

FDA's Proposed Revised 21 CFR 207 Rule and Electronic Drug Registration and Listing Systems (e-DRLS)

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U.S. Department of Health and Human Services

Food and Drug Administration

Proposed Revised 21 CFR 207

- **Electronic submission of Registration and Listing information**
 - Establishment Registration through DFRM/FURLS
 - Drug Product Listing information through eLIST
- **Electronic submission of Content of Labeling**
- **FDA issues the complete NDC number**
 - FDA posts valid NDC numbers in NDC Directory & DailyMed
- **NDC number printed on product labels**
 - Most recent firm's NDC number (traceable back to origin)
- **Firms must re-certify their Listing information every 6 months**

What is DRLS?

- **Establishment Registration and Drug Listing laws were enacted to help protect the public from adulterated and misbranded drugs**
- **Drug establishments must Register annually with FDA, providing names, addresses, contact information, and manufacturing roles**
- **Firms must List with FDA all drug products being marketed in the United States, providing names, ingredients, manufacturer, etc.**

DRLS Use: Drug Regulation and Enforcement

- **Repository of NDC numbers; Registration provides labeler component of NDC**
- **Registration provides locations and contact information for drug establishments and identifies sites for inspection**
- **Listing provides manufacturing information and ingredients for marketed drug products**
- **Helps identify violative drug products**
- **Assists with control of drug imports**

DRLS Use: Drug Safety

- **Supports SPL/DailyMed Initiative and provides linkage of drug product identification with drug product labeling, FDA approval, and manufacturer and marketer information**
- **Helps support Counter-Terrorism efforts**
- **Helps support BSE control programs**
- **Supports FDA safety-related databases**
- **Identifies products in drug shortages and product ingredients for recalls**
- **Provides repository of drug product labeling**

DRLS Use: Drug Billing and Reimbursement

- **CMS uses DRLS information to determine drug eligibility for Medicare and Medicaid reimbursement and rebate programs**
- **The NDC Directory is widely used by public and private organizations to identify drug products for third-party reimbursement and for additional data analyses**
- **Nearly all drug/pharmacy billing systems use the NDC numbers archived in DRLS and published in the NDC Directory**

Database History

- **Started as paper system in 1970s**
- **Current Oracle system created 1991**
- **Electronic Registration and Listing Systems currently in development**
 - **DFRM/FURLS — Online Drug Facility Registration**
 - **eLIST — Electronic Drug Product Listing**

DRLS Database*

■ Total Active Facilities

- *Human Drug Domestic Manufacturing Sites – 9,417*
- *Human Drug Foreign Sites – 6,068*
- *Domestic Private Label Distributor Sites – 8,586*
- *Veterinary Drug Sites – 3,441*

■ Total Active Products

- *Total Rx Drug Products – 68,219*
- *Total Bulk Ingredients – 17,446*

■ 10,337 registration forms and 30,571 listing forms entered in 2005

* as of 8/4/2006

Registration Database Information

■ Firm information:

- Name
- Labeler code
- Contacts & Compliance address (usually HQ)
- US Agent and Importers (if foreign)

■ Manufacturing site information:

- FEI number (FDA Establishment Identifier)
- Site address and function
- Mailing address
- Parent Company
- Other firms operating at site
- Registration History
- Country code (based on Site address)
- Human drug site, Vet drug site, or both
- Types of Operations performed

Drug Listing Database Information

■ Product information

- Listing Status
- Full NDC (National Drug Code [Labeler-Product-Package])
- Trade name and generic name
- Rx/OTC; DEA class
- Formulation – includes active and inactive ingredients and active ingredient strengths
- Dosage form and route of administration
- Packaging information: size, type, quantity

■ Firm's function

- Manufacturer
- Repacker
- Labeler
- Private Label Distributor

Future → e-DRLS

- **Plans for e-DRLS to provide electronic submission and online annual/semi-annual verification/updating of registration/listing**
- **This will greatly improve data accuracy, minimize data input requirements, and allow more focus on safety and regulatory issues**
- **Plans for e-DRLS to implement new features of registration and listing, including partially-automated validation of listings**

Drug Establishment Registration

- **Electronic registration is coming!**
- **The Drug Facility Registration Module (DFRM) is implemented in the FDA Uniform Registration & Listing System (FURLS)**
- **FURLS will soon provide access for industry**
- **Firms logging-in to FURLS will utilize DFRM to enter firm and importer information**
 - **All paper forms will eventually be eliminated**
 - **Annual updating will be greatly simplified**
 - **Other FDA systems will eventually utilize FURLS as the master inventory of drug establishments & their official contact and importer information**

DFRM Update Registration

[Hypothetical Firm]

DFRM
Drug Facility Registration Module



FDA

[FURLS HOME](#)

[DFRM HOME](#)

[Step 1](#)

[Step 2](#)

[Step 3](#)

[Step 4](#)

[Step 5](#)

[Step 6](#)

[Step 7](#)

Step 8

[Get Help](#) 

Please review your registration.

If all information is correct, click the **Submit** button below.
To make changes to a section, click the **Edit** button for that section.

Date: 09/07/2006 11:56:14

Last Updated: 09/07/2006 11:56:14

Last Modified by: DFRM-MIG

Registration Status: VALID

Section 01

Type of Registration

[> Edit](#)

DFRM Update Registration

[Hypothetical Firm]

Section 01

Type of Registration

> Edit

1a. Domestic Registration

1b. FEI Number: 1000110317

1c. Update of Registration Information : *Registration number : 114714 Pin number : p\$!3703*

Are you the new Owner of this Previously Registered Facility? Yes No

Type of Registration:

- Medicated Feed
- Human Drug
- Human Biologic
- Veterinary Drug
- Veterinary Biologic

Type of Ownership : Corporation

DFRM Update Registration

[Hypothetical Firm]

Section 02

Facility Name / Address Information

> Edit

Facility Name : AVE ITURREGUI ESQ CALLE B

Labeler Code: 058238

Facility Street Address, Line 1 : 18 SABANA ABAJO IND PARK

Facility Street Address, Line 2 :

City : CAROLINA

State/Province/Territory : PUERTO RICO

Zip Code (Postal Address):

Country : United States

Phone Number (Include Area & Country Code, if applicable): 787 7013312

Fax Number (Include Area & Country Code, if applicable):

Email Address:

DFRM Update Registration

[Hypothetical Firm]

Section 03

Preferred Mailing Address Information

[> Edit](#)

(Complete this section only if different from Section 2, Facility Name/Address Information)

Name: NO GIVEN ADDRESS HEADER

Address, Line1:

Address, Line2:

City: SAN JUAN

State/Province/Territory: PUERTO RICO

Zip Code(Postal Code):

Country: UNITED STATES

Phone Number (Include Area & Country Code, if applicable): 787 7013312

Fax Number (Include Area & Country Code, if applicable):

Email Address:

DFRM Update Registration

[Hypothetical Firm]

Section 04

Parent Company Name/Address Information

> Edit

(If applicable and if different from Sections 2 and 3).

Name of the Parent Company: NO FIRM

Street Address of the Parent Company, Line 1: 2190 PKY LAKE DR

Street Address of Parent Company, Line2:

City: BIRMINGHAM

State/Province/Territory: ALABAMA

Zip Code(Postal Code):

Country: UNITED STATES

Phone # of Individual at Parent Company (Include Area & Country Code, if applicable):

Fax # of Individual at Parent Company (Include Area & Country Code, if applicable):

Email Address of Individual at Parent Company:

DFRM Update Registration

[Hypothetical Firm]

Section 05

Facility Official Contact Information

[> Edit](#)

Individual's Name: NO GIVEN ADDRESS HEADER

Title:

Emergency Contact Phone(Including Area/Country code): 787 7013312

Email Address:

Section 06

Trade Names

[> Edit](#)

Alternate Trade Name #1:

Alternate Trade Name #2:

Alternate Trade Name #3:

Alternate Trade Name #4:

DFRM Update Registration

[Hypothetical Firm]

Section 07

United States Agent

[> Edit](#)

(Not Applicable)

(To be Completed by Facilities located outside any state or territory of the United States, District of Columbia, or the commonwealth of Puerto Rico)

United States Agent Address is Applicable for Foreign Registrations only.

Name of U.S. Agent:

Title:

Address, Line1:

Address, Line2:

City:

State:

Zip Code(Postal Code):

Country:

Phone Number (Include Area & Country Code, if applicable):

Fax Number (Include Area & Country Code, if applicable):

Email Address:

Structured Product Labeling

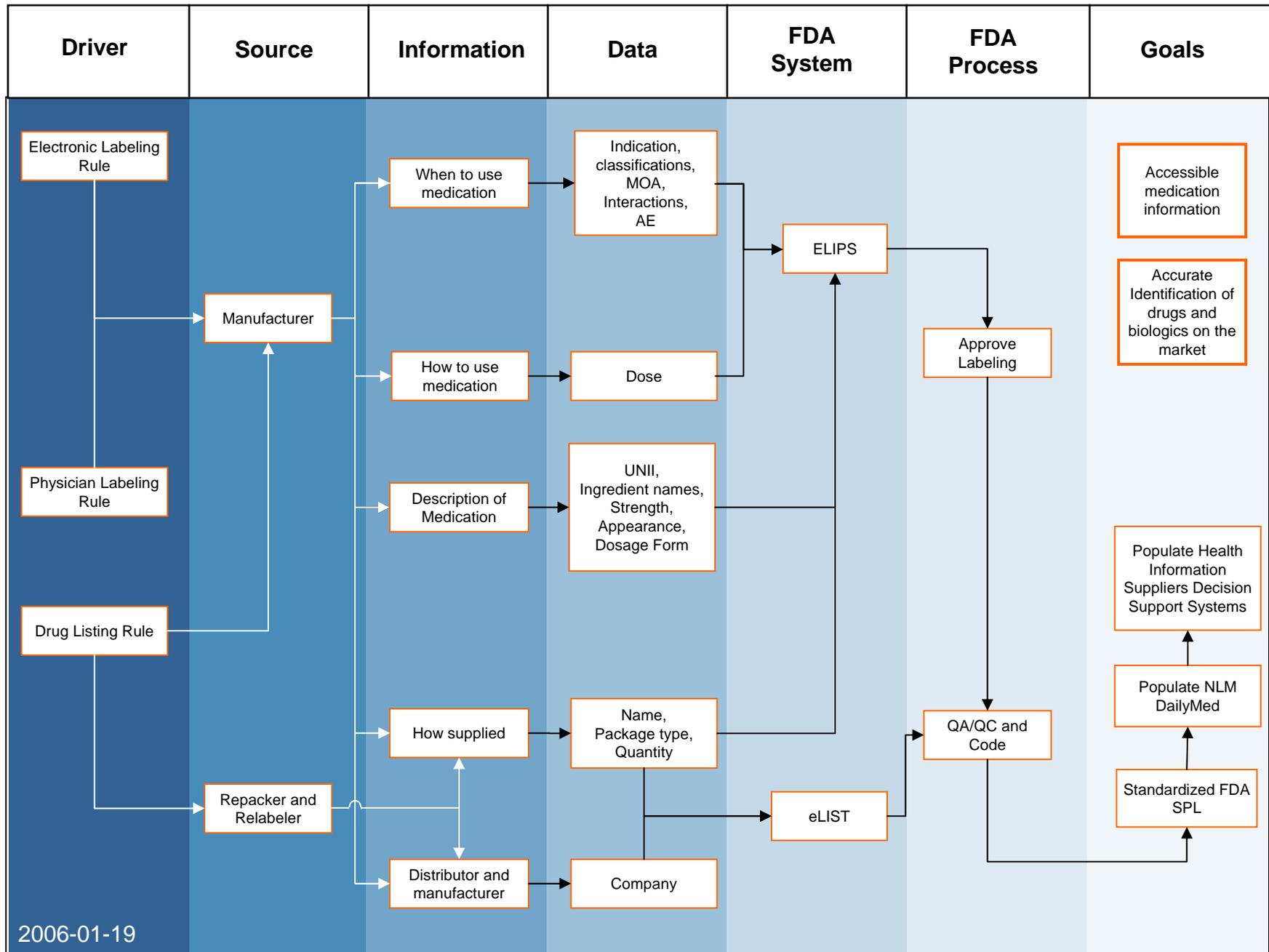
- The Electronic Labeling Rule provided a platform for XML electronic Structured Product Label (SPL) – content of labeling
- SPL allows electronic edit, search, review, and archiving of drug labeling – [prescriber package insert]
- In October 2005 industry started providing SPL for application human prescription drugs
- After FDA review, these are posted for public access/download at NLM's DailyMed web site
<http://dailymed.nlm.nih.gov/dailymed/>
- This will eventually integrate with electronic prescribing & public drug information access

Electronic Listing – eLIST

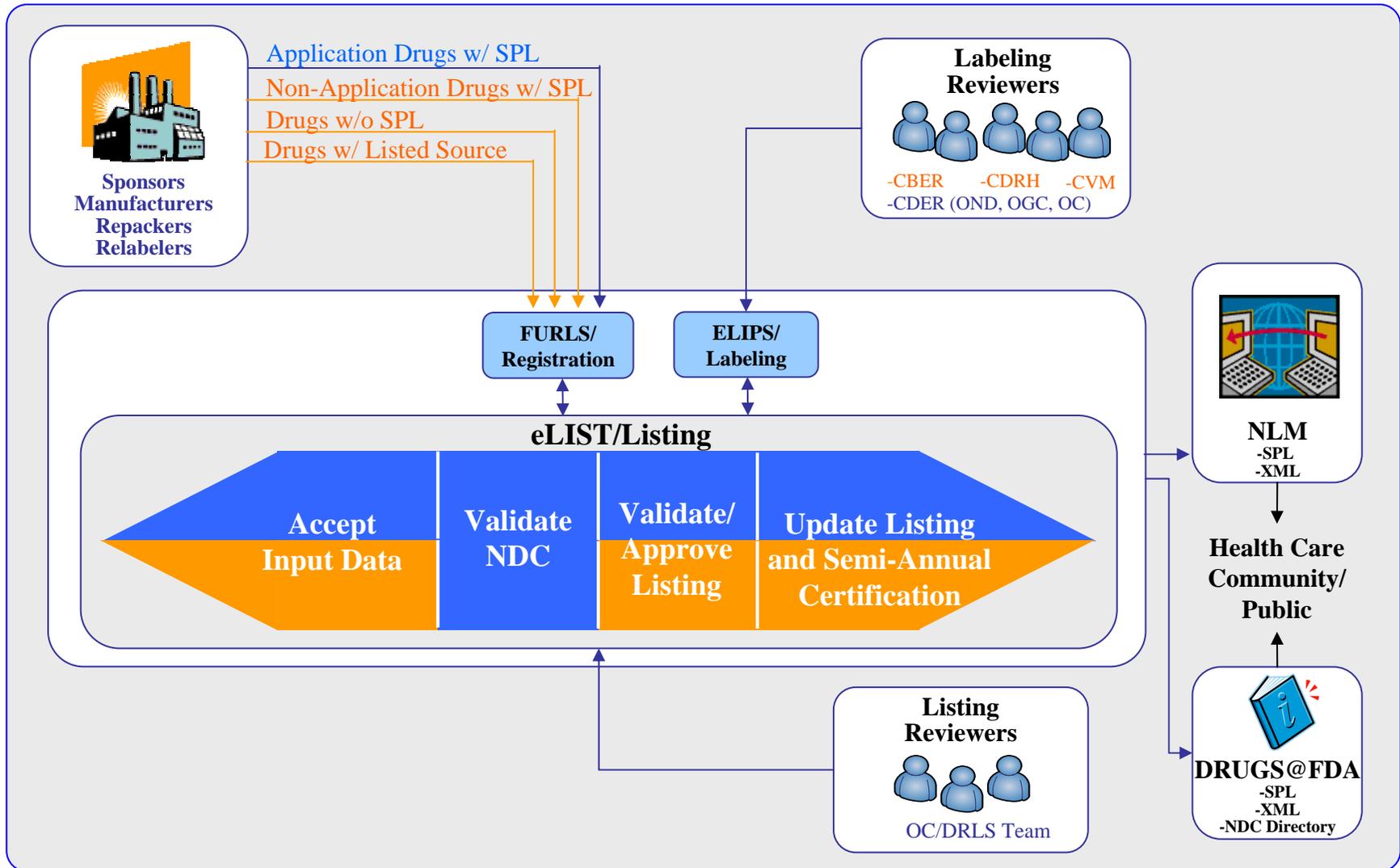
- **FDA is developing an electronic listing system (eLIST) that will eventually allow industry to provide listing information via SPL submission**
- **SPL includes coded data elements for most of the required listing information**
- **eLIST will extract coded data from the SPL for Listing; industry will log-in through FURLS to provide some information not in the SPL**
- **eLIST will validate listing information, including NDC number, drug approval, and label approval prior to public posting in DailyMed and the NDC Directory**

Efficiencies with eLIST

- **The planned eLIST is designed to greatly facilitate drug listing for industry and improve accuracy and completeness of data**
 - **Eliminate duplicative and redundant data entry**
 - **Ensure that listing data matches labeling (SPL)**
- **eLIST will automate validation of drug approval status and of compliance with certain OTC Monograph requirements**
- **eLIST will provide electronic archiving for drug product labels**
- **eLIST will provide accurate linkage with NDC Directory and FDA's drug information systems**



LISTING PROCESS



Scope of Meeting – NDC Issues

- **NDC number printed on product label**
 - **Appropriate NDC number (of last firm handling product)**
 - **Format of printed NDC number (NDC XXXXX-YYYY-ZZ)**
- **FDA assigns/issues the full NDC number**
- **NDC number & use restrictions**
 - **Product code must be different for different formulation or manufacturer**
 - **Must be the same for same formulation & manufacturer**
 - **May not use same NDC number for different products**
 - **May not use NDC for non-drugs**
- **NDC chain exempted from public disclosure**
- **Configuration of NDC number (10 vs 11 digits)**