

Preparing Electronic Drug Establishment
Registration Submissions in SPL Format
– Medicated Animal Feed Mills

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.
- **NOTE: This document is for medicated feed mill registrants ONLY.**
- 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>

Registering Drug Establishments in SPL Format

- Each Registrant (owner/operator firm) should submit **one** SPL file with registration information for all of its facilities (unlimited amount of domestic or foreign establishments permitted per file)
- Subsidiaries can be considered as registrants in ER SPL files
- **Enter current registration year in effective date field**

Registration Number

- “FDA intends to use the Data Universal Numbering System (D-U-N-S®) as the registration number for the electronic system. Therefore, to facilitate and expedite processing of the SPL file, the registrant should submit their D-U-N-S® Number with the registration information. If the business entity does not submit a D-U-N-S® Number with its submission, FDA intends to make arrangements for obtaining a D-U-N-S® Number for that entity. An explanation of the D-U-N-S® Number and how to obtain one is described in section IV.B of this document.”

***from May 2009 Guidance for Industry – Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing

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

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/?template=templates/medicated-feed-establishment-registration.xml>

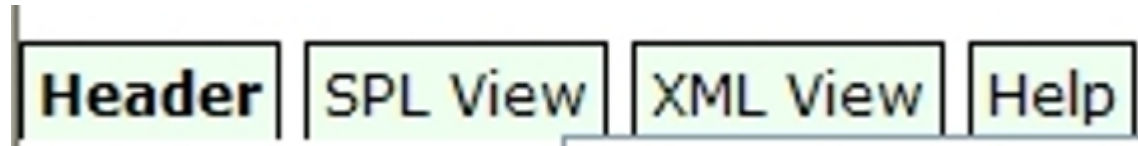
Technical Terms Glossary

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.

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

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)

Document Tracking Information

The screenshot shows a software interface with the following elements:

- Template: Medicated Animal Feed Establishment (dropdown menu)
- Buttons: Load Template, Load File, Save
- Header: SPL View, XML View, Help, Show Metadata
- Document Type: ESTABLISHMENT REGISTRATION (dropdown menu) (51725-0)
- Document Id [*]: 1182bc37-c771-486e-aa58-400f77365842
- Effective Time: [*]: 20120325
- ▼ Please Open[-]

- 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 unless you are updating the file to prepare a subsequent submission. If you need to alter the document tracking information, see the SPL Xforms Button Legend on previous page with 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.)

Entering the Registrant's Name

▼ Registrant [-] [[public] Name Acme Medicated Feed Mill

- Type in the name of the registrant.
- The registrant is the owner/operator of the drug establishment(s)
- Enter the **headquarters business name** of the registrant registering the establishment(s).

Registrant's DUNS Number

▼ Registrant[-][public]Name **Acme Medicated Feed Mill** DUNS Number **124356578**

- Type the DUNS Number for the registrant's headquarters location.
- DUNS Numbers consist of **nine** digits
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Note About Address & Contact Information Data Entry

- Instructions on the next few pages should be also be used to complete fields for the:
 - Registrant contact's address
 - Establishment's address
 - Establishment contact person's information.

Entering Registrant's or Establishment's Contact Person's Name

| Contact[-][%][&][public]Name Tammy Powell

- Enter the first name and last name of contact person.
- The registrant or establishment contact person is the individual FDA contacts regarding the establishment registration information.

Contact Person's or Establishment's Street Address

| Street 5600 Fishers Lane

- Enter the street and number of the mailing address of the establishment or the registrant and establishment's contact person.

Enter City

Rockville

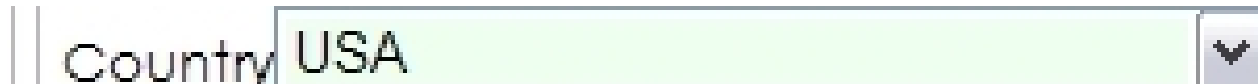
- Enter the name of the city for the mailing address of the establishment or the registrant and establishment's contact person.

Enter State or Province

State [-] MD

- Enter the state's name for the mailing address of the establishment, or registrant's and establishment's contact person.
- Use abbreviation for states located in the USA
- If there is no state, as with certain addresses outside the United States, DELETE the empty state field.
- Provinces can be entered in the state field.

Entering Country Code



A screenshot of a web form field labeled "Country". The field contains the text "USA" and has a dropdown arrow icon on the right side. The background of the field is light green.

- Select the **three-character** character country code from the drop-down menu. The ISO 3166-1 standard is used as the country code for the mailing address of the establishment or the registrant or establishment's contact person.
- Do not include spaces (created w/space bar) before or after country code.
- Link to country code lists:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm>

Postal Codes

Postal Code[-] 20857

- Enter the postal code for the mailing address of the establishment or the registrant's and establishment's contact person.
- If there is no postal code, as with certain addresses outside the United States, DELETE the empty postal code field.

Registrant or Establishment Contact Person's Telephone Number

| Phone `+1-888-888-8888`

- Enter the telephone number for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after telephone number.
- Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; **include hyphens to separate the country code, area codes and subscriber number**; extensions are separated by “;ext=”).

Registrant or Establishment's Contact Person's E-mail Address

EMail `tammy.powell@acme.com`

- Enter the email address for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

Entering the Establishment's Name

└─ ▼ Registrant[-][public]Name **Acme Medicated Feed Mill**

- Enter the name of the drug establishment.

Establishment's DUNS Number

▼ Registrant [-][public] Name **Acme Medicated Feed Mill** DUNS Number **124356578** -

- Type the 9-digit DUNS Number for the establishment.
- The DUNS Number is site specific.
- Each establishment should have it's own DUNS Number.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/keyboard space bar) before or after DUNS Number

FEI Number

FEI Number[-] 30003000

- If an FEI number is assigned for this site, then enter the FEI Number.
- FEI numbers are 7- or 10-digit number. Use leading zeros if necessary.
- If an FEI number is not assigned, DELETE empty FEI number field if there is no FEI # assigned to your site.

Establishment's Address and Contact Person's Information

- Use the instructions related to the entry of the name, address, and contact person's information on the previous pages of this document to use as a guide to enter the establishment's address, contact person's information, telephone number.
- You may also use the “copy to clipboard” [%] and “paste to clipboard” [&] buttons to copy and paste the data if, for example, the address of the contact person is the same as the establishment's address.

Type(s) of Operation for Establishments

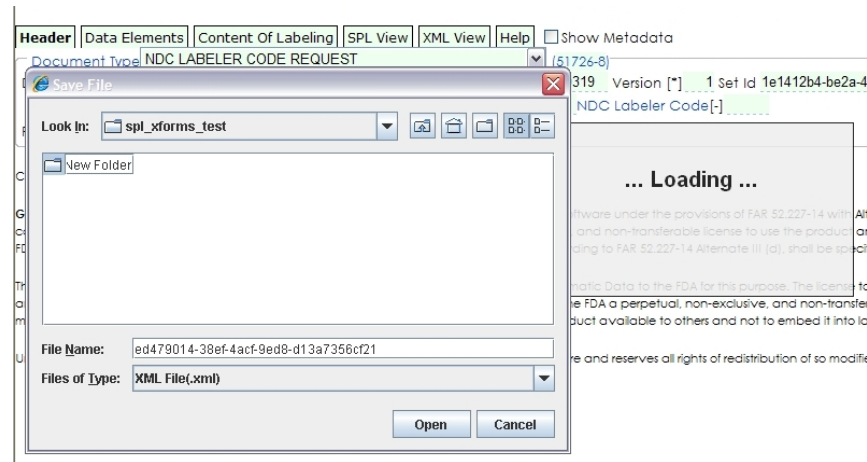
Business Operation[-][+][#]Type|medicated animal feed manufacture 

- The type of operation “medicated animal feed manufacture” is automatically entered. You should not have to make changes to this field.

ER SPL Notes

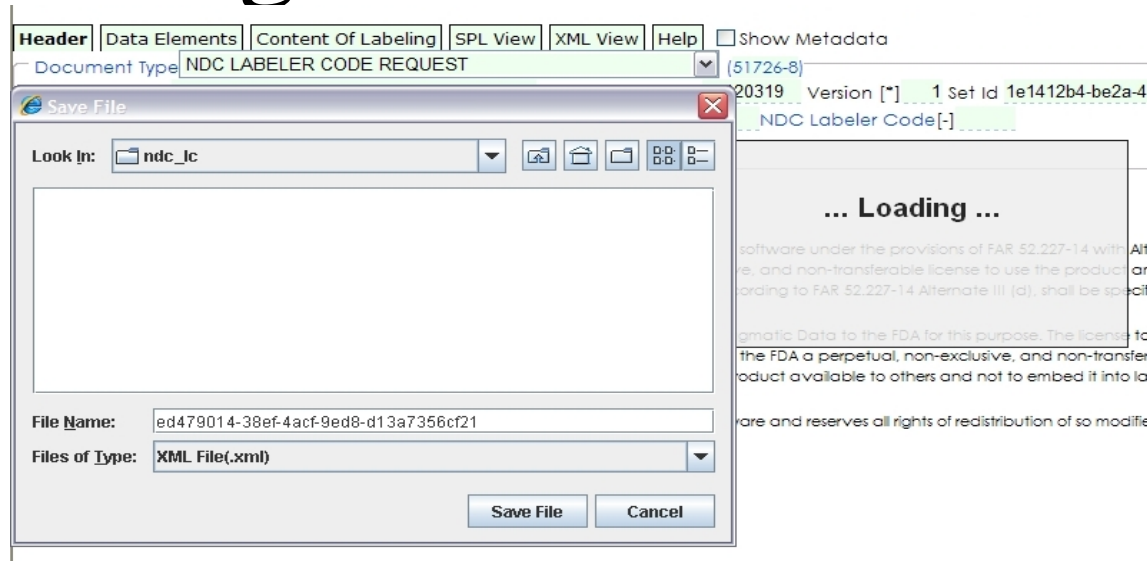
- Include postal code for all establishments unless one does not exist.
- Entering provinces - The province, "BC", goes in the <state> tag.
- No limit to number of establishments in one SPL
- Use “USA” as the country code for Puerto Rico

Saving SPL Files



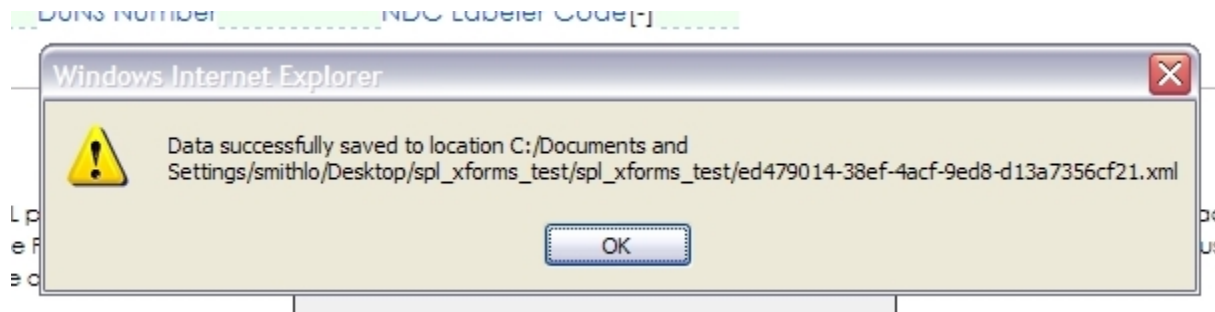
- The “**Save In**” button must be used when saving a brand new file for the first time.
- Navigate to computer location in which file should be saved.
- Create a folder using the “Create new folder button” by clicking the folder icon. Name the folder by clicking “New folder” name and entering a new 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.

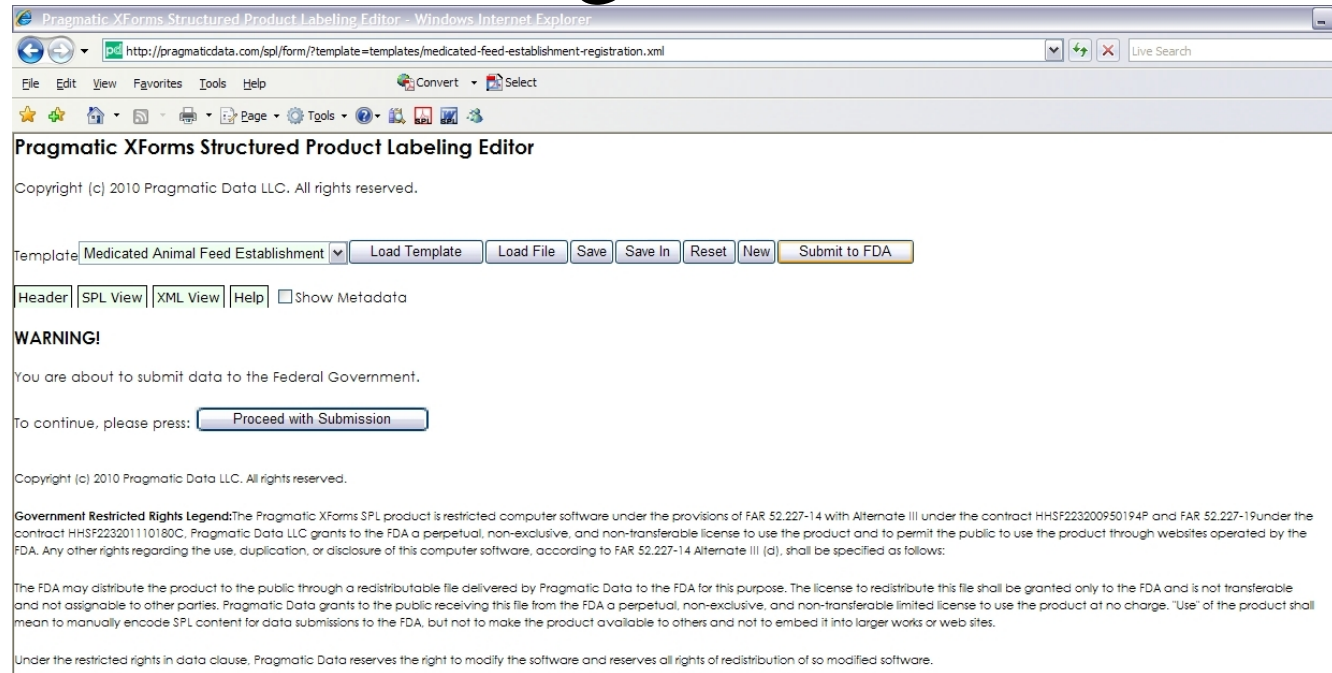
Establishment Registration SPL Example (SPL View)

ESTABLISHMENT REGISTRATION

Registrant - Acme Medicated Feed Mill (124356578)			
Contact	Address	Telephone Number	Email Address
Tammy Powell	Address: 5600 Fishers Lane City, State, Zip: Rockville, MD, 20857 Country: USA	+1-888-888-8888	tammy.powell@acme.com

Establishment			
Name	Address	ID/FEI	Operations
Acme Medicated Feed Mill	Address: 1722 Rockville Pike City, State, Zip: Rockville, MD, 20857 Country: USA	433212341/30003000	medicated animal feed manufacture
Contact	Address	Telephone Number	Email Address
Sherry Thompson	Address: 1722 Rockville Pike City, State, Zip: Rockville, MD, 20857 Country: USA	+1-877-222-5218	sherry.thompson@acme.com

Submitting a Medicated Feed Mill Establishment Registration SPL File



- Review the data entered by selecting the [SPL View] button
- To submit file to FDA, Select [Submit] button.
- Select the [Proceed with Submission] button when you are ready to submit file to FDA.

Submission Acknowledgment

Template: **Medicated Animal Feed Establishment** | | | | | | |

| | | | | Show Metadata

Success!

Your document with the id 1182bc37-c771-486e-aa58-400f77365842 for **Acme Medicated Feed Mill** has been submitted to the FDA.

A copy has been emailed to the designated contact **Tammy Powell** <tammy.powell@acme.com> whom you specified in the document. This person will be contacted should any problems arise.

NOTE: If this contact person is not receiving the copy of your submission, you may have mistyped the contact email address and you would need to submit a correction.

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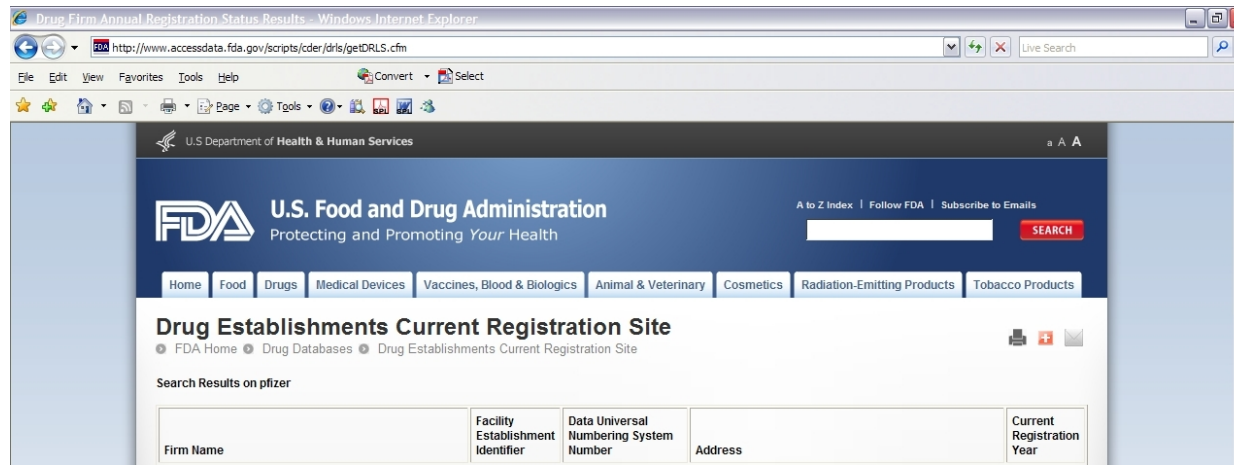
Government Restricted Rights Legend:The Pragmatic XForms SPL product is restricted computer software under the provisions of FAR 52.227-14 with Alternate III under the contract HHSF223200950194P and FAR 52.227-19 under the contract HHSF223201110180C. Pragmatic Data LLC grants to the FDA a perpetual, non-exclusive, and non-transferable license to use the product and to permit the public to use the product through websites operated by the FDA. Any other rights regarding the use, duplication, or disclosure of this computer software, according to FAR 52.227-14 Alternate III (d), shall be specified as follows:

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Under the restricted rights in data clause, Pragmatic Data reserves the right to modify the software and reserves all rights of redistribution of so modified software.

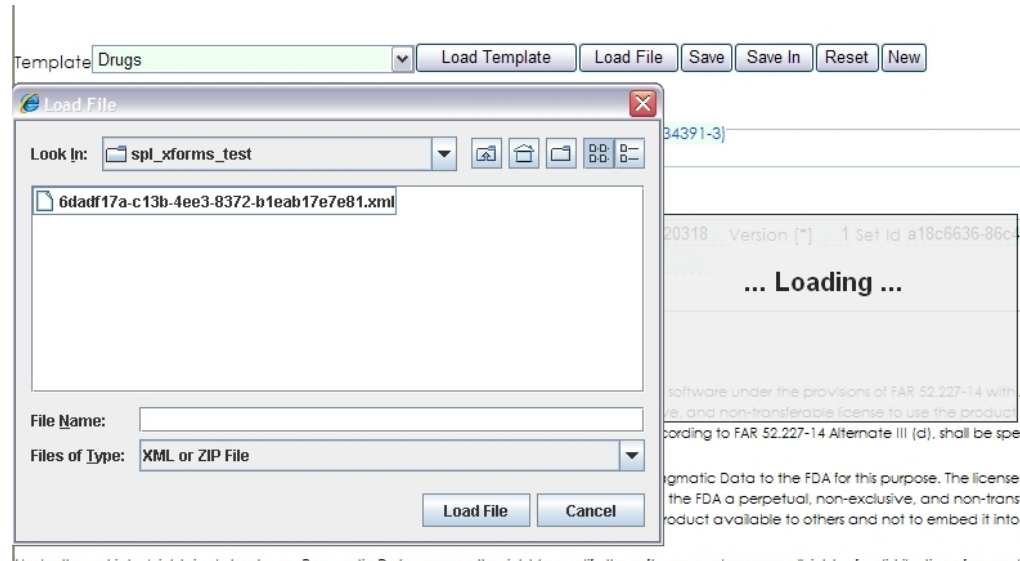
- If the submission was a success, you should receive the success screen similar to the above image
- A copy of the submission will automatically be sent to the contact person's e-mail address you entered in your file.

Confirming Electronic Registration of Feed Mill



- Within 24-48 hours (business days) of your submission, check the Drug Establishment Current Registration Status website <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
- Note: If you entered the current registration year in the Establishment Registration SPL document's effective time field then that is the year which will appear in the current registration year field.
- If your site's information does not appear within 24-48 hours (business days) of your submission, please contact us at spl@fda.hhs.gov.

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 on your computer (where you last saved the file.)
 - Select the SPL file for update.
 - 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.

Updating an Establishment Registration SPL

- Update information for an **electronically** registered establishment
- Update **anytime** during year **or** for annual registration
 - Use the “Load” button to locate and upload the previous SPL file and fill in the new information **without changing the other existing information.**
 - Use
 - **new id root**
 - **new version number**
 - **original setId root (DO NOT CHANGE THE SETID)**
 - appropriate effective time.

Adding a New Establishment

- Add a new establishment to your ER SPL file:
 - Use the “Load” button to locate and upload the previous SPL file
 - Fill in the information on a new establishment **without changing the information on the other establishments.**
 - Use
 - **new id root**
 - **new version number**
 - **original setId root (DO NOT CHANGE THE SETID)**
 - appropriate effective time.

Removing an Establishment

- Remove a previously **electronically** registered establishment
 - Use the “Load” button to locate and upload the previous ER SPL file, **without changing the existing information on the other establishments**, and remove the specific establishment information.
 - Use
 - **new id root**
 - **new version number**
 - **original setId root (DO NOT CHANGE THE SETID)**
 - appropriate effective time.

Establishment Re-Registration

No Changes

- No changes to registration information
 - Each year when the information is updated, if there is no change:
 - Use the “Load” button to locate and upload to update the previously submitted SPL file with a **new** id root and **new** version number with the **original** setId (**DO NOT CHANGE THE SETID**) and the appropriate effective time.

Going Out of Business?

- Applicable for registrants who have **previously electronically registered** drug establishments at least once.
- If the registrant goes out of business, create an SPL file with the *document type* **Out of business notification** using a **new** id root and **new** version number with the **original** setId and the appropriate effective time.
- Registrant and establishment information is not included with an SPL file with the *document type* **Out of business notification**.

Certified 2656 Paper Form?

- No certified paper forms for e-registered establishments
- Check Drug Establishment Current Registration Site (DECRS) website:
<http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm> for electronically registered establishments
- FDA inspectors requesting paper 2656 form?
 - Recommend DECRS website
 - If necessary, contact your local District Office as part of the conflict prevention and resolution process.

Test Your SPL Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>

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 red envelope icon and the text 'Sign up for email updates.' with an arrow pointing to the right. Below this is a paragraph describing the FDA Data Standards Council's role in coordinating the evaluation, development, maintenance, and adoption of health and regulatory data standards. A link for 'Structured Product Labeling' is also visible.

SPL-related Technical Assistance/Questions

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