Preparing Electronic NDC Labeler Code and Drug Establishment Registration Submissions in SPL Format

Version 1.0

Preface

- This document provides basic instructions for using Structured Product Labeling (SPL) Xforms to create NDC Labeler Code and Establishment Registration SPL files. 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

SPL Xforms

Basic Instructions for Use

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

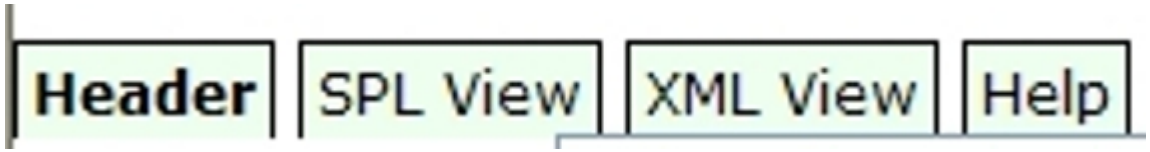
Technical Terms Glossary

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 yyyymmdd.
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

Types of Fields

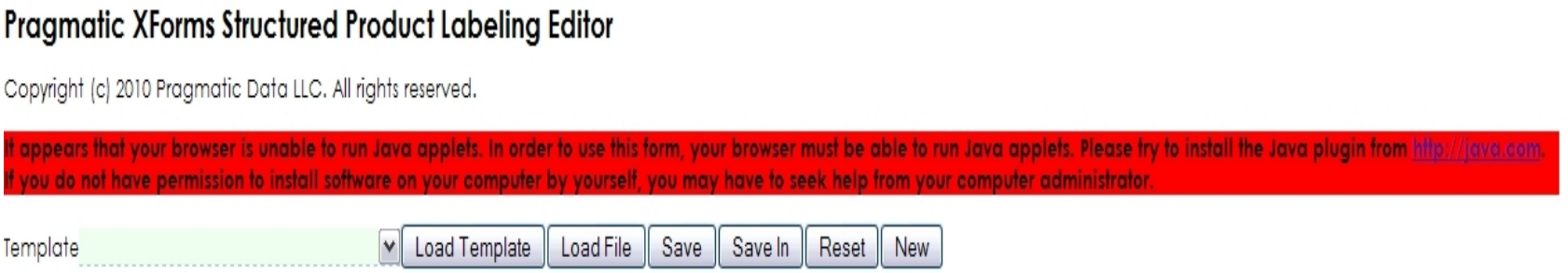
- Text – You may enter data as free-text in the field.
- Drop-down menu (two types)
  - Type 1 - Click field to select from list of terms
  - Type 2 – Begin typing term name (e.g. tablet) and drop-down list will appear
- Auto-populated – When form is opened, fields are automatically completed (e.g. document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

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.

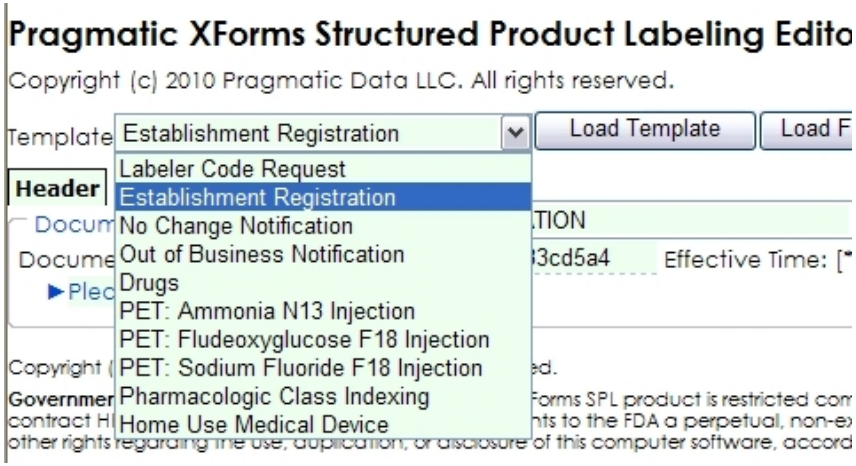
SPL Xforms Issue
Trouble Shooting - Java Error



- 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.

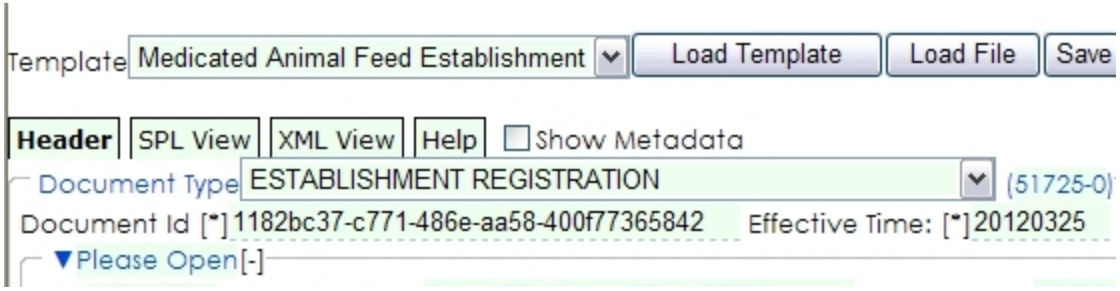
Creating NDC Labeler Code SPL Documents

Selecting a Template



- Select a template from drop-down menu to choose the type of SPL you would like to create.
- Click “Load Template” to load the selected SPL Xforms template.
- Note: “Labeler Code Request” document type is also used to create files in which an already assigned labeler code will be entered.

Document Tracking Information



- 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.

Entering the Labeler's Name

- Type in the name of the labeler.
- The labeler is the registrant or private label distributor (PLD) requesting the NDC Labeler Code or the registrant or PLD who is submitting an already assigned NDC Labeler Code.

Labeler’s DUNS Number

- Type the **9-digit** DUNS Number for the labeler code owner’s headquarters.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Adding an NDC Labeler Code

- If **requesting** a labeler code, **DO NOT** enter data in this field.
- If you do not have a labeler code, **DELETE** the NDC Labeler Code field
- If your labeler code is **already assigned**, enter 4-5 digit NDC Labeler Code which is completely identical to the NDC Labeler Code that is the first segment of your 3-segment 10-digit NDC.

Note About Address & Contact Information Data Entry

- Instructions on the next few pages should be used to complete fields for the:
  - Labeler's contact's name and address (including telephone number and e-mail address)
  - Establishment Registration SPL
    - Registrant contact's address
    - Establishment's address
    - Establishment contact's information (including telephone number and e-mail address)

Entering Contact Person’s Name

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

Contact Person's or Establishment's Street Address

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

Enter City

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

Enter State or Province

- Enter the state’s name for the mailing address of the establishment, or labeler’s, 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

- Select the **three-character** character country code form the drop-down menu. The ISO 3166-1 standard is used as the country code for the mailing address of the establishment or the labeler's, registrant's, 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

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

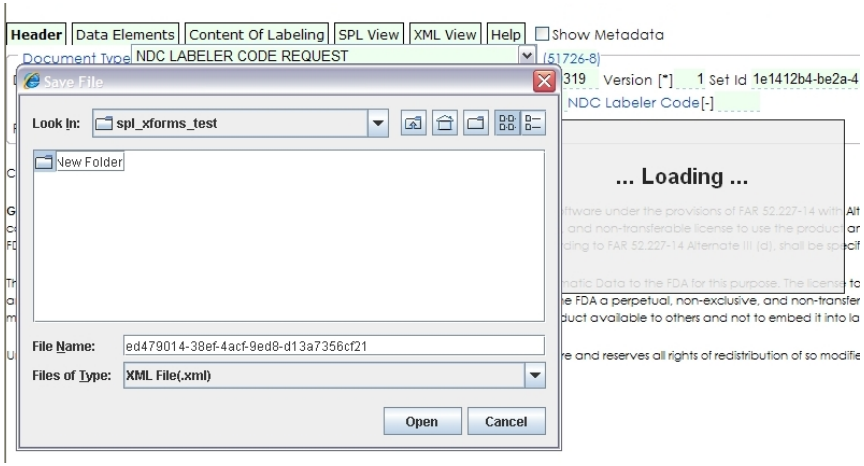
Telephone Number

- 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=”).

E-mail Address

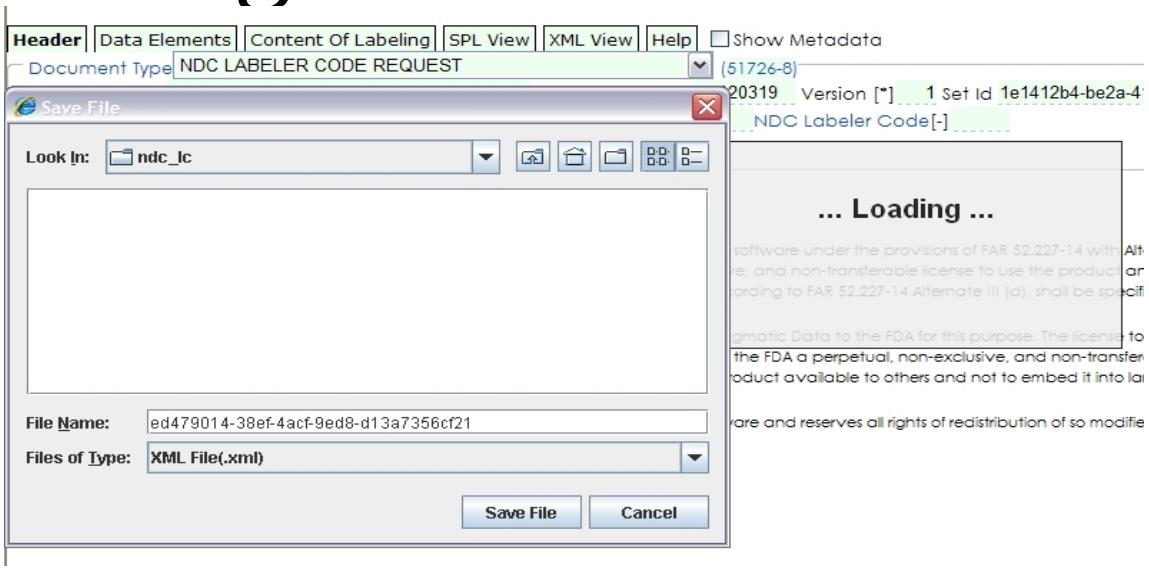
- Enter the email address for the contact person.
- Ensure that there are no spaces (created w/space bar) before or after e-mail address.

Saving SPL Files



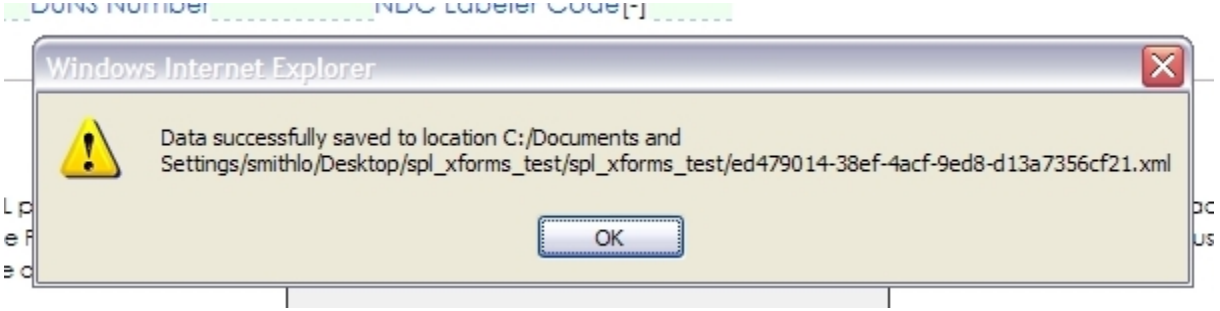
- The "**Save In**" button must be used when saving a brand new file for the first time.
- Navigate to computer location in which file should be saved.
- Create a folder using the "Create new folder button" by clicking the folder icon. Name the folder by clicking "New folder" name and entering a new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

NDC Labeler Code
SPL Example

Acme, Inc.
NDC LABELER CODE REQUEST

Labeler – Acme, Inc. (539003112) **NDC Labeler Code:** 10000

Contact	Address	Telephone Number	Email Address
Justin Jones	Address: 5600 Fishers Lane City, State, Zip: Rockville, MD, 20857 Country: USA	+1-888-438-9745	justin.jones@acme.com

Revised: 03/2012

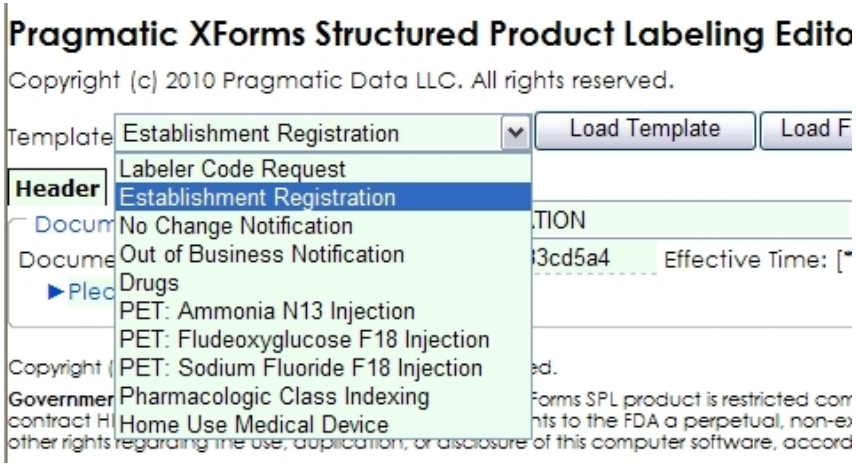
Acme, Inc.

Creating Establishment Registration SPL Documents

Registering Drug Establishments in SPL Format

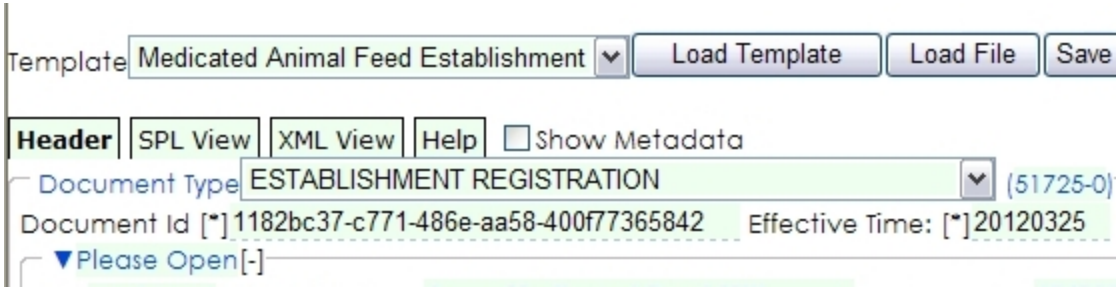
- Each Registrant (owner/operator firm) should submit **one** SPL file with registration information for all of its facilities (unlimited amount of domestic or foreign establishments permitted per file)
- Subsidiaries can be considered as registrants in ER SPL files
- **Enter current registration year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

Selecting a Template



- Select a template from drop-down menu to choose the type of SPL you would like to create.
- “Establishment Registration” should be selected to create an Establishment Registration SPL file.
- Click “Load Template” to load the selected SPL Xforms template.

Document Tracking Information



- 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

- 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

- 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 used to complete fields for the:
  - Registrant contact's address
  - Establishment's address
  - Establishment contact's information (including telephone number and e-mail address)

Entering Contact Person’s Name

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

Contact Person's or Establishment's Street Address

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

Enter City

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

Enter State or Province

- Enter the state’s name for the mailing address of the establishment, or labeler’s, 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

- Select the **three-character** character country code form the drop-down menu. The ISO 3166-1 standard is used as the country code for the mailing address of the establishment or the labeler's, registrant's, 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

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

Note About Telephone & E-mail Information Data Entry

- Instructions on the couple of pages should be used to complete fields for the:
  - Registrant's contact's telephone number and e-mail address
  - U.S. Agent's telephone number and e-mail address
  - Importer's telephone number and e-mail address

Telephone Number

- 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=”).

E-mail Address

- 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

- Enter the name of the drug establishment.

Establishment's DUNS Number

- 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

- 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.

Note: Establishment's Address and Contact Person's Information

- 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.
- This will eliminate the need to re-type identical information.

Type(s) of Operation for Establishments

- Select a type of operation.
- If there is more than one type of operation, select the [+] to add more types of operation.

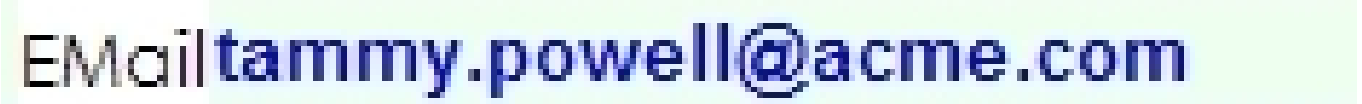
US Agent Name & DUNS Number

- If the establishment is located **outside the US**, provide information about the US agent for that foreign drug establishment.
- To enter US Agent information, expand the form's Agent/Importer field.
- Delete the Agent/Importer fields if US agents field is not needed.
- Enter the **business** name of the US agent.
- Do not enter person's name in this field unless that name is the same as business' name.
- Type the DUNS Number for the US Agent's location.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Telephone Number

- Enter the telephone number for the US agent.
- 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=”).

E-mail Address



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

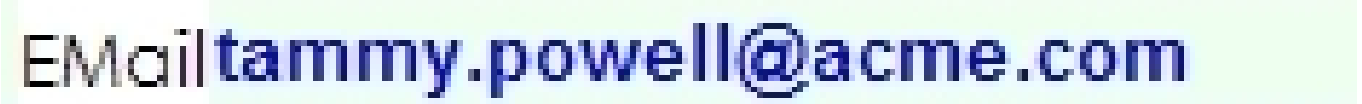
Importer's Name & DUNS Number

- To enter importer information, expand the form's Agent/Importer field.
- May or may not be an importer for each foreign establishment
- **DELETE** fields if you do not have importer information to include.
- Unlimited amount of importers can be included for each foreign establishment.
- Enter the **business** name of the importer.
- Do not enter person's name in this field unless that name is the same as business' name.
- Enter the DUNS Number for the importer's location.
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Telephone Number

- Enter the telephone number for the importer.
- 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=”).

E-mail Address



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

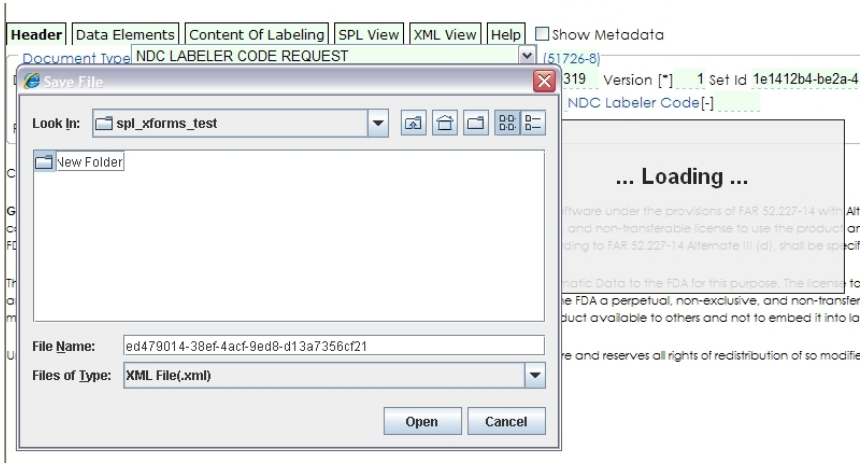
Additional Establishments

- To add additional drug establishments to the file, select [+] and proceed with entering information for your other drug establishments.
- Use information in preceding pages as guide for entering data.

Establishment Registration SPL Notes

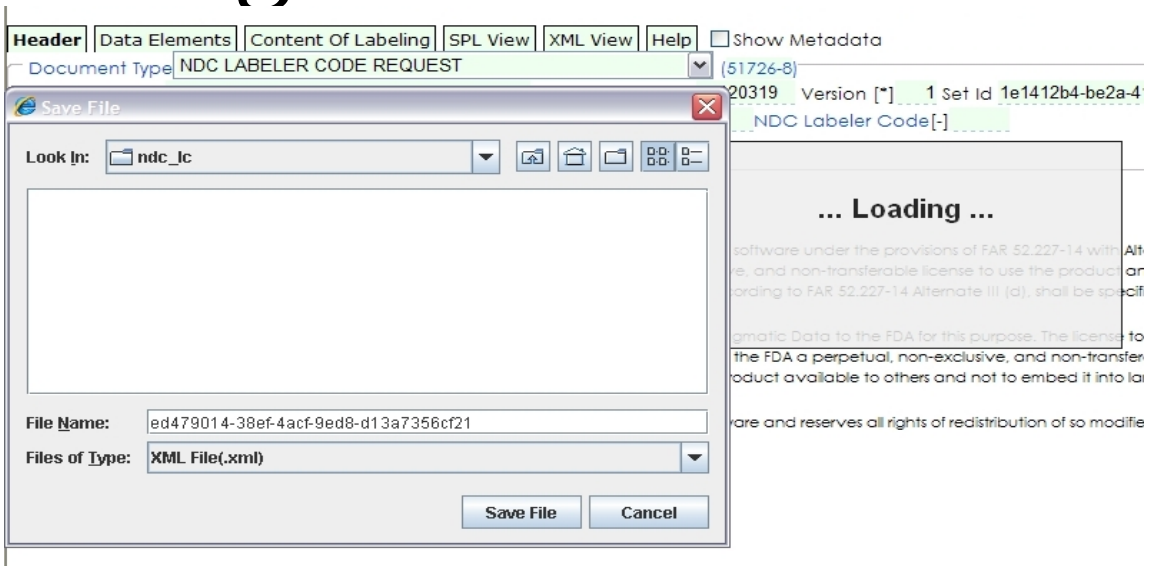
- Include postal code for all establishments unless one does not exist.
- Entering provinces - The province, "BC", goes in the <state> tag.
- No limit to number of establishments in one SPL
- Use “USA” as the country code for Puerto Rico

Saving SPL Files



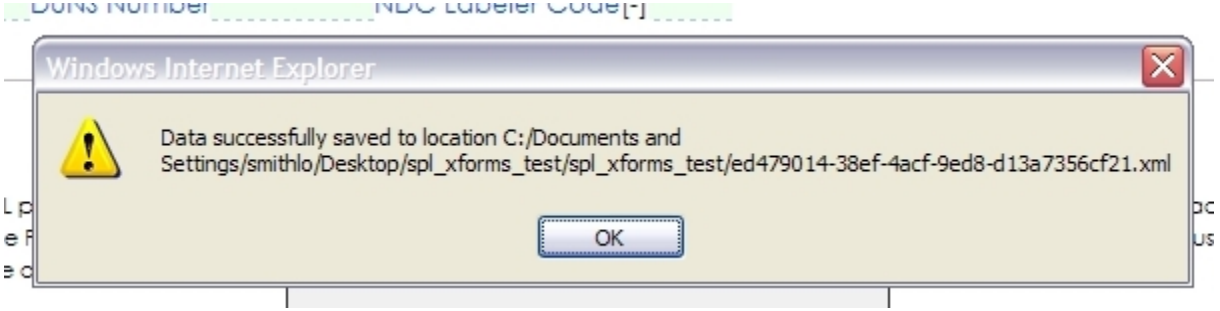
- The "**Save In**" button must be used when saving a brand new file for the first time.
- Navigate to computer location in which file should be saved.
- Create a folder using the "Create new folder button" by clicking the folder icon. Name the folder by clicking "New folder" name and entering a new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

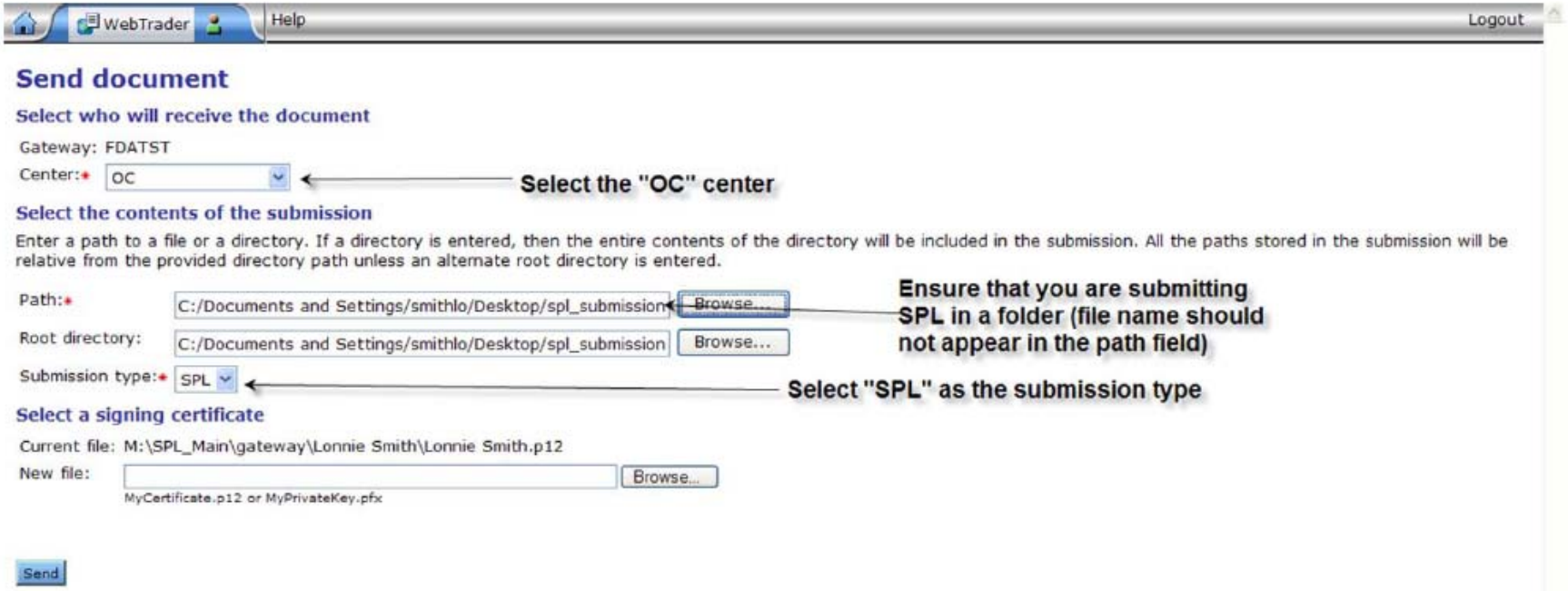
ESTABLISHMENT REGISTRATION

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

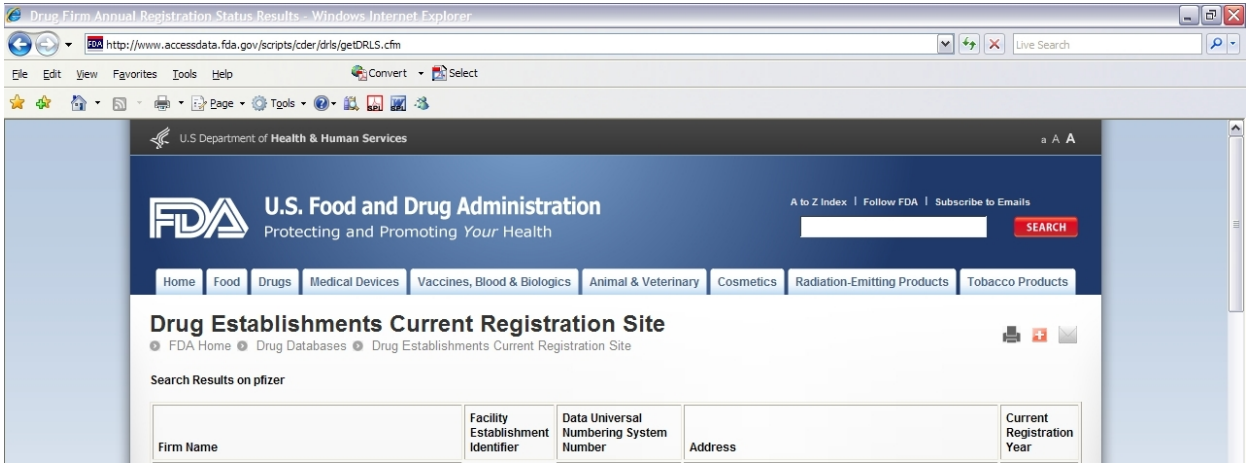
Establishment			
Name	**Address**	**ID/FEI**	**Operations**
Acme Medicated Feed Mill	Address: 1722 Rockville Pike City, State, Zip: Rockville, MD, 20857 Country: USA	433212341/30003000	medicated animal feed manufacture
Contact	**Address**	**Telephone Number**	**Email Address**
Sherry Thompson	Address: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

Revised: 03/2012

Submitting Files via FDA Gateway



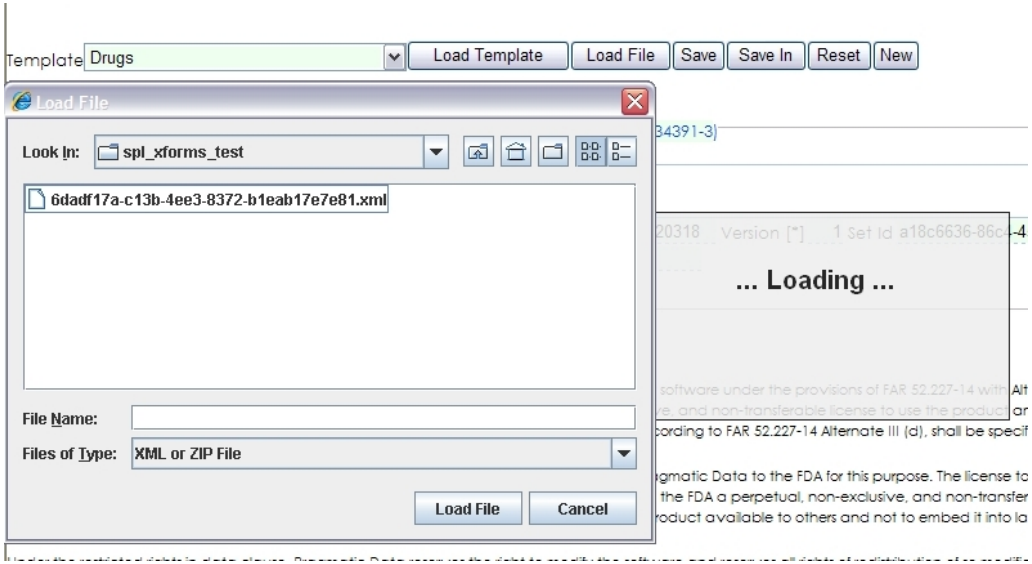
Confirming Electronic Registration of Drug Establishment



- Within 24-48 hours (business days) of your submission, if you did not receive a second acknowledgment (error message) in your Gateway My Submission Inbox 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.

Updating SPL Files &
Other SPL-related Information

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.

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

SPL-related Technical Assistance/Questions

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