SPL Release Four Training
Animal Drugs - Preparing Electronic Drug Establishment Registration & Drug Listing Submissions

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FDA Data Standards Council

Overview

- Introduction to Structured Product Labeling (SPL) Standard
- Using the SPL Format to Electronically Register Drug Establishments and List Drug Products

SPL's Goal is to make the labels and drug listing information:

- **People friendly**
  - Labeling content in electronic format
    - Improve readability
    - Better access
- **Computer friendly**
  - Product information that is **computer readable**
    - Structured labeling content and product listing elements **-** Computer can "find" a specific section of the labeling and specific elements within labeling and product listing sections.
- **Information system friendly**
  - Product information in computer readable form - Easily imported into information systems
  - FDA systems extract the coded data from the SPL file to accomplish drug establishment registration and drug product listing
- **Publicly available**
  - Content of Labeling (up-to-date version) is made available by the FDA thru NLM (DailyMed) to consumers and health information suppliers
  - Drug listing and establishment registration information is made available by the FDA via NDC Directory, Drug Firms Annual Registration, and future FACTS@FDA websites.

The Standard:

Structured Product Labeling (SPL)

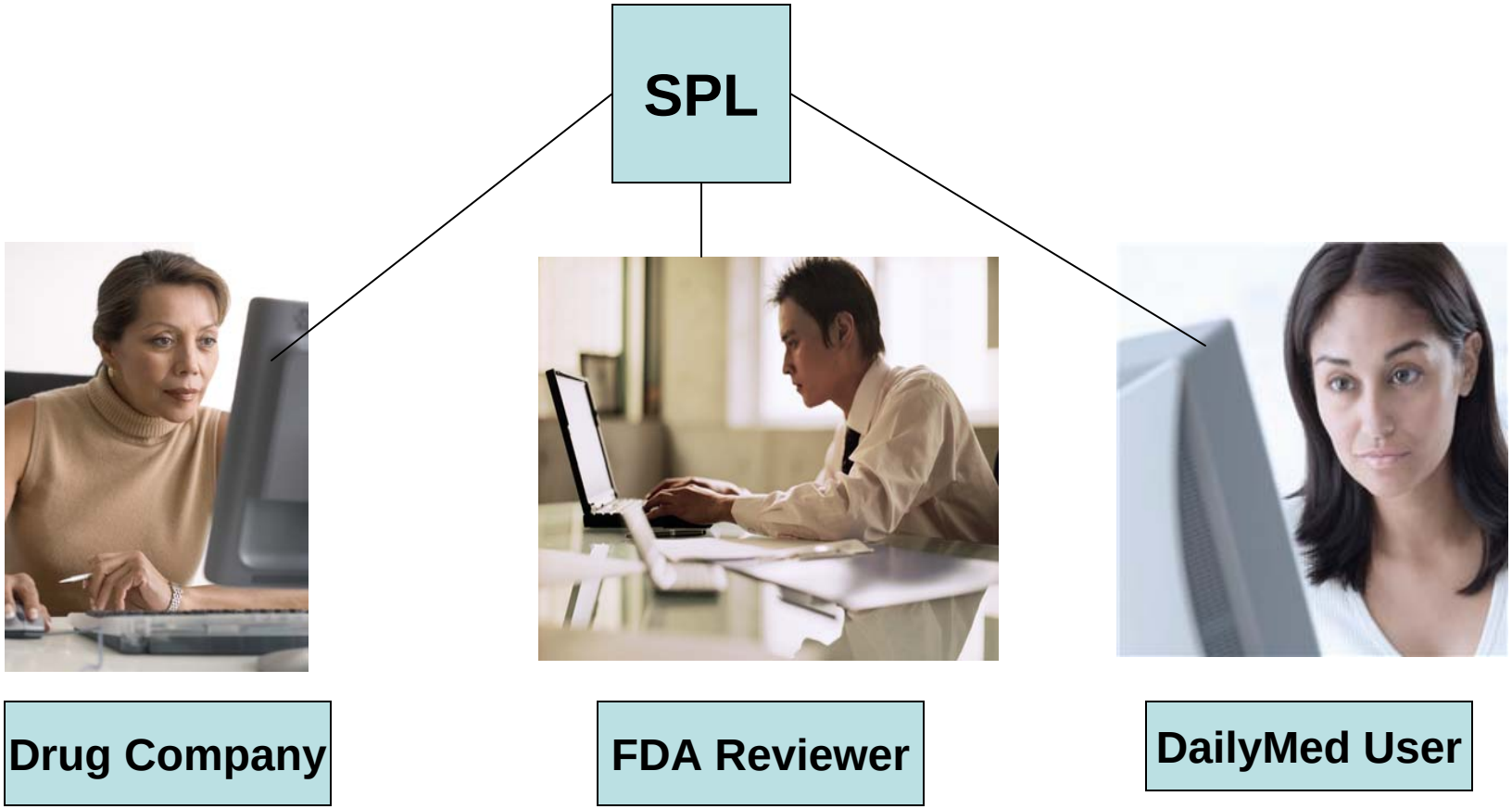
Structured Product Labeling

The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information.

XML & XSL Stylesheet

- SPL is created using E**X**tensible **M**arkup **L**anguage (XML) – similar to HTML for webpages
- XML
  - Relatively human-legible
  - Machine readable
  - Tags (elements) permit search of key information
- XML Documents – created via Notepad, Word Pad, XML editing tools, SPL authoring tools, SPL conversion services, Xforms, etc…
- XSL Stylesheet – transforms the XML data to be viewed via web browser or printed documents

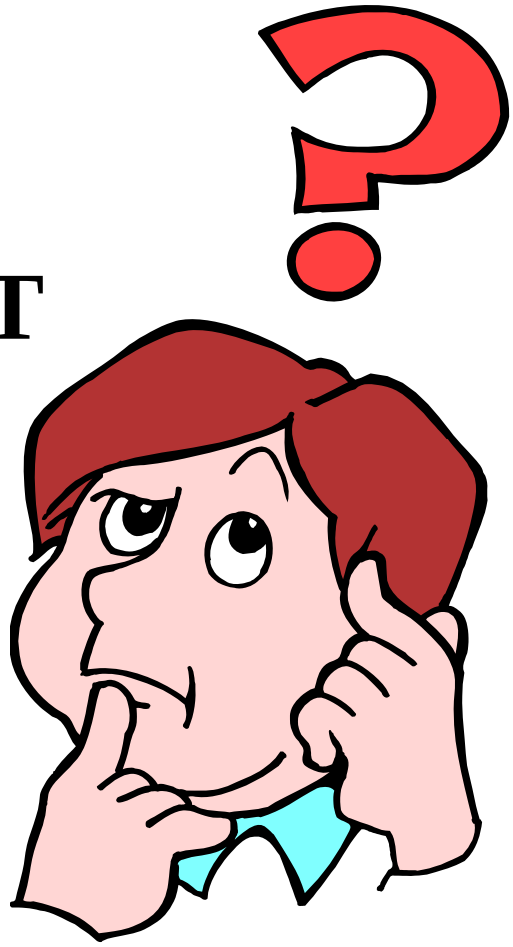
Information Exchange
SPL

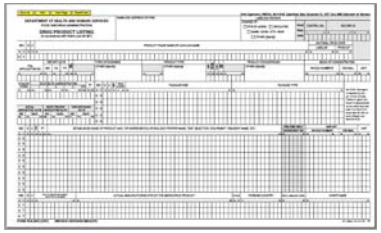


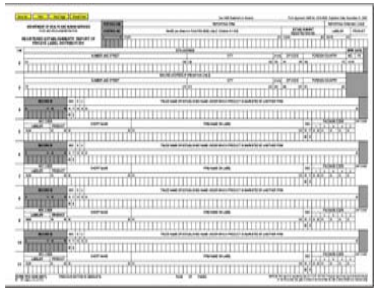
SPL is a standard that is used by drug companies, FDA and public to exchange or review or view product information. All three entities use computer or systems that "understand" SPL

Transitioning from Paper to Electronic Drug Establishment Registration & Drug Listing

WHY CHANGE
THE **DRUG LISTING AND ESTABLISHMENT REGISTRATION PROCESS** THAT HAS WORKED FOR DECADES ????







- Eliminate duplicative and redundant data entry
- Automate processing of data in a submission type in electronic format in a manner that FDA can adequately process, review, and archive.

Transition from Paper to Electronic Drug Establishment Registration & Drug Listing

- Changes in FD&C Act require electronic registration of drug establishments and listing of human prescription drugs, OTC, animal drug, biologic products – September 2007
- Draft Guidance document for electronic drug establishment registration and listing – July 2008
- FDA is adopting the use of extensible markup language (XML) files in SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

Benefits of Electronic Registration and Listing

- Electronic registration and listing process is more efficient and effective for industry and the Agency
- Accurate, up-to-date inventory of marketed drugs
- Eliminates data entry errors
- Well formed and properly created SPL files can be processed in minutes
- Use existing technology and data standard – **SPL (Used by FDA (CDER) since 2004)**
- SPL Release Four (R4) includes data elements needed to register drug establishments and list drug products

More Benefits of Electronic Registration and Listing

- Data maintenance
  - Content of Labeling and listing information in one file.
  - Registrant can list all it's establishments in one file.
  - Update information – Use one file instead of creating several paper forms and resubmit.
- Eliminates the use of paper forms for listing and registration
- 24-hour submission window – FDA Gateway
- Manage data using same source (files) as FDA
- Reduces the amount of time for FDA to receive and process your information.
- Permit the fulfillment of two regulatory requirements (providing labeling in electronic format and listing electronically) with **one** file.

...three e-Files for Registration & Listing – SPL Format

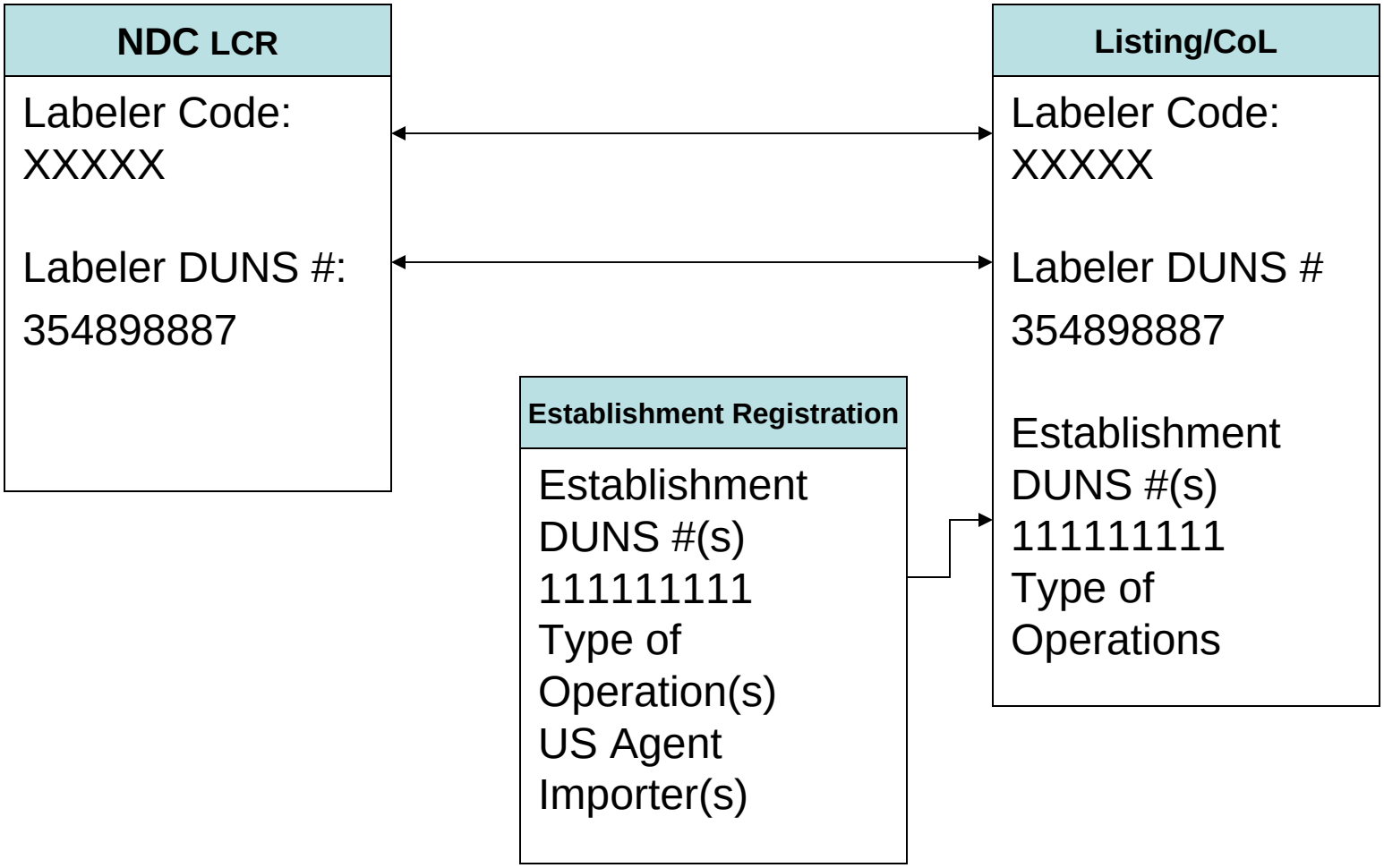
- NDC Labeler Code Request
- Establishment Registration
- Content of labeling (CoL)/Listing

Order of Submissions

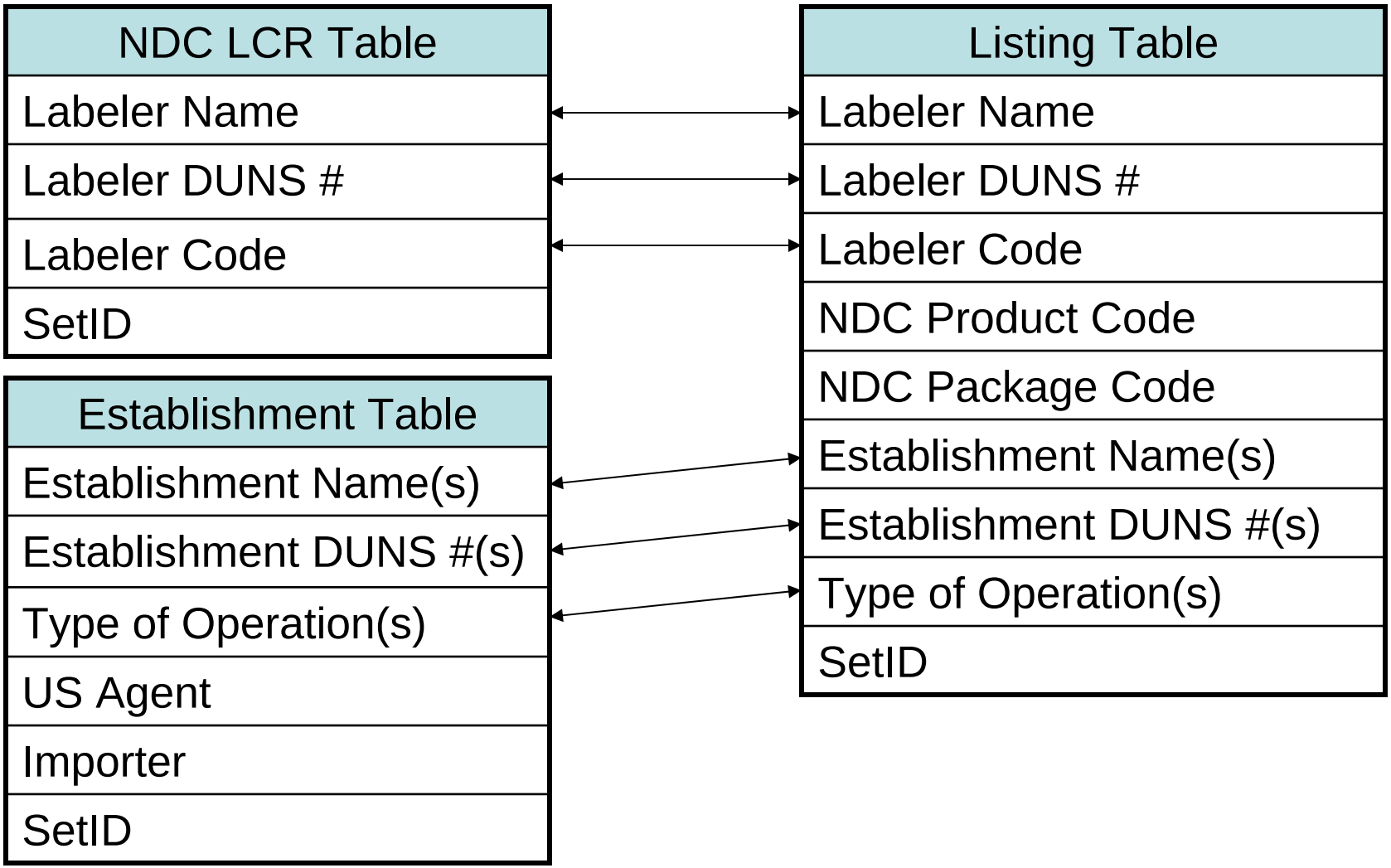
1. NDC Labeler Request (LCR) and Establishment Registration (ER) SPL
2. CoL/Listing SPL

- CoL/Listing validates against data submitted in NDC LCR and ER SPL

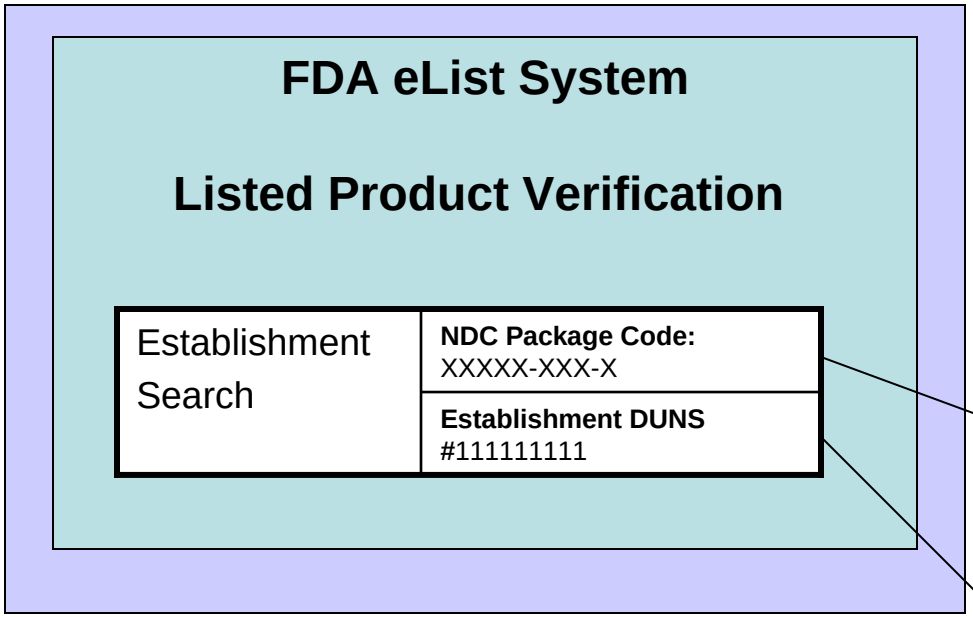
Data Source – SPL Documents



eList Data Relationships Mockup



Query Example Mockup



Listing Database Table

Field Name	Field Value
Labeler Name	Jaysonian Pharm
Labeler DUNS #	354898887
Labeler Code	XXXXX
NDC Product Code	XXXXX-XXX
NDC Package Code	XXXXX-XXX-X
Establishment Name(s)	Pham Pharma
Establishment DUNS #(s)	111111111
Type of Operation(s)	Manufacture
SetID	027005a5-4c40-4931-85cd-79933f99e338

Miracle Drug XR (good drug) Tablets

30 Tablets
NDC: XXXXX-XXXX-X

Product Package

Important: not a depiction of FDA's System – for demo only

You Control the Published Electronic Drug Listing and Establishment Registration Data

Drug Company

Drug Listing Content of Labeling SPL file

Establishment Registration SPL file

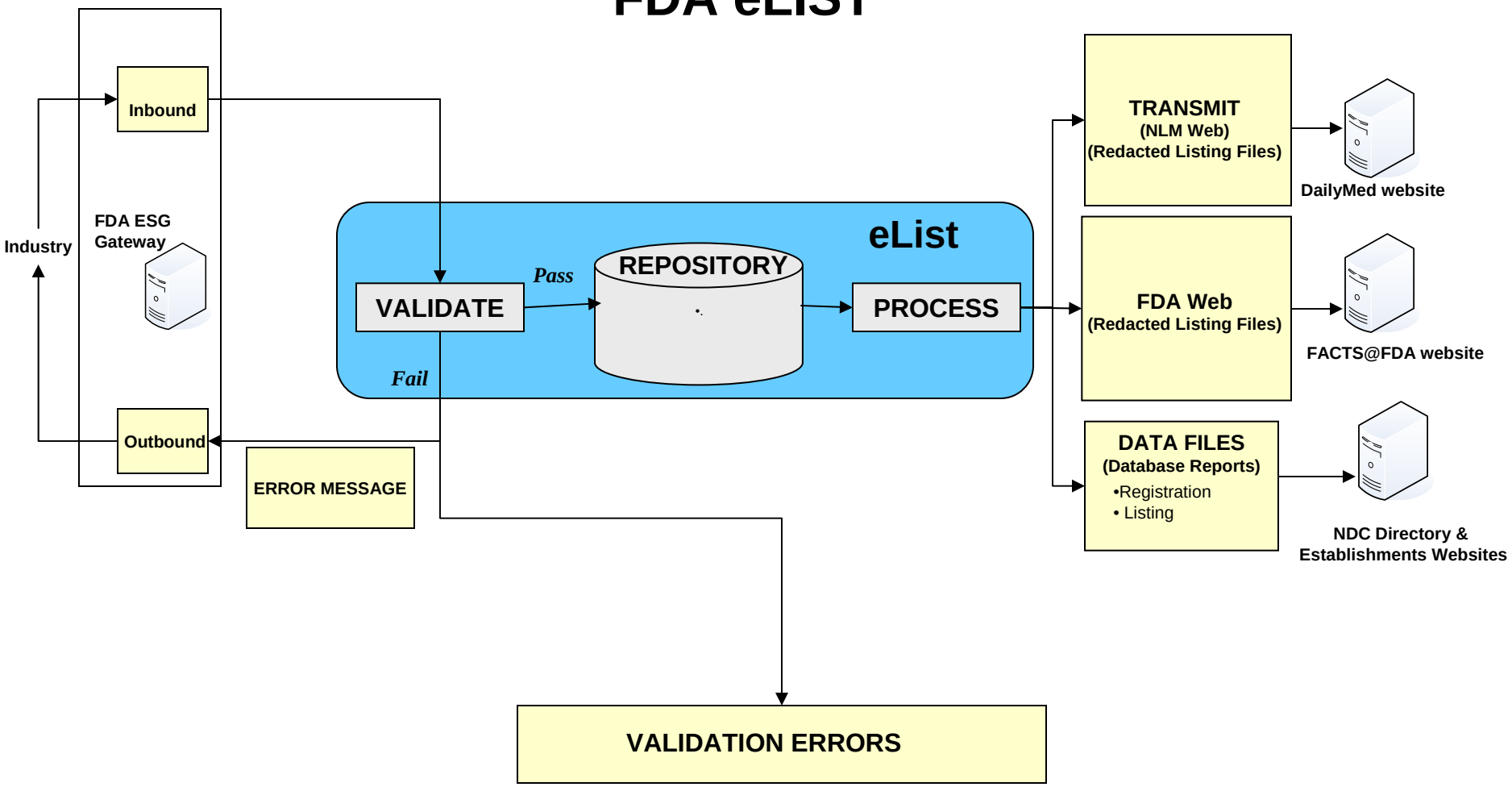
FDA Gateway and FDA eList System

DailyMed Website

FACTS @ FDA Website

Drug Firms & NDC Directory Websites

FDA eLIST


Inbound
Outbound
FDA ESG Gateway
Industry
eList
VALIDATE
Pass
Fail
REPOSITORY
PROCESS
ERROR MESSAGE
VALIDATION ERRORS
TRANSMIT
(NLM Web)
(Redacted Listing Files)
DailyMed website
FDA Web
(Redacted Listing Files)
FACTS@FDA website
DATA FILES
(Database Reports)
•Registration
• Listing
NDC Directory &
Establishments Websites

Electronic Content of Labeling

Content of Labeling

- Sections and Subsections
- Symbols and Characters
- Font Effects
- Footnotes
- Lists
- Tables
- Images

Blocks of Text

PDF

Description:

This is the description of the product

Indications and Usage:

This is the indication for use of this product

Contraindications:

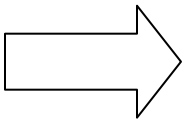
These are the contraindications

Warnings:

These are the warnings.

How supplied:

This is how the product is supplied.



SPL

<Description>

This is the description of this product

<Indication and Usage>

This is the indication of the product

<Contraindications>

These are the contraindications

<Warnings>

These are the warnings

<How supplied>

This is how the product is supplied

SPL Stylesheet View/Source Code

CONTRAINDICATIONS

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
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<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson&amp;#8217;s disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

Terminology

Data Elements

- Data Element
  - A basic unit of identifiable and definable information. It occupies the space provided by a field in a record or a block on a form, and has an identifying name and value or values for expressing a specific fact. A data element is defined by its name, description, source, length, structure, and format.
- Product Data Elements
  - Formerly known as Drug Listing Data Elements
  - Drug listing data elements are **metadata** displayed via SPL stylesheet for purpose of review
  - Computer friendly information - product information which is tagged that permits search of key information.
  - Information system friendly – Medication information in computer readable form - Easily imported into information systems

Terminology

- **Standard terminology** is used for SPL product data elements. Information about the controlled vocabulary for SPL is available at http://www.fda.gov/oc/datacouncil/spl.html under “SPL Terminology.”

Terminology

- Each term in the controlled terminology is associated with a code
- The term (SPL Acceptable term or name) – displayed is for humans to understand and the code is for the computer to comprehend.
- The code can be utilized by international systems. The term may be displayed in two different languages in an international system; however the code can be the same.

Controlled Terminology

- Route of administration
- Dosage form
- Package type
- Units of measure and units of presentation
- Color
- Shape
- Coating **(obsolete for SPL R4 documents)**
- Size
- Scoring
- Imprint codes
- Symbols **(obsolete for SPL R4 documents)**
- SPL DEA Schedule
- Section headings
- Code system object identifiers (OIDs)
- Document Type including Content of Labeling Type
- Time Units: Unified Code for Units of Measure (UCUM)
- Substances/Unique Ingredient Identifiers (UNIIs)
- Business Operation
- Marketing Category
- Marketing Status
- Equivalence Codes
- Flavor
- ISO 3166-1 Alpha-3 Country Code

Terminology

- Product
  - Proprietary and nonproprietary name and code
- Description
  - Ingredients
    - Active and inactive ingredient and active moiety name and code (Unique Ingredient Identifier (UNII) from FDA Substance Registration System (SRS)
    - Active and inactive ingredient strength (National Cancer Institute (NCI) Thesaurus, Unified Codes for Units of Measure (UCUM)
    - Dosage form (NCI Thesaurus)
    - Appearance (imprint, color, shape, size, score, coating, symbol) (NCI Thesaurus and HL7)
    - Route of administration (NCI Thesaurus)
    - DEA schedule (NCI Thesaurus)
- Packaging
  - Package type (NCI Thesaurus), quantity and packaging code

Ingredients (Terminology)

- Ingredient name (substance name)
  - SRS preferred name of ingredient (active and inactive)
  - Source – FDA SRS
- Ingredient code (substance code)
  - Unique Ingredient Identifier
  - Source –FDA SRS
- Active moiety name (active moiety entity name)
  - active ingredient or portion of active ingredient without counter ion (if relevant)
  - Source –FDA SRS
- Active moiety code (active moiety code)
  - Unique Ingredient Identifier (UNII)
  - Source –FDA SRS

Unique Ingredient Identifier (UNII)

- Joint FDA/USP Substance Registration System (SRS) to support health information technology initiatives by generating unique ingredient identifiers (UNIIs) for substances in drugs, biologics, foods, and devices.

- Non-proprietary, free, unique, unambiguous, alphanumeric identifier based on a substance's molecular structure and/or descriptive information

UNII Assignment

- UNII, an ingredient must be a ‘substance’, which is defined as “Any physical material that has a discrete existence, irrespective of origin.” **Products will not be assigned a UNII.**
- More information about UNII codes and the SRS is available at: http://www.fda.gov/oc/datacouncil/SRS.htm
- Missing UNIIs or other terms? – Send request to spl@fda.hhs.gov

Terminology Resources

- Data Standards Manual: http://www.fda.gov/cder/dsm/ (definitions of terms)
- FDA DSC SPL web page: http://www.fda.gov/oc/datacouncil/spl.html (acceptable terms for use in SPL documents)
- Substance Registration System: http://cdsuxpa1.fda.gov:7779/ePS/
- National Cancer Institute Thesaurus: http://www.cancer.gov/cancertopics/terminologyresources

Hyperlinks to Data Standards Manual and SPL Terminology Web Pages

- **Dosage Forms**
  - SPL web page: http://www.fda.gov/oc/datacouncil/splncicodes.html#dosage
- **Routes of Administration**
  - SPL ROA terms: http://www.fda.gov/oc/datacouncil/splncicodes.html#route
- **Units of Measure/Units of Presentation**
  - SPL web page: http://www.fda.gov/oc/datacouncil/splncicodes.html#potency
- **Colors**
  - SPL web page: http://www.fda.gov/oc/datacouncil/splncicodes.html#color
- **Shapes**
  - SPL web page: http://www.fda.gov/oc/datacouncil/splncicodes.html#shape
- **Package Types**
  - SPL web page: http://www.fda.gov/oc/datacouncil/splncicodes.html#package

Product Data Elements

Product Name and NDC Product Code

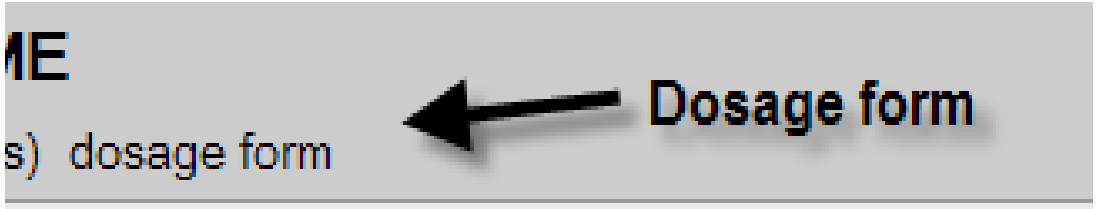
- The proprietary/trade and ingredient name data elements only include the name and do not include any additional qualifiers such as trademark symbols, route of administration, or dosage forms. (SPL R4 only: Suffix element may contain “XL” “ER”)
- The NDC product code in SPL documents is comprised of the first two segments of the NDC

Proprietary name: “PROPRIETARY NAME”

Name of active ingredient: “name(s) of active ingredient(s)”

Dosage Form

- The dosage form is the name for the drug dosage form taken from the controlled terminology. Only terms in the controlled terminology are allowed.



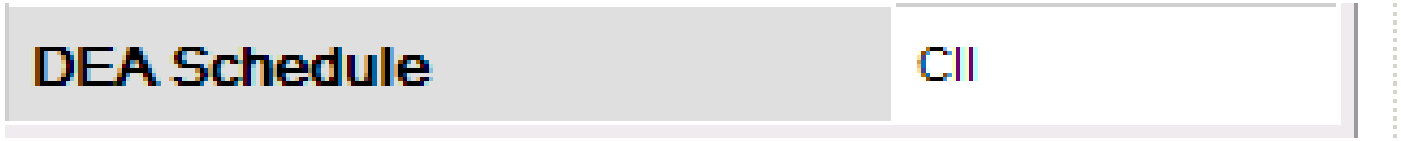
Route of Administration

- Labeled route of administration is the name of the route of administration taken from the controlled terminology. Only terms in the controlled terminology are allowed. A product may have one or more route of administration.

Route Of Administration	SUBCUTANEOUS, INTRAMUSCULAR

Controlled Substance Code

- The abuse potential category to which an active ingredient, or combination of active ingredients, is assigned, as regulated by both the United States Drug Enforcement Administration (DEA) and the United States Food and Drug Administration. The controlled schedule may be found near the title of the label or in the narrative portion of the label.



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.

- SPL R4 note: Active moieties - more than one active moiety can be included for each active ingredient.

Active Ingredient

- Active Ingredients - SPL R3

INGREDIENTS		
Name (Active Moiety)	**Type**	**Strength**
name(s) of active ingredient(s) (name of active moiety)	Active	500 MILLIGRAM In 1 TABLET

- Active Ingredients - SPL R4

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

Inactive Ingredient

- The inactive ingredient includes the ingredient name, identifier, and strength. The drug listing data elements may include the inactive ingredients listed in the labeling, however, products (proprietary mixtures of ingredients such as coatings and inks), ambiguous ingredients (such as flavors and fragrances) or other “ingredients” that don’t qualify for a UNII are not included. Only the ingredient name is included in the drug listing data elements. The inactive ingredient strength is included if it is in the label. Future enhancements will allow inclusion of confidential inactive ingredients.

Inactive Ingredients	
Ingredient Name	Strength
name of inactive ingredient	

Strength

- Strength should be described as a ratio. The units of measure (e.g., milligrams) and units of presentation (e.g., tablets) names are taken from controlled terminology. Only terms in the controlled terminology are allowed. The metric system is used for units of measure. The strength used should be the one used to describe the drug clinically and may be based on either the active moiety or active ingredient.

- Strength for powder is presented as reconstituted. For ranges, use middle, upper or lower limit as best for **clinical understanding and safety**.

- In most cases, the strength used is that for a single dose following the conventions in the table on the next slide. In the table, an example of “weight” is milligrams, an example of “volume” is milliliter, and an example of “each” is tablet.

ld

Slide 44

lds3 Rik Lostritto to provide verbiage on strength of ingredients

FDA User, 9/20/2007

Strength cont…

- SPL R4 documents will allow companies to **designate strength based on the active ingredient, active moiety or a reference drug.**

  Example of non-solid dosage form

  Numerator: **10 mg**
  Denominator: **1 mL**

  Example of solid dosage form

  Numerator: **10 mg**
  Denominator: None

ld

Slide 45

lds4 Rik Lostritto to provide verbiage on strength of ingredients

FDA User, 9/20/2007

Strength cont…
Release Three & Four

Product	Numerator unit	Denominator unit
Oral solid	Weight	Each
Oral liquid	Weight	Volume
Oral powder for reconstitution with a known volume	Weight	Volume
Oral powder for reconstitution with a variable volume	Weight	Each
Suppository	Weight	Each
Injection liquid	Weight	Volume
Injection powder for reconstitution with a known volume	Weight	Volume
Injection powder for reconstitution with a variable volume	Weight	Each
Inhaler powder	Weight	Each
Inhaler liquid	Volume	Each
Inhaler blister	Weight	Each
Topical cream or ointment	Weight	Weight
Topical gel or lotion	Weight	Volume
Transdermal patch	Weight	Time
Bulk liquid	Weight	Volume
Bulk solid	Weight	Weight

Color

- The color of the solid or liquids dosage form is the **predominant color or approximate color**, not the specification for the name in the labeling. There can be **more than one color** such as the color of the sides of a tablet and halves of capsules. **Imprints and bands on capsules are not included in the color.**

- There are **twelve SPL colors** –black, gray, white, red, purple, pink, green, yellow, orange, brown, blue, turquoise. The name is taken from these terms and only terms in the controlled terminology are allowed. **An original text field may be used to more specifically describe colors.** However, applicant should not include “cap” or “body” in the description of color. (e.g. purple cap, yellow body)

Color	WHITE (white to off-white)

Shape

- 2-D representation of the outside perimeter of an oral solid dosage form
- **Includes rounding of corners; excludes embossing, scoring, debossing, internal cutouts**
- **19 SPL shapes**: bullet, capsule, clover, diamond, double circle, freeform, gear, heptagon, hexagon, octagon, oval, pentagon, rectangle, round, semi circle, square, tear, trapezoid, triangle.
- The name is taken from these terms and only terms in the controlled terminology are allowed. An **original text (free text) field is available to specifically describe a shape.**

Shape	OVAL (capsule-shaped)

Size

- The size is the longest single dimension for an oral solid dosage form; Length for rectangle, diameter for circle. **Millimeters rounded to the nearest millimeter**

Size	12mm

Score

- The score is the number of equal pieces that an oral, solid, dosage form can be divided using the score line(s).

Description	Value
No score	No score
Bisect (two equal pieces)	2 pieces
Trisect (three equal pieces)	3 pieces
Quadrisect (four equal pieces)	4 pieces
Unequal pieces	

Imprint Code

- The imprint code is the alphanumeric text on solid dosage forms. **Includes embossed, debossed, engraved, and printed; Excludes trademark letters, marks, symbols, internal and external cutouts**
- Start top left with **semi-colon** to show separation between words or line divides

Imprint Code	XXX;1234

Packaging

Single level of packaging

PACKAGING			
#	NDC	Package Description	Multilevel Packaging
1	0009-3776-01	42.5 GRAM In 1 TUBE, WITH APPLICATOR	None

Multi-level of packaging

PACKAGING			
#	NDC	Package Description	Multilevel Packaging
1	63481-445-01	1 VIAL In 1 BOX	contains a VIAL, MULTI-DOSE
1		10 MILLILITER In 1 VIAL, MULTI-DOSE	This package is contained within the BOX (63481-445-01)

SPL Release Four
Product Data Elements Example

- See next slide

PROPRIETARY NAME - name(s) of active ingredient(s) dosage form
Labeler

SPL Release Four Drug Listing Data Elements (Example w/Nonsolid Oral Dosage Form) - Revised Stylesheet

PROPRIETARY NAME

name(s) of active ingredient(s) dosage form

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**NDC Product Code (Source)**	0001-0001
Route of Administration	ORAL	**DEA Schedule**	

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

Inactive Ingredients

Ingredient Name	Strength
name of inactive ingredient	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	0001-0001-02	5 mL In 1 VIAL	None

NDC Labeler Code Request

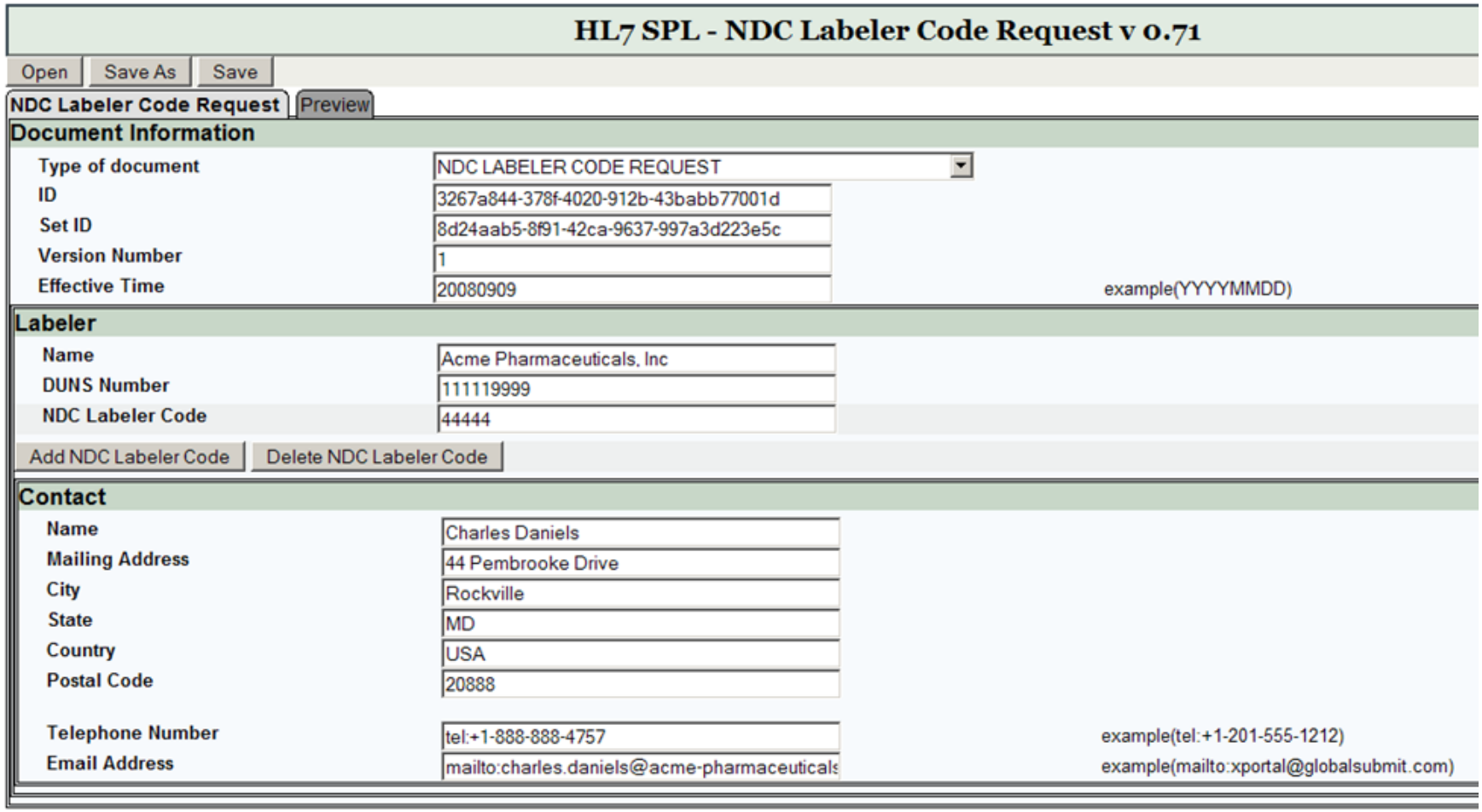
NDC Labeler Code Request Data

- **Document Information**
  - Type of document
  - ID
  - Set ID
  - Version Number
  - Effective Time
- **Labeler**
  - Name
  - DUNS Number
  - NDC Labeler Code
- **Contact**
  - Name
  - Mailing Address
  - City
  - State
  - Country
  - Postal Code
  - Telephone Number
  - Email Address

NDC Labeler Code Request Data

- **Document Information**
  - Type of document
  - ID
  - Set ID
  - Version Number
  - Effective Time
- **Labeler**
  - Name
  - DUNS Number
  - NDC Labeler Code
- **Contact**
  - Name
  - Mailing Address
  - City
  - State
  - Country
  - Postal Code
  - Telephone Number
  - Email Address

NDC Labeler Code Request Xforms View



NDC Labeler Code Request SPL Document

Acme Pharmaceuticals, Inc

Product Information	
Product Type	NDC LABELER CODE REQUEST

Labeler – Acme Pharmaceuticals, Inc (111119999) **NDC Labeler Code:** 44444

Contact	Address	Telephone Number	Email Address
Charles Daniels	Address: 44 Pembrooke Drive City, State, Zip: Rockville , MD, 20888 Country: USA	+1-888-888-4757	charles.daniels@acme-pharmaceuticals.com

NDC LCR SPL Scenarios

- **Requesting a new NDC Labeler Code**
  - Fill out the *NDC Labeler Code request* as described in sections 2.1 through 2.4 leaving the NDC Labeler Code field empty.
  - Requests for NDC Labeler Codes are individually evaluated prior to entry into the NDC System. The initial request will be automatically stopped because there is no NDC Labeler Code provided and is diverted to a FDA reviewer. Once the evaluation is completed, the response to the request is directed to the designated contact person.
  - Once the NDC Labeler Code is assigned, open the original SPL file and add the newly assigned NDC Labeler Code and resubmit the corrected file.
- **Initial electronic submission when NDC Labeler Code already assigned**
  - Fill out the *NDC Labeler Code request.* Only one NDC Labeler Code is included in an SPL file. In other words, use a different setId root for each NDC Labeler Code request.

NDC LCR SPL
Scenarios cont…

- **Correct SPL file validation error**
  - If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.
- **Correct a mistake in an SPL file just submitted**
  - Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

NDC LCR SPL
Scenarios cont…

- **Update the NDC Labeler Code information**
  - Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.
- **Requesting a second NDC Labeler Code**
  - Only one NDC Labeler Code is associated with each *NDC Labeler Code request*. If a second NDC Labeler Code is requested, fill out a separate SPL file with a **different setId root**. The labeler information and contact information is the same as the SPL file for the first NDC Labeler Code request

Notes

- Use NDC Labeler Code used in NDC Package Code (3-segment NDC)
- Submit NDC labeler codes that are used in NDCs associated with distributed products. (NDC on packaging)
- Only one NDC labeler code per NDC Labeler Code Request.
- NDC Labeler Code – Code should be identical to first segment of NDC (no leading zeros)

Electronic Registration of **Drug** Establishments

- Each Registrant (owner/operator firm) must submit one SPL file with registration information for all of its facilities (unlimited amount of domestic or foreign establishments permitted per file)
- Updates of information require re-submission of the same updated SPL file (i.e., same setID; at least annually)
- Simplified SPL files are submitted for ‘No Change’ or ‘Out of Business’ notification

Benefits

- Registrant can include all **drug** establishments it owns/operates in one SPL file (replaces need to submit one paper 2656 form for each establishment.)
- Update registration data “instantly” (No FDA data entry required)
- Re-register all establishments annually with one file
- View updated information on Drug Firms Annual Registration Status (DFARS) website.
- Locate DUNS Numbers of manufacturers on DFARS website

Transitioning from Paper to Electronic: Drug Registration and Listing Note

- If you register your drug establishment(s) **electronically**, do not register the same drug establishment(s) using the **paper** (FDA Form 2656)
- Applies to establishment electronically registered (beginning July 200**8**)

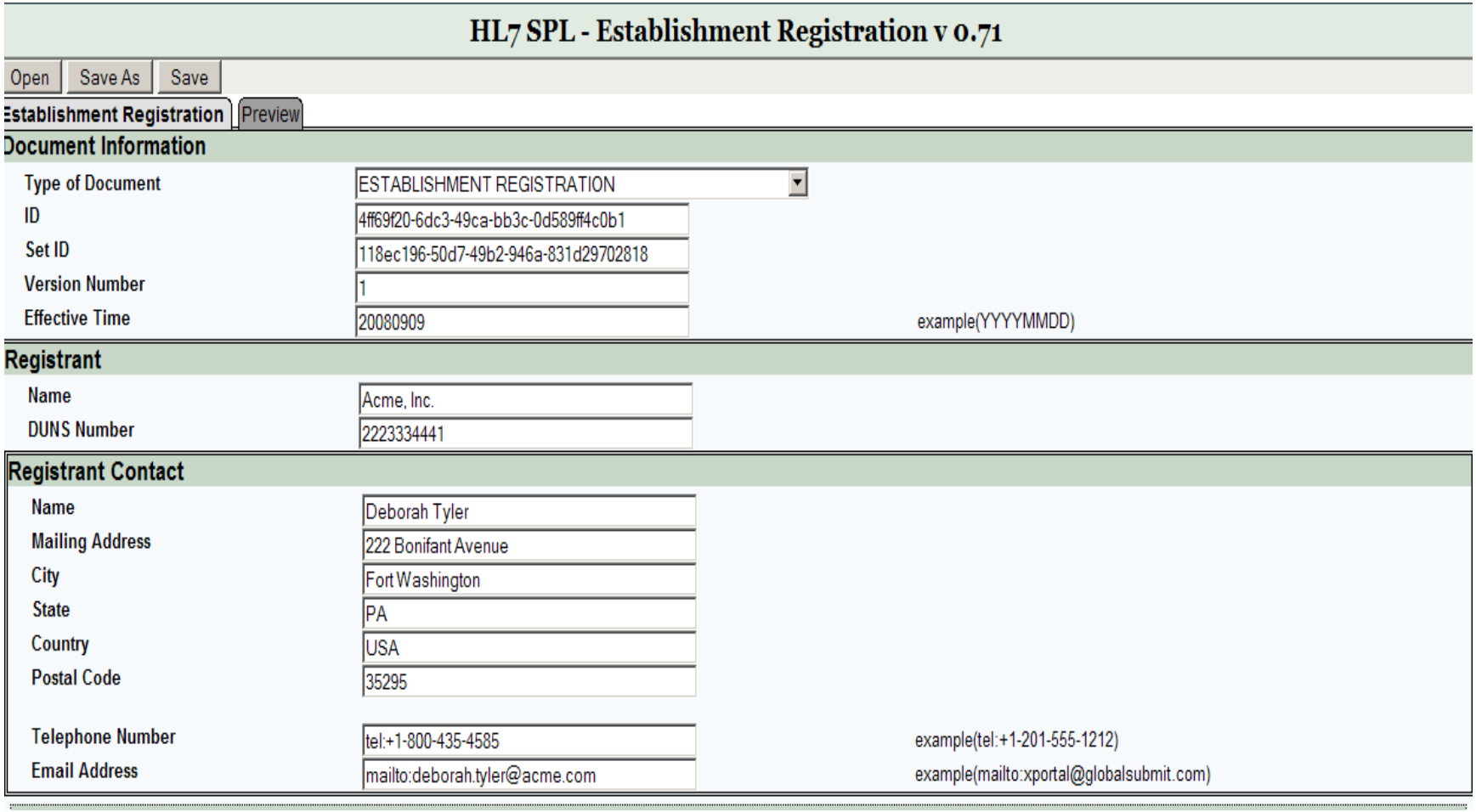
Establishment Registration Data

- **Document Information**
  - Type of Document
  - ID
  - Set ID
  - Version Number
  - Effective Time
- **Registrant**
  - Name
  - DUNS Number
- **Registrant Contact**
  - Name
  - Mailing Address
  - City
  - State
  - Country
  - Postal Code
  - Telephone Number
  - Email Address

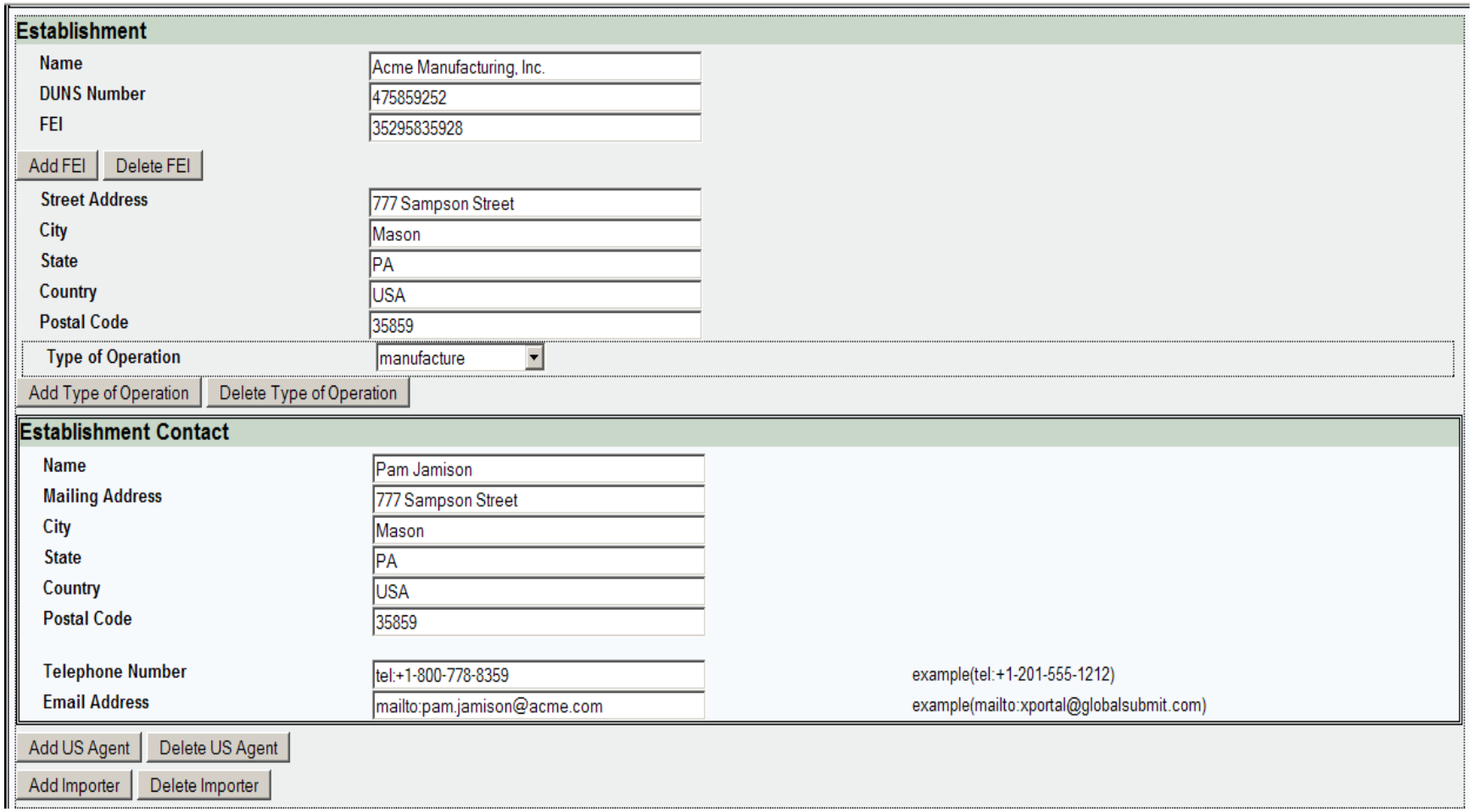
Establishment Registration Data (cont…)

- **Establishment**
  - Name
  - DUNS Number
  - FEI
  - Street Address
  - City
  - State
  - Country
  - Postal Code
  - Type of Operation(s)
- **Establishment Contact**
  - Name
  - Mailing Address
  - City
  - State
  - Country
  - Postal Code
  - Telephone Number
  - Email Address

Establishment Registration
SPL Xforms View



Establishment Registration
SPL Xforms cont…



Establishment Registration SPL Document

Product Information	
Product Type	ESTABLISHMENT REGISTRATION

Registrant – Acme, Inc. (2223334441)

Contact	Address	Telephone Number	Email Address
Deborah Tyler	Address: 222 Bonifant Avenue City, State, Zip: Fort Washington, PA, 35295 Country: USA	+1-800-435-4585	deborah.tyler@acme.com

Establishment

Name	Address	ID/FEI	Operations
Acme Manufacturing, Inc.	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	475859252	manufacture

Contact	Address	Telephone Number	Email Address
Pam Jamison	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	+1-800-778-8359	pam.jamison@acme.com

Electronically Registered Drug Establishments Online

- Example of actual Drug Firms Annual Registration Status Website Display

Pfizer approved use of their data in presentation

Website address: **http://www.fda.gov/cder/dfars/docs/querydrls.htm**

Pfizer Laboratories Div Pfizer Inc	1819598	006059075	100 Pfizer Drive Terre Haute, IN 47802 USA	2008
Pfizer Laboratories Div Pfizer Inc	2410924	134489525	630 Flushing Avenue Brooklyn NY 11206 USA	2008
Pfizer Labotories Div Pfizer Inc	1211022	148697167	Eastern Point Road Groton, CT 06340 06340	2008

Initial Establishment Registration Submission

- Initial electronic submission for establishments already registered
  - Registrants include information for **all** of their establishments in one *Establishment Registration* SPL file. Each establishment is in only one **ER** SPL file.
  - If establishment is included in another **ER** SPL w/different setID, SPL will FAIL validation

Electronically Requesting an FEI Number

- Request an FEI Number using SPL
  - Include all establishments in one file.
  - Add the FEI numbers for all of the previously registered establishments (registered in paper or electronic format)
  - Include information for new establishment (leave FEI number field empty)
  - Request for FEI will be routed to appropriate FDA team

Correcting an ER SPL with Validation Error

- Correct SPL file validation error

  – If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.

  SPL file **never** made it into the FDA eList system

Correcting Mistake in Valid SPL Just Submitted

- Correct a mistake in an SPL file just submitted

  – Open the SPL file, correct the mistake,
  – Use
    - **new id root**
    - **new version number**
    - **original setId root**
    - appropriate effective time.

  ***SPL file was **valid** and loaded into FDA eList system

Updating an ER SPL

- Update information for an **electronically** registered establishment
- Update anytime during year **or** for annual registration

  – Open 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**
    - appropriate effective time.

Adding a New Establishment

- Add a new establishment to your ER SPL file:
  - Open 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
    - appropriate effective time.

Removing an Establishment

- Remove a previously **electronically** registered establishment

  - Open 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 of your ER SPL
    - appropriate effective time.

Establishment Re-Registration No Changes

- Simple process for annually re-registering establishments which have no changes
- Must have already **electronically** registered the establishments once.
- Submit No Change Notification SPL

Establishment Re-Registration No Changes

- No changes to registration information
  - Each year when the information is updated, if there is no change:
    - Create an SPL file with the *document type* **No change notification** with 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* **No change notification**.

Establishment
No Change Notification SPL

Product Information	
Product Type	NO CHANGE NOTIFICATION

Revised: 04/2008

Going Out of Business?

- Registrant goes out of business
  - 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**.
  - Applicable for registrants who electronically registered establishments

Establishment
Out of Business Notification

Product Information	
Product Type	OUT OF BUSINESS NOTIFICATION

Revised: 09/2008

Certified 2656 Paper Form?

- No certified paper forms for e-registered establishments
- Check DFARS website for electronically registered establishments

Common Errors in Establishment Registration SPL

- Incorrect telephone format
- Wrong e-mail format
- Incorrect ISO-3166 Country Code
- Mismatch for DUNS Number & Establishment name
- Files uploaded to Gateway without a folder

Participation in Voluntary Pilot Program

- Start with NDC Labeler Code Request
  - Receive feedback from Agency
  - Slowly acclimate to the new eList system
  - Prepare for June 1, 2009

Accomplishments

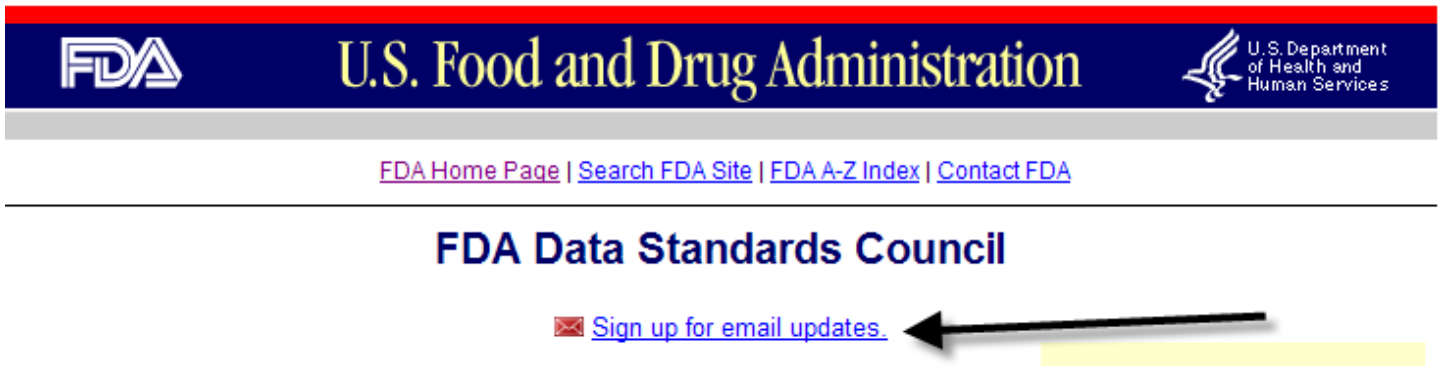
- FDA (CDER) has been using the SPL standard for over 3 years
- Quality of SPL documents has improved significantly since October 2005
- DailyMed - **1.6 million** hits per month – (New website less than 3 years old)
- Over **4,350** SPL documents posted on DailyMed (as of February 2009)
- Several companies have participated in drug eList & eReg pilot

SPL R4 2009 Winter/Spring Training Session Schedule

- Session 1 – February 4, 2009 – March 11, 2009, Web Conferences
- Session 2 – March 18, 2009 – April 22, 2009, Web conferences
- Session 3 - May 21, 2009, Face-to-Face – Rockville, MD, Parklawn Conference Room D, 9:30 a.m. – 3:30 p.m.
- Session 4 – February 5, 2009 – March 12, 2009
- Session 5 – March 19, 2009 – April 23, 2009

Stay Informed

- FDA Data Standards Council website listserv
  - Over **26,000** listserv subscribers as of February 2009
  - http://www.fda.gov/oc/datacouncil/



SPL-related Technical Assistance/Questions

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

Thank you!