Electronic Labeling Information Processing System (ELIPS) Validation and Conformance Rules[1]

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[1] This document is not an HL7 informative document. It is used with the *SPL Implementation Guide for FDA Content of Labeling Submissions* posted on the FDA website at http://www.fda.gov/oc/datacouncil/spl.html). Questions or comments regarding this document should be directed to Binh Ta at binh.ta@fda.gov

1. Purpose and Scope

The purpose of this document is to provide the Electronic Labeling Information Processing System (ELIPS) validation and conformance rules for the submission of Structured Product Labeling (SPL). The concept of 'validation' is well-defined in XML to mean the successful parsing of an instance against a DTD or Schema, in this case the SPL Schema. In addition, an SPL instance must also conform to the business rules as documented in the *SPL Implementation Guide for FDA Content of Labeling Submissions*.

2. SPL Validation

SPL validation includes three tiers. The detailed business rules for the first two tiers are presented in the following sub-sections. Final tier involves a manual review of data elements in SPL.

2.1 First Tier Validations

The first tier validation includes file validation, XML validation, and header and section data element validation on the SPL submission files. **Failure of first tier validation prevents SPL from loading into ELIPS**. The validation results will be reported to the review division.

2.1.1 File Validation

Table 1, *File Validation Business Rules for Incoming SPL Submissions* lists the rules used to check the SPL submission files. SPL will fail to load into ELIPS if any of the rules are violated.

Table 1. File Validation Business Rules for Incoming SPL Submissions

No.	Business Rule
1.	• SPL submission files must be accessible (opened and copied) from the electronic submission media (e.g., CD-ROM)
2.	• SPL submission files (SPL and all associated image files) must be present in the SPL folder/directory
3.	• SPL submission files must have valid extensions (XML, JPG, GIF)

2.1.2 XML Validation

Table 2, *XML Validation Business Rules for Incoming SPL Submissions* lists the rules used to check the SPL xml file. SPL will fail to load into ELIPS if any of the rules are violated.

Table 2. XML Validation Business Rules for Incoming SPL Submissions

No.	Business Rule
1.	• The SPL document must validate successfully against the SPL schema

Table 2. XML Validation Business Rules for Incoming SPL Submissions

No.	Business Rule
2.	• The references to the image files in the SPL XML must have a valid path relative to the SPL folder.

Note: ELIPS uses the javax.xml.parsers.SAXParser utility to parse and validate the SPL against schema. Additional information about the parser can be found at http://java.sun.com/j2se/1.4.2/docs/api/javax/xml/parsers/SAXParser.html.

2.1.3 Data Element Validation

Table 3, *Data Elements Validation Business Rules for Incoming SPL Submissions* lists the rules used to check the SPL data elements. SPL will fail to load into ELIPS if any of the rules are violated.

Table 3. Data Elements Validation Business Rules for Incoming SPL Submissions

No.	Data Element	Business Rule
SPL Header Data Elements		
1.	setId	• Data element must be present
2.	id	• Data element must have an unique value for each SPL file submitted • This value must be a properly formatted GUID
3.	code	• Data element must have a value representing the LOINC code (34391-3) for Human Prescription Drug Label
4.	title	• Data element must be present
SPL Elements Within <section> Element		
5.	id	• Data element must be present • Data element must have a unique value for the particular logical instance. • Value for data element must be a properly formatted GUID
6.	code	• Value for data element must be a valid LOINC code if specified. May be omitted for sections having no LOINC code assigned.
7.	component	• Data element must be present for nested <section>s

2.2 Second Tier Validations

The second tier validation includes an automated data element validation. Failure of second tier

validations causes the SPL data elements to be flagged for manual review during the labeling review process. Problems found during tier 2 must be corrected prior to transmission to NLM.

Table 4, *Data Elements Validation Business Rules during Labeling Review* lists business rules that will result in the flagging of data elements.

Table 4. Data Elements Validation Business Rules during Labeling Review

No.	Conceptual Data Element	Business Rule
SPL Data Elements		
1.	Proprietary Name	• Name element must be present and have a value
2.	Nonproprietary Name	• Data element must be present • Data element must have a value
3.	Active Ingredients	• Data element must be present • Data element (<name>) must have a value • Active ingredient name must be from the Substance Registration System /Ingredient Dictionary (SRS/ID). • Quantity and code must be present and must have values. Value for code must be from NCI Thesaurus.
4.	Inactive Ingredients	• Data element (<name>) must have a value if data element tag is present • Inactive ingredient name must be from the SRS/ID. • If inactive ingredient is specified, the quantity and code may also be present and have values. If present, value for code must be from NCI Thesaurus.
5.	Dosage Form	• Data element must be present • Data element must have a value • Value must be from NCI Thesaurus
6.	Labeled Route of Administration	• Data element must be present • Data element must have a value • Value must be from NCI Thesaurus
7.	Package Type, Quantity, and NDC	• Data elements must be present • Quantity must have valid code and value. Code must be from NCI Thesaurus. • Code for package type must have value. Code must be from NCI Thesaurus.
8.	DEA Schedule	• Data element must have a value if present • Value must be from NCI Thesaurus
9.	Color	• If the data element tag is present, then the data element must have a value • Value must be from NCI Thesaurus
10.	Score	• If the data element tag is present, then the data element must

Table 4. Data Elements Validation Business Rules during Labeling Review

No.	Conceptual Data Element	Business Rule
		have a value
11.	Shape	• If the data element tag is present, then the data element must have a value • Value must be from NCI Thesaurus
12.	Size	• If the data element tag is present, then the data element must have a value
13.	Coating	• If the data element tag is present, then the data element must have a value • Value must be true or false
14.	Symbol	• If the data element tag is present, then the data element must have a value • Value must be true or false
15.	Imprint	• If the data element tag is present, then the data element must have a value