

# SPL Portal

## US Product Labeling in One XML Repository

Centrally manage the product labeling and listing lifecycle in an XML repository.  
Stay updated with nightly FDA and NLM updates.



### Top Features

- RLD Update Notification
- Central XML Repository
- Automatic Nightly FDA Terminology Updates
- Full NLM Search
- Product Listing Notification
- Customized Templates
- Centralized Establishment Repository
- Submission Management
- Progress Reporting
- Full Audit Trail

### Function

SPL Portal is a web-based application with a central repository that allows pharmaceutical companies to manage and create product labeling compliant with the latest FDA electronic registration and listing regulations.

### Central Repository

XML content is stored and versioned at the section level within the SPL database. Associations are created between products, establishments, and labelers allowing for centralized updates. Updates made to contacts, addresses, and establishment operations are automatically propagated to all mapped products, allowing for the most up-to-date information to be included with the next product listing.

### Automated Updates

SPL Portal downloads the full content of the National Library of Medicine DailyMed site and the FDA SPL Terminologies nightly. This feature ensures SPL Portal users will have the most current data available at their finger tips. Users can search all the National Library of Medicine DailyMed in seconds.

### RLD Subscriptions

SPL Portal sends daily notifications to users notifying them when products have been listed or when products have been updated on the National Library of Medicine DailyMed website. This feature allows SPL users to know immediately when product labeling has been updated!

### Multiple Delivery Models

SPL Portal can be hosted internally by your organization or companies can subscribe to the hosted Software-as-a-Service (SaaS) application. The SaaS model provides immediate global access with no software to purchase or install.

### Audit Trail

All modifications are captured by user name and date. Additionally, SPL Portal captures content values before and after an update. This feature provides the basis for SPL Portal's audit trail functionality.

### Statistics Dashboard

SPL Portal provides robust statistics dashboard that detail how many submissions an organization has created by, date, submission type, labeling type, and product.



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# Features

## Minimum Server Technical Requirements

- Microsoft Windows Server 2003 SP 3 or greater
- IIS version 6 or greater
- Microsoft Word 2003 or greater
- 4.0 GHz Processor (Minimum)
- 4.0 GB RAM (Minimum)
- 100 GB Storage (Minimum)
- Windows SQL Server 2005
- .Net Framework 3.5

## Establishment Repository

- On Demand Validation
- Multiple Labelers
- Multiple Registrants
- Multiple Establishments
- Full FDA validation
- Single location update
- Multiple product association
- Audit Trail

## Editor

- On Demand Validation
- Multiple formats
  - USPI
  - PLR
  - OTC
  - Medical Gases
  - Bulk Product
- Version Control
- Audit Trail
- LOINC association
- PDF rendition creation
- Word rendition creation
- Internal hyperlinks
- Font emphasis
- Table boarders
- Image insertion
  - Inline
  - Stand alone

## Product Data Elements

- On Demand Validation
- SetID validation
- NDC code validation
- UNII code validation
- Strength to packaging validation
- Listing validation
- Formulation validation
- Audit Trail

## SPL Import

- FDA validation
- GUID management
- Content / Product Data Element distinction

## NLM Function

- Full NLM Search by
  - Company
  - Product Name
  - Proprietary Name
  - Established Name
  - Dosage Form
  - Labeling Type
  - Release Format
- RLD notification
- NLM update notification

## Training

- Documentation
- Videos
- FAQ
- Announcements

## Support

- Online support
- Call support
- LinkedIn group

## Reporting

- Submission reports by
  - Date
  - Submission type
  - Labeling type
  - Top 10