FDA Electronic Registration & Listing Structured Product Labeling (SPL)

Prepared By

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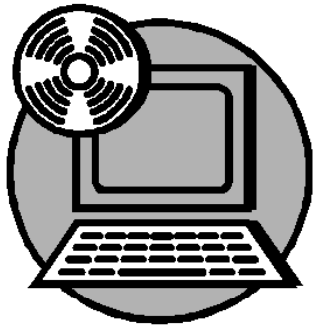
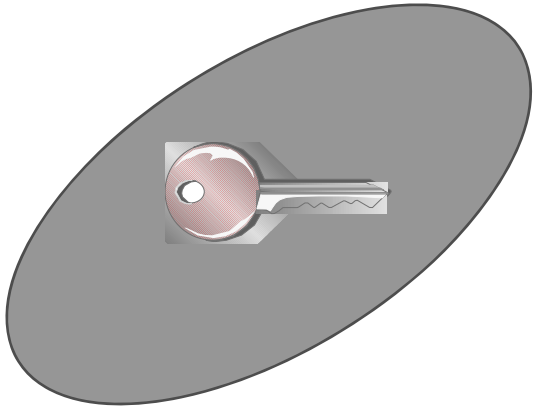
Agenda

- We will cover the following areas:
  - Electronic Registration and Drug Listing Overview – ARE YOU READY?
  - What is SPL?
  - What is XML?
  - What Is Needed to Prepare and Submit SPL Files
  - Roadblocks and Pitfalls
  - Resources and Information
  - Q & A





Electronic Establishment Registration & Drug Listing
Are you ready?

- **WHEN?**
  - **June 1, 2009 – FDA cutoff for submitting paper registration & listing**
  - **Dec. 31, 2009 – Deadline for 2010 registration and drug listing**
- **WHAT?**
  - **Electronic Structured Product Labeling (SPL)**
  - **Digital ID Acquisition**
  - **FDA Global Submit Test Account**
  - **FDA WebTrader Production Account**
- **WHO?**
  - **All drug manufacturers, labelers, re-labelers, processors and re-packagers**
  - **Initial Establishment Registrations, Drug Listings, Re-registrations and Renewals**
    - **Including labeling as specified under 21 CFR 207.25**
- **HOW?**
  - **Electronic extensible markup language (XML) files in a standard SPL format**

What is FDA Authority to Implement Electronic Registration?

- **FDA authority comes from 21 CFR Part 207.3, section 510 of the FD&C Act, and section 351 of the Public Health Service Act**
- **These laws give FDA the authority to require drug manufacturers to annually**
  - **Register their establishments**
  - **Submit product listing information for all drugs in commercial distribution**
- **FDA is also given the authority to set the administrative processes they will use to manage these types of systems**
- **The registration window is each year, not a rolling 12 month time frame**

What is SPL?

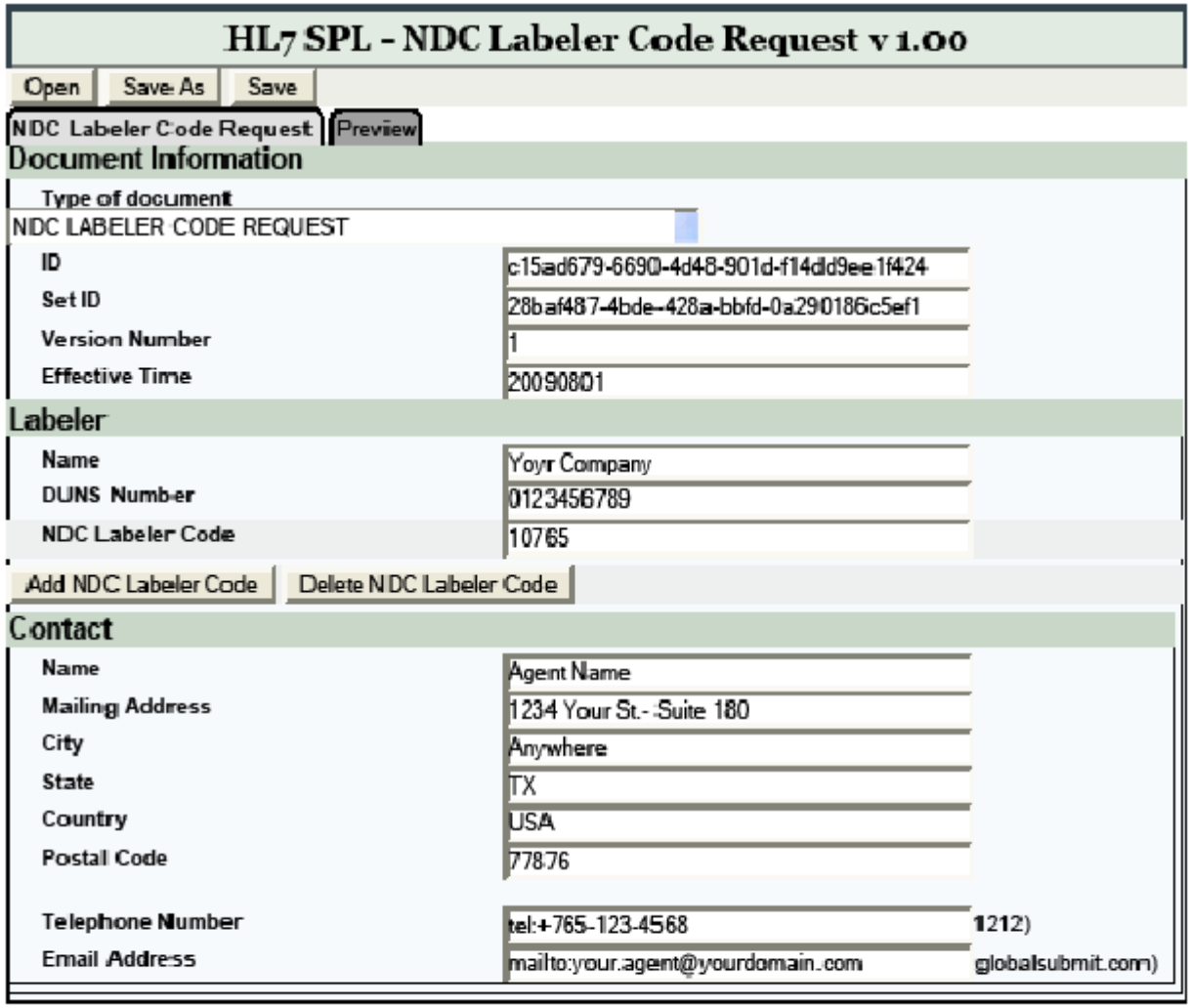
- **Structured Product Labeling (SPL) is a document markup standard developed by Health Level Seven (HL7)**
- **Adopted by FDA as their mechanism for submitting and sharing product information**
- **Provides public access to labeling & drug information on the Web – Daily Med**
- **PDF files are no longer accepted by FDA when sending them electronically submitted labeling & registration information**

Why SPL?

- **FDA is Migrating to SPL Because:**
  - **SPL will result in a database of labeling, registration and listing data that is computer searchable**
  - **Fewer resources required to manage system**
  - **Faster approval processes**
  - **Easier updates to registration and listing data**
  - **Eliminate redundancies**
  - **Make SPL data available to public through Daily Med website**

What Does SPL Look Like?

Structured Product Label Form - Labeler Code file:///C:/XForms/XForm_Templates/SPL_Xform/SPL/XForms/SPLFo...



What Does XML Look Like?

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="http://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3
http://www.accessdata.fda.gov/spl/schema/spl.xsd">
   <id root="c15ad679-6690-4d48-901d-f14dd9ee1f424"/>
  <code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC LABELER CODE REQUEST"/>
  <effectiveTime value="20090801"/>
  <setId root="28baf487-4bde-428a-bbfd-0a290186c5ef1"/>
  <versionNumber value="1"/>
  <author>
                                <time/>
                                <assignedEntity>
                                                <representedOrganization>
                                                                <id extension="0123456789" root="1.3.6.1.4.1.519.1"/>
                                                                <id extension="10765" root="2.16.840.1.113883.6.69"/><name>Yoyr
Company</name>
                                                                <contactParty>
                                                                                <addr>
                                                                                                <streetAddressLine>1234 Your St.-
Suite 180</streetAddressLine>
                                                                                                <city>Anywhere</city>
                                                                                                <state>TX</state>
                                                                                                <postalCode>77876</postalCode>
                                                                                                <country>USA</country>
                                                                                </addr>
                                                                                <telecom value="tel:+765-123-4568"/>
                                                                                <telecom
value="mailto:your.agent@yourdomain.com"/>
                                                                                <contactPerson>
                                                                                                <name>Agent Name</name>
                                                                                </contactPerson>
                                                                </contactParty>
                                                                </representedOrganization>
                                </assignedEntity>
                </author>
   <component>
    <structuredBody/>
   </component>
  </document>
```

What Is Needed to Prepare and Submit SPL Files

- **Electronic Web Trader Submissions Gateway Account**
  - **14 or more technical steps**
  - **2-3 Weeks of effort**
- **Digital ID and Internet Web Domain Setup**
  - **In-depth computer knowledge**
  - **3rd party Digital Certificate purchase and maintenance**
  - **Internet Service Provider (ISP) Involvement**
  - **Communication verification process with FDA**
- **Experience in the "Structured Product Labeling“ Process**
  - **XML programming**
  - **SPL template structure**
  - **Solving computer code & system “errors”**

What Is Needed to Prepare and Submit SPL Files - II

- **A DUNS number must be obtained for each registered location**
  - **Corporate DUNS account is required**
  - **Some expense involved**
- **The computer used to submit SPL must be specially configured**
- **Drug labels must be formatted into the XML code**
- **Digital copies of all drug labels must be prepared**
- **Completed files must be run processed through FDA's validation software to be accepted**

Successfully Navigating the SPL Process

- **Potential Roadblocks and Pitfalls Include:**
  - **Time to obtain electronic web trader account(s)**
  - **Computer hardware & software configuration issues**
  - **Review & Validation of submitted files by FDA**
  - **Extensive ramp-up time for understanding SPL requirements and technology**
  - **XML language and SPL file formatting – Finding & Fixing Errors**
  - **Understanding, finding, and fixing errors in Web Trader SPL file submissions**

Resources and Information Links

- Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (Final)(PDF)
- Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v2.0 (PDF)
- Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v2.0 (PDF)
- Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing v2.0 (PDF)
- SPL Docket 92S-0251 - Drug Establishment Registration and Drug Listing (PDF)
- Guidance to industry: Providing Regulatory Submissions in Electronic Format - *Content of Labeling* (Final) (PDF)
- SPL Standard for Content of Labeling Technical Questions and Answers (PDF)
- SPL Docket 92S-0251 - Content of Labeling-CDER (PDF)
- SPL Docket 92S-0251 - Content of Labeling - CBER (PDF)
- SPL Implementation Guide Archive (zip file of older versions of the SPL implementation guides)
- Guidance for Industry: Indexing Structured Product Labeling (Final) (PDF)
- http://dailymed.nlm.nih.gov/dailymed/about.cfm (Daily Med Website)

Help Is Available !!!

Reg-E-Stration™

provides a cost effective turnkey solution to SPL registration, drug and labeling listing & FDA web portal submission.

Contact Us:

For more information on our services, or to get a price quote on registering your company with FDA through Reg-E-Stration give us a call at (610) 390-7483, or visit us online at www.reg-e-stration.com

Questions???