FDA SPL (Structured Product Labeling)

The Structured Product Labeling (SPL) is a document markup standard developed by Health Level Seven (HL7). Adopted by FDA as a mechanism for exchanging product and facility information, using extensible markup language (XML).

Since October 31, 2005, labeling submissions to the FDA's Center for Drug Evaluation and Research **(CDER) must be in SPL format**. It became mandatory for submission to **CBER** in **October 15, 2008**.

SPL TYPES

Labeler Code	Code to identify the labeler, needed for the NDC (National Drug Code)
Prescribing Information	Draft labeling SPL (of the package insert) with the eCTD
Product Drug Listings	Initial electronic listing, Updates and Annual Drug Listing Certification (between October 1st and December 31st).
GDUFA Self-Identification	Operators of facilities involved in the development and manufacturing of generic drugs. Annual renewal between May 1st and June 1st.
Establishment Registration	Listing of Establishments related with the manufacturing of any product approved in FDA. Annual renewal between October 1st and December 31st (for expedited updates to be provided within 30 days of a change).
LDR (Lot Distribution Reports)	Licensed manufacturers of products distributed under a BLA must submit every 6 months about the quantity of the product distributed.
REMS (Risk Evaluation and Mitigation Strategies)	All REMS documents submitted to FDA on or after December 28, 2022 must be in SPL format.

Asphalion Regulatory Services

We can support you throughout the whole SPL procedure in a variety of activities:

- SPL creation with available software like SPL XForms.
- SPL validation and troubleshooting.
- SPL pre-population templates.
- FDA submission (ESG NextGen or CDER Direct) and communication.
- Tailored trainings.
- Wider regulatory consulting.