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SPL: KEY REQUIREMENT FOR REGULATORY

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ABSTRACT

In the world of globalization people gets each & every information on internet by the utilization of different website, with the use of daily med website peoples were aware about all information of particular drug product & it is possible with the concept of structure product labelling (SPL). SPL is the key requirement for the regulated market. By keeping in mind the awareness of people in the medicines or drugs, health level seven (HL7) members approved or introduced the concept of SPL that has been adopted by the U.S. Food and Drug Administration (FDA) as a mechanism for exchanging medication information. SPL is also used by the FDA for the submission of other regulatory information supporting product labeling, specifically for establishment registration and labeler information.

Keywords: SPL, HL7, FDA, Regulatory

INTRODUCTION

Structured Product Labelling (SPL) defines the content of human prescription drug labeling in an XML format. This format is defined within the SPL schema and is displayed in a web browser using the SPL style sheet. It is approved by health level seven (HL7) and has been adopted by FDA as a mechanism for exchanging medication information. Like most documents, an SPL document has sections and sections contain text (paragraphs, lists, tables); SPL documents can be rendered and published in these standard narrative presentations.

At the same time, the SPL specification provides semantic markup that permits extraction of relevant data embedded in the narrative so that it can be used for other purposes. In other words, SPL markup of a product labeling document both preserves the human readability of the content and facilitates machine processing of that content.

The SPL specification includes a detailed description of an information model for structured product labeling documents as well as the XML representation of that model. The information model is based on the HL7 Reference Information Model (RIM) and uses the HL7 Version 4 Data Types. Substantially SPL, Structured Product Labeling, is an XML file that must meet the structural and data information content criteria defined by the SPL definition. The major purpose of the SPL specification is to facilitate the review, editing, storage, dissemination of, and access to, product labeling document content. [1, 2]

PURPOSE OF SPL

SPL format is used for submission of content of labeling in electronic format. As required in New Drug Application (NDAs), Abbreviated New Drug Application (ANDAs), Biological license application (BLAs) and Annual reports on approved drug. FDA encourages applicants to submit this labeling material and updates primarily through the drug establishment registration and drug listing system.

Rather than make duplicate submissions, applicants are then encouraged to reference the SPL labeling file

submitted through the electronic drug registration and listing system in making labeling updates to application under the content of labeling requirement [3,4].

MEANING OF ELECTRONIC SUBMISSION

FDA is developing an electronic listing system (eList) that will eventually allow industry provide listing information via SPL submission. SPL includes coded data elements for most of the required listing information.eList will extract coded data from the SPL listing; industry will log-in through FURLS to provide some information not in the SPL. eList will validate listing information, including NDC number drug approval and label approval prior to public posting in Daily maid and the NDC directory.[5]

TYPES OF SPL FORMAT

As far as pharmaceutical industries are concerned types of SPL includes human Prescription Drug, human OTC Drug ,animal OTC drug label , bulk ingredient, establishment registration, establishment de-registration, prescription animal drug label, prescription medical device label etc. many more types are also available.

PARAMETERS TO BE DISCUSSED IN SPL

SPL file contains following parameters:

1) Name of Establishment(s) Manufacturing or processing the listed drug and the type of operation(s) performed.
2) DEA Schedule
3) Route(s) of administration.
4) Inactive ingredients
5) Marketing information
6) Information related to application (e.g. Type and Year of approval) or OTC Monograph citation number
7) Package size, type as like.
In addition to these;
a) NDC product code product code for a source Drug Repacked or Relabeled:
Repackers and Relabelers should submit the NDC product code for the source drug that is repacked or relabeled in order to reference manufacturing establishment information submitted in the listing entry for the source drug
2) Unique Ingredient Identifier (UNII) and other code set.
3) Confidentially Flag : Through the confidentially flag FDA determines whether drug establishment registration and drug listing information can be disclosed to the public pursuant to the trade secrets act, the freedom of information act, and the other applicable law.

Distinctive Characteristic of Certain Listed Drug: Flavor, Color: for liquid dosage form the color change examines whether the contamination occurs or not. Image: for solid dosage form.

Spl Document Creation and Submission

1) Create the XML SPL File according to your submission needs (e.g. Product Label, Establishment Registration, NDC Labeler Code Request), by adding all relevant data such as DUNS Numbers, NDC Labeler Codes, etc.
2) Validate your XML SPL File online with Pragmatic Data Validator: http://validator.pragmaticdata.com/validator-lite/validator/spl/
3) Correct any errors and revalidate online until the Pragmatic Data Validator reports no error.
4) Submit your SPL XML File trough your FDA Test Account
5) If the FDA response is positive, submit the SPL XML File to your FDA Production Account. [6, 7, 8, 9]

APPLICATION OF SPL

With the help of SPL, patient healthcare professionals and providers will have electronic health records, electronic prescribing system, and an array of clinical decision support system and tools at their disposal. The SPL Standards enables the inclusion of indexing elements which are machine readable tags that can be added to product labeling to enable users to rapidly search and sort information. FDA has been making labeling information for prescription drug available free of charge on the internet through the use of SPL. Daily Maid is commercially used sight for SPL. [10]

CONCLUSION

SPL has gained a lot of attention since it is one of the first to mandate XML for electronic submissions. Great efforts have been put forth by HL7, FDA, the SPL Working Group and others to develop the SPL standard and increase the awareness and knowledge of it. As the industry and health authorities become more knowledgeable and comfortable with XML and understand the capabilities and possibilities of structured content, the evolution of XML-based standards in the life sciences industry will continue at a more rapid pace. Creating and submitting SPL documents will require every company to make some type of additional investment, whether in the form of

time, cost, new tools, or any combination of these. It is up to each one to determine how best to achieve SPL compliance, but the successful organizations will be those that look beyond SPL and recognize the opportunity to create measurable impacts throughout their enterprise.

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