

Basic Instructions for Using the SPL Xforms

Version 1.0

Preface

- This document provides basic instructions for using Structured Product Labeling (SPL) XForms. The SPL Xforms is an SPL document authoring tool which can be used to create SPL files.
- This document focuses on using free software provided by FDA, however, a number of vendors have created other options for creating and submitting SPL files ranging from user friendly SPL editing software to service providers who create the SPL files for you. These options can be found at the following web site:
 - <http://spl-work-group.wikispaces.com/Vendors>
- More information about SPL (including additional **SPL training materials specific to your submission type**,) is available on the FDA's SPL web page:
 - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Transmitting SPL Files to FDA

FDA Gateway (WebTrader)

- Once your SPL files have been generated, these documents should be sent to the FDA using WebTrader (Gateway.) WebTrader is free software that you downloaded from FDA. With WebTrader and a standard security certificate, you can securely send your files to FDA.
- You can set up your account using the “Setting up a WebTrader Account Checklist” at the following web site:
- <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>
- To request a WebTrader account contact esgprep@fda.hhs.gov
- For assistance with setting up your account contact esgreg@gnsi.com

SPL Xforms - System Requirements

- Web-based forms - No download required
- Compatible with the following types of browsers:
 - Internet Explorer (version 7 and higher)
 - Mozilla Firefox (version 6 and higher)
 - Google Chrome (version 8 and higher)
 - Apple Safari (version 4 and higher)
- Compatible with the following types of computers:
 - Macs
 - PCs

Basic Technical Features

- All templates (NDC Labeler Code, Establishment Registration, etc...) included in one form.
- Automatic population of document root ID, set ID, version number, and effective time
- Automatically names the SPL document.
- **Note:** This eBook does not include instructions related to features such as font effects, creating tables, inserting images, etc... which are specific to the content of labeling/product data elements SPL document. The instructions for these features are included in the SPL Xforms training eBook for the aforementioned type of SPL file.

Location of the SPL Xforms

- Link to web page with SPL Xforms:
 - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm>
- Direct link to SPL Xforms:
 - <http://pragmaticdata.com/spl/form/>

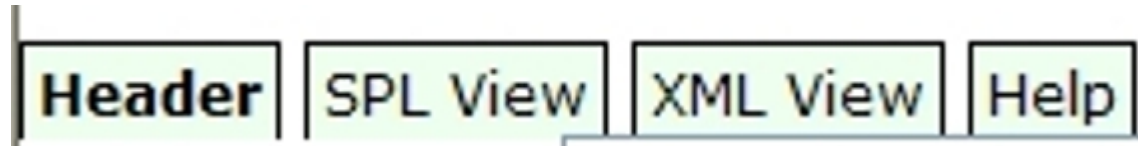
Technical Terms Glossary

Term	Definition
Core ID	•A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes.
Document Root ID	•Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
SetID	•Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
Effective Time	•Provides a date reference to the SPL document version or a section including the year, month and day as yyymmdd.
Version Number	•Integer greater than zero that provides a sequence to the versions of the document.
FDA Gateway	FDA system used by industry to transmit SPL files via the OC “center.” The FDA Gateway deposits the files for processing by the FDA HL7 Data Exchange Service (also known as “eLIST”)

SPL Xforms Buttons Legend

▶	Collapse and expand parts of the form. If the arrow is pointing right, the part of the form is currently collapsed. If the arrow is pointing downward, the part of the form is currently expanded.
[+]	adds an item of the same kind
[-]	removes the present item
[#]	clones the present item with all its data
[*]	Update information (e.g. date) or increase number (e.g. version number)
[%]	Copy information to clipboard
[&]	Paste information from clipboard
▶ [Please Open]	Expands form to display most of fields associated with the template selected.
[public]	Mark “confidential” information associated with this button.
[confidential]	Remove confidential mark from information associated with this button.

Navigational Tabs



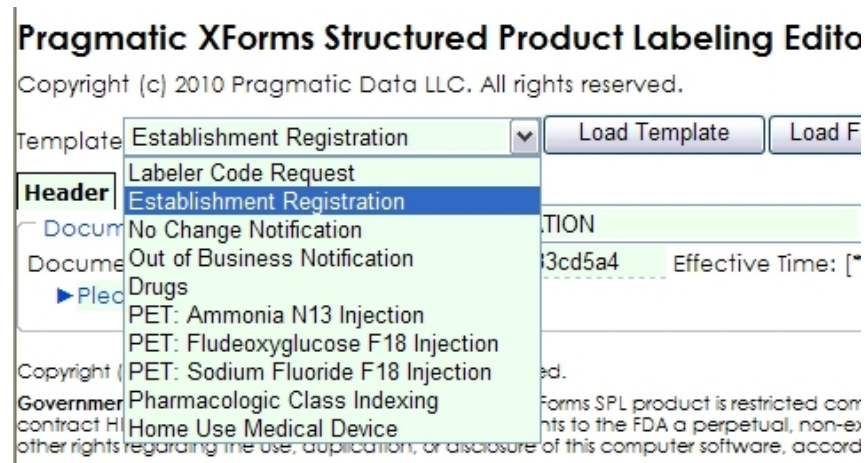
- Listed below are the main navigational tabs used to access the SPL Xforms' fields, views, and Help page.
 - Header – document tracking information (e.g. document root ID) and labeler or establishment data
 - SPL View – Displays your data in a stylesheet format
 - XML View – Renders the code view of your file
 - Help – Page with detailed information about the SPL Xforms

Document Tracking Information

Document Type: NDC LABELER CODE REQUEST (51726-8)
Document Id [*]ed479014-38ef-4acf-9ed8-d13a7356cf21 Effective Time: [*]20120319 Version [*] 1 Set Id 1e1412b4-be2a-41cd-b640-fd5eb8562a8a

- The following fields are auto-populated when SPL Xforms are opened or template selected:
 - Document ID
 - Effective Time
 - Version
 - Set ID
 - Document Type field is auto-populated if the Labeler Code or Establishment Registration templates are selected.
- You should NOT have to change this information. If you need to alter the document tracking information, see the SPL Xforms Button Legend on previous page for instructions for using the buttons associated with these fields. (Note: to change the setID, delete the current setID with the computer keyboard's delete key.)

Selecting and Loading the Template

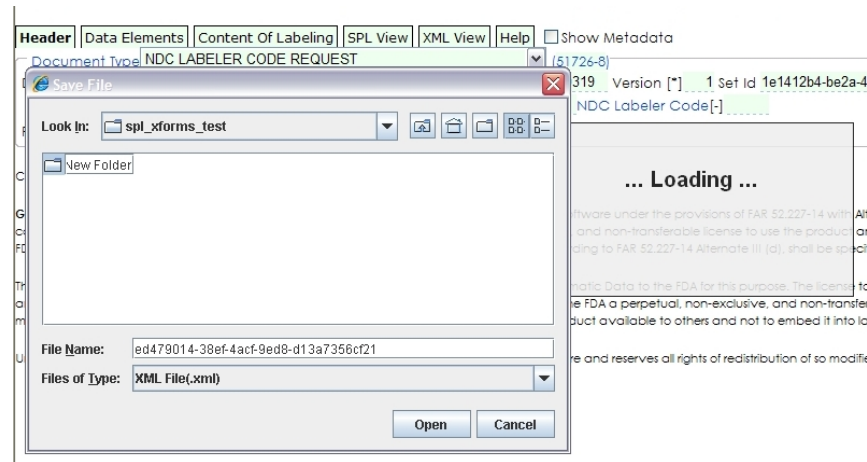


- Select the appropriate template (form for SPL document type) from drop-down menu.
- Then select the “Load Template” button.
- After the template loads, click the ► button to expand the form to begin entering data.

Types of Fields

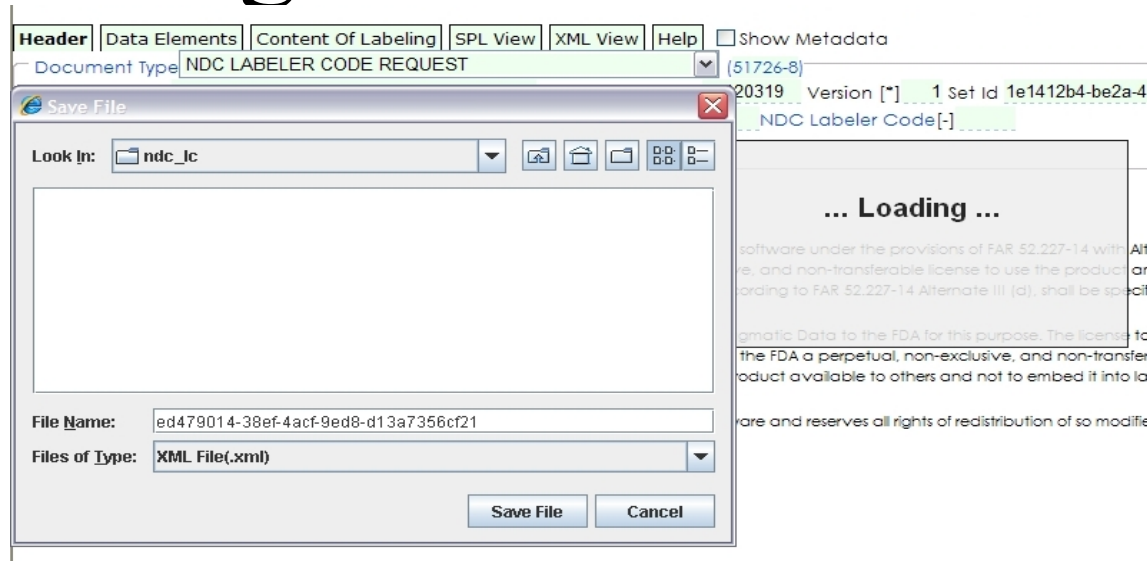
- Text – You may enter data as free-text in the field.
- Drop-down menu (two types)
 - Type 1 - Click field to select from list of terms
 - Type 2 – Begin typing term name (e.g. tablet) and drop-down list will appear
- Auto-populated – When form is opened, fields are automatically completed (e.g. document root ID)

Saving SPL Files



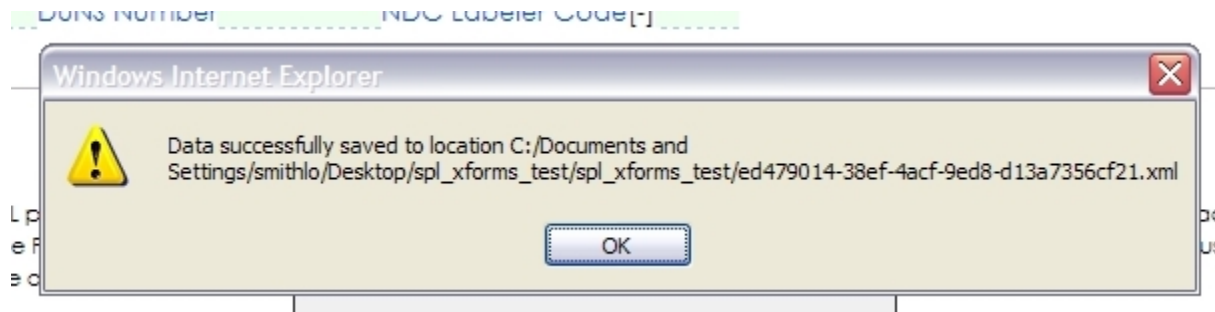
- The “**Save In**” button must be used when saving a brand new file for the first time.
- Navigate to computer location in which file should be saved.
- Create a folder using the “Create new folder button” by clicking the folder icon. Name the folder by clicking “New folder” name and entering a new name. Do not use special characters or symbols in the folder name.
- After renaming folder, click folder icon so that folder’s name appears in the “Look in:” window.

Saving SPL Files cont...



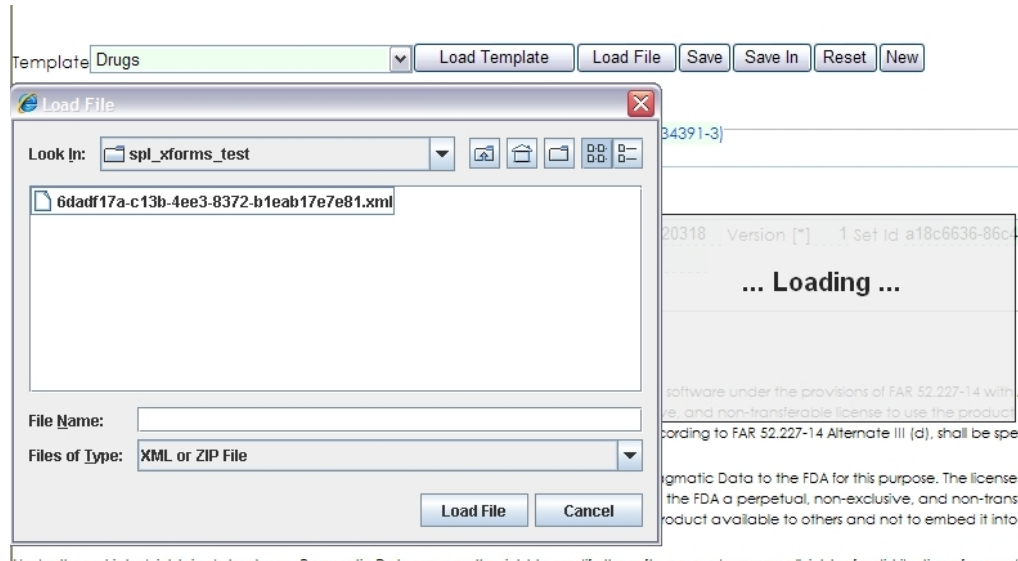
- Save the file by selecting the “Save File” button in the lower right corner of the prompt.
- NOTE: **DO NOT** rename the file.

Data Saved Message



- Once you have saved the file, you should receive a message indicating that the data has been successfully saved.
- After a file is first saved using the “Save In” button, you may then use the “Save” button to save newly added or updated data to that file.

Updating SPL Files



- To update or revise a previously created SPL file,
 - Click the “Load File” button near top of SPL Xforms
 - Navigate to the location of your SPL file
 - Select the SPL file
 - Click the “Load File” button in the window prompt
 - File should now be available for editing.

SPL Xforms Issues

Trouble Shooting

- **To avoid, Internet Explorer running slow warning.** For some operations, internet explorer may give a warning message - "A script on this page is causing Internet Explorer to run slowly..." To avoid this message, create a new file and copy below 3 lines in the file.
Windows Registry Editor Version 5.00
[HKEY_CURRENT_USER\Software\Microsoft\Internet Explorer\Styles]
"MaxScriptStatements"=dword:00000000
Save the file with .reg extension (eg. SetMaxScriptForIE.reg). Execute the file and try form operations after restarting Internet Explorer. Note that this setting is needed to be done only once.
- **Note on performance for first time use:** While using the forms for the very first time, the forms may take some time to load and certain operations can be slow. This is due to one time initialization cost for the forms.

SPL Xforms Issue

Trouble Shooting - Java Error

Pragmatic XForms Structured Product Labeling Editor

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It appears that your browser is unable to run Java applets. In order to use this form, your browser must be able to run Java applets. Please try to install the Java plugin from <http://java.com>. If you do not have permission to install software on your computer by yourself, you may have to seek help from your computer administrator.

Template

- If you receive the Java Error displayed above, the instructions are in the message. However, do not just update your Java as it will impact the version you have installed for the Gateway.
- Contact us at spl@fda.hhs.gov if you receive this message.

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>

The screenshot shows the FDA website header with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below the header is the FDA logo and the text 'U.S. Food and Drug Administration'. There is a search bar and an 'A-Z Index' button. A navigation bar contains links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled 'For Industry' and includes links for 'Email this page', 'Print this page', and 'Change Font Size'. The 'Data Standards' section is highlighted in a blue box and contains links for Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The 'FDA Resources for Standards' section features a sign-up link for email updates, a description of the FDA Data Standards Council's role, and a link for Structured Product Labeling.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search GO

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards
Validators
Data Council
Structured Product Labeling
Individual Case Safety Reports
Regulated Product Submission

FDA Resources for Standards

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The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)