sheet.

Only file formats detailed in the table below are permitted:

| **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. | World Wide Web Consortium (W3C) XML 1.0 | xml |

## Excerpt Information

Outlined in this section are all aspects relating to the SPL documents excerpt content.

### XML

<excerpt>

<highlight>

<text>

<list listType="unordered">

<item>Aplastic anemia has been observed in 8% ...(<linkHtml href=”#Section\_5.1”>5.1</linkHtml>)</item>

<item>Monitor for hematological adverse reactions …(<linkHtml href=”#Section\_5.2”>5.2</linkHtml>)</item>

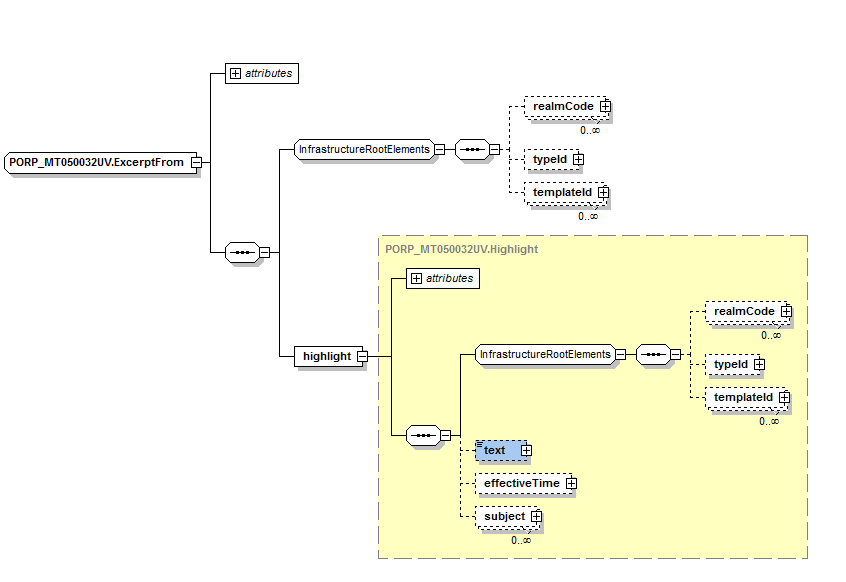
</list>

</text>

</highlight>

</excerpt>

The diagram below shows the XML structure for the < excerpt > element.



### Excerpt Details

The text blocks for Highlights are coded with the <excerpt> <highlight> elements of the major section of labeling in which they are contained.

<section>

<excerpt>

<highlight>

<text>...</text>

Highlight text is placed under the main section and not under subsections. The following is an example:

<component>

<section>

<id root="47ef84cd-8314-48c3-8ee2-bdff3087f83f"/>

<code code="210" codeSystem="2.16.840.1.113883.2.20.6.8" displayName=" Warnings and Precautions"/>

<title>Warnings and Precautions</title>

<excerpt>

<highlight>

<text>

<list listType="unordered">

<item>Aplastic anemia has been observed in 8% ...(<linkHtmlhref=”#Section\_5.1”>5.1</linkHtml>)

</item>

<item>Monitor for hematological adverse reactions …(<linkHtml href=”#Section\_5.2”>5.2</linkHtml>)

</item>

</list>

</text>

</highlight>

</excerpt>

<component>

<section ID="Section\_5.1">

<id root="a857689e-9563-43c0-a244-8a6d5a25966a"/>

<title>5.1 Aplastic anemia</title>

<text>

<paragraph>Aplastic anemia has been observed in…..</paragraph>

</text>

</section>

</component>

</section>

</component>

This example illustrates the following principles:

The <text> block for the Highlights is included as the <excerpt> <highlight> <text> children of the respective section. In the example above, the text block rendered in the highlights section is the child of the “Warnings and Precautions” section.

The coding of the highlights text block is not in a subsection.

The text block is rendered similar to any other text block, although in a location separate from its actual position in the rendered SPL document.

Links to the section or subsection where the primary content exists are explicitly entered in the Highlights text block.

## Product Data Information

Outlined in this section are all aspects relating to the SPL document’s Product Data aspects.

### Location in Document

<document>

<component>

<structuredBody>

<component>

<section>

<subject>

<manufacturedProduct>

### XML

<manufacturedProduct>

<manufacturedProduct>

<!-- elements detailed later in this section-->

</manufacturedProduct>

<!-- elements detailed later in this section-->

</manufacturedProduct>

<section>

<id root="ae4e1587-e25c-4332-9297-47abd89b4be3"/>

<code code="48780-1" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="SPL product data elements section"/>

<title/>

<text/>

<effectiveTime value="20151207"/>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<!-- elements detailed later in this section-->

</manufacturedProduct>

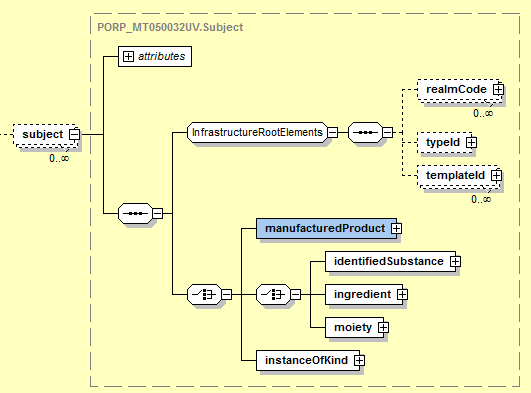
<!-- elements detailed later in this section-->

</manufacturedProduct>

</subject>

</section>

The diagram below shows the XML structure for the <subject> element.



The following is an example for a drug product:

<manufacturedProduct>

<manufacturedProduct>

<code code="*DIN*" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>*proprietary name* <suffix>*suffix to name*</suffix></name>

<formCode code="*dose form code*" codeSystem="2.16.840.1.113883.2.20.6.3” displayName="*display name*"/>

<asEntityWithGeneric>

<genericMedicine>

<name>*non-proprietary name*</name>

</genericMedicine>

</asEntityWithGeneric>

</manufacturedProduct>

<subjectOf>

<approval>

<!-- possibly approval number -->

<code code="C73594" displayName="NDA" codeSystem="2.16.840.1.113883.2.20.6.11"/>

<!-- possibly other attributes in the marketing category -->

</approval>

</subjectOf>

</manufacturedProduct>

The following is an example for a device:

<manufacturedProduct>

<manufacturedProduct>

<code code="*Device Item Code*" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>*proprietary name* <suffix>*suffix to name*</suffix></name>

<desc>*Brief description of product (up to 512 characters)*</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code*" codeSystem="2.16.840.1.113883.2.20.6.27" displayName="*display name*"/>

</generalizedMaterialKind>

</asSpecializedKind>

</manufacturedProduct>

<subjectOf>

<approval>

<!-- possibly approval number -->

<code code="C80441" displayName="Premarket Application" codeSystem="2.16.840.1.113883.2.20.6.11" />

<!-- possibly other attributes in the marketing category -->

</approval>

</subjectOf>

</manufacturedProduct>

General information relating to the product data elements are provided below:

* Code (Item Code): The unique identification of this product whether or not the (item) code is printed on the product itself. The item code is the DIN assigned by HPFB.
* Name: When specific manufactured or marketed products are described, the name is the proprietary name as it appears on the label divided between <name> and <suffix>. The <name> is the initial portion of the proprietary name describing the ingredients without any other descriptors including trademarks and dosage forms. If necessary, <suffix> is used for descriptors such as “extended release”. When using the <suffix>, a space after the proprietary name is added as necessary. Non-proprietary or generic names of drugs are found in the <genericMedicine><name> element. Device type codes and descriptions use <asSpecializedKind>.
* Description: A brief description is added in the <desc> element that states succinctly the kind of device. This text should be brief to be able to list it in short summary listings. While the text can be up to 512 characters in length, it should normally be much shorter so that it will be useful for listing in tables. A device also has a device-nomenclature code in the <asSpecializedKind> element. This code comes from the Product Classification terminology (OID: 2.16.840.1.113883.2.20.6.27).

The following is an example for a drug product:

<subject>

<manufacturedProduct>

<manufacturedProduct>

<code code="*Product Code*" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>*proprietary name* <suffix>*suffix to name*</suffix></name>

<formCode code="*dose form code*" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="*display name*"/>

<asEntityWithGeneric>

<genericMedicine>

<name>non proprietary name</name>

</genericMedicine>

</asEntityWithGeneric>

</manufacturedProduct>

<subjectOf>

<approval> <!-- possibly approval number -->

<code code="C73594" displayName="NDA" codeSystem="2.16.840.1.113883.2.20.6.11" />

<!-- possibly other attributes in the marketing category -->

</approval>

</subjectOf>

</manufacturedProduct>

</subject>

The following is an example for a device:

<subject>

<manufacturedProduct>

<manufacturedProduct>

<code code="Device Item Code" codeSystem=" 2.16.840.1.113883.2.20.6.42"/>

<name>*proprietary name* <suffix>*suffix to name*</suffix></name>

<desc>Brief description of product (up to 512 characters)</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code*" codeSystem="2.16.840.1.113883.2.20.6.27" displayName="*display name*"/>

</generalizedMaterialKind>

</asSpecializedKind>

</manufacturedProduct>

<subjectOf>

<approval> <!-- possibly approval number -->

<code code="C80441" displayName="Premarket Application" codeSystem="2.16.840.1.113883.2.20.6.11" />

<!-- possibly other attributes in the marketing category -->

</approval>

</subjectOf>

</manufacturedProduct>

</subject>

### Equivalence to other Products, Product Source

The following is for referencing information already submitted for a source drug:

<manufacturedProduct>

<manufacturedProduct>

<code code="Product Code" codeSystem=" 2.16.840.1.113883.2.20.6.42"/>

<name>proprietary name

<suffix>suffix to name</suffix>

</name>

<asEquivalentEntity classCode="EQUIV">

<code code="C64637" codeSystem="2.16.840.1.113883.2.20.6.12"/>

<definingMaterialKind>

<code code="source product DIN" codeSystem="2.16.840.1.113883.2.20.6.42"/>

</definingMaterialKind>

</asEquivalentEntity>

</manufacturedProduct>

</manufacturedProduct>

This is a special case of referencing other products for various purposes. Another purpose is for products that are updated with improvement, where it may be useful to indicate a succession to a previous version of the product identified by the item code of the predecessor product. This can be done using the equivalence relationship with <asEquivalentEntity> with a different Role code as in outlined in the example below:

<manufacturedProduct>

<manufacturedProduct>

...

<asEquivalentEntity classCode="EQUIV">

<code code="C64637" codeSystem="2.16.840.1.113883.2.20.6.12"/>

<definingMaterialKind>

<code code=”source product DIN” codeSystem=”2.16.840.1.113883.2.20.6.42”/>

The equivalency code would identify if it was a predecessor or same product being referenced.

Product source may be specified under a product

<subject>

<manufacturedProduct>

<manufacturedProduct>

<asEquivalentEntity>

or under parts

<part>

<partProduct>

<asEquivalentEntity>

### Additional Identifiers for this Product

A multitude of other identifiers may be assigned to products by various parties, manufacturers, distributors, wholesalers, regulators. These identifiers are of a varying quality in terms of control for uniqueness and meaning. They may be unique item codes from other ISO 15459 item code systems, or they may be less well defined codes such as “model number” or “catalog number” etc. While those “model numbers” or “catalog numbers” are often not safe for referencing, such identifiers are customer facing and may encode minor product variants, which would be recognized by customers and hence listing such identifier cross references can aid in finding the correct item code.

<manufacturedProduct>

<manufacturedProduct>

...

<asIdentifiedEntity classCode="IDENT">

<id extension="other identifier" root="other identifier root"/>

<code code="other identifier type code" codeSystem="2.16.840.1.113883.2.20.6.13" displayName="model number"/>

HL7 requires any identifier to be made globally unique, therefore submitters must acquire an OID of their own through any of several sources (e.g. HL7 provides an OID registration service). Submitters must not allow conflicting assignments of model numbers among their own products. Submitters can still create unique identifiers from these model numbers by giving different root OIDs for each kind of identifiers that may be in conflict. Once a company has acquired a root OID this root OID can be freely sub-divided. For example, ACME Fine Devices Inc. may have acquired the OID 2.16.840.1.113883.3.98765 from the HL7 registry. ACME then decided to use a sub-branch .2 under their OID to manage model numbers for the models from models release before 2007 and sub-branch .5 for models released after 2007. There is no specific rule that must be obeyed when sub-dividing OIDs as long as it results in the concatenation of model number code and codeSystem OID to be a unique identifier.

Different types of identifications are assigned different codes from the Identifier Type CV (OID: 2.16.840.1.113883.2.20.6.23)

### Ingredient

Ingredients may be specified for products

<subject>

<manufacturedProduct>

<manufacturedProduct>

<ingredient/>

and parts.

<part>

<partProduct>

<ingredient/>

Ingredient information includes the Class Code specifying the role of the ingredient (e.g., active, inactive, etc) where the class code is derived from OID: 2.16.840.1.113883.2.20.6.39 along with the code, name, and strength, and possibly the active moiety name(s) and identifier and a reference ingredient name and identifier. Detailed below are the Class Code options and definitions, not the term hierarchy.

| **Level** | **Code** | **Name** | **Description** |
| --- | --- | --- | --- |
| 1 | INGR | ingredient | Relates a component to a mixture. E.g., Glucose and Water are ingredients of D5W, latex may be an ingredient in a tracheal tube.  This code is used to group related items together and is not used directly in the identification of the role. |
| 2 | ACTI | active ingredient | A therapeutically active ingredient in a mixture , where the mixture is typically a manufactured pharmaceutical. It is unknown if the quantity of such an ingredient is expressed precisely in terms of the playing ingredient substance, or, if it is specified in terms of a closely related substance (active moiety or reference substance).  This code is used to group related items together and is not used directly in the identification of the role. |
| 3 | ACTIB | active ingredient - basis of strength | An active ingredient, where the ingredient substance is itself the "basis of strength", i.e., where the Role.quantity specifies exactly the quantity of the player substance in the medicine formulation.  Examples: Lopressor 50 mg actually contains 50 mg of metoprolol succinate, even though the active moiety is metoprolol, but also: Tenormin 50 mg contain 50 mg of atenolol, as free base, i.e., where the active ingredient atenolol is also the active moiety. |
| 3 | ACTIM | active ingredient - moiety is basis of strength | An active ingredient, where not the ingredient substance, but the ingredient active moiety is the "basis of strength", i.e., where the Role.quantity specifies the quantity of the player substance's active moiety in the medicine formulation. Examples: 1 mL of Betopic 5mg/mL eye drops contains 5.6 mg betaxolol hydrochloride equivalent to betaxolol base 5 mg. |
| 3 | ACTIR | active ingredient - reference substance is basis of strength | An active ingredient, where not the ingredient substance but another reference substance with the same active moiety, is the "basis of strength", i.e., where the Role.quantity specifies the quantity of a reference substance, similar but different from the player substance's in the medicine formulation. Examples: Toprol-XL 50 mg contains 47.5 mg of metoprolol succinate equivalent to 50 mg of metoprolol tartrate. |
| 2 | ADJV | adjuvant | A component added to enhance the action of an active ingredient (in the manner of a catalyst) but which has no active effect in and of itself. Such ingredients are significant in defining equivalence of products in a way that inactive ingredients are not. |
| 2 | ADTV | additive | An ingredient that is added to a base, that amounts to a minor part of the overall mixture. |
| 2 | BASE | base | A base ingredient is what comprises the major part of a mixture. E.g., Water in most i.v. solutions or Vaseline in salves. Among all ingredients of a material, there should be only one base. A base substance can, in turn, be a mixture. |
| 2 | CNTM | contaminant ingredient | An ingredient whose presence is not intended but may not be reasonably avoided given the circumstances of the mixture's nature or origin. |
| 2 | IACT | inactive ingredient | An ingredient which is not considered therapeutically active, e.g., colors, flavors, stabilizers, or preservatives, fillers, or structural components added to an active ingredient in order to facilitate administration of the active ingredient but without being considered therapeutically active. An inactive ingredient need not be biologically inert, e.g., might be active as an allergen or might have a pleasant taste, but is not an essential constituent delivering the therapeutic effect. |
| 3 | COLR | color additive | A substance influencing the optical aspect of material. |
| 3 | FLVR | flavor additive | A substance added to a mixture to make it taste a certain way. In food the use is obvious; in pharmaceuticals flavors can hide disgusting taste of the active ingredient (important in pediatric treatments). |
| 3 | PRSV | preservative | A substance added to a mixture to prevent microorganisms (fungi, bacteria) from spoiling the mixture. |
| 3 | STBL | stabilizer | A stabilizer added to a mixture in order to prevent the molecular disintegration of the main substance. |
| 2 | MECH | mechanical ingredient | An ingredient of a medication that is inseparable from the active ingredients, but has no intended chemical or pharmaceutical effect itself, but which may have some systemic effect on the patient.  An example is a collagen matrix used as a base for transplanting skin cells. The collagen matrix can be left permanently in the graft site. Because it is of bovine origin, the patient may exhibit allergies or may have cultural objections to its use. |

If the ingredient is confidential, the element <ingredient> includes:

<confidentialityCode code="1" codeSystem="2.16.840.1.113883.2.20.6.21 displayName=”Company Confidential Information"/>

Outlined below is an example of an active ingredient:

Devices may have active ingredients as discussed above (device with embedded ingredient).

<ingredient classCode=”class code including basis of strength”>

<confidentialityCode code="1" codeSystem="2.16.840.1.113883.2.20.6.21"

displayName=”Company Confidential Information"/>

<quantity>

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

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

</quantity>

<ingredientSubstance>

<code code="I*D*" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>active ingredient name</name>

<activeMoiety>

<activeMoiety>

<code code="*ID*" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>*active moiety name*</name>

</activeMoiety>

</activeMoiety>

<asEquivalentSubstance>

<definingSubstance>

<code code="*ID*" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>reference substance name</name>

</definingSubstance>

</asEquivalentSubstance>

</ingredientSubstance>

</ingredient>

Outlined below is an example of an active ingredient, where the basis of strength is the moiety:

<ingredient classCode="ACTIR">

<ingredientSubstance>

<activeMoiety>

<activeMoiety>

<code code="0987654321" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>tazminic acid</name>

Outlined below is an example of an inactive ingredient:

<ingredient classCode="IACT">

<confidentialityCode code="1" codeSystem="2.16.840.1.113883.2.20.6.21" displayName=”Company Confidential Information "/>

<quantity>

<numerator value="value" unit=“code”/>

<denominator value="value" unit=“code”/>

</quantity>

<ingredientSubstance>

<code code="*ID*" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>inactive ingredient name</name>

</ingredientSubstance>

</ingredient>

Outlined below is an example of a reference ingredient for the strength:

<ingredient classCode=“ACTIR”>

<ingredientSubstance>

<asEquivalentSubstance>

<definingSubstance>

<code code="A123455678" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>tazemate formate</name>

Source ingredient means using an existing product as one of the ingredient in other compounded drug.

<ingredient classCode="INGR">

<quantity>

<numerator value="12" unit="mg"/>

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

</quantity>

<ingredientSubstance>

<code code="88888-333" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>MIDAZOLAM HYDROCHLORIDE</name>

</ingredientSubstance>

</ingredient>

The strength is represented as a numerator and denominator along with a unit of measure. The Units of Measure code for a unit that is an “each” is “1”. In most cases, the strength used is that for a single dose following the conventions in the Table below. In the table, an example of “mass” is milligrams, an example of “volume” is milliliter, an example of “time” is hour, and an example of “each” is tablet.

Table 2: Conventions for expressing strength

| Product | Numerator unit | Denominator unit |
| --- | --- | --- |
| Oral solid | Mass | Each |
| Oral liquid | Mass | Volume |
| Oral powder for reconstitution with a known volume | Mass | Volume |
| Oral powder for reconstitution with a variable volume | Mass | Each |
| Suppository | Mass | Each |
| Injection liquid | Mass | Volume |
| Injection powder for reconstitution with a known volume | Mass | Volume |
| Injection powder for reconstitution with a variable volume | Mass | Each |
| Inhaler powder | Mass | Each |
| Inhaler liquid | Volume | Each |
| Inhaler blister | Mass | Each |
| Topical cream or ointment | Mass | Mass |
| Topical gel or lotion | Mass | Volume |
| Transdermal patch | Mass | Time |

### Packaging

The packaging includes the quantity of product in the package and the package type and Package Item Code (such as NDC Package Code or other Item Code for the package).

Packaging may be specified for the product,

<manufacturedProduct>

<manufacturedProduct>

<asContent/>

for parts,

<part>

<partProduct>

<asContent/>

and for packages.

<asContent>

<containerPackagedProduct>

<asContent/>

An example of the packaging specification format is:

<asContent>

<quantity>

<numerator value="*value*" unit="*code*"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="*Package Item Code*" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<formCode code="*value*" codeSystem="2.16.840.1.113883.2.20.6.38" displayName="*display name*"/>

</containerPackagedProduct>

</asContent>

### Kits, Parts, Components and Accessories

Products may be combined in various ways such as:

• Drug kit with a device part

• Device kit with a drug part

• Device with an embedded drug

• Drug in a delivery device

• Products sold separately but meant to be used together

**Kits and Parts:** When products have more than one part, each part is described under <partProduct>. The total amount of the part in the product is included as follows:

<part>

<quantity>

<numerator value="total amount of part in product" unit="Ingredient ID"/>

<denominator value="1"/>

</quantity>

<partProduct> <!-- same as above for drug or device. -->

When a drug product has parts, it is considered a Kit indicated by the formCode for KIT:

<manufacturedProduct>

<manufacturedProduct>

<code code="11234560012349" codeSystem=" 2.16.840.1.113883.2.20.6.42"/>

<name>Easy-Go PreciFuse PorterPump Kit</name>

<formCode code="C47916" displayName="KIT" codeSystem="2.16.840.1.113883.2.20.6.38"/>

<part>

<!-- ... -->

Device products may also be kits (in this case a device with the HPFB product classification code but also with formCode specifying KIT. However, devices themselves may also be specified with parts, such as distinguishing component options or field replaceable parts, in this case the top-level device need not have a formCode for KIT:

<manufacturedProduct>

<manufacturedProduct>

<code code="*item code of device*" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>*name of device*</name>

<desc>brief description of device</desc>

<asSpecializedKind ... product classification for device ... />

<part>

<quantity>

<numerator value="1"/>

<denominator value="1"/>

</quantity>

<partProduct>

<code code="*item code of part*" codeSystem="*code system OID*"/>

<name>name of part</name>

<desc>brief description of device part</desc>

### Drug Kit with a Device Part

<manufacturedProduct>

<manufacturedProduct>

<code code="DIN of kit" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>name of kit</name>

<formCode code="C47916" displayName="KIT" codeSystem="2.16.840.1.113883.2.20.6.16"/>

<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="*code of drug part*" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<name>name of drug part</name>

<formCode code="*form code of drug part*" displayName="*form name of drug part*" codeSystem="2.16.840.1.113883.2.20.6.16"/>

<ingredient ... />

<asContent>

<quantity>

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

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="code of part’s package" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<formCode code="package type" displayName="package type name" codeSystem="2.16.840.1.113883.2.20.6.38"/>

</containerPackagedProduct>

</asContent>

</partProduct>

</part>

<part>

<quantity>

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

<denominator value="1"/>

</quantity>

<partProduct>

<code code="item code of this device part" codeSystem="item code system OID"/>

<name>name of device part</name>

<desc>description of device part</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="product classification code of device part" codeSystem="2.16.840.1.113883.2.20.6.27" displayName="display name of device part"/>

</generalizedMaterialKind>

</asSpecializedKind>

</partProduct>

</part>

### Device Kit with a Drug Part

<manufacturedProduct>

<manufacturedProduct>

<code code="item code of device kit" codeSystem="item code system OID"/>

<name>*name of kit*</name>

<desc>brief description of kit</desc>

<formCode code="C47916" displayName="KIT" codeSystem="2.16.840.1.113883.2.20.6.16"/>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code of kit*" displayName="*display name of kit*" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

<part> same as device part above </part>

<part> same as drug part above </part>

**Device with an embedded drug:** For example, a drug eluting stent with an embedded active ingredient. Notice that such products do not involve kits and parts:

<manufacturedProduct>

<manufacturedProduct>

<code code="device item code" codeSystem="device item code system OID"/>

<name>*device name*</name>

<desc>*brief description*</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code of device*" displayName="*display name of device*" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

<ingredient classCode="ACTIB">

<quantity .../>

<ingredientSubstance>

<code code="*ID code of active ingredient*" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>*paclitaxel*</name>

**Drug in a delivery device:** For example, drug in pre-filled syringe. Note that the syringe filled with the drug is a different product than the empty syringe. Hence it would not be correct to put the item code for the empty syringe on the one filled with the drug. In fact, since the pre-filled syringe already has (or should have) an NDC code, there is no need for another item code for it. However, one may want to refer to the item code for the empty syringe as a generalization of the filled syringe:

<manufacturedProduct>

<manufacturedProduct>

<code code="*DIN*" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>*name of drug*</name>

<formCode code="*form code of drug*" displayName="*form display name of drug*" codeSystem="2.16.840.1.113883.2.20.6.16"/>

<ingredient classCode="ACTIB">

<!-- active ingredient -->

</ingredient>

<asContent>

<quantity>

<numerator value="*amount of drug in prefilled device*" unit="*unit of amount*"/> <denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="code for prefilled device" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<formCode code="form code of prefilled device" displayName="form display name of prefilled device" codeSystem="2.16.840.1.113883.2.20.6.38"/>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="item code of empty device" codeSystem="item code system of empty device"/>

<desc>brief description of empty device</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="product classification code of device" displayName="display name of device" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

</generalizedMaterialKind>

</asSpecializedKind>

</containerPackagedProduct>

**Products sold separately but meant to be used together:** when products are used together but packaged separately, the data element <asPartOfAssembly> is used to identify the other product. The products could be drugs or devices.

<manufacturedProduct>

<manufacturedProduct>

<code code="item code of device" codeSystem="code system OID"/>

<name>*name of device*</name>

<desc>brief description of device</desc>

<asSpecializedKind ... product classification for device .../>

<asPartOfAssembly>

<quantity>

<numerator value="1"/>

<denominator value="1"/>

</quantity>

<wholeProduct><!-- this is the assembly, but has no identifier -->

<part>

<quantity>

<numerator value="1"/>

<denominator value="1"/>

</quantity>

<partProduct>

<code code="item code of accessory component" codeSystem="code system OID"/> <name>name of accessory component</name>

<desc>brief description of accessory component</desc>

<asSpecializedKind ... product classification for device .../>

Parts may be specified for the product,

<manufacturedProduct>

<manufacturedProduct>

<part/>

and for part products.

<part>

<partProduct>

<part/>

### Marketing Category and Application Number

The approval structure specifies in the <code> the marketing category under which the product is approved for marketing. Products marketed under an approved application have an application number in the <id extension> and application tracking system under <id root>. Products marketed under a monograph provide the regulatory citation for the monograph <id extension> and the application tracking system under <id root>. If there is no application number or monograph citation, the id element is omitted.

<subjectOf>

<approval>

<id extension="application or monograph number" root="2.16.840.1.113883.2.20.6.???"/>

<code code="code for marketing category" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="display name"/>

<author>

<territorialAuthority>

<territory>

<code code="CAN" codeSystem="2.16.840.1.113883.2.20.6.17"/>

</territory>

</territorialAuthority>

</author>

</approval>

</subjectOf>

Marketing category is connected through the <subjectOf> element which may appear on the main product:

<subject>

<manufacturedProduct>

<manufacturedProduct/>

<subjectOf/>

or on parts:

<part>

<partProduct/>

<subjectOf/>

Example:

<subjectOf>

<approval>

<id extension="NDA123456" root="2.16.840.1.113883.2.20.6.???"/>

<code code="C73594" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="NDA"/>

<author>

<territorialAuthority>

<territory>

<code code="CAN" codeSystem="2.16.840.1.113883.2.20.6.17"/>

### Marketing status

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

<subject>

<manufacturedProduct>...</manufacturedProduct>

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.18"/>

<statusCode code="active"/>

<effectiveTime> <low value="20040120"/>

The <code> indicates the activity of “marketing”. 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. 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>. Example of a currently marketed product:

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.18"/>

<statusCode code="active"/>

<effectiveTime>

<low value="date when on the market"/>

</effectiveTime>

</marketingAct>

</subjectOf>

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

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.18"/>

<statusCode code="active"/>

<effectiveTime>

<low value="date when on the market"/>

<high value="date when the product is going to be off the market"/>

</effectiveTime>

</marketingAct>

</subjectOf>

For some types of products, a marketing status may be provided on the package level:

<asContent>

<containerPackagedProduct>...</containerPackagedProduct>

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.18"/>

<statusCode code="active"/>

<effectiveTime>

<low value="20040120"/>

### General Characteristics

Several characteristics may be specified for products. In general, the structure allows specifying properties of the product in a code-value pair, the code saying which property is being specified, the value saying what the property is for the given product. The structure connects to the product Role through the subjectOf element.

<manufacturedProduct>

<manufacturedProduct> ... </manufacturedProduct>

<subjectOf>

<characteristic>

<code code="*characteristic code*" codeSystem=“2.16.840.1.113883.2.20.6.23”/>

<value xsi:type="*characteristic value type*" ...>

Some characteristics may be specified for packaged products:

<manufacturedProduct>

<manufacturedProduct>

...

<asContent>

<containerPackagedProduct> ... </containerPackagedProduct>

<subjectOf>

<characteristic>

<code code="*characteristic code*" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="characteristic value type" ...>

Characteristics use one of a number of different data types. Each data type uses slightly different XML elements and attributes as shown in the templates below:

Characteristic of type physical quantity (PQ):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="PQ" value="quantity value" unit="quantity unit">

Characteristic of type number (REAL):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="REAL" value="quantity value"/>

Characteristic of type integer number (INT):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="INT" value="*quantity value*"/>

Characteristic of coded type (CV):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="CV" code="value code" codeSystem="value code system OID" displayName="value code display name">

Characteristic of type character string (ST):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

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

Characteristic of type interval of physical quantity (IVL\_PQ):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="IVL\_PQ">

<low value="quantity value low boundary" unit="quantity unit"/>

<high value="quantity value high boundary" unit="quantity unit"/>

</value>

Characteristic of type Boolean (true/false value)

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="BL" value="true or false"/>

### Product characteristics

Product characteristics include dosage form appearance. Dosage form characteristics are used to describe the appearance of the drug product and include the color, score, shape, size, imprint code and image. These are all under <subjectOf> which is a child of <manufacturedProduct>. Product characteristics also include product flavor and what the product contains.

<subjectOf>

<characteristic classCode="OBS">

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Color"/>

<value code="C48325" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="White" xsi:type="CE">

<originalText>optional original color description text</originalText>

</value>

</characteristic>

</subjectOf>

#### Color

<subjectOf>

<characteristic>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Color"/>

<value code="C48333" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="blue" xsi:type="CE">

<originalText>LIGHT BLUE</originalText>

#### Shape

<subjectOf>

<characteristic>

<code code="3" 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="capsule" xsi:type="CE"/>

<originalText>capsule like</originalText>

#### Size

<subjectOf>

<characteristic>

<code code="11" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Size"/>

<value unit="mm" value="18" xsi:type="PQ"/>

#### Scoring

<subjectOf>

<characteristic>

<code code="5" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=”Score”/>

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

#### Imprint Code

<subjectOf>

<characteristic>

<code code="12" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=”Imprint”/>

<value xsi:type="ST">05</value>

#### Flavor

<subjectOf>

<characteristic>

<code code="4" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=”Flavor”/>

<value code="C73391" codeSystem="2.16.840.1.113883.2.20.6.26" displayName="grape" xsi:type="CE">

<originalText>wild grape</originalText>

#### Image

<subjectOf>

<characteristic>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=”Image”/>

<value xsi:type="ED" mediaType="image/jpeg"> <reference value="8837a946-1912-4c1f-8035-e313fdd11ef2.jpg"/>

#### Combination Product Type

To mark products as combination products, the nearest combining package should bear the combination product type characteristic:

<manufacturedProduct>

<manufacturedProduct>

...

<asContent>

...

<subjectOf>

<characteristic>

<code code="7" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=” Combination Product”/>

<value code="C102835" codeSystem="2.16.840.1.113883.2.20.6.30" xsi:type="CV" displayName="Type 2: Prefilled Drug Delivery Device/System">

#### Production Amount

The production amount for a package is specified as:

<manufacturedProduct>

<manufacturedProduct>

...

<asContent>

...

<subjectOf>

<characteristic>

<code code="6" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=” Production Amount”/>

<value xsi:type="INT" value="10000"/>

Unlimited production amounts are specified as:

<value xsi:type="INT" nullFlavor="PINF"/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct | N/A | 1:1 |  |  |
| Conformance | 1. There is a manufacturedProduct element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is one or more subjectOfelement elements 5. SPL Rule 3 identifies that the element has not been defined. 6. There is a consumedIn element 7. SPL Rule 3 identifies that the element has not been defined. 8. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct | N/A | 1:1 |  |  |
| Conformance | 1. There is a manufacturedProduct element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is an code element 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that more than one element is defined. 7. There is a name element 8. SPL Rule 3 identifies that the element has not been defined. 9. SPL Rule 6 identifies that the name is empty. 10. There may be a desc element 11. Informational only (no validation aspect). 12. There is a formCode element 13. SPL Rule 3 identifies that the element has not been defined. 14. SPL Rule 4 identifies that more than one element is defined. 15. There is a asEntityWithGeneric element 16. SPL Rule 3 identifies that the element has not been defined. 17. SPL Rule 4 identifies that more than one element is defined. 18. There is an ingredient element 19. SPL Rule 3 identifies that the element has not been defined. 20. There is an asContent element 21. SPL Rule 3 identifies that the element has not been defined. 22. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1 | N/A | 1:1 |  |  |
| Conformance | 1. There is an section element 2. SPL Rule 3 identifies that the element has not been defined. 3. There is an id element 4. Informational only (validation aspects are detailed at the element level). 5. There is a code element 6. Informational only (validation aspects are detailed at the element level). 7. There is an title element 8. Informational only (validation aspects are detailed at the element level). 9. There is an text element 10. Informational only (validation aspects are detailed at the element level). 11. There is an effectiveTime element 12. Informational only (validation aspects are detailed at the element level). 13. There is an subject element 14. Informational only (validation aspects are detailed at the element level). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1].id | N/A | 1:1 |  | Provides a globally unique ID for a specific section. |
| root | 1:1 |  |  |
| Conformance | 1. There is an id element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a root attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The id@root is a GUID 7. The id@root is unique for each section 8. The id@root does not have an extension 9. The id@root does not match any other id in the document 10. The id@root is unique across all documents, sections and any other ids 11. Currently this is not validated. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1].code | N/A | 1:1 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is an code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The code value is: 48780-1 7. SPL Rule 10 identifies that the attribute value is incorrect. 8. There is a codeSystem attribute 9. SPL Rule 5 identifies that the attribute has not been defined. 10. The codeSystem value is: 2.16.840.1.113883.2.20.6.8 11. SPL Rule 2 identifies that the OID value is incorrect. 12. There is a displayName 13. SPL Rule 5 identifies that the attribute has not been defined. 14. The displayName shall display the appropriate label. 15. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1].title | N/A | 0:1 |  |  |
| Conformance | 1. There is no content in the title element 2. SPL Rule 21 identifies that there is content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1].text | N/A | 0:1 |  |  |
| Conformance | 1. There is no content in the text element 2. SPL Rule 21 identifies that there is content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1].subject | N/A | 1:n |  | Provides the content for the document. |
| Conformance | 1. There is one or more subject element. 2. SPL Rule 3 identifies that the element has not been defined. 3. Due to the complexity of this element it has been detailed in section 4.10.4 Product Data Information Details 4. Informational only (no validation aspect). | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[1].section[1].effectiveTime | N/A | 1:1 |  |  |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. SPL Rule 3 identifies that the element has not been defined. 3. There is an value attribute 4. SPL Rule 5 identifies that the attribute has not been defined. 5. The effectiveTime@value has as a minimum precision of day. 6. The format is year, month and day (yyyymmdd) if the precision is a date if the precision is greater than date the format is year, month and day (yyyymmdd) space hour, minute, second (hhmmss) | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.code | N/A | 1:1 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is an code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code attribute with a value derived from the OID. 5. SPL Rule 5 identifies that the attribute has not been defined. 6. SPL Rule 10 identifies that the attribute value is incorrect. 7. There is a codeSystem attribute with a value of: 2.16.840.1.113883.2.20.6.42 8. SPL Rule 5 identifies that the attribute has not been defined. 9. SPL Rule 2 identifies that the OID value is incorrect. 10. There is a displayName attribute that displays the appropriate label. 11. SPL Rule 5 identifies that the attribute has not been defined. 12. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct. formCode | N/A | 1:1 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is an formCode element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code attribute with a value derived from the OID 5. SPL Rule 5 identifies that the attribute has not been defined. 6. SPL Rule 8 identifies that the code is not in the CV. 7. There is a codeSystem attribute with a value of: 2.16.840.1.113883.2.20.6.3 8. SPL Rule 5 identifies that the attribute has not been defined. 9. SPL Rule 2 identifies that the OID value is incorrect. 10. There is a displayName attribute that shall display the appropriate label. 11. SPL Rule 5 identifies that the attribute has not been defined. 12. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEntityWithGeneric | N/A | 1:1 |  |  |
| Conformance | 1. There is a asEntityWithGeneric element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a asEntityWithGeneric.genericMedicine element 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that more than one element is defined. 7. There is one or more asEntityWithGeneric.genericMedicine.name element 8. SPL Rule 3 identifies that the element has not been defined. 9. SPL Rule 6 identifies that the name is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ingredient | N/A | 1:n |  |  |
|  | classCode | 1:1 |  |  |
| Conformance | 1. There is one or more ingredient element with a class code derived from OID: 2.16.840.1.113883.2.20.6.39 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 5 identifies that the attribute has not been defined. 4. SPL Rule 8 identifies that the code is not in the CV. 5. There may be a confidentialityCode element 6. Informational only (no validation aspect) as part of the ingredient element, however should the confidentialityCode be present it shall be validated as per the element rules. 7. There may be a quantity element 8. Informational only (no validation aspect) as part of the ingredient element, however should the quantity be present it shall be validated as per the element rules. 9. There shall be an ingredientSubstance element 10. SPL Rule 3 identifies that the element has not been defined. 11. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| quantity | N/A | 0:1 |  |  |
|  |  |  |  |  |
| Conformance | 1. There may be a quantity (strength) with a numerator and denominator    1. When there is a unit of measure it is derived from OID: 2.16.840.1.113883.2.20.6.15    2. For percentages numerator unit is not 1, instead use a volume unit for volume fractions and a mass unit for mass fractions.    3. The strength numerator is based on mass (e.g., mg or g) and not volume (e.g. mL or L), except for ingredients such as water, alcohol, and gases.    4. Active ingredients must have both a numerator and denominator strength value, the values must both be greater than 0 (zero)    5. In cases that there is no strength, the quantity element is to be omitted.    6. Note: At this point in time HPFB does not support the concept of May Contain, Does Not Contain and Trace for anything but Contaminants. 2. The denominators values and units for all ingredients in this product are the same. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| numerator | N/A | 0:1 |  |  |
|  |  |  |  |  |
| Conformance | 1. There may be a numerator element | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| denominator | N/A | 0:1 |  |  |
|  |  |  |  |  |
| Conformance | 1. There may be a denominator element | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ingredientSubstance | N/A | 1:1 |  |  |
|  |  |  |  |  |
| Conformance | 1. There is an code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is an code attribute with a value derived from the OID 5. SPL Rule 5 identifies that the attribute has not been defined. 6. SPL Rule 8 identifies that code is not in the CV. 7. There is an codeSystem attribute with a value of: 2.16.840.1.113883.2.20.6.14 8. SPL Rule 5 identifies that the attribute has not been defined. 9. SPL Rule 2 identifies that the OID value is incorrect. 10. There is a displayName attribute that shall display the appropriate label. 11. SPL Rule 5 identifies that the attribute has not been defined. 12. SPL Rule 7 identifies that label does not match the CV. 13. There is a name element that shall display the appropriate label. 14. SPL Rule 3 identifies that the element has not been defined. 15. SPL Rule 4 identifies that more than one element is defined. 16. SPL Rule 7 identifies that label does not match the CV.      1. The ingredient substance code usage may restrict a substance to being: medicinal (active), non –medicinal (inactive) or both. 2. The same ingredient substance code is not used more than once per product. 3. If the product has no parts and is not a part, then there are one or more active ingredients. 4. If the product has parts, or is a part then the active ingredients are under parts. 5. If the strength is based on a reference then, then there is an asEquivalentSubstance element with a defining substance otherwise there is no asEquivalentSubstance element | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asContent | N/A | 1:1 |  |  |
| Conformance | <pbx: here on revalidation>  <pbx: here on cleanup and consolidation>   1. A product may have an “as content” (package information) element (optional for parts) 2. If a quantity is specified it includes a numerator and denominator. 3. The numerator has a value greater than zero and a unit 4. The denominator has value 1 and a unit of “1” 5. If the product has parts, then the initial numerator value and unit is “1” 6. The unit of the numerator of the initial package is the same as the units for the denominators of all the ingredient quantities (strengths) 7. The unit of the numerator of an outer package is the same as the unit for the denominator of the quantity of the inner package 8. There is a form code and display name 9. The code system for form code is 2.16.840.1.113883.2.20.6.??? 10. SPL Rule 2 identifies that the OID value is incorrect 11. The display name matches the language code of the document. 12. If the Package Item Code has been previously submitted, then the package form code and quantity value and unit are the same as in the most recent submission for this item code. 13. If the Package Item Code is mentioned elsewhere in the document, then the package form code and quantity value and unit are the same and the content of both packages have an Item Code that is the same. 14. Package Item Code does not match any other Package Item Code in the same package hierarchy. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| confidentialityCode | N/A | 1:1 |  |  |
| Conformance | 1. <pbx: here> | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| quantity | N/A | 1:1 |  |  |
| Conformance | 1. <pbx: here> | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEquivalentEntity | N/A | 1:1 |  |  |
| Conformance | 1. There is a asEquivalentEntity element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. The asEquivalentEntity@classCode value is EQUIV. 5. The code@codeSystem value is 2.16.840.1.113883.2.20.6.??? 6. There is a code@code value 7. The defining material kind code matches an Item Code in an SPL file with a different set id 8. The equivalent Item Code is not the same as the Item Code for the product 9. The equivalent Item Code is not the same as the Item Code for another equivalence stated for this product. 10. There is only one product source per product. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| Part | N/A | 1:1 |  |  |
| Conformance | 1. If the product form code is ‘C47916’ (KIT), then there is one or more parts 2. Each part has an overall quantity 3. If there is an “as content” (package information) 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” (package information) data element in the part, then the numerator unit is 1 5. If there is a code, then the general rules for product code apply (see Para 4.10.4.6 bullet #2). 6. There is a name 7. Procedures for source, ingredients, characteristics and packaging are the same as for products without parts | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| approval | N/A | 1:n |  |  |
|  |  |  |  |  |
| Conformance | 1. There is an approval element for each product and product part 2. There is one marketing category for every product and product part 3. There is a marketing category code. 4. The code comes from the Marketing category list. 5. Display name matches the code 6. The display name is based upon the document language. 7. Code system is 2.16.840.1.113883.2.20.6.??? 8. SPL Rule 2 identifies that the OID value is incorrect. 9. Territorial authority is as above. 10. If the application number was already submitted, then the ingredients are the same as in the previous submission of a product with the same application number. 11. approval element 12. There is one marketing category for every product and product part 13. SPL Rule 3 identifies that the element has not been defined. 14. SPL Rule 4 identifies that more than one element is defined. 15. There is a code attribute. 16. SPL Rule 5 identifies that the attribute has not been defined. 17. The code comes from the Marketing category list. 18. Display name matches the code 19. The display name is based upon the document language. 20. Code system is 2.16.840.1.113883.2.20.6.?? 21. SPL Rule 2 identifies that the OID value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| marketingAct | N/A | 1:1 |  |  |
| Conformance | Validation  1. There is one marketing status code for each top-level product (part products do not need this) 2. There is not more than one marketing status on any one item. 3. Code is ??? and code system is 2.16.840.1.113883.2.20.6.???. 4. SPL Rule 2 identifies that the OID value is incorrect. 5. Status code is active or completed 6. If the status code is active, then there is a low value (marketing start date) and no high value (marketing end date) 7. If the code is completed, then there is a low and high value 8. The effective time low (marketing start date) and high boundary (marketing end date) have at least the precision of day in the format YYYYMMDD 9. If there is a high value (marketing start date,) then it is not less than the low value (marketing end date.) 10. A marketing status cannot be on an inner package. 11. A marketing status cannot be on a package for a part of a kit. 12. If the marketing start or end date is on a package, then the start date is not before the marketing start date of the product and the end date not after the end date of the product. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| characteristic | N/A | 1:1 |  |  |
| Conformance | 1. There is a characteristic property code with a code, displayname and code system, the code system is 2.16.840.1.113883.2.20.6.23 2. SPL Rule 2 identifies that the OID value is incorrect. 3. There is a characteristic value with specified type appropriate for the characteristic property when appropriate 4. There is only one instance per characteristic type. 5. When values are numbers they shall be an integer greater than zero. 6. Coded types shall have a value element, with code, codeSystem and displayName attributes.    1. The code shall be derived from the OID       1. Color = 2.16.840.1.113883.2.20.6.24       2. Shape = 2.16.840.1.113883.2.20.6.25       3. Flavour = 2.16.840.1.113883.2.20.6.26    2. The display name matches the code.    3. The display name is based upon the document language. 7. Non-Coded types have a value element with the applicable attributes as per the data type 8. Size is not a coded type, therefore there a value element, with the unit, value and type attributes defined.    1. The value attribute is derived from OID: 9. Scoring is not a coded type, therefore there a value element, with the unit, value and type attributes defined. 10. Imprint is not a coded type, therefore there a value element, with the unit, value and type attributes defined.     1. Value has only letters and numbers separated by semicolon without spaces 11. If there is an image, then it is not a coded type and shall have the following:     1. The value element has an xsi:type of “ED”     2. The Value element shall have a mediaType which will be “image/<file type>” where the file type is permitted file format (see Image Details for details).     3. The reference elements value attribute is the file name for a valid image.     4. The image file is submitted together with the SPL file.     5. There are no product characteristics other than the ones mentioned above. 12. If the product is a Combination Product then it is a coded type and shall have a value codeSystem of 2.16.840.1.113883.2.20.6.30     1. The combination product type characteristic is on the inner-most packaging unless stated otherwise in the document type specific information.  Validation  1. If there is a Production Amount then it is not a coded type and shall have the following:    1. The value element has an xsi:type of “INT” with a value attribute or a null flavor of “PINF” to indicate unlimited. | | | |

## Product Data Information – Drug Products

Outlined in this section are all aspects relating to the SPL document’s Product Data – Drug Product aspects.

The drug product data elements includes the product codes, proprietary and non-proprietary name, dosage form, ingredient and active moiety name, ingredient identifier, ingredient strength, package quantity, type and code, marketing category, marketing status, dosage form appearance, schedule, and route of administration.

Drug products are products with the marketing category Pharmaceutical or Biologic in OID: 2.16.840.1.113883.2.20.6.???.

The drug product consists of a DIN as per OID: 2.16.840.1.113883.2.20.6.42, proprietary and non-proprietary name, and dosage form. These are children of <manufacturedProduct>. The proprietary name is the name as it appears on the label divided between <name> and <suffix>. The <name> is the initial portion of the proprietary name describing the ingredients without any other descriptors including trademarks and dosage forms. If necessary, <suffix> is used for descriptors such as “extended release”. When using the <suffix>, a space after the proprietary name is added as necessary. If there is no proprietary name, the non-proprietary name is used without any descriptors. The dosage form is described in <formCode>. The <genericMedicine><name> is the non-proprietary name of the product.

### Code and Name

<section>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<code code="0001-0001" codeSystem=" 2.16.840.1.113883.2.20.6.42"/>

<name>Tazmin <suffix>XR</suffix></name>

<formCode code="C42998" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="tablet"/>

<asEntityWithGeneric>

<genericMedicine>

<name>tazminate hydrochloride</name>

</genericMedicine>

#### Validation

1. Product codes must be assigned to the DIN owner.
2. Code has the same DIN owner as the product/item code of all top-level products in this document, except under parts.
3. There is only one product element for each product/item code, i.e., the same product is not described more than once except under parts.
4. If the product/item code is mentioned elsewhere in the document, then the product and generic name, dosage form and strength of all ingredients are the same.
5. There is a name (Brand Name)
   1. Display name matches the code.
   2. The display name is based upon the document language.
6. There is a form code (dosage form)
   1. The form code contains a <code> element.
   2. The code system 2.16.840.1.113883.2.20.6.3.
   3. The code has a code value.
   4. The code value is derived from the code system.
   5. The code has a code display name.
   6. The code display name shall display the label corresponding to the code value based upon the document language.
   7. If the product has parts, then the form code is C47916 (for KIT)
7. There is a generic medicine name (Proper Name or Common Name)
   1. Generic medicine name contains no suffix.
   2. Generic medicine name contains no more than 512 characters.
8. If the product/item code was previously submitted, then:
   1. The active ingredient and active ingredient strength are the same as in the most recent submission for this product/item code.
   2. The product dosage form is same as in the most recent submission for this product/item code.

### Product source

<asEquivalentEntity classCode=“EQUIV”>

<code code=“C64637” codeSystem=”2.16.840.1.113883.2.20.6.12”/>

<definingMaterialKind>

<code code=“source product DIN” codeSystem=“2.16.840.1.113883.2.20.6.42”/>

#### Validation

1. As equivalent entity class code, code and code system are as above
2. If there is a classCode, it is “EQUIV”.
   1. Defining material kind code matches a product/item code in a SPL file with a different set id.
   2. Product/item code for the source is not the same as the product/item code for the product.

### Packaging

The format for packaging specification is:

<asContent>

<quantity>

<numerator value="100" unit="1"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<code code="0001-0001-05" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<formCode code="C43169" codeSystem="2.16.840.1.113883.2.20.6.38" displayName="bottle"/>

#### Validation

1. Every product as well as every kit has an “as content” (package information) element (optional for parts).
2. The outer package description has a production quantity characteristic.
3. There are no characteristics other than the ones mentioned in this document.

### Parts

Products with one or more parts

<part>

<quantity>

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

<denominator value="1"/>

</quantity>

<partProduct>

<code code="0001-0001" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<name>Tazmin <suffix>XR</suffix></name>

<formCode code="C42916" codeSystem="2.16.840.1.113883.2.20.6.16" displayName="capsule, extended release"/>

<asEntityWithGeneric>

<genericMedicine>

<name>tazminate hydrochloride</name>

#### Validation

1. If the product form code is ‘C47916’ (KIT), then there is one or more parts
2. If the product has parts, then at least one part has one or more active ingredients.
3. Procedures for code, name, dosage form code, source, ingredients, characteristics and packaging are the same as for the main products (see section 4.10 Product Data Information – Product in General)

### Marketing Category

Example:

<subjectOf>

<approval>

<id extension="NDA123456" root="2.16.840.1.113883.2.20.6.???"/>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="NDS"/>

<author>

<territorialAuthority>

<territory>

<code code="CAN" codeSystem="2.16.840.1.113883.2.20.6.17"/>

#### Validation

1. There is one marketing category for a specific product per submission.

### Marketing Status and Date

The procedures for marketing status and date (if any) are the same for all products and are described in section 4.10.13 Marketing status.

#### Validation

1. Every product as well as every kit has a marketing status code (part products do not require a marketing status).

### Controlled Substance

The type of controlled substance is detailed in the schedule. And when applicable it is described under <policy> which is a child of <subjectOf> a child of <manufacturedProduct> as illustrated in the following example of a drug that is schedule II.

<subjectOf>

<policy classCode="ORGPOL">

<code code="6" codeSystem="2.16.840.1.113883.2.20.6.22" displayName="Prescription"/>

#### Validation

1. If there is a Schedule, then the code system is 2.16.840.1.113883.2.20.6.22
2. The display name matches the code
3. The display name is based upon the document language.
4. The policy element has a class code of “ORGPOL”.

### Route of administration

Route of administration may be specified for products

<subject>

<manufacturedProduct>

<consumedIn/>

and their parts:

<part>

<consumedIn/>

Route of administration is specified as follows:

<consumedIn>

<substanceAdministration>

<routeCode code="C38288" codeSystem="2.16.840.1.113883.2.20.6.7" displayName="oral"/>

#### Validation

1. There is one or more “consumed in” (route of administration) substance administration with route code.
   1. Rule 4
2. substanceAdministration
   1. Rule 4 and 5
3. The Route code system is 2.16.840.1.113883.2.20.6.7
   1. SPL Rule 2
4. There is a code.
5. There is a display name.
6. The display name matches the code.
7. The display name is based upon the document language.

## Device Product

<manufacturedProduct>

<code code="91234561234569" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>SuperTape 2000</name>

<desc>Adhesive tape for orthopedic use.</desc>

<asSpecializedKind classCode="GEN">

<generalizedMaterialKind>

<code code="MCA" displayName="Tape, Surgical, Internal" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

Device products are products with the marketing category “device” in OID: 2.16.840.1.113883.2.20.6.???.

### Item Code and Name

#### Validation

1. There may be an product/item code
2. If there is a product/item code, the following general procedures apply:
   1. Code system is 2.16.840.1.113883.2.20.6.42.
   2. Code is compliant with the code system’s allocation rules.
3. There is a name, i.e., the trade or proprietary name of the medical device as used in product labeling or in the catalog
4. Markings such as ®, or ™ should not be included
5. There is a device type (asSpecializedKind element) with a code.
6. Code system is 2.16.840.1.113883.2.20.6.27 for the Product Classification System
7. There is a valid medical device product classification code
8. There is a display.
9. The display name matches the code
10. The display name is based upon the document language.

### Additional Device Identifiers

<document>

<section>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<asIdentifiedEntity classCode="IDENT">

<id extension="ST2000/A" root="1.2.3.99.1"/>

<code code="C99286" displayName="model number" codeSystem="2.16.840.1.113883.2.20.6.13"/>

</asIdentifiedEntity>

These additional identifiers may also appear under device parts:

<part>

<partProduct>

<asIdentifiedEntity>

#### Validation

1. There may be one or more additional identifiers, including model number, catalog number, and reference number.
2. There is a code with code system 2.16.840.1.113883.2.20.6.???
3. There is one id
4. Id has a root OID
5. The actual identifier is in the extension.
6. Id extension is compliant with the code system’s allocation rules.
7. There is at most one Model Number reference.
   1. The id root can be any root OID over which the DIN Owner has authority. If the DIN Owner has no such root OID of its own, then the root is constructed by concatenating the Company ID (without leading zeroes) to the fixed string “1.3.6.1.4.1.32366.3???.”
8. There is at most one Catalog Number
   1. The id root can be any root OID over which the DIN Owner has authority. If the DIN Owner has no such root OID of its own, then the root is constructed by concatenating the Company ID (without leading zeroes) to the fixed string “1.3.6.1.4.1.32366.3???.”
9. The product may have multiple reference numbers (i.e., secondary identifiers.
   1. The id root is 2.16.840.1.113883.2.20.6.28 (HPFB CTS), or may be constructed by concatenating the Company ID (without leading zeroes) to the fixed string “1.3.6.1.4.1.32366.3???.”

### Device Ingredient

Ingredients included in devices that are not identified as active ingredients include the ingredient class code, ingredient name, identifier, and strength. The element <ingredient> is a child of <manufacturedProduct>, where the class code, and units adhere to the specifications outlined in the Ingredient section.

<ingredient classCode="INGR">

<quantity>

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

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

</quantity>

<ingredientSubstance>

<code code="code" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>ingredient name</name>

</ingredientSubstance>

</ingredient>

Note that devices may have active ingredients as well, such as in a medicated stent, i.e., where the device serves in part the function of releasing a built-in drug. This is to be distinguished from devices such as syringes which are delivery devices for a drug product that they contain.

### Device Parts

Device parts may be specified for the product in the same way as for other product kits (see section 4.10.9 Kits, Parts, Components and Accessories)

<partProduct>

<code code="91234561234569" codeSystem="2.16.840.1.113883.2.20.6.???"/>

<name>SuperTape 2000</name>

<asSpecializedKind classCode="GEN">

<generalizedMaterialKind>

<code code="MCA" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

#### Validation

1. There is a name, i.e., the trade or proprietary name of the medical device as used in product labeling or in the catalog
2. Markings such as ®, or ™ should not be included

### Part of Assembly

When products are used together but packaged separately, the data element <asPartOfAssembly> is used to identify the other product. The products could be drugs or devices.

<asPartOfAssembly>

<wholeProduct><!-- this is the assembly, but has no identifier -->

<part>

<partProduct>

<code code="item code of accessory component" codeSystem="code system OID"/>

### Regulatory Identifiers

Regulatory identifiers, marketing status and characteristics are all connected through the <subjectOf> element which may appear on the main product:

<subject>

<manufacturedProduct>

<manufacturedProduct/>

<subjectOf/>

The regulatory identifier:

<subjectOf>

<approval>

<id extension="K123456" root="2.16.840.1.113883.2.20.6.???"/>

<code code="C80442" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="Premarket Notification"/>

<author>

<territorialAuthority>

<territory>

<code code="CAN" codeSystem="2.16.840.1.113883.2.20.6.17"/>

#### Validation

1. There is one regulatory identifier for each product
2. The code system is 2.16.840.1.113883.2.20.6.???.
3. The display name matches the code
4. The display name is based upon the document language.
5. Territorial authority is as above

### Marketing status and date

The procedures for marketing status and date (if any) are the same for all products and are described in section 4.10.13 Marketing status.

#### Validation

1. There is one marketing status code for each top-level product (part products do not require this).

### Device Characteristics

Many characteristics exist for devices and are listed here in tabular form. The characteristic structure allows specifying any properties of the product in a code-value pair, the code saying which property is being specified, the value saying what the property is for the given product. The characteristics structure connects to the product Role through the subjectOf element.

<manufacturedProduct>

<manufacturedProduct>

...

</manufacturedProduct>

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="characteristic code system"/>

<value xsi:type="characteristic value type" ...>

Characteristics use one of a number of different data types as per OID: 2.16.840.1.113883.2.20.6.23. Each data type uses slightly different XML elements and attributes as shown in the templates in Section 4.10.14 Characteristics.

#### Validation

1. There are no device characteristics other than the ones mentioned in this document.
2. All general characteristic rules apply.

### Reusability

<subjectOf>

<characteristic>

<code code="8" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=”Use”/>

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

#### Validation

1. Reusability is not a coded type, therefore there a value element, with the value and type attributes defined.
   1. The value is an integer number greater or equal 1 (1 meaning single use, and number greater than 1 meaning reusable up to this many times.)

### Sterile Use

<subjectOf>

<characteristic>

<code code="9" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=” Sterile Use”/>

<value xsi:type=“BL” value="true"/>

#### Validation

1. Reusability is not a coded type, therefore there a value element, with the value and type attributes defined.
   1. The value is a boolean with allowed values of “true” or “false”.

### Marketing status and date

The procedures for marketing status and date (if any) are the same for all products and are described in section 4.10.13 Marketing status.

#### Validation

1. There is one marketing status code for each top-level product (part products do not require this)