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| Guidance Document: Preparation of Regulatory Documents using the Structured Product Labelling (SPL) Standard – Product Monograph |
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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:   1. Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, 2. 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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**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

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# Introduction

This document serves as the technical implementation guide and technical specification for the Health Product and Food Branch’s (HPFB) use of Health Level 7’s (HL7) Structured Product Label (SPL) standard.

The content of this guidance only includes the technical conformance, business conformance and validation rules related to the product monograph document type. This guidance is to be read in conjunction with the Guidance Document: Preparation of Regulatory Documents using the Structured Product Labelling (SPL) Standard – Common Guidance for all Document Types.

## Purpose

To provide guidance on the technical conformance, business conformance and validation rules needed to prepare a Product Monograph using the Structured Product Label (SPL) standard.

## Scope

### In-scope

* human pharmaceutical drugs, biologic drugs and radiopharmaceuticals
* Veterinary drugs (under consideration)
* 2016 Product Monograph templates
* Legacy Template
* Regulatory activities submitted in the eCTD format

### Out of Scope

* self-care products, natural health products, medical devices and food
* Regulatory activities submitted in the Non-eCTD format

## Policy Objectives

In recent years Health Canada announced a number of measures that will be taken to support the health and safety of Canadian families, one of which is improving drug product labels.  As part of the HPFB’s strategic plan, the goal is to:

* provide more relevant and easier to understand drug information on labels, in order to help Canadians make better informed decisions about their medications; and
* encourage the adoption of digital health technology to improve access, increase efficiency, and improve outcomes for patients.

As part of this initiative, the HPFB recognized that unstructured formats, like Portable Document Format (PDF), are not adequately positioned to support the objectives mentioned above. We will therefore need to transition to more advanced technology formats. Particular attention will be focused on formats that are open source and supported by international standards.

# Important Considerations

## Legal Copy

The SPL document is the legal document. The Microsoft® Word copies are considered convenience copies to facilitate review.

## SPL Product Monograph Lifecycle

Once a product monograph is approved in the SPL format all subsequent regulatory activities for that product monograph must be filed in the SPL format.

The SPL product monograph takes the place of the PDF. Therefore, only the Word and SPL formats are required in a regulatory activity.

1. The SPL product monograph is only provided with the initial sequence and with the final sequence (i.e., the pristine product monograph).
2. The Word product monograph is provided with all sequences except for the final sequence with pristine product monograph; e.g., initial sequence and responses to solicited information during review.

## Validation

The HPFB will only provide validation reports for SPL documents that fail validation. Sponsors are expected to validate their SPL documents and correct any warning(s) and error(s) before submitting them to the HPFB.

# Template Types

## 2016 Templates

As per the December 9, 2017 Notice[[1]](#footnote-1): As of June 9, 2017, the following submission types are required to file under the 2016 format, for biologics and radiopharmaceuticals and for prescription pharmaceutical products:

1. New Drug Submissions (NDS)
2. Abbreviated New Drug Submissions (ANDS) and Supplements to Abbreviated New Drug Submissions (SANDS), where the corresponding innovator PM is in the 2016 format

The following is a list of the 2016 templates supported by SPL:

1. Product Monograph Template - Standard
2. Product Monograph Template - Notice of Compliance with Conditions
3. Product Monograph Template - Subsequent Entry Product (except for Schedule C and D products)
4. Product Monograph Template - Schedule C
5. Product Monograph Template - Schedule D
6. Product Monograph Template - Schedule D - Biosimilar Biologic Drug

## Legacy Template

Legacy Template refers to any product monograph that does not comply with the 2016 templates. I.e., 2014 templates, 2004 templates, pre-2004 templates or any combination thereof.

Since the 2016 template is relatively new most approved product monographs fall into the legacy template category. The legacy template will allow sponsors to recreate their non-2016 product monograph in the SPL format without compromising the validation rules related to section headings.

However, the Legacy Template cannot be used to bypass the 2016 Template requirements. The following conditions must be met before being eligible to use the Legacy Template:

* Condition #1 – Pre-existing approved products: New products are expected to begin their lifecycles with the 2016 template. Therefore, only products approved with a legacy template are eligible.
* Condition #2 – No content changes: The SPL document is a direct copy of the approved product monograph; i.e., the content in the SPL document is identical to the approved version and no content changes have been made.
* Condition #3 – Metadata reflects what is approved: The SPL document metadata reflects only what is in the approved product monograph. E.g., the SPL document metadata cannot include strengths or ingredients not in the approved product monograph.
* Condition #4 – Compliant with the SPL schema: The SPL document is compliant with the SPL schema

# Transition Process

## New Products

TBD

## Approved Products (content change)

TBD

## Approved Products (No content change)

TBD

# Lifecycle Management

## Formats

For the initial sequence (e.g., NDS, SNDS, ANDS, ASNDS) product monographs shall be provided in the following formats:

1. Product monograph (clean) – SPL (.xml and images)
2. Product monograph (clean) – Word 2010 format (.docx)
3. Product monograph (annotated) – Word 2010 format (.docx)

For sequences submitted during review (e.g., response to request for clarification) product monographs shall be provided in the following formats:

1. Product monograph (clean) – Word 2010 format (.docx)
2. Product monograph (annotated) – Word 2010 format (.docx)

For final sequences (e.g., Pristine sequence following NOC) product monographs shall be provided in the following format within 20 calendar days:

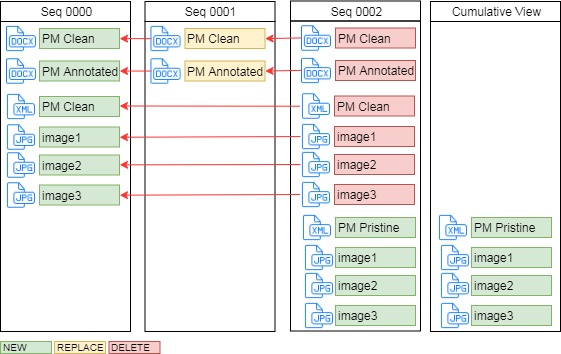
1. Product monograph (clean) English – SPL (.xml and images)
2. Product monograph (clean) French – SPL (.xml and images)

## Lifecycle for Regulatory Activities in the eCTD

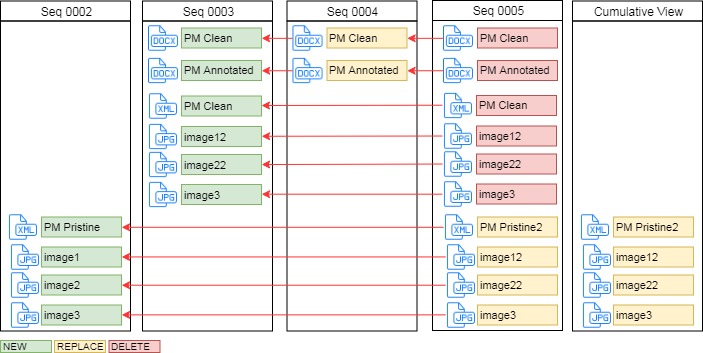
Sponsors should use the following eCTD lifecycle attributes to manage Word and SPL product monographs under the following circumstances (Refer to Figure 1 and Figure 2 for examples):

* ‘**NEW**’ when a clean or annotated product monograph is provided as part of the first transaction of a regulatory activity (e.g., NDS, SNDS).
* ‘**REPLACE**’ when a clean or annotated product monograph is provided in response to clarification request, SDN, NOD, or NON.
* ‘**NEW**’ when a pristine product monograph is provided for the first time. The last clean and annotated product monographs provided as part of that regulatory activity should be assigned the operation attribute ‘**DELETE**’.
* ‘**REPLACE**’ when a pristine product monograph is provided to replace a previously approved pristine product monograph. The last clean and annotated product monographs provided as part of that regulatory activity should be assigned the operation attribute ‘**DELETE**’.

**Figure 1 Example of an eCTD lifecycle for the first regulatory activity and its transactions (e.g., NDS or ANDS)**



**Figure 2 Example of an eCTD lifecycle for a subsequent regulatory activity and its transactions (e.g., SNDS, SANDS)**



## Lifecycle for Regulatory Activities in the Non-eCTD

Non-eCTD format is out of scope at this time.

# Derived Content

Some content is manually created, formatted and displayed as intended by the author; e.g., tables and paragraphs. However, certain content is derived; i.e., they are automatically generated from metadata using a style sheet. Refer to Table 2 for a listing of content that is derived.

**Table 1 Listing of Derived Product Monograph Sections**

| **Items** | | **Metadata Source(s)** |
| --- | --- | --- |
|  | All labels | OID 2.16.840.1.113883.2.20.6.8 |
|  | Title Page – DIN Owner Information | Various details from the representedOrganization element |
|  | Title Page – Company Roles | The actDefinition values for all identified organizations |
|  | Title Page – Date of Initial Approval | Part of the documents effectiveTime element |
|  | Title Page – Date of Revision | Part of the documents effectiveTime element |
|  | Title Page – Submission Control Number: | The values from the documents templateId element values derived from OID 2.16.840.1.113883.2.20.6.49 |
|  | Numbering of section headings | Ordered list of sections elements |
|  | Table of Contents | The numbered list of section headings where the OID 2.16.840.1.113883.2.20.6.36 specifies the section is to be included in the TOC |
|  | Product Description | Various aspects of the SPL product data elements section |
|  | Organizations | Various aspects of the author element |

# Business Conformance Rules

## Prolog

[Business rules to be added]

## Document Information

[Business rules to be added]

## Author Information

### Assigned Organization and Represented Organization Roles

[Business rules to be added]

### Represented Organization and Represented Organization Roles

[Business rules to be added]

## Product Information

### Manufactured Product Name

[Business rules to be added]

### Generic Name

[Business rules to be added]

### Ingredient

#### Ingredient Role

[Business rules to be added]

#### Quantity

### Container Closer System

[Business rules to be added]

### Characteristics

[Business rules to be added]

### Marketing Date (Low and High)

[Business rules to be added]

Marketing Date Low = Date of initial approval

Marketing Date High = Date of revision

## Content

[Business rules to be added]

## Image

[Business rules to be added]

# Validation Rules

## General

Outlined in this section are all PM specific aspects that apply to the overall document, aspects that are common to all HPFB SPL documents are omitted from this document.

1. For simplicity only, the English display name has been included in this document, the display names are detailed in the controlled vocabulary (CV) documentation.
2. N.B. There are no validation aspects.
3. Numbers (1) are used to detail technical conformance requirements; validation rules are detailed directly below the requirements and are organized using letters (a).
4. N.B. There are no validation aspects.
5. Only items that have specific Doctype validation are included.
6. N.B. There are no validation aspects.
7. Time values (such as effectiveTime@value, [effectiveTime.low@value](mailto:effectiveTime.low@value) and [effectiveTime.high@value](mailto:effectiveTime.high@value)) shall utilize only the date aspect (time and GMT offset based time values are not permitted). Refer to Appendix 4 for an example of how to use effectiveTime
8. N.B. There are no validation aspects.
9. For initial submissions the Date of Revision will be set to equal the Date of Initial Approval, this does not apply to Marketing effectiveTime elements.
10. N.B. currently this is not validated, however it is planned to introduce this in the future.
11. For all other submissions the Date of Revision will greater than the Date of Initial Approval, this does not apply to Marketing effectiveTime elements.
12. N.B. currently this is not validated, however it is planned to introduce this in the future.
13. Terms (context=Term)

The usage of CV terms is restricted to specific term statuses depending on the context of the PM, these rules are outlined below, however they are validated at the element level:

* For initial draft (ie. Where Document Date of Initial Approval = Document Date of Revision and versionNumber.description = Draft) terms having a status of 1; 2; 3; 5 are permitted.
* For initial final (ie. Where Document Date of Initial Approval = Document Date of Revision and versionNumber.description = Final) terms having a status of 1; 5 are permitted.
* For revision draft (ie. Where Document Date of Initial Approval < Document Date of Revision and versionNumber.description = Draft) terms having a status of 1; 2; 3; 5; 7 are permitted.
* For revision final (ie. Where Document Date of Initial Approval < Document Date of Revision and versionNumber.description = Final) terms having a status of 1; 5 are permitted.

The SPM term context validation works along the following concept: Term Status in (valid term status) where valid term status is defined as above.

1. N.B. currently this is not validated, however it is planned to introduce this in the future.
2. Doctype (context=Document)

The usage of CV terms is restricted to specific term statuses depending on the context of the document type, these rules are outlined below, however they are validated at the element level:

* The Doctype for the SPM is 1 (please refer to OID 2.16.840.1.113883.2.20.6.10), both document|1| and document|\*| are applicable.

The SPM doctype context validation works along the following concept: if the context is document the valid constructs are as above.

1. N.B. currently this is not validated, however it is planned to introduce this in the future.
2. Template (context=Document)

The usage of CV terms is restricted to specific term statuses depending on the document template, outlined below is a table showing the relationship, however please refer to OID 2.16.840.1.113883.2.20.6.9 for the authoritative list):

**Table 2 List of document templates**

| **Document Template** | **templateId@extension Value** |
| --- | --- |
| 2016 Standard Product Monograph | 6 |
| 2016 NOCC Product Monograph | 7 |
| 2016 Subsequent Entry Product Product Monograph | 8 |
| 2016 Schedule C Product Monograph | 9 |
| 2016 Schedule D Product Monograph | 10 |
| Product Monograph Template – Legacy | 11 |
| 2016 Schedule D Biosimilar Biologic Drug Product Monograph | 14 |

This implies that document|1|\* or any of document|1|7 trough document|1|11 are applicable, note document|\*|1 is not a valid nomenclature.

The SPM template context validation works along the following concept: if the context is document the valid template ID’s and constructs are as above.

1. N.B. currently this is not validated, however it is planned to introduce this in the future.

## Document Prolog Validation

Outlined in this section are all PM specific aspects relating to the Document prolog.

1. There is a stylesheet declaration for both xsl and css
2. An instance of Rule Category 40 identifies that that the Processing Instructions are not compliant to the IG.
3. The location of the stylesheet is: <https://rawgit.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/SPM/current/hpfb-spm.xsl>
4. An instance of Rule Category 40 identifies that that the Processing Instructions are not compliant to the IG.
5. The type is text/xsl
6. An instance of Rule Category 40 identifies that that the Processing Instructions are not compliant to the IG.
7. The location of the stylesheet is: <https://rawgit.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/SPM/current/hpfb-spm.css>
8. An instance of Rule Category 40 identifies that that the Processing Instructions are not compliant to the IG.
9. The type is text/css

a) An instance of Rule Category 40 identifies that that the Processing Instructions are not compliant to the IG.

## Document Information Validation

Outlined in this section are all PM specific aspects relating to the Document Information.

1. There is a templateId element with a root value of 2.16.840.1.113883.2.20.6.49 and an extension value in accordance to OID, that captures the Submission Control Number.
2. N.B. currently this is not validated, however it is planned to introduce this in the future.
3. There is a templateId element with a root value of 2.16.840.1.113883.2.20.6.11 and an extension value in accordance to OID, that captures the Marketing Category associated with the current version.
4. An instance of DT Rule Category 33 identifies that the element has not been defined.
5. An instance of DT Rule Category 35 identifies that the value is not in the CV.
6. There is a title element.
7. An instance of DT Rule Category 30 identifies that the element has not been defined.

1. There is an effectiveTime@value attribute that shall contain the Date of Revision (for the entire document, regardless of the change or reason for change)
2. N.B. currently this is not validated, however it is planned to introduce this in the future.
3. There is an effectiveTime.originalText element that shall contain the Date of Initial Approval (i.e., NDS or ANDS) the format for is year, month and day (yyyymmdd).
4. An instance of DT Rule Category 30 identifies that the element has not been defined.
5. An instance of DT Rule Category 33 identifies that the attribute is missing required information.
6. The [effectiveTime.originalText@description](mailto:effectiveTime.originalText@description) attribute shall contain “Date of Initial Approval “.
7. An instance of DT Rule Category 33 identifies that the attribute is missing required information.

## Author Information Validation

Outlined in this section are all PM specific aspects relating to the Author Information.

1. Undefined company ID’s are not allowed
2. An instance of DT Rule Category 38 identifies that the (extension) attribute value is incorrect (i.e. “Pending”).

## Product Information

Outlined below are the PM specifics relating to the Product Data (the section where the code@code is 48780-1 and the code@codeSystem is 2.16.840.1.113883.2.20.6.8), this excludes all overall document and labeling content information.

1. There is a section where the code@code is 48780-1 and the codeSystem is 2.16.840.1.113883.2.20.6.8 (i.e component.structuredBody.component[section/code/@code = “48780-1”].section)
2. DT-Rule-30001 (Category 30) identifies that required content is missing.
3. The effectiveTime element shall contain a low element.
4. An instance of DT Rule Category 30 identifies that the element has not been defined.
5. The effectiveTime.low@value attribute captures the Date of Initial Approval (for entire product section)
6. N.B. No validation aspects.
7. The effectiveTime element shall contain a high element.
8. An instance of DT Rule Category 30 identifies that the element has not been defined.
9. The effectiveTime.high@value attribute captures the Date of Revision (for entire product section)
10. N.B. No validation aspects.
11. Each product has a templateId element where the root attribute is equal to the product-type OID, it is used to capture the type of product.
12. An instance of DT Rule Category 30 identifies that the element has not been defined.
13. For all 2016 based templates each active ingredient has an activeMoiety element, it is used to capture the basis of strength.
14. An instance of DT Rule Category 30 identifies that the element has not been defined.
15. Each product has and approval element, that captures the relevant approval information.
16. An instance of DT Rule Category 30 identifies that the element has not been defined.
17. There are one or more subject elements
18. An instance of DT Rule Category 30 identifies that the element has not been defined.
19. For each subject element there is an manufacturedProduct.manufacturedProduct.name element.
20. N.B. No validation aspects.
21. For each subject element there may not be a marketingAct.effectiveTime.low element.
22. An instance of DT Rule Category 38 identifies that a disallowed element has been defined.
23. For each subject element there may be a marketingAct.effectiveTime.high element, that captures the date off the market (product and/or package).
24. N.B. No validation aspects.
25. For each subject element there is an approval.code element that captures the i.e. the Regulatory Activity (e.g., A/NDS, A/SNDS, NC, Level III, Level IV) this version of the SPM is associated with.
26. An instance of DT Rule Category 30 identifies that the approval element has not been defined.
27. N.B. No validation aspects required on the code element.
28. For each subject element there is an approval.effectiveTime.low element that captures the Date of Initial Approval of the specific product.
29. An instance of DT Rule Category 30 identifies that the element has not been defined.
30. For each subject element there is an approval.effectiveTime.high element that captures the Date of Revision of the specific product.
31. An instance of DT Rule Category 30 identifies that the element has not been defined.
32. For each subject element there is one or more characteristic elements where the [code@codeSystem="2.16.840.1.113883.2.20.6.23](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.23)" and the code@code=”13” that captures the Pharmaceutical Standard.
33. An instance of DT Rule Category 30 identifies that the element has not been defined.
34. For each subject element there is one or more characteristic elements where the [code@codeSystem="2.16.840.1.113883.2.20.6.23](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.23)" and the code@code=”14” that captures the Scheduling Symbol.
35. An instance of DT Rule Category 30 identifies that the element has not been defined.
36. For each subject element there is one or more characteristic elements where the [code@codeSystem="2.16.840.1.113883.2.20.6.23](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.23)" and the code@code=”15” that captures the Therapeutic Class.
37. An instance of DT Rule Category 30 identifies that the element has not been defined.
38. For each subject element there is an manufacturedProduct.manufacturedProduct.name element that captures the Brand Name.
39. N.B. No validation aspects.
40. For each subject element there is one or more manufacturedProduct.manufacturedProduct.asEntityWithGeneric.genericMedicine.name elements that captures the Proper Name.
41. N.B. No validation aspects.
42. For each subject element there is a manufacturedProduct.manufacturedProduct.formCode element that captures the Dosage Form.
43. N.B. No validation aspects.
44. For each subject element there are one or more manufacturedProduct.consumedIn.substanceAdministration.routeCode elements that capture the Route of Administration.
45. An instance of DT Rule Category 30 identifies that the element has not been defined.
46. The outer package description for a product shall detail the production quantity characteristic.
47. N.B. currently this is not validated, however it is planned to introduce this in the future.

The following elements are deemed out of scope at this time and should not be included in the SPM file:

* asEquivalentEntity

1. An instance of DT Rule Category 38 identifies that a disallowed element has been defined.

## Labeling Section Information Validation

Outlined below are the specifics relating to the PM Content Sections. Sections may contain sub sections as well as content unless specified in the section validation rules.

1. When a specific section relates to one or more products or packages it may be linked to the specific item using a templateId element, refencing either the MPID or PCID OID.
2. N.B. No validation aspects.
3. Section 999999 (SPL UNCLASSIFIED SECTION) may only be used in template 11.
4. An instance of DT Rule Category 38 identifies that the element is used incorrectly.
5. Each section shall have an effectiveTime.low element that captures the Date of Initial Approval for the specific content section.
6. An instance of DT Rule Category 30 identifies that element is missing.
7. Each section shall have an effectiveTime.high element that captures the Date of Revision for the specific content section. Note this value changes if a link target is changed (changing the file content requires the reference to have a new effectiveTime).
8. An instance of DT Rule Category 30 identifies that element is missing.
9. The title for a labeling section will be the same as the name in the OID 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. OID 2.16.840.1.113883.2.20.6.36 encodes the validation details for sections
10. An instance of DT Rule Category 34 identifies that title does not match the CV.
11. The Section Details are encoded in OID 2.16.840.1.113883.2.20.6.36 (structure-aspects), it is included in Appendix A as a reference, it details the code@code value, as well as the heading level and cardinality for each labeling section:
12. N.B Verification that no additional sections are included is currently not validated, however it is planned to introduce this in the future.
13. N.B Verification that no required sections are omitted is currently not validated, however it is planned to introduce this in the future.
14. N.B Verification that the sections are in the right order is currently not validated, however it is planned to introduce this in the future.
15. N.B Verification that the sections nesting is correct is currently not validated, however it is planned to introduce this in the future.
16. N.B Verification that the section cardinality is correct is currently not validated, however it is planned to introduce this in the future.
17. An instance of DT Rule Category 38 identifies that derived content is included in the content.
18. An instance of DT Rule Category 38 identifies that the title content is included in the content.
19. An instance of DT Rule Category 37 identifies that there is a notification flag for the content.
20. An instance of DT Rule Category 41 identifies that the section is incorrect or contextually incorrect.
21. Section 48780-1 (Product Data), shall not contain any content other than nested content sections.
22. N.B. No validation aspects.
23. Section 10 (Title Page), shall not contain any text or title nor shall it have content other than nested content sections.
24. An instance of DT Rule Category 38 identifies that the title element has content.
25. An instance of DT Rule Category 38 identifies that the text element has content.
26. Section 20 (Part I: Health Professional) section, shall not contain any text nor shall it have content other than nested content sections.
27. An instance of DT Rule Category 38 identifies that the text element has content.
28. Section 30 (Part II: Scientific Information) section, shall not contain any text nor shall it have content other than nested content sections.
29. An instance of DT Rule Category 38 identifies that the text element has content.
30. Section 40 (Part III: Consumer Information) section, shall not contain any text nor shall it have content other than nested content sections.
31. An instance of DT Rule Category 38 identifies that the text element has content.
32. Section 530 (Title Page Warning Box) section shall not have a Title.
33. An instance of DT Rule Category 38 identifies that the title element has content.
34. Section 370-10 (Serious Warnings and Precautions Box) section shall not have a Title.
35. DT Rule Category 4 identifies that the section has content.
36. Section 580 (Serious Warnings and Precautions Box) section shall not have a Title.
37. DT Rule Category 4 identifies that the section has content.
38. Date of Initial Approval, may not be modified after the initial submission.
39. N.B. No validation aspects.

# Appendices

## Appendix 1: Definitions

[To be added]

## Appendix 2: Reference Documents

[To be added]

## Appendix 4: effectiveTime and Marketing Activity Details

The following table illustrates events and the element and or attribute that shall be used to identify the changes (red underline has been used to identify changes):

| **SPM Components** | **NDS Approved Products 1,2,3 on 2013-01-01** | **SNDS#1 Added Products 4,5 on 2014-01-01** | **SNDS#2 Modified Products 2,3 on 2015-01-01** | **Level III Change to correct Typos in Part III on 2016-01-01** | **SNDS#3 Removed Products 1,4 on 2017-02-01** |
| --- | --- | --- | --- | --- | --- |
| **SPM v1 Dates** | **SPM v2 Dates** | **SPM v3 Dates** | **SPM v4 Dates** | **SPM v5 Dates** |
| **Document** |  |  |  |  |  |
| * Date of Initial Approval   document/effectiveTime/originalText | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Date of Revision   document/effectiveTime@value | 20130101 | 20140101 | 20150101 | 20160101 | 20170201 |
| * Submission Type   extension value with name-eng in ()  templateId extension="???" root="2.16.840.1.113883.2.20.6.11" where ??? is the term from the CV. | 308 (NDS) | 314 (SNDS) | 314 (SNDS) | 306 (Level III Changes) | 314 (SNDS) |
| **Product Root** |  |  |  |  |  |
| * Date of Initial Approval   component/section[@code = ‘48780-1’]/effectiveTime/low@value | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Date of Revision   component/section[@code = ‘48780-1’]/effectiveTime/high@value | 20130101 | 20140101 | 20150101 | 20150101 | 20170201 |
| **Product #1** |  |  |  |  |  |
| * Marketing Effective Time Low   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/low@value |  |  |  |  |  |
| * Marketing Effective Time High   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/high@value |  |  |  |  | 20170201 |
| * Marketing Activity   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/approval/code | 308 (NDS) | 308 (NDS) | 308 (NDS) | 308 (NDS) | 314 (SNDS) |
| * Approval Effective Time Low   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/approval/effectiveTime/low@value | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Approval Effective Time High   component/section[@code = ‘48780-1’]/subject[1]/manufacturedProduct/subjectOf/approval/effectiveTime/high@value | 20130101 | 20130101 | 20130101 | 20130101 | 20170201 |
| **Product #2** |  |  |  |  |  |
| * Marketing Effective Time Low   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/low@value |  |  |  |  |  |
| * Marketing Effective Time High   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/marketingAct/effectiveTime/high@value |  |  |  |  |  |
| * Marketing Activity   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/approval/code | 308 (NDS) | 308 (NDS) | 314 (SNDS) | 314 (SNDS) | 314 (SNDS) |
| * Approval Effective Time Low   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/approval/effectiveTime/low@value | 20130101 | 20130101 | 20130101 | 20130101 | 20130101 |
| * Approval Effective Time High   component/section[@code = ‘48780-1’]/subject[2]/manufacturedProduct/subjectOf/approval/effectiveTime/high@value | 20130101 | 20130101 | 20150101 | 20150101 | 20150101 |
| **Title Page**   * EffectiveTime   component/section[@code = ‘10’]/ /effectiveTime@value | 20130101 | 20140101 | 20150101 | 20160101 | 20170201 |
| **Part I**   * EffectiveTime   A nested section under component/section[@code = ‘20]/ /effectiveTime@value | 20130101 | 20140101  (Assuming content changes due to new products) | 20150101  (Assuming content changes due to revised products) | 20150101 | 20170201  (Assuming content changes due to revised products) |
| **Part II**   * EffectiveTime   A nested section under component/section[@code = ‘30]/ /effectiveTime@value | 20130101 | 20140101  (Assuming content changes due to new products) | 20150101  (Assuming content changes due to revised products) | 20150101 | 20170201  (Assuming content changes due to revised products) |
| **Part III**   * EffectiveTime   A nested section under component/section[@code = ‘40]/ /effectiveTime@value | 20130101 | 20140101  (Assuming content changes due to new products) | 20150101  (Assuming content changes due to revised products) | 20160101 | 20170201  (Assuming content changes due to revised products) |

1. Notice - Final Release: Part I - Health Professional Information and Part II - Scientific Information of the Guidance Document - Product Monograph; December 9, 2016; Reference number: 16-113259-317 [↑](#footnote-ref-1)