Creating a Content of Labeling/ Drug Listing SPL Document – Homeopathic Drug Product**s**

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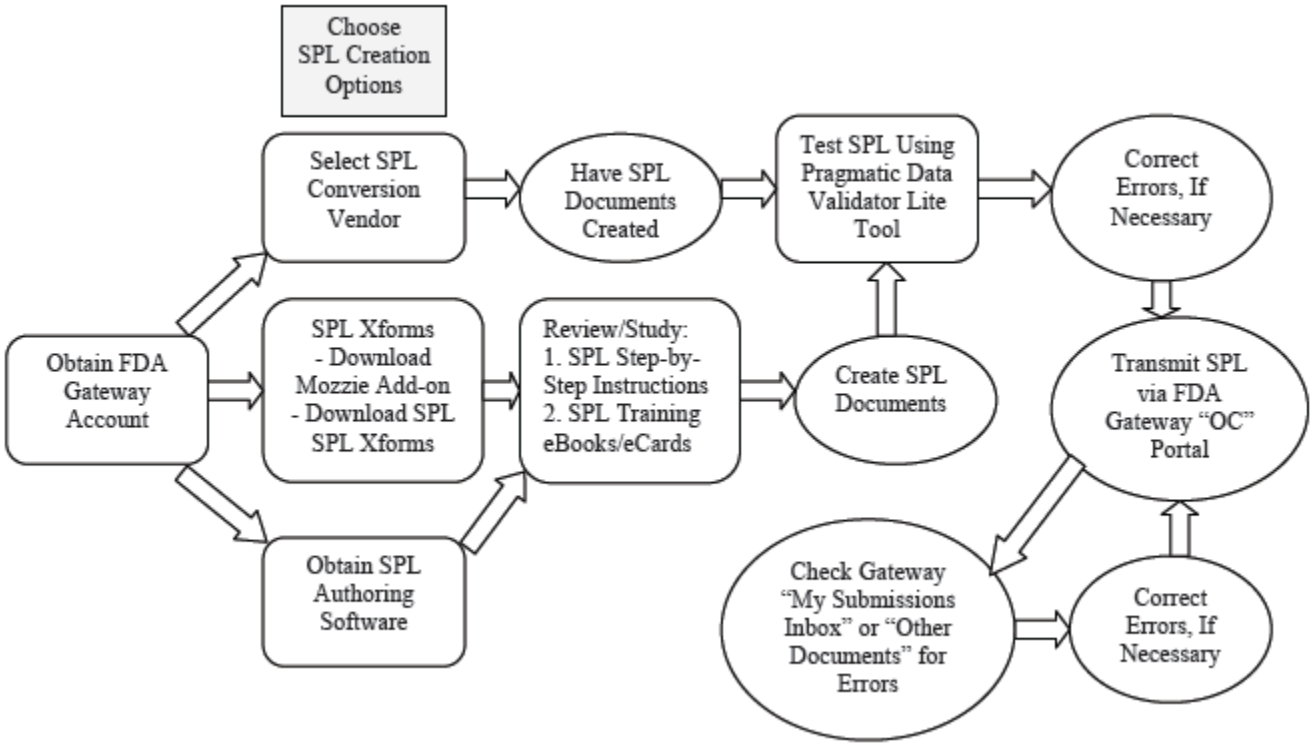
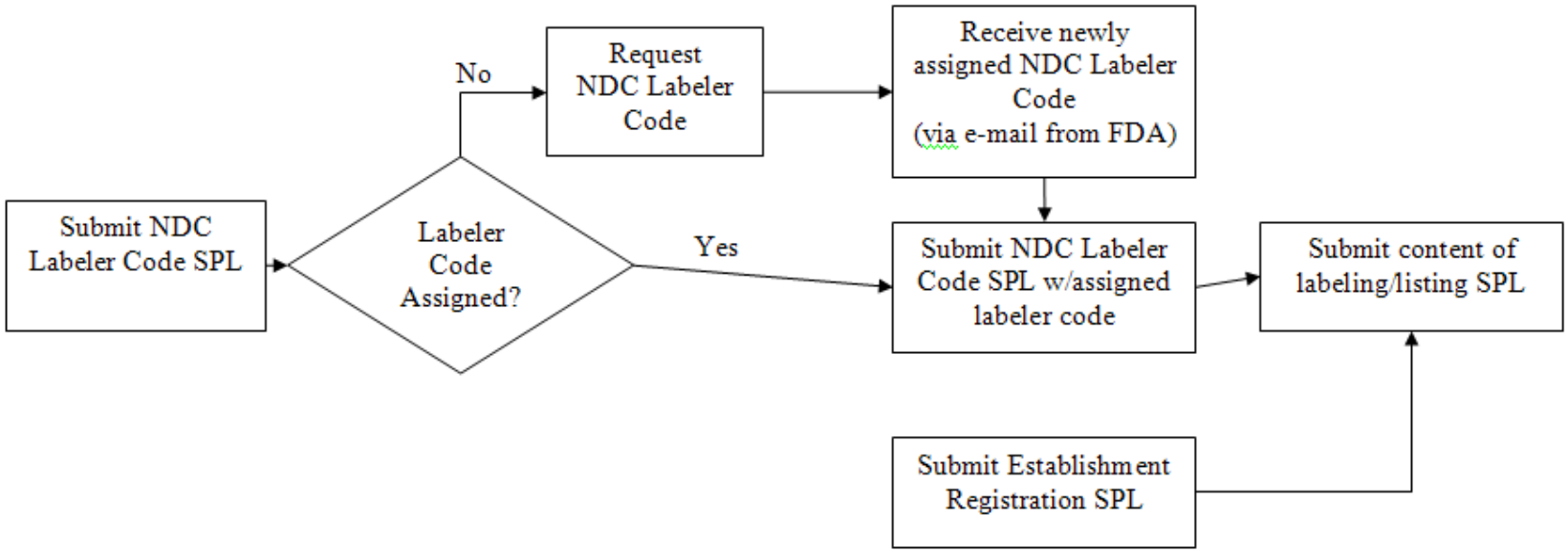
Technical Terms Glossary

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 yyyymmdd.
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.

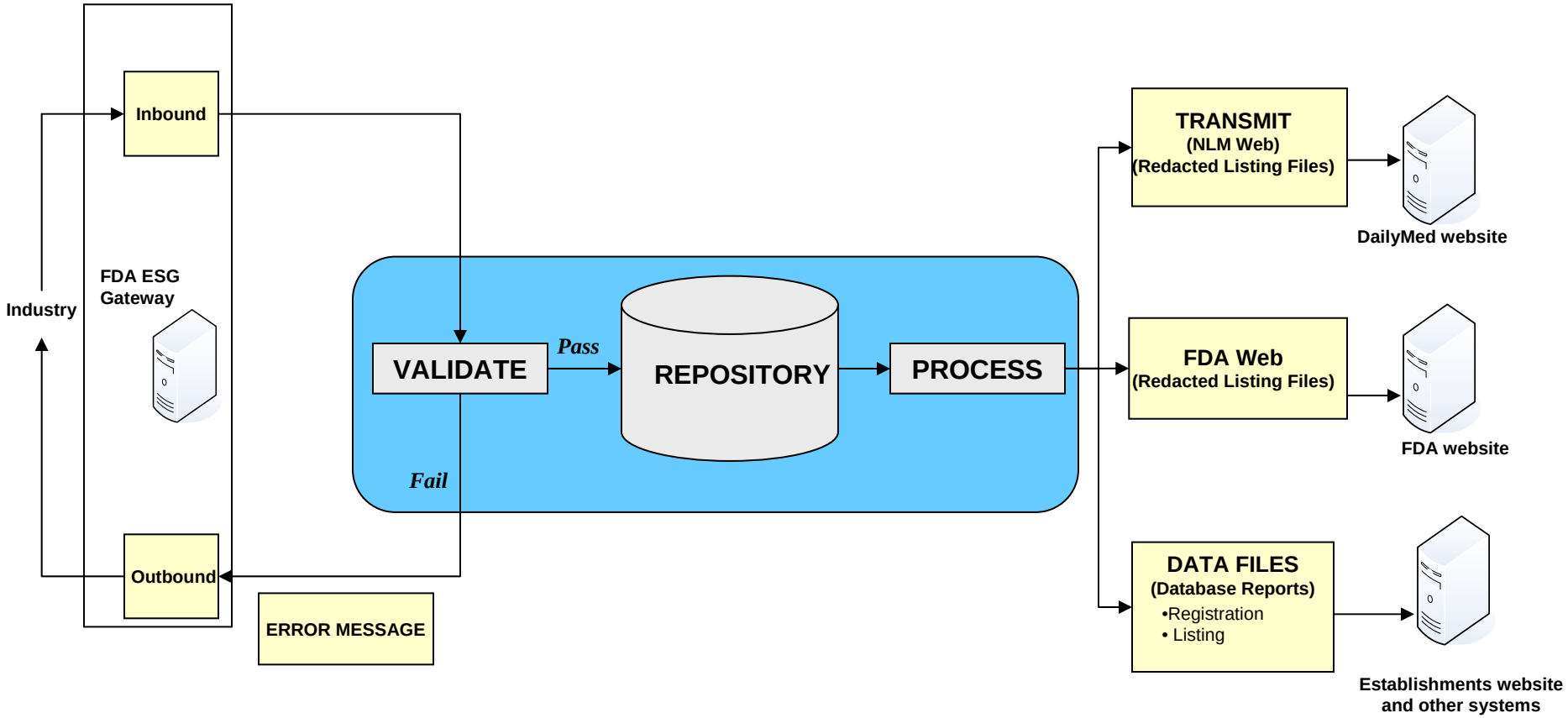
Road Map” Creation & Submission



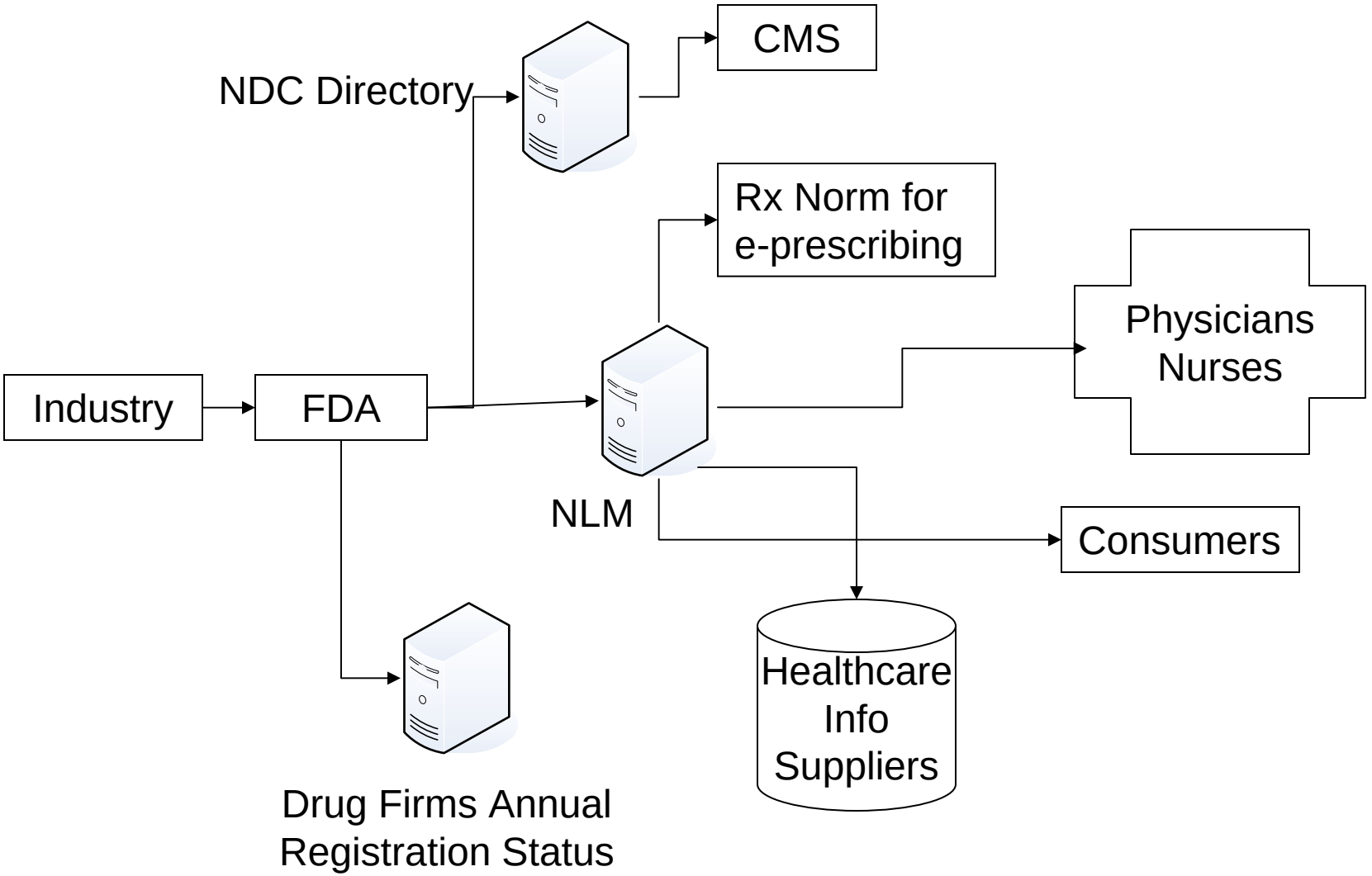
SPL Submission Process



eLIST


Inbound
FDA ESG Gateway
Industry
Outbound
ERROR MESSAGE
VALIDATE
Pass
Fail
REPOSITORY
PROCESS
TRANSMIT
(NLM Web)
(Redacted Listing Files)
DailyMed website
FDA Web
(Redacted Listing Files)
FDA website
DATA FILES
(Database Reports)
•Registration
• Listing
Establishments website and other systems

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 UNIIs 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 UNIIs 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

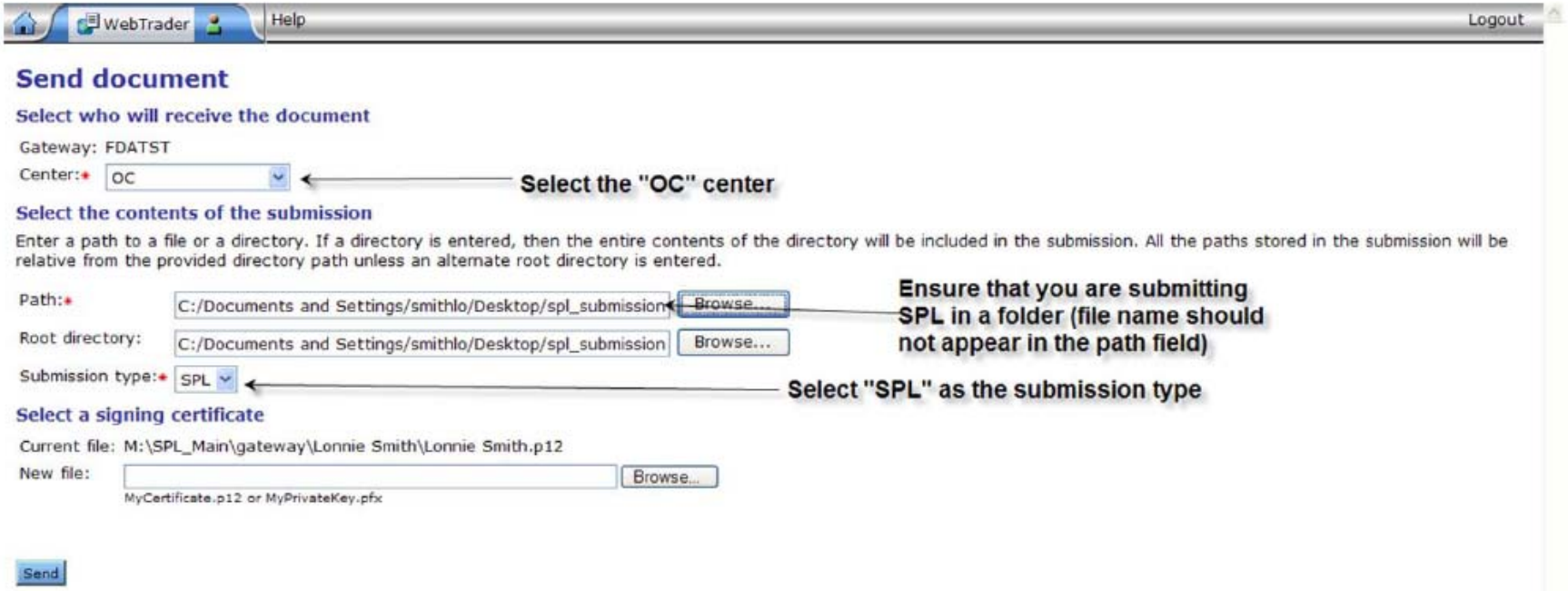
- Status of product
  - **Active:** on the market
  - **Completed**: when marketing is done the drug is no longer going to be available on the market.
  - Active or completed timestamp: effectiveTime value.
- Low value
  - Time on the market
  - Determines release of CoL/Listing SPL to public
- High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

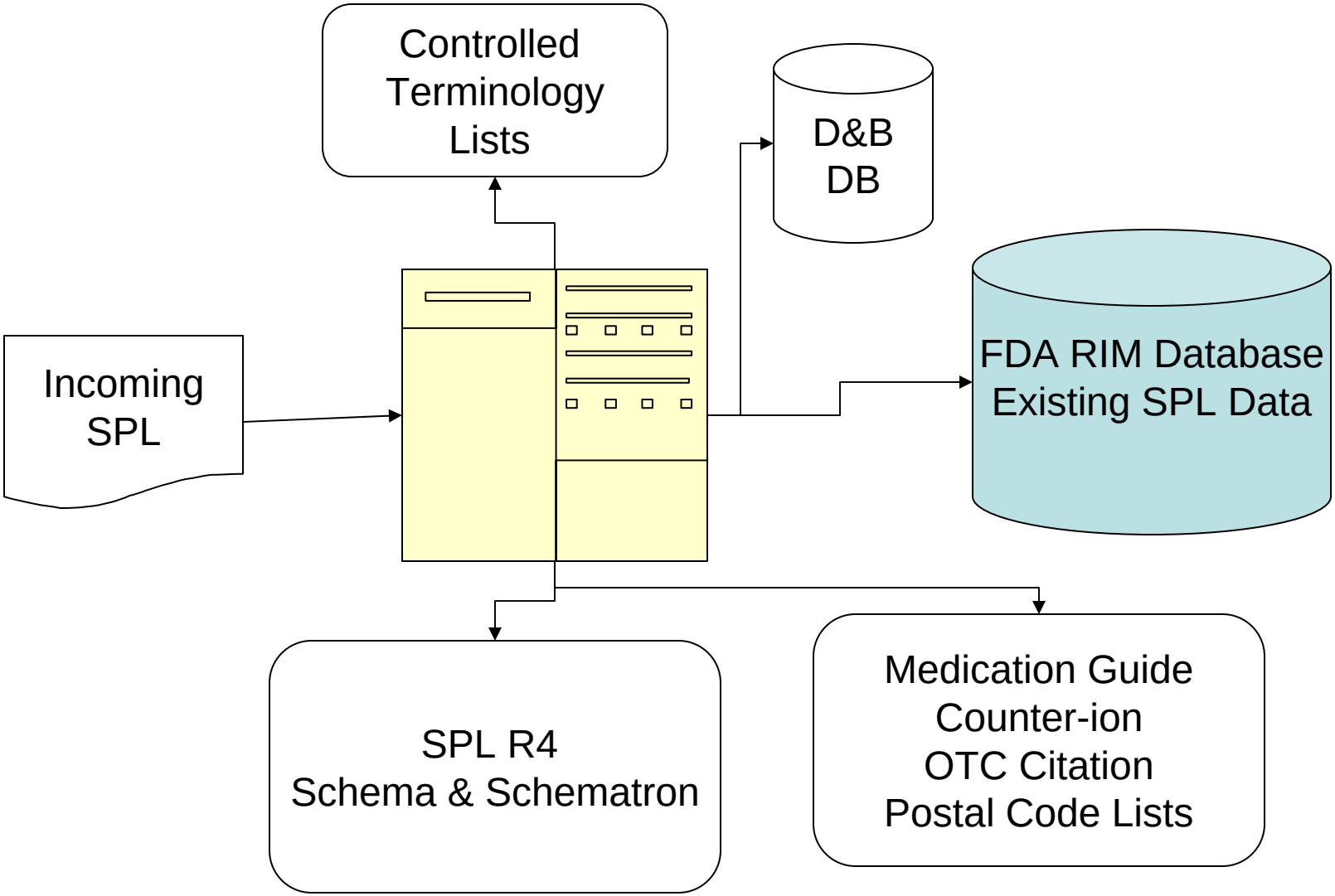
Submitting Files via FDA Gateway



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

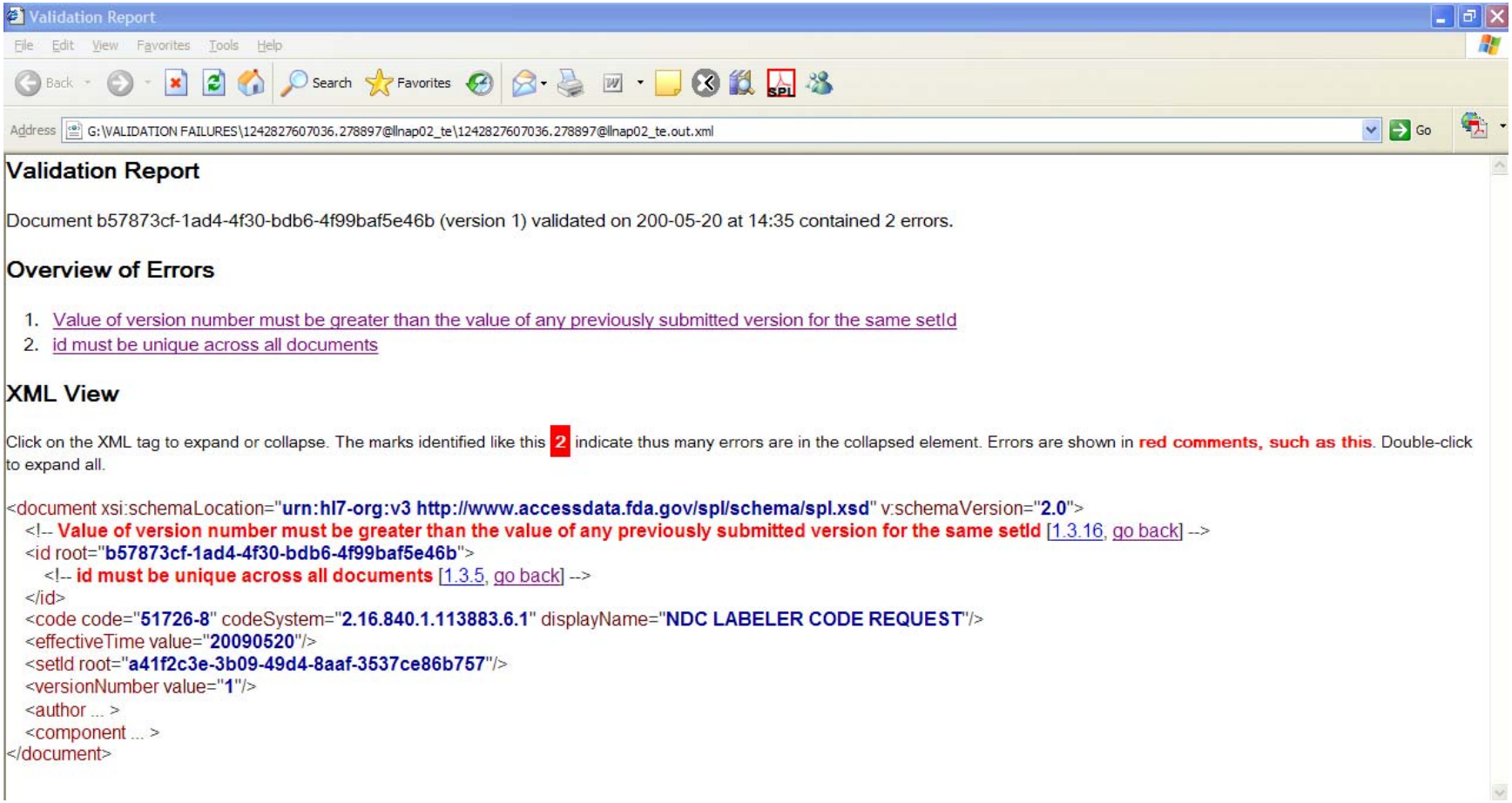
Validation Model



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

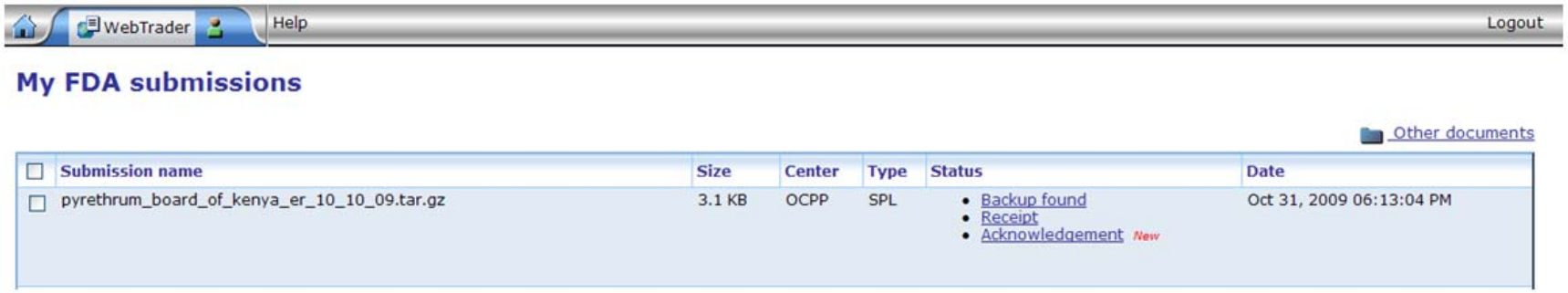


Test Your SPL R4 Docs

- 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™

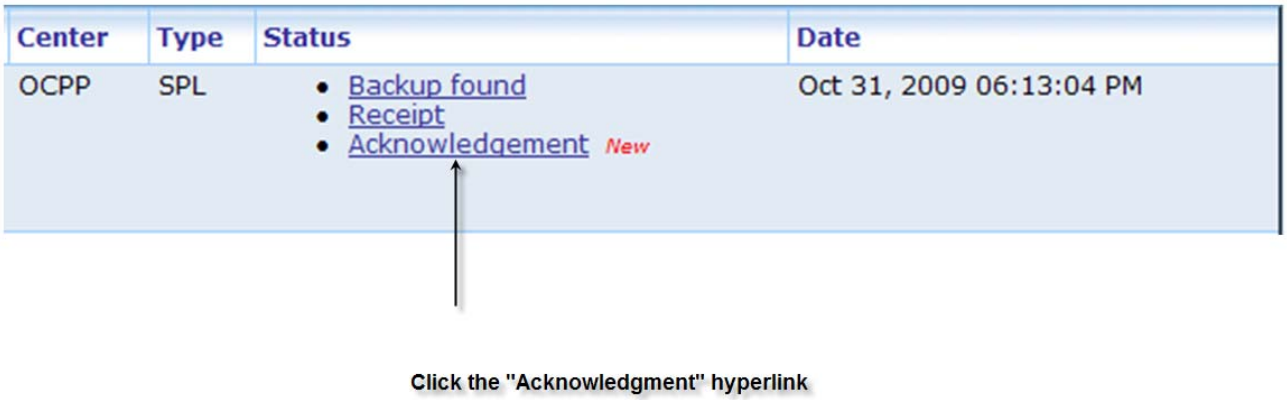
Locating the Gateway Core ID

Log onto FDA Gateway



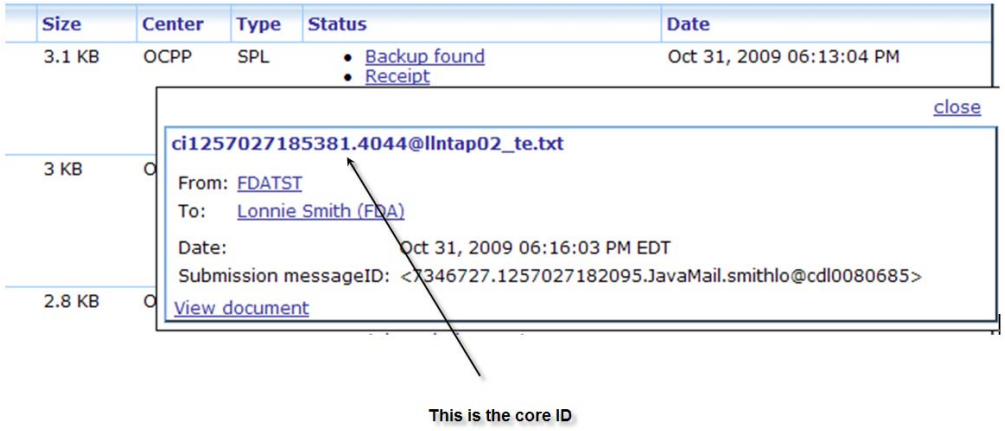
- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID



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

Finding the Core ID



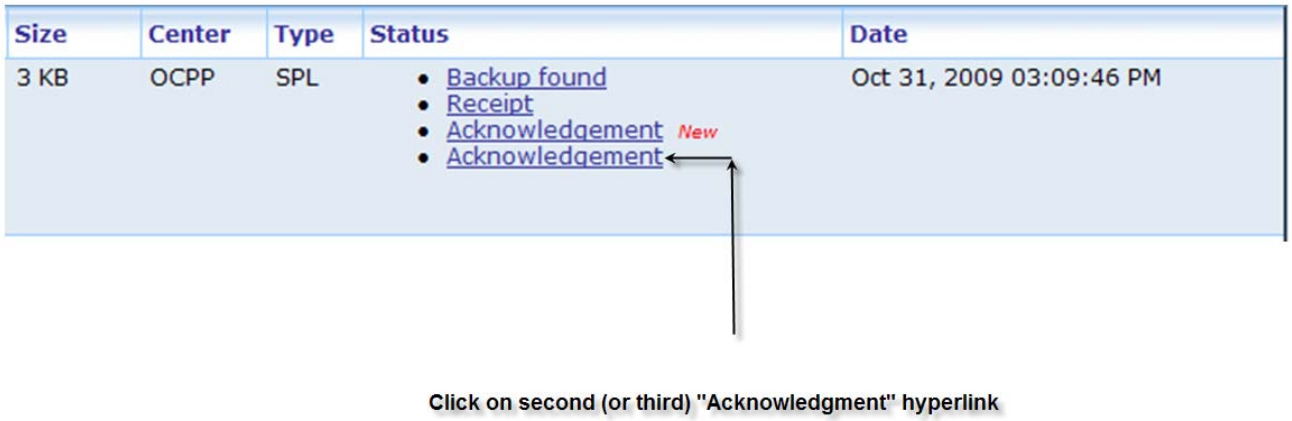
- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Downloading Error Messages

Finding Error Messages

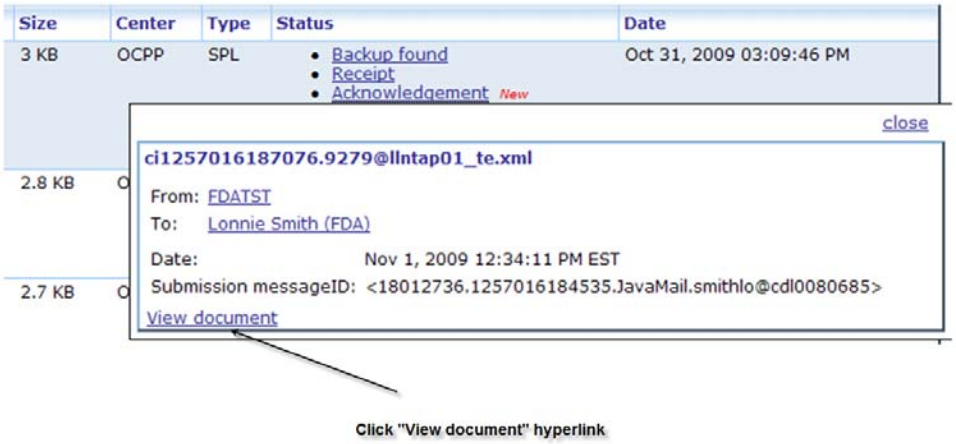
- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message



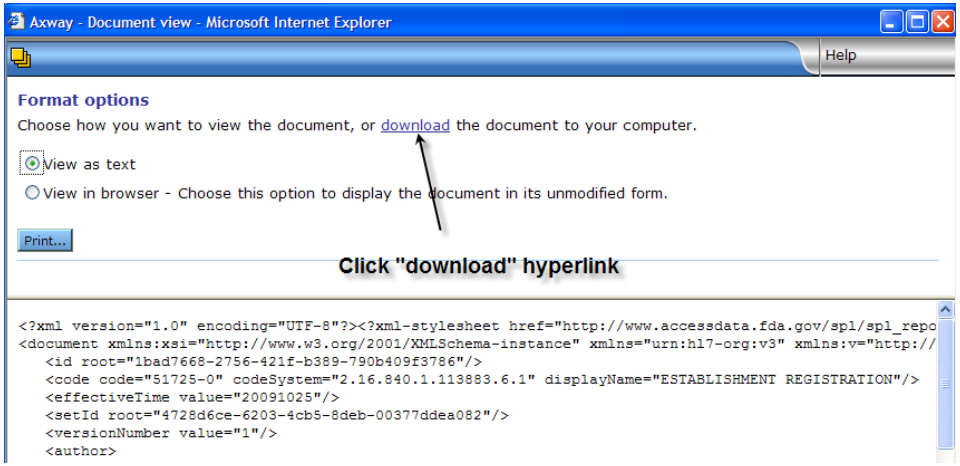
- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages



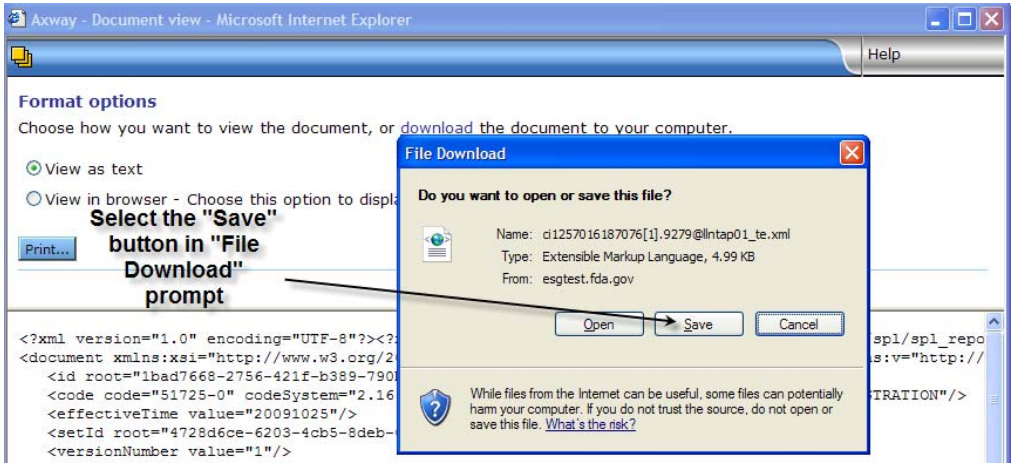
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



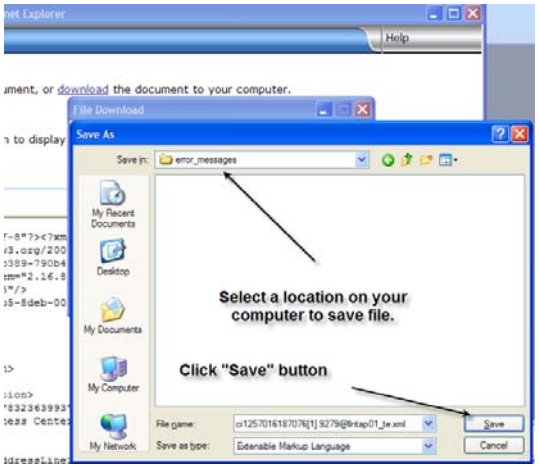
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



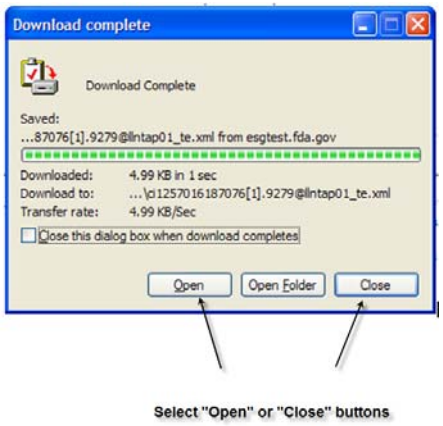
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont…



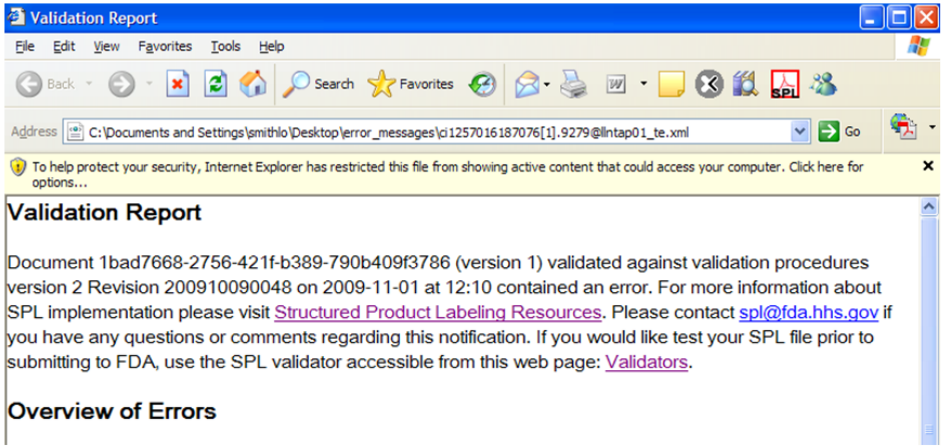
- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

Completing Download



- 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

SPL-related Technical Assistance/Questions

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

QUESTIONS