# 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**

## 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

## 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

## 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

- **1999** — FDA accepts electronic content of labeling in Portable Document Format (PDF)
- **2004** — FDA regulation published requiring that content of labeling be submitted in a form that FDA can process, review, and archive
- **2005** — FDA requires submission of physician (US Package Insert [USPI]) and patient labeling in SPL format
- **2009** — FDA requires submission of drug establishment registration and drug listing information in SPL format
- **2016** — 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
- **2019** — Drug Listing Yearly Renewal: Outdated or unconfirmed information will be pulled from the NDC directory

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