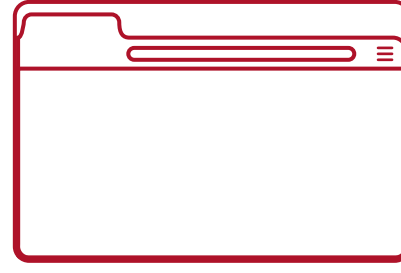


Structured Product Labeling (SPL)

SPL is a document markup standard:

Approved by
Health Level Seven International (HL7)

Accredited by the
American National Standards Institute (ANSI)



Based on **Clinical Document Architecture and HL7 Reference Information Model (RIM)**

Adopted by FDA as a way to
exchange product and facility information

Submission Timing

Initial product listings: required within 14 days after product approval

The FDA recommends that updates should be made immediately but are required **no later than June or December following a change**

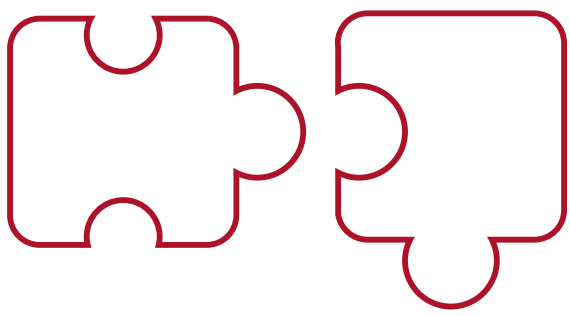
When no product updates are necessary: a company may submit a "blanket" no changes certification once a year **during the October 1 to December 31 renewal period**

As of 2016: annual requirement to update listings or certify that no changes have occurred for products that were not initially listed or updated during the past calendar year

SPL COMPONENTS

Content of Labeling

- Text
- Tables
- Figures



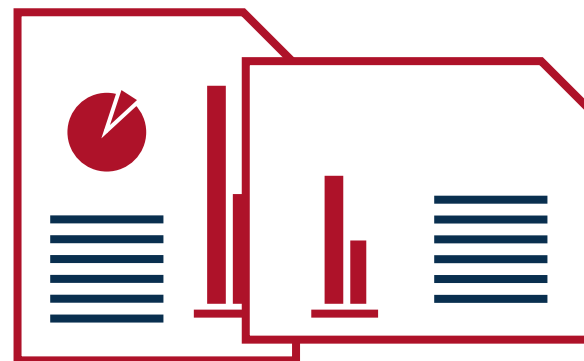
Drug Listing Data

Product

- Product or Generic Name
- Ingredients
- Ingredient Strength
- Dosage Form
- Routes of Administration
- Appearance
- DEA Schedule

Package

- Quantity
- Type
- Configuration



Recent FDA Warnings

- Active ingredient listed in the electronic listing file does not match labeling
- The product's listing includes an incorrect copy of the carton label
- Discrepancy in the statement of the active ingredient of the drug product
- Product's listing submission includes an incorrect/incomplete copy of the label
- Incorrect application number in the listing file
- Incorrect proprietary name in the listing file
- Incorrect quantity for the package sizes in the listing file
- Missing the drug's DEA schedule in the listing file



Important Websites

FDA SPL Resources Site:

<https://www.fda.gov/industry/fda-resources-data-standards/structured-product-labeling-resources>

NATIONAL DRUG CODE (NDC) Directory:

<https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm>

Current Establishment Registrations:

<https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>

DailyMed:

<https://dailymed.nlm.nih.gov/dailymed/index.cfm>

NDC Codes

10 or 11 digits
3 segments

1

Labeler Code

Assigned by FDA to
Manufacturer or Distributor

2

Product Code

Assigned by Manufacturer
or Distributor Changes
when there is a change
in formulation

3

Commercial Package Code

Assigned by Manufacturer
or Distributor Changes
when there is a change
in packaging

SPL History

FDA accepts electronic content of labeling in Portable Document Format (PDF)

1999

FDA requires submission of physician (US Package Insert [USPI]) and patient labeling in SPL format

2004

FDA regulation published requiring that content of labeling be submitted in a form that FDA can process, review, and archive

2005

FDA requires annual update to your listings or certification that no changes have occurred for products that were not initially listed or updated during the past calendar year

2009

FDA requires submission of drug establishment registration and drug listing information in SPL format

2016

2019

Drug Listing Yearly Renewal: Outdated or unconfirmed information will be pulled from the NDC directory