

Creating a Content of Labeling/ Drug Listing SPL Document – Homeopathic Drug Products

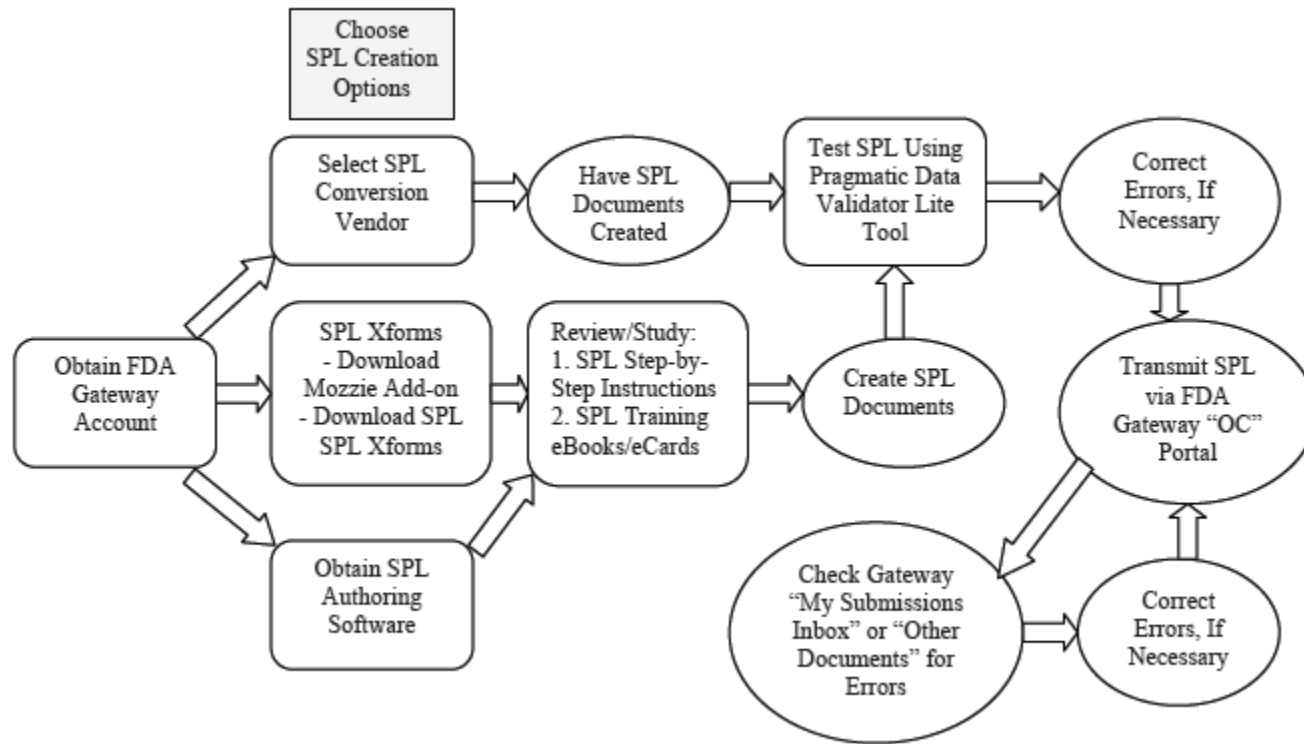
Lonnie Smith
Policy Analyst
Structured Product Labeling Team
FDA Data Standards Council



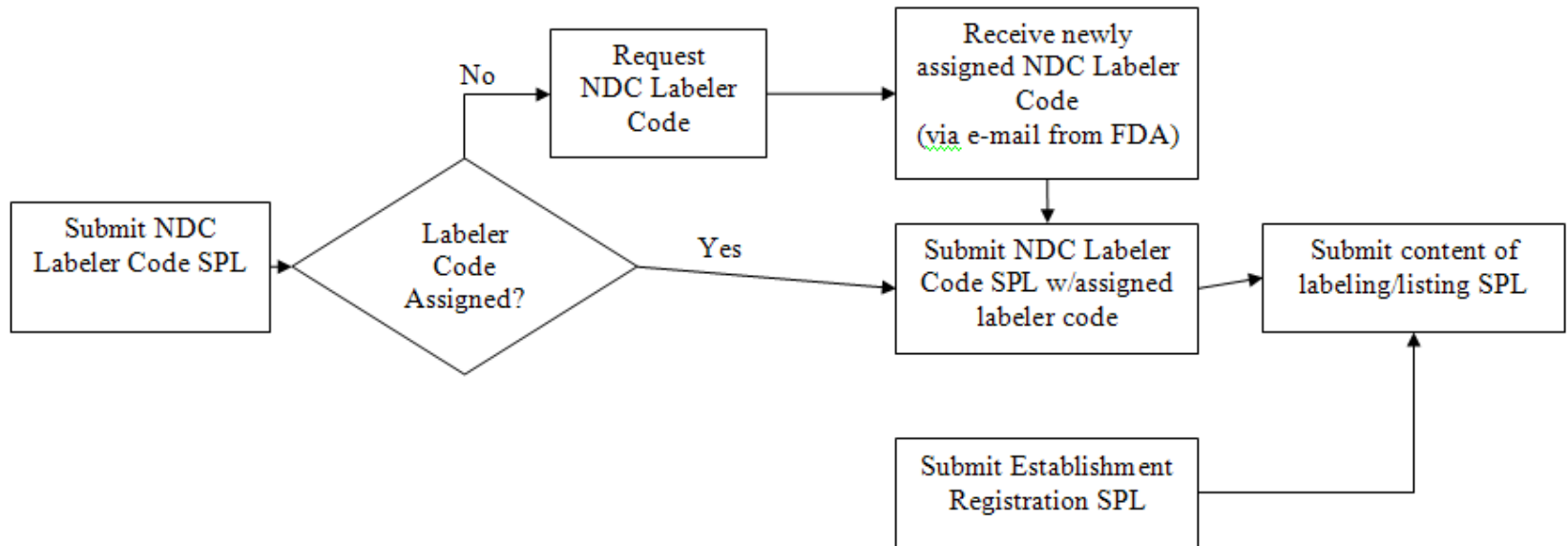
Technical Terms Glossary

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.”
Effective Time	•Provides a date reference to the SPL document version or a section including the year, month and day as yyymmdd.
GUID	•Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	•Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	•Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	•Integer greater than zero that provides a sequence to the versions of the document.

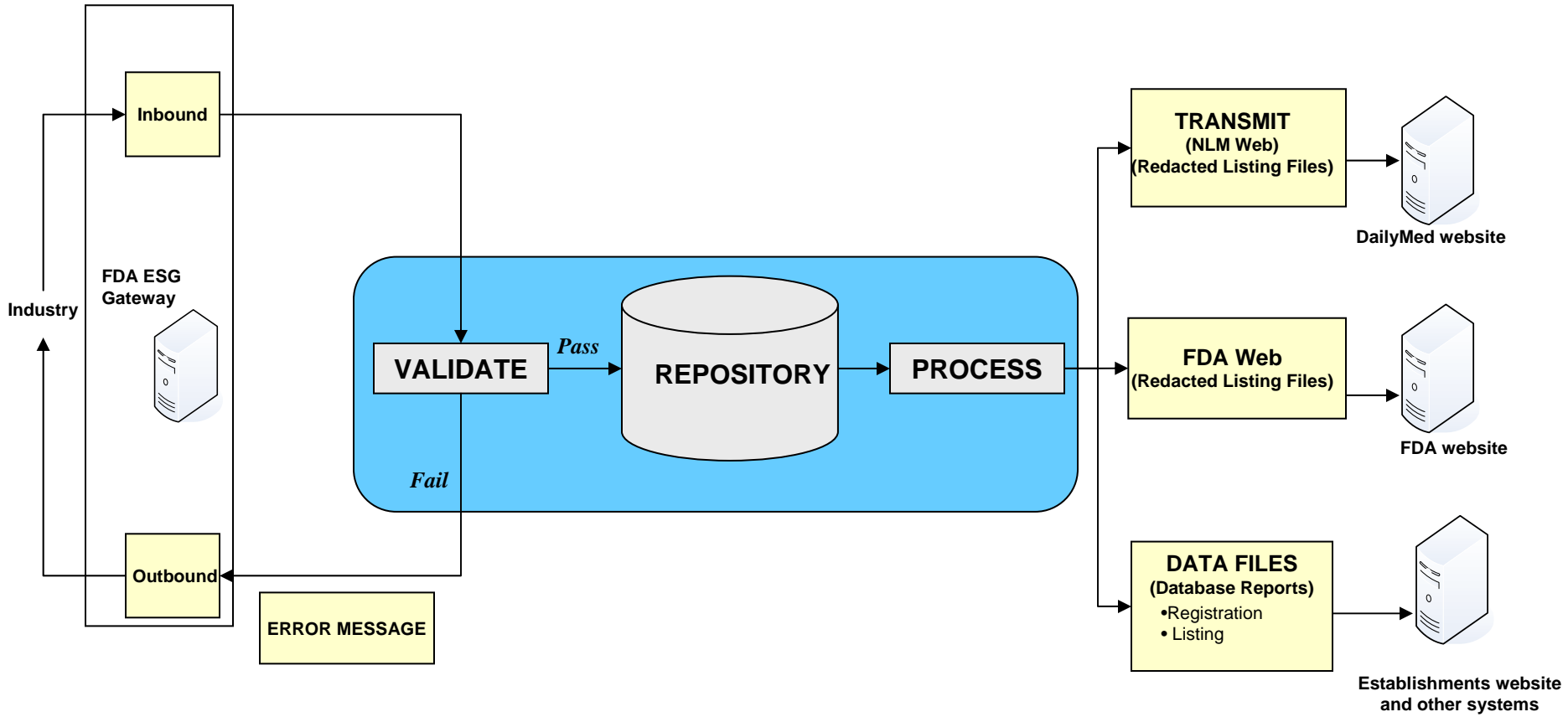
Road Map” Creation & Submission



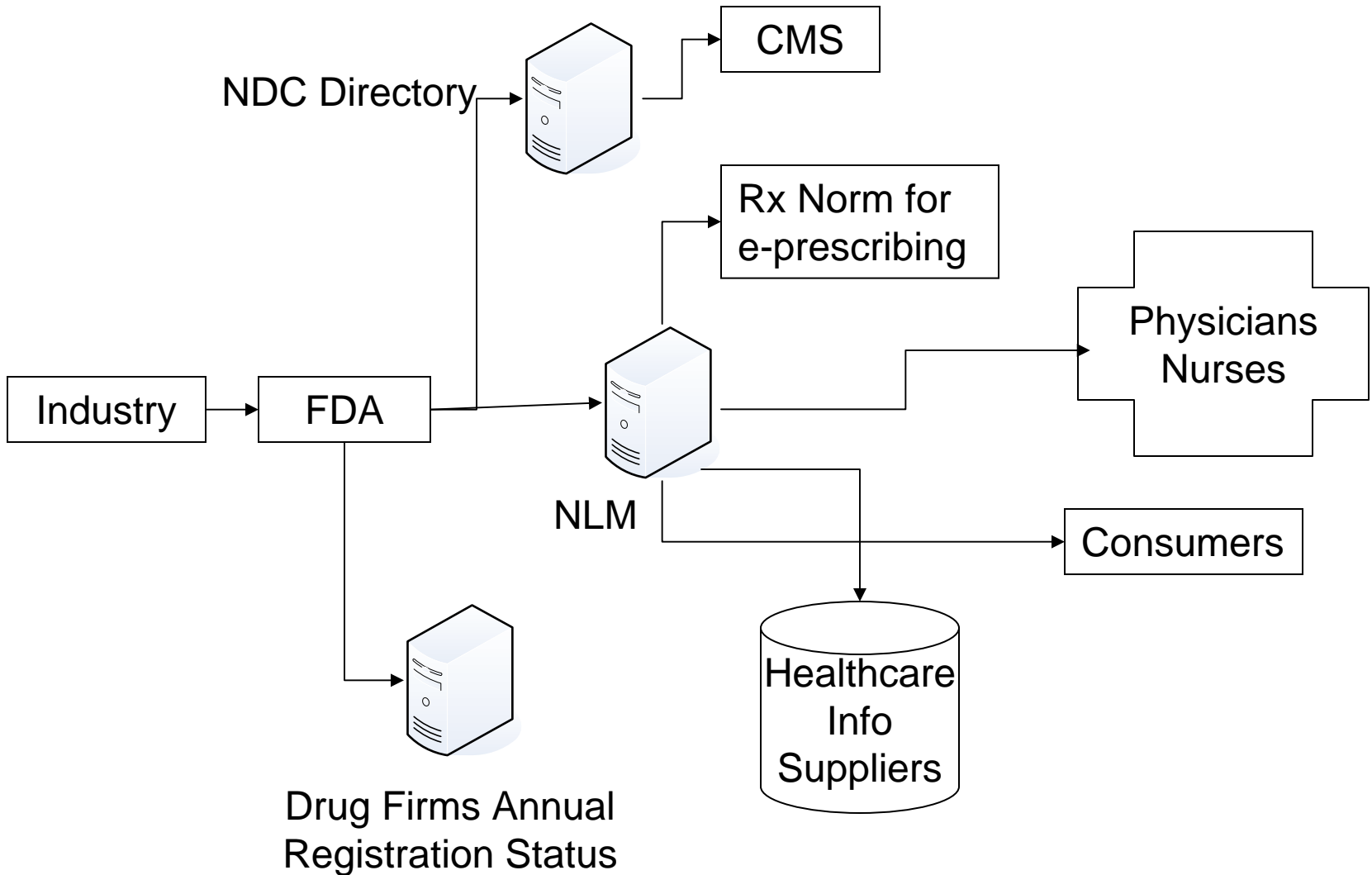
SPL Submission Process



eLIST



Data Sharing



Components of Homeopathic Drug Listing

- Drug Facts (content of labeling) (OTC)
- Package insert (Rx)
- Carton or container images
- Product Data Elements (drug listing)

Active Ingredient

- The active ingredient includes the active ingredient name and identifier (Unique Ingredient Identifier (UNII)), strength, and the active moiety names and identifier (UNII). All active ingredients have at least one active moiety (in some cases two active moieties). Names of active ingredient **should not include designations such as USP or NF**. The name is taken from controlled terminology. Only terms in the controlled terminology are allowed. For ingredients, the controlled terminology is found in the FDA Substance Registration System/Ingredient Dictionary (SRS/ID). The **UNII is linked to the name** of the ingredient.
- Active moieties - more than one active moiety can be included for each active ingredient.

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
name(s) of active ingredient(s) (name of active moiety number 1 and name of active moiety number 2)	name(s) of active ingredient(s)	50 mg

Active Ingredients – Homeopathic Drug Products

- Do not repeat the same active ingredient in a product data elements section.
- Enter the largest amount of active ingredient in the product for homeopathic drug products only – Product Data Elements section ONLY

UNIIs

- Select UNIIIs from list accessible via this web page: <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.
- Request all UNIIIs needed to list your products as soon as possible.

Homeopathic Units of Measure

UCUM Name	UCUM
HOMEOPATHIC POTENCY OF CENTESIMAL SERIES	[hp_C]
HOMEOPATHIC POTENCY OF CENTESIMAL KORSAKOVIAN SERIES	{kp_C}
HOMEOPATHIC POTENCY OF MILLESIMAL SERIES	[hp_M]
HOMEOPATHIC POTENCY OF QUINTAMILLESIMAL SERIES	[hp_Q]
HOMEOPATHIC POTENCY OF DECIMAL SERIES	[hp_X]

Marketing Status & Date

- The marketing status describes the activity of the product
- The expiration date of the last lot released to the marketplace.

Marketing Status & Dates

- Status of product
 - **Active:** on the market
 - **Completed:** when marketing is done the drug is no longer going to be available on the market.
 - Active or completed timestamp: effectiveTime value.
- Low value
 - Time on the market
 - Determines release of CoL/Listing SPL to public
- High value
 - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

Marketing Category

- Use appropriate marketing category
 - Unapproved homeopathic
 - Drug for further processing (bulk products)

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

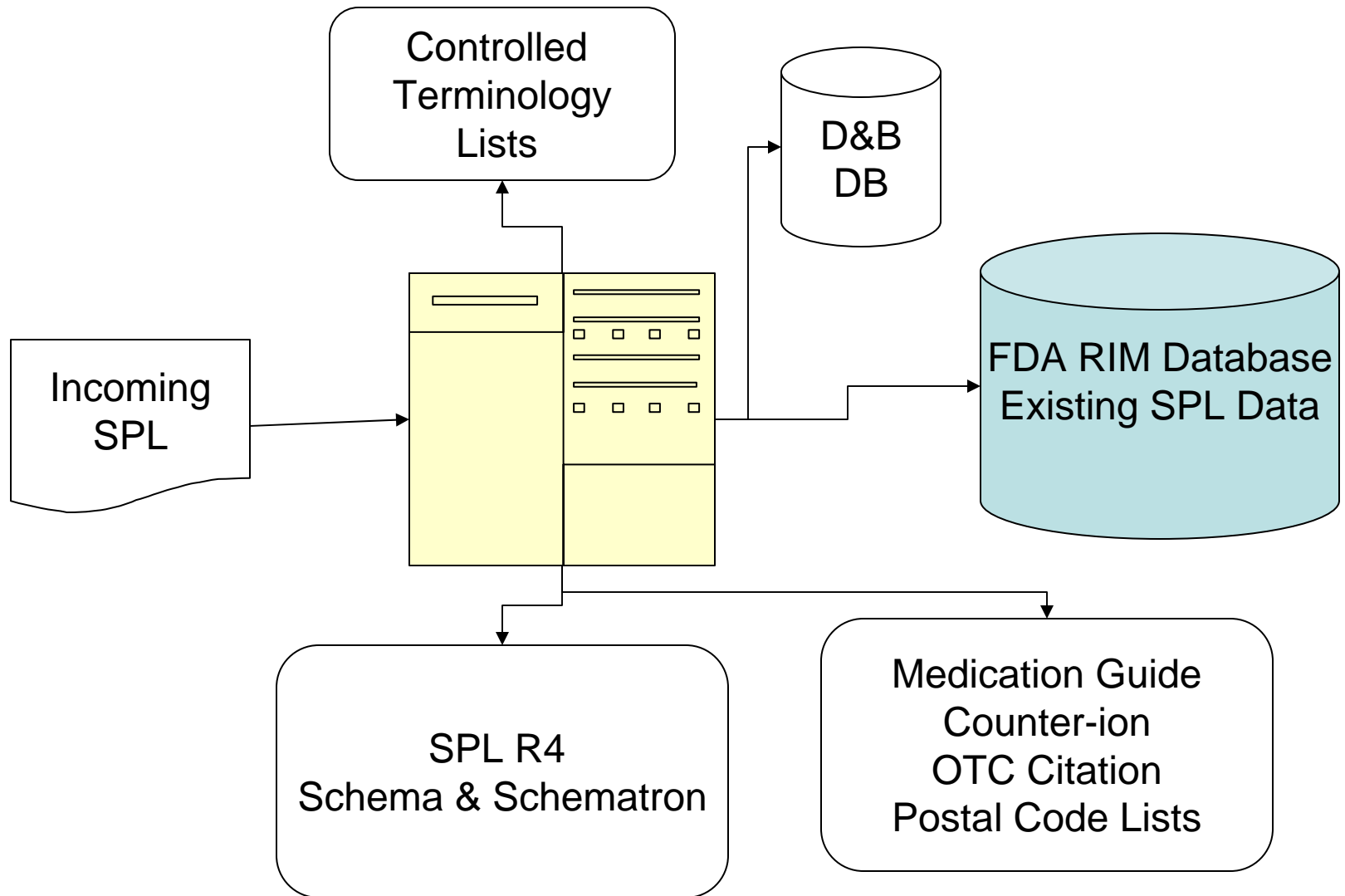
New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Updating SPL Document Tracking Information

- **Use**
 - **new** id root
 - **new** version number
 - original setId
 - appropriate effective time
- **Misplaced SetID/SPL File**
 - E-mail core ID to spl@fda.hhs.gov
- Include contact person's name and DUNS Number which were included in original SPL file

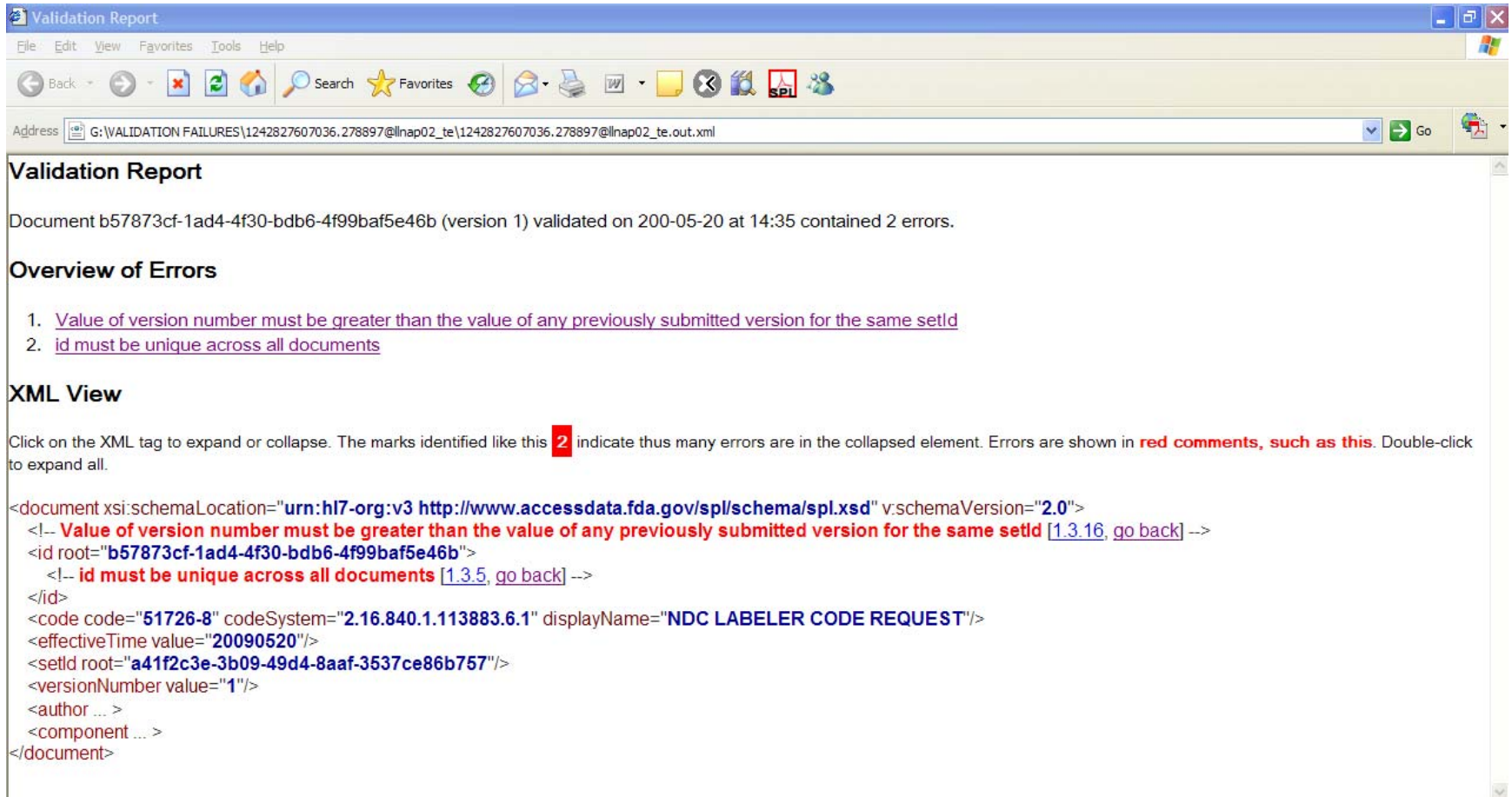
Validation Model



Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Sample System Generated Validation Report



The screenshot shows a web browser window titled "Validation Report". The address bar contains the path: G:\VALIDATION FAILURES\1242827607036.278897@llnap02_te\1242827607036.278897@llnap02_te.out.xml. The main content area is titled "Validation Report" and contains the following text:

Document b57873cf-1ad4-4f30-bdb6-4f99baf5e46b (version 1) validated on 200-05-20 at 14:35 contained 2 errors.

Overview of Errors

- [Value of version number must be greater than the value of any previously submitted version for the same setId](#)
- [id must be unique across all documents](#)

XML View

Click on the XML tag to expand or collapse. The marks identified like this **2** indicate thus many errors are in the collapsed element. Errors are shown in **red comments, such as this**. Double-click to expand all.

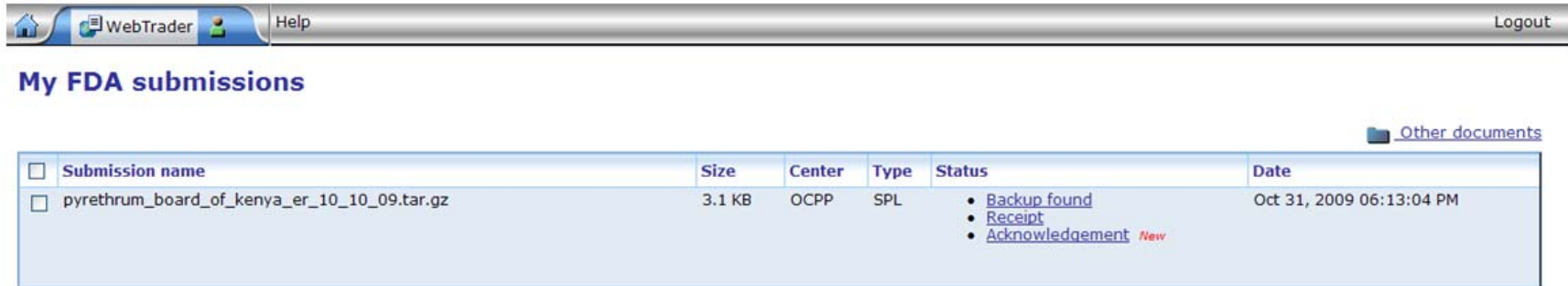
```
<document xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd" v:schemaVersion="2.0">
  <!-- Value of version number must be greater than the value of any previously submitted version for the same setId [1.3.16, go back] -->
  <id root="b57873cf-1ad4-4f30-bdb6-4f99baf5e46b">
    <!-- id must be unique across all documents [1.3.5, go back] -->
  </id>
  <code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC LABELER CODE REQUEST"/>
  <effectiveTime value="20090520"/>
  <setId root="a41f2c3e-3b09-49d4-8aaf-3537ce86b757"/>
  <versionNumber value="1"/>
  <author ... >
  <component ... >
</document>
```

Test Your SPL R4 Docs

- Provision of SPL R4 Validator Tool
- Test SPL R4 files prior to submission
- Discover ~90 – 95% of validation errors prior to submission.
- Schematron technology – permits quick updates to validation procedures
- FDA in collaboration with Pragmatic Data made available a validation tool:
[Pragmatic Validator Lite™](#)

Locating the Gateway Core ID

Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top, there is a navigation bar with a home icon, 'WebTrader', a user profile icon, 'Help', and 'Logout'. Below the navigation bar, the page title is 'My FDA submissions'. On the right side, there is a link for 'Other documents'. The main content area displays a table of submissions.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID

Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.

Finding the Core ID

The screenshot shows a table with columns: Size, Center, Type, Status, and Date. The first row is highlighted and has a detailed view window open below it. The detailed view window shows the following information:

Size	Center	Type	Status	Date
3.1 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceipt	Oct 31, 2009 06:13:04 PM

Below the table, a detailed view window is open for the 3.1 KB record. The window title is `ci1257027185381.4044@lntap02_te.txt`. The content of the window is:

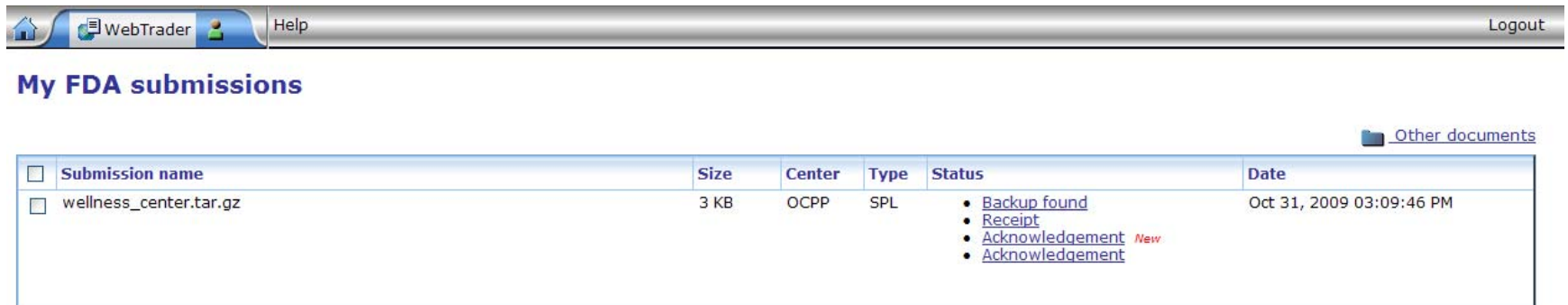
From: [FDATST](#)
To: [Lonnie Smith \(FDA\)](#)
Date: Oct 31, 2009 06:16:03 PM EDT
Submission messageID: <7346727.1257027182095.JavaMail.smithlo@cdl0080685>
[View document](#)

An arrow points from the text "This is the core ID" below the screenshot to the core ID in the window title.

- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Downloading Error Messages

Finding Error Messages



The screenshot shows the FDA Gateway WebTrader interface. At the top, there is a navigation bar with a home icon, the text "WebTrader", a user profile icon, and a "Help" link. On the right side of the navigation bar is a "Logout" link. Below the navigation bar, the page title is "My FDA submissions". To the right of the title is a folder icon and the text "Other documents". Below this is a table with the following columns: "Submission name", "Size", "Center", "Type", "Status", and "Date". The table contains one row with the submission name "wellness_center.tar.gz", a size of "3 KB", center "OCP", type "SPL", and a date of "Oct 31, 2009 03:09:46 PM". The "Status" column for this submission contains a bulleted list of links: "Backup found", "Receipt", "Acknowledgement", and "Acknowledgement". The second "Acknowledgement" link is followed by the word "New" in red text.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement• Acknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>• Acknowledgement	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages

Size	Center	Type	Status	Date
3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

[close](#)

ci1257016187076.9279@lntap01_te.xml

2.8 KB O

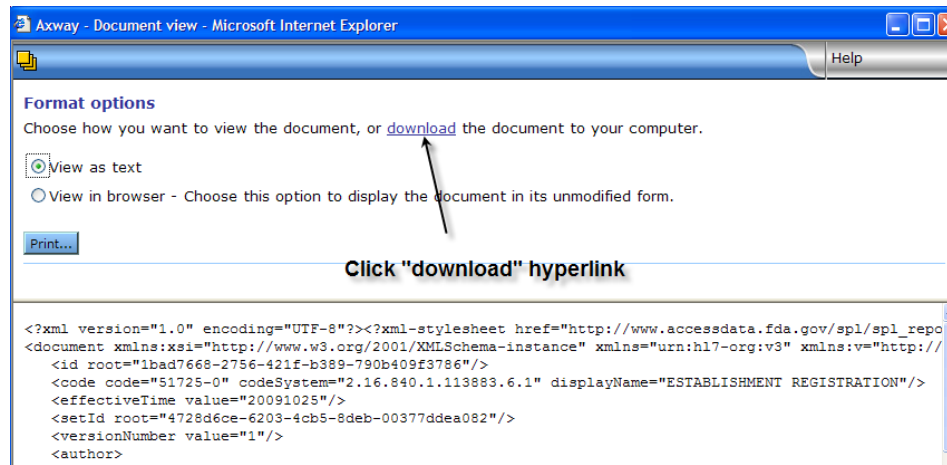
From: [FDATST](#)
To: [Lonnie Smith \(FDA\)](#)
Date: Nov 1, 2009 12:34:11 PM EST
Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>
[View document](#)

2.7 KB O

Click "View document" hyperlink

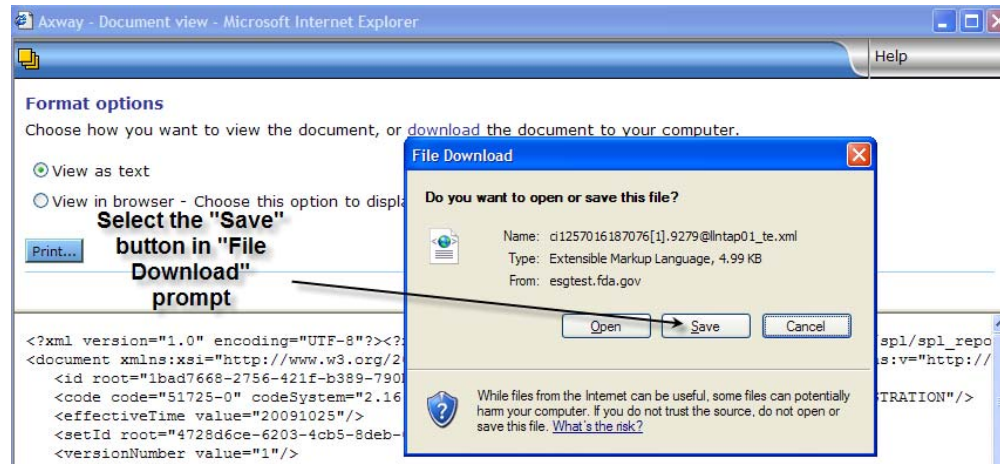
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



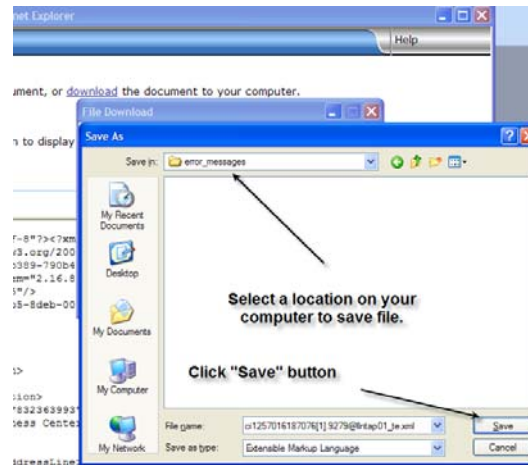
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



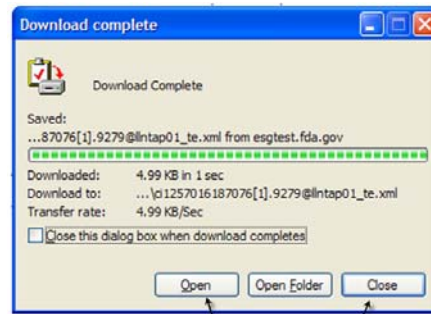
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

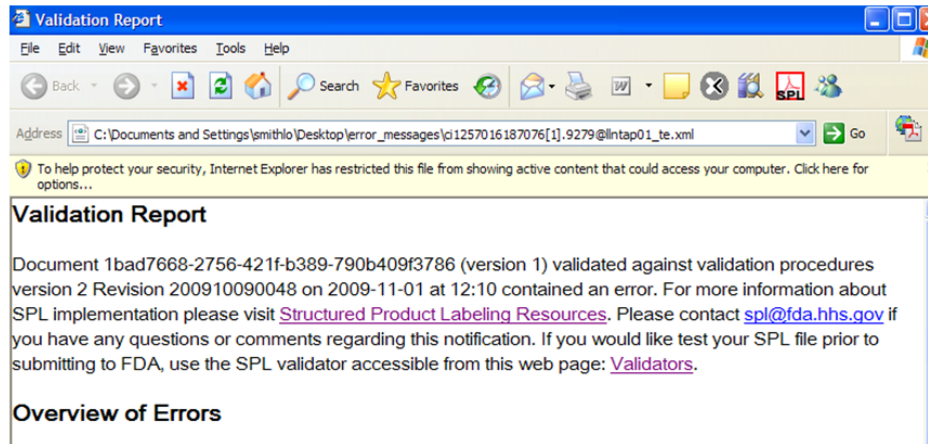
Completing Download



Select "Open" or "Close" buttons

- You can open the message from the “Download complete” window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message



- Review the error 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 menu includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the right, there are links for 'Email this page', 'Print this page', and 'Change Font Size'. The main content area is divided into two columns. The left column is titled 'Data Standards' and contains a list of links: Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The right column is titled 'FDA Resources for Standards' and features a red envelope icon with the text 'Sign up for email updates.' and an arrow pointing to the right. Below this is a paragraph: '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.' At the bottom of the right column is 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

 [Sign up for email updates.](#) ←

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)

QUESTIONS