

SPL Data Exchange Standard - Content of Labeling

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Disclaimer



- The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.
- The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.

Overview



- Overview of SPL
- Processing of SPL Files
- Public Utilization of SPL

Overview of SPL

Over 12 years
ago...



Paper Content of Labeling



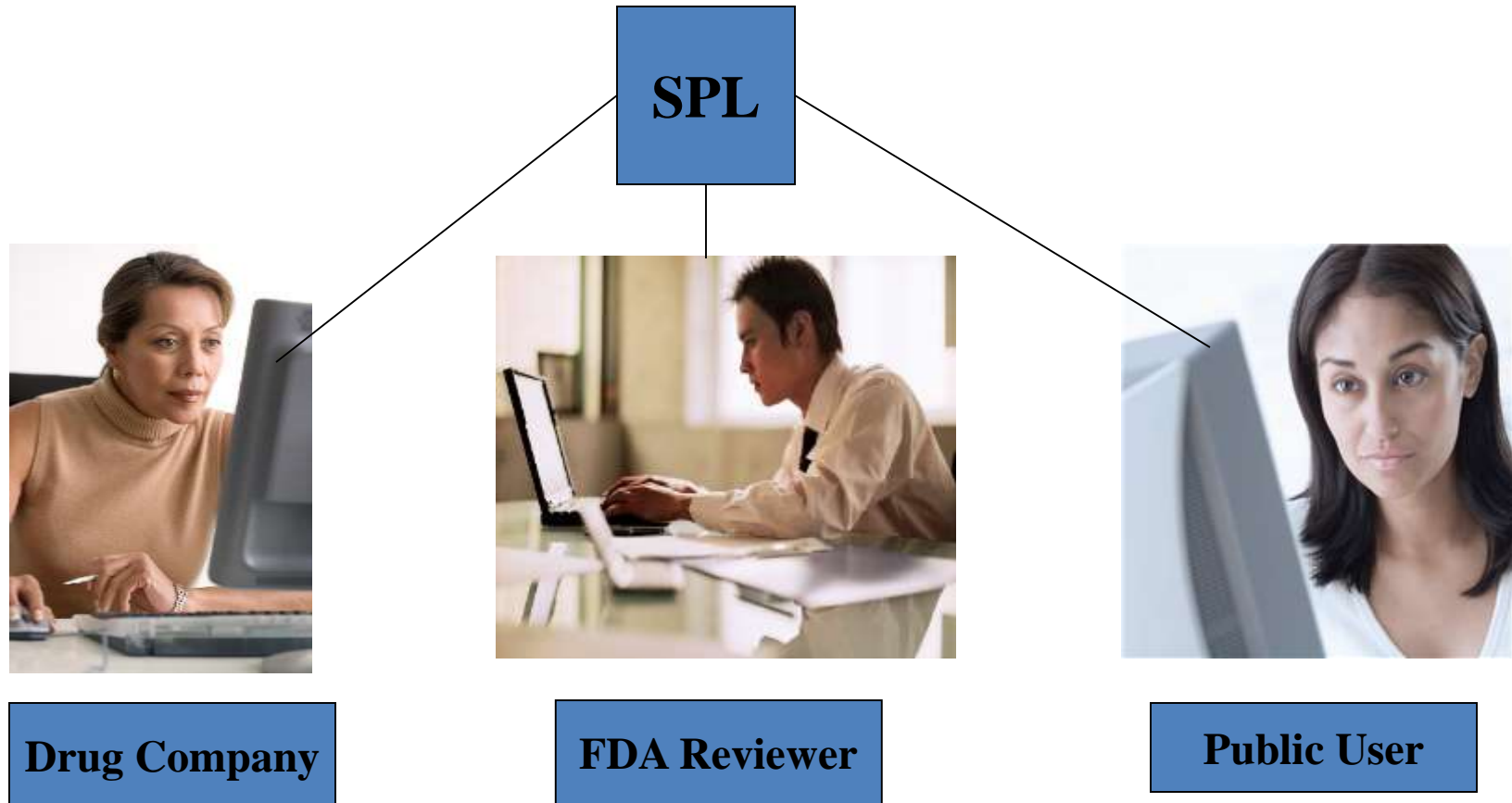
- The Labeling Rips when it is Removed!
- Critical data is missing.
- The Product can outdate the Labeling
- The Labeling is often in the Container

Benefits of Using SPL for the Provision of Content of Labeling



- Provide public with better access to content of labeling
- 24-hour submission window
- Reduces the amount of time for FDA to receive and process your information
- Automated notification of technical issues in SPL files
- Posting of up-to-date content of labeling within one business day

Information Exchange



SPL is a standard that is used by drug companies, FDA and public to exchange, review or view product information. All three entities use computer or systems that “understand” SPL

Blocks of Text

PDF

Description:

This is the description of the product

Indications and Usage:

This is the indication for use of this product

Contraindications:

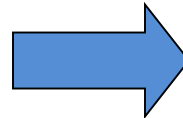
These are the contraindications

Warnings:

These are the warnings.

How supplied:

This is how the product is supplied.



SPL

<Description>

This is the description of this product

<Indication and Usage>

This is the indication of the product

<Contraindications>

These are the contraindications

<Warnings>

These are the warnings

<How supplied>

This is how the product is supplied

XML & XSL Stylesheet



- SPL is created using EXtensible Markup Language (XML)
 - Relatively human-legible
 - Machine readable
 - Tags (elements) permit search of key information
- XML Documents – created via Notepad, Word Pad, XML validation tools, FDA-provided or commercial software tools, etc...
- XSL Stylesheet – transforms the XML data to be viewed via web browser or printed documents

SPL Stylesheet View/ Source Code

CONTRAINDICATIONS

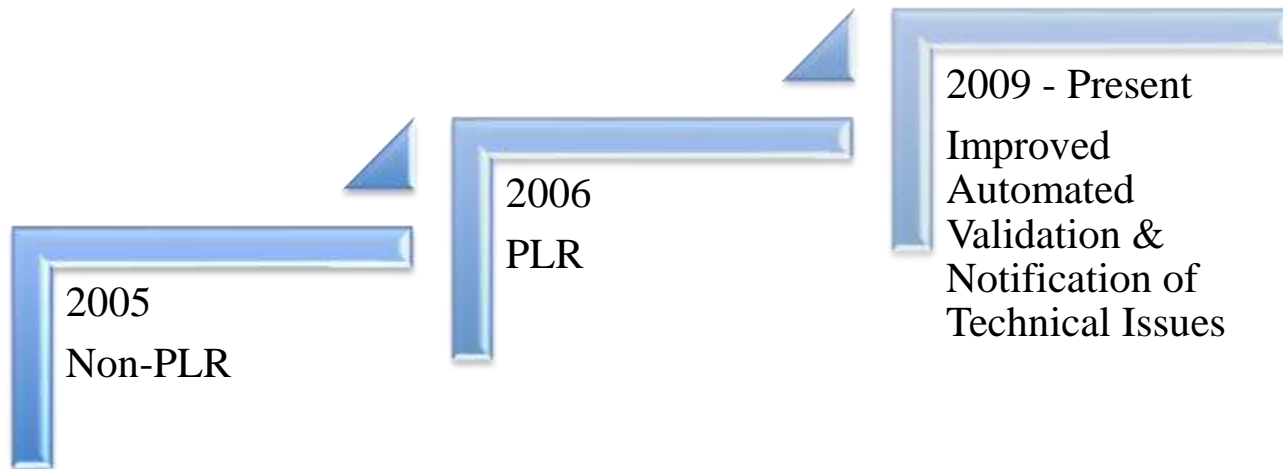
Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from
any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

Processing of SPL Files

Evolution of SPL

Content of Labeling Updates



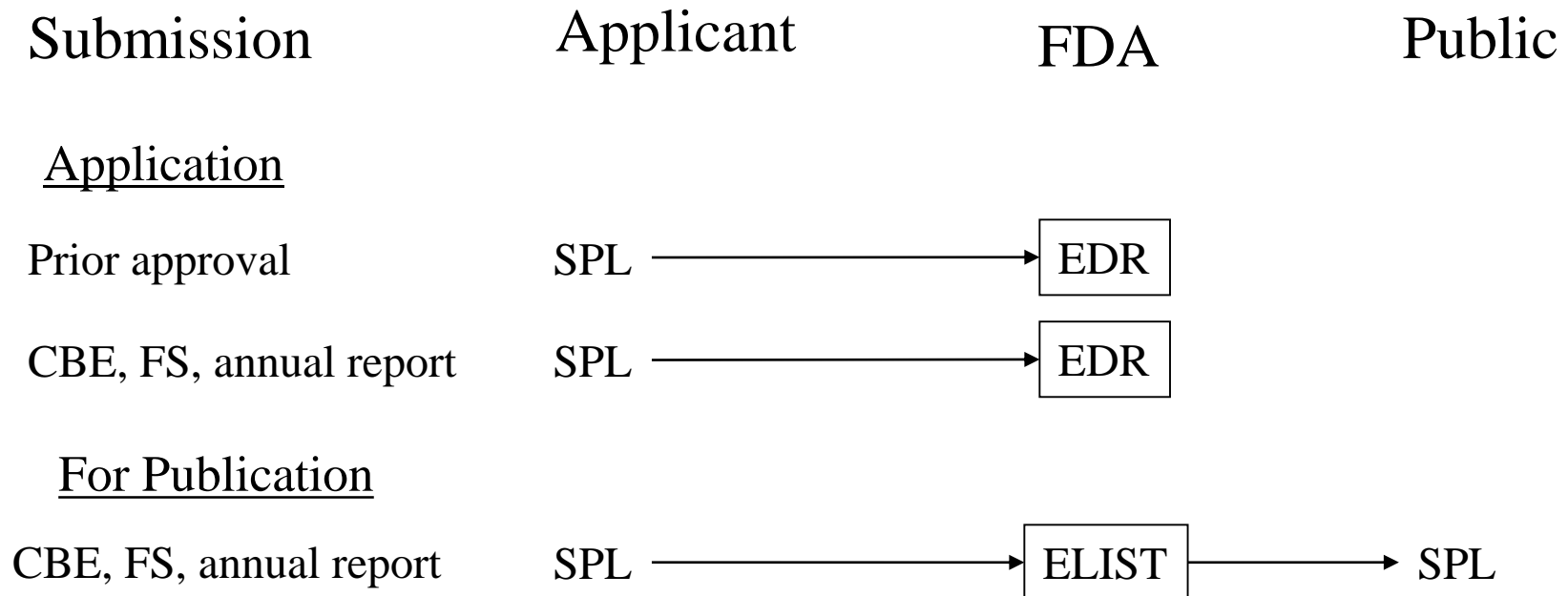
SPL Lifecycle Management



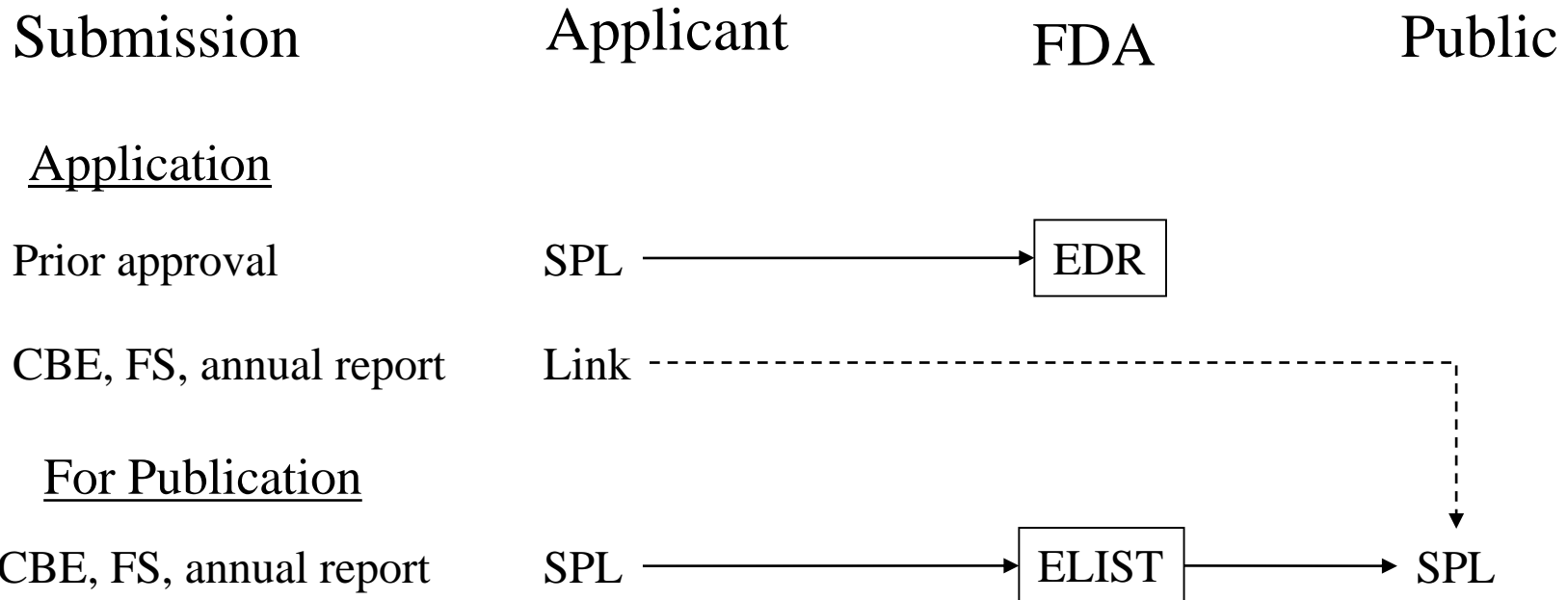
- Lifecycle management is now controlled by Industry SPL authors
- Proper management of your document's setID is very critical.
- Set ID
- Document ID
- Section IDs
- Version Number



SPL Submission to Application



Publishing SPL in Public SPL Web Repositories

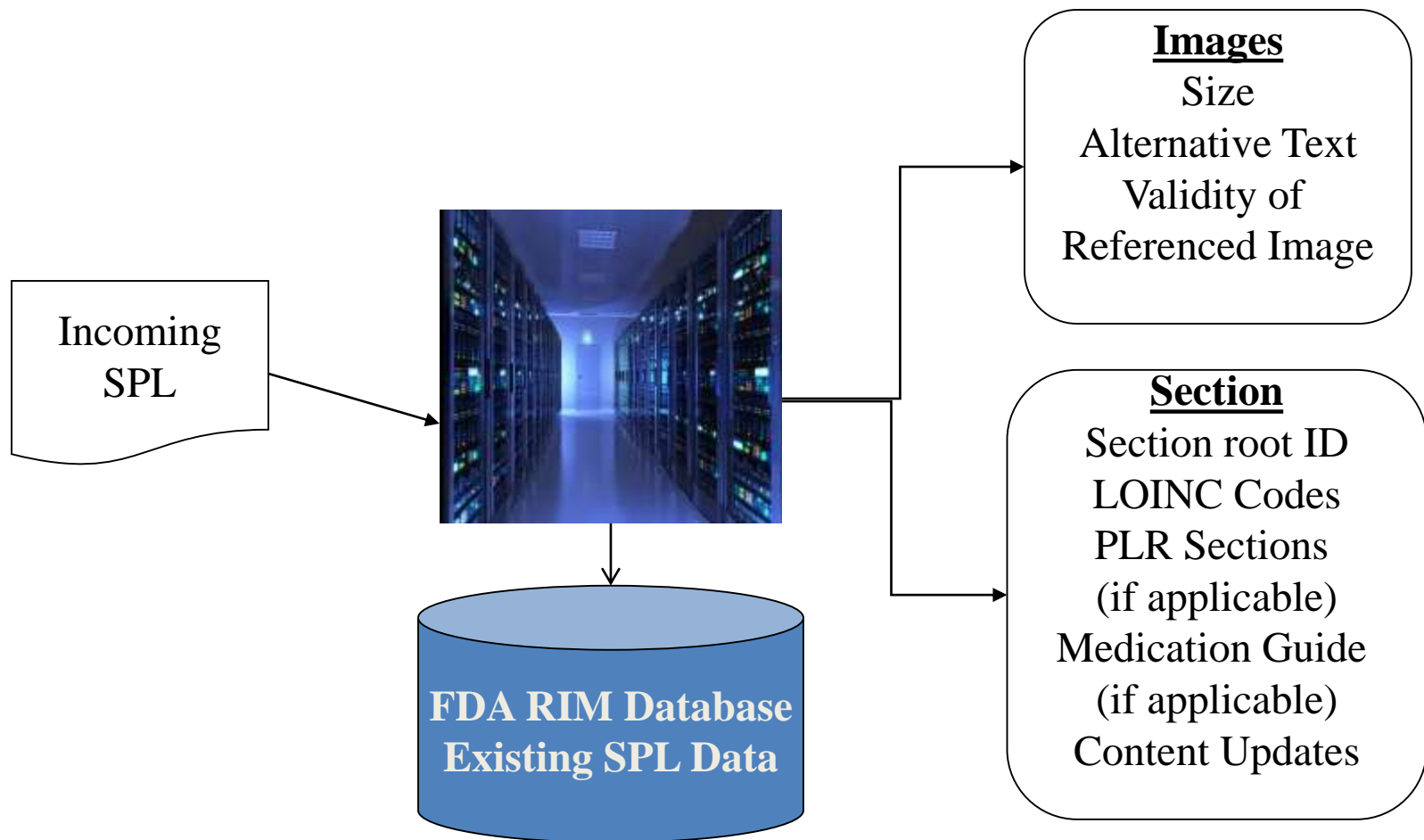




Linking the Public Version of SPL File to Application Submission

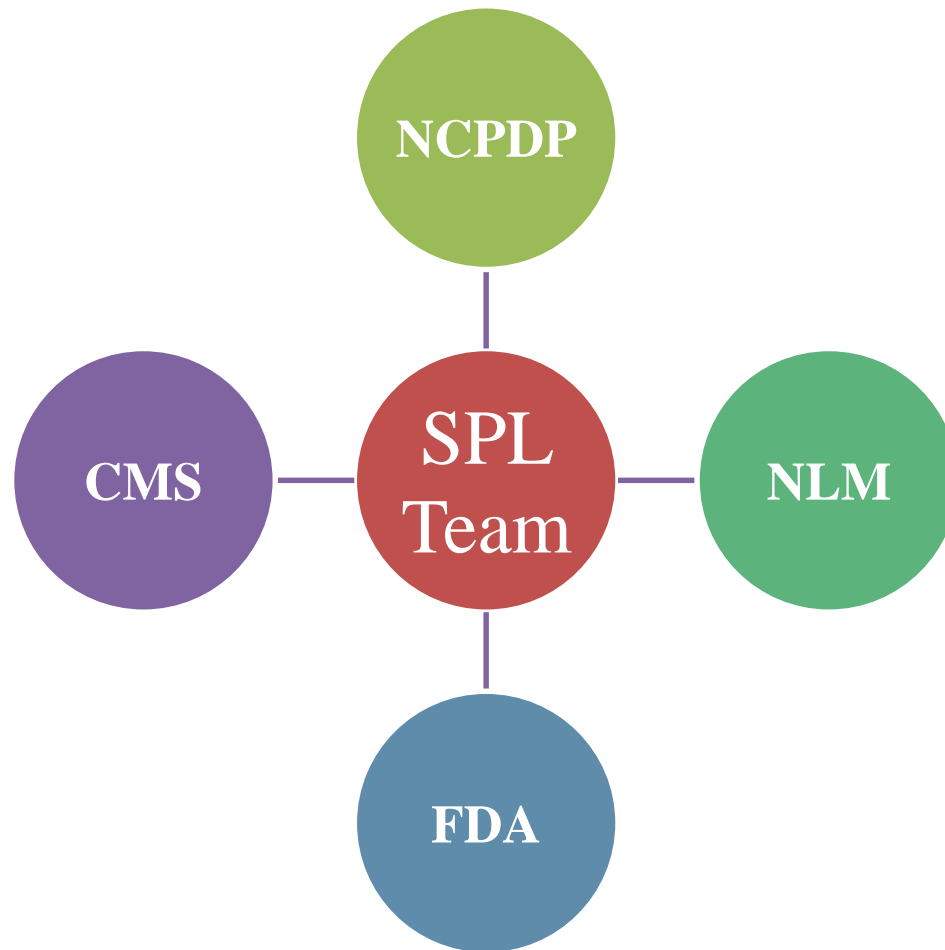
- Referencing the identical content of labeling submitted during listing process
- Include a statement and hyperlink in your application submission
- (e.g., “We have submitted the SPL file with drug listing; it can be found at the following location <http://www.accessdata.fda.gov/spl/data/> [*insert your SPL document id root here/insert SPL document id root here*].xml”]

SPL Validation of Content of Labeling - Automated



Another SPL Validation Method

Manual Human Review



Combining Product SPL Documents

Original SPL Files

- Select one as the new combined SPL
- Select the set ID from that file

Combined SPL File

- Add Related Document Element
- Enter set ID(s) document ID(s) & version Numbers from replaced SPL documents to related document element

Public Posting of Combined SPL

Combined SPL file posts to the publicly websites
(Note: At this time, DailyMed does not automatically remove outdated version – please contact spl@fda.hhs.gov)

Separate Section for SPL Med. Guide Content

- [Guidance for Industry: SPL Standard for Content of Labeling Technical Questions and Answers \(Draft\)](#)
- **23. Should I submit patient package inserts (PPIs) and Medication Guides (MGs) in SPL?**

Approved patient labeling documents should be included at the end of the SPL file. There are specific Logical Observation Identifiers Names and Codes (LOINC) codes for PPIs and MGs. Use the appropriate LOINC code for identifying this information. Each PPI or MG should have a separate LOINC code.

Missing or Misidentified Med. Guide Content in SPL Files



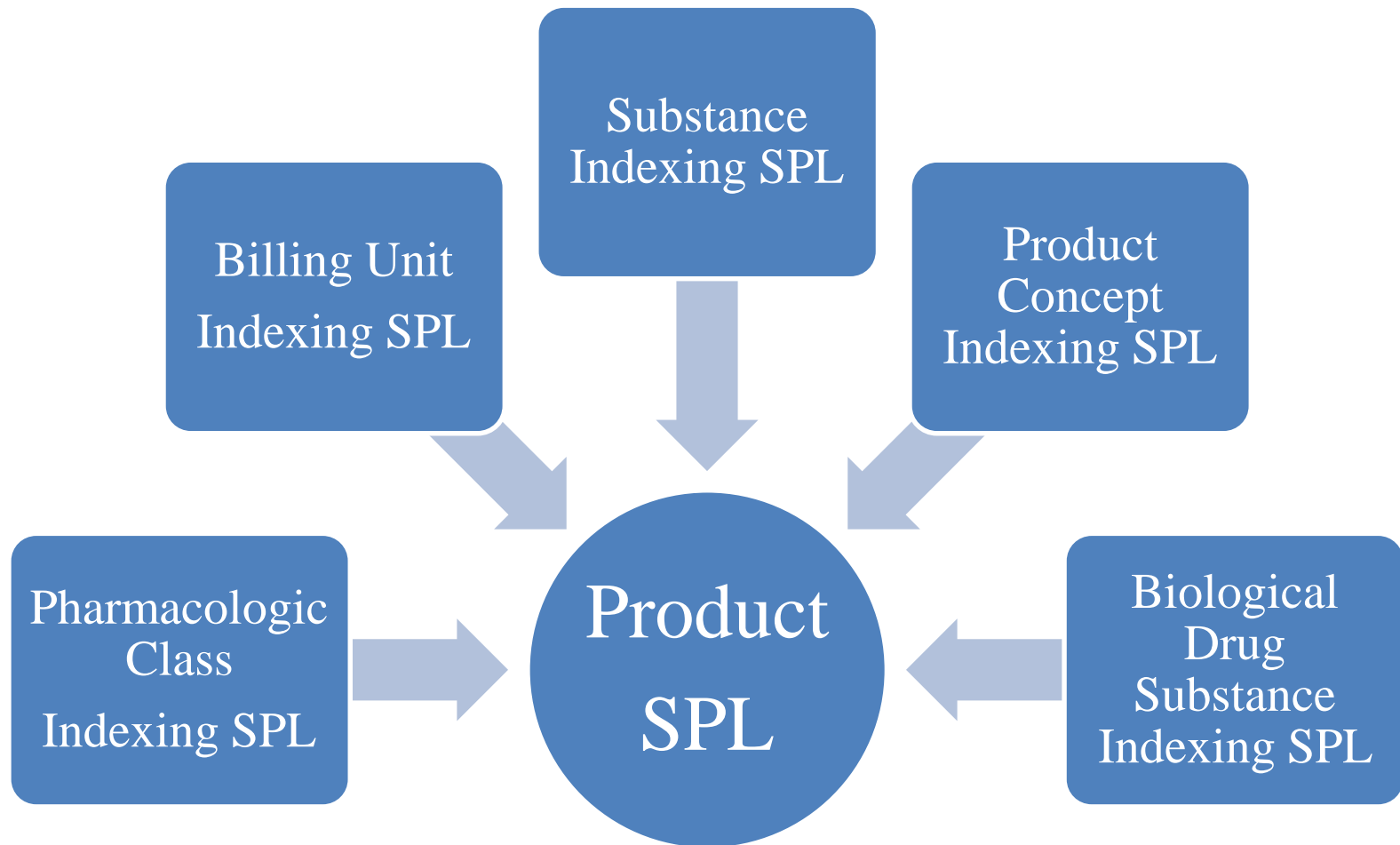
**New Improved Medication Guide Section
Validation File for Incoming SPL Files**

**List of Currently Posted SPL Files
w/Missing Medication Guide Section**

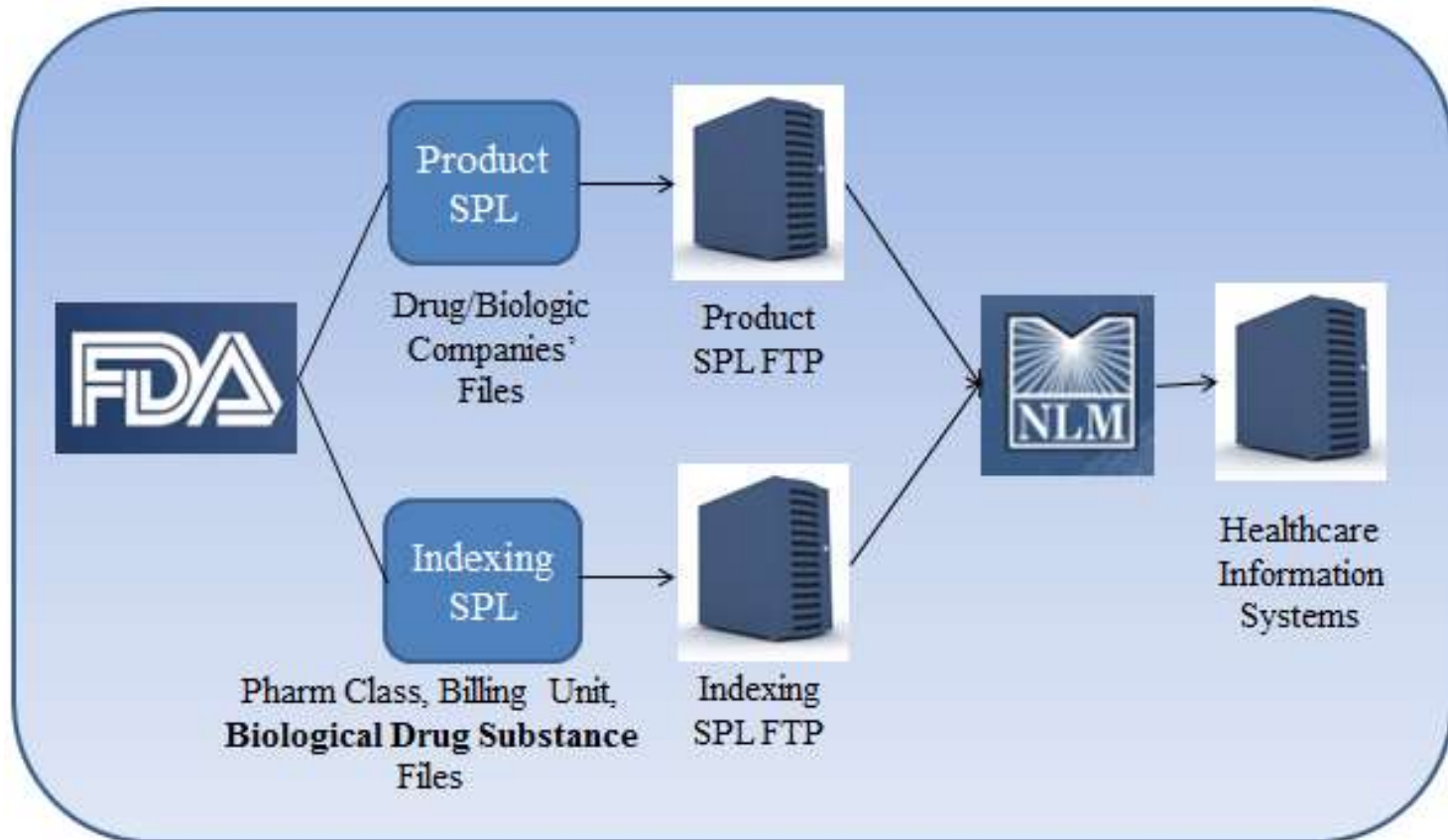
- Posted on FDA SPL web page in XML and Excel Format
- Report of SPL files with missing content of medication sections in SPL files

Public Utilization of SPL

Indexing SPL Documents



FDA-to-NLM-to-Healthcare Information Systems



SPL Dissemination

Correct One File – Update These Sites



DailyMed



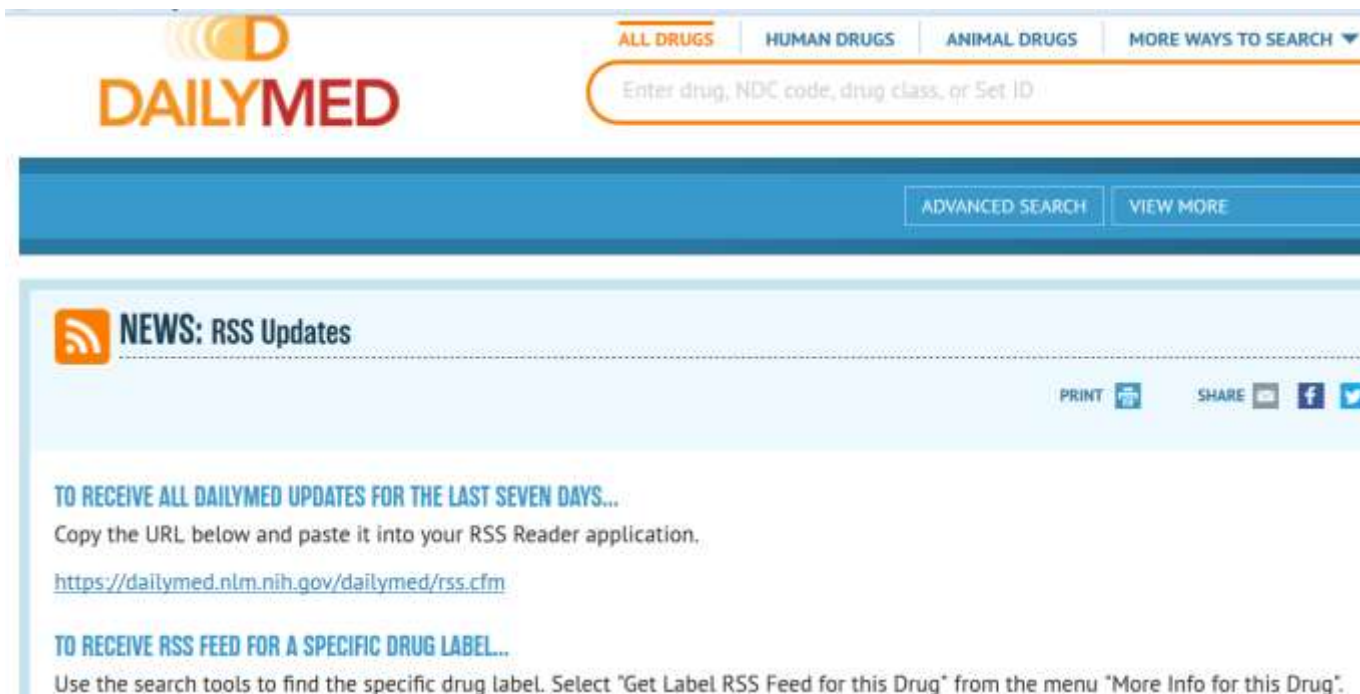
Labels.fda.gov



openFDA

Automate Receipt of Notification of SPL Publication

- Automated notification of updates to SPL files
 - DailyMed RSS Feed



The screenshot shows the DailyMed website interface. At the top, there is a navigation bar with the DailyMed logo and a search bar. The search bar contains the text "Enter drug, NDC code, drug class, or Set ID". Below the search bar, there are buttons for "ADVANCED SEARCH" and "VIEW MORE". The main content area is titled "NEWS: RSS Updates" and includes an RSS icon. Below the title, there is a section for "TO RECEIVE ALL DAILYMED UPDATES FOR THE LAST SEVEN DAYS..." which provides instructions on how to use the URL <https://dailymed.nlm.nih.gov/dailymed/rss.cfm> in an RSS reader application. There is also a section for "TO RECEIVE RSS FEED FOR A SPECIFIC DRUG LABEL..." which provides instructions on how to use the search tools to find the specific drug label and select "Get Label RSS Feed for this Drug" from the menu "More Info for this Drug".

Product SPL Public Data Flow

