# Structured Product Labeling Project for the DailyMed Initiative

June 4, 2004

# Purpose

- Improve patient safety through accessible product information
- Support initiatives to improve patient care by better management of health care information
  - Electronic prescribing
  - Decision support systems
- Meet mandates to provide standards for drug information (labeling, terminology, code sets)
  - Medicare Modernization Act
  - Electronic Health Record

# Current Problems to Address

- Drug labeling information inaccessible
  - Difficult to read - Font size and paper shape limits readability and duplication
  - Difficult to access – distribution limited (e.g., pharmacy shelf)
  - Difficult to use – information in paper labels cannot be accessed by computer systems
- Drug terminology and code sets inadequate
  - Not standardized, code sets incomplete and not up to date
- As a result current health care systems use information from third party sources
  - Not FDA/pharmaceutical information - outdated, incorrect, misleading
  - No standards for drug terminology and code sets

# Solution

- Improve Drug information
  - Better organization
  - Consistent structure
  - Computer format
  - Standard terminology and code sets

# Partners

- Manufacturers
  - Provide up to date product information in electronic format (Structured Product Labeling, product listing)
- National Library of Medicine
  - Distribute information (DailyMed)
- Health information suppliers
  - Use in systems (e.g., electronic prescribing, decision support)

# Structured Product Labeling

- Computer file standard for product information
  - Consistent organization of product information
    - Information for each type of product in same location
    - Flexible to accommodate different labeling requirements
  - Electronic file
    - Information can be used by computer systems
  - Standards
    - Information can be exchanged between different systems (interoperable)

# Structured Product Labeling

- SPL has three basic parts
  - Header
    - General information about the label and product
  - Sections
    - Divide the label into blocks of text (e.g., indications section, contraindications section, warnings section)
    - Define list of acceptable sections based on regulations and needs
  - Data elements
    - Specific information about the product (e.g., active ingredient, dosage form, how supplied)
    - New data elements can be added
- Extensible – additions can be made to the standard based on the requirements for the product label

# SPL Sections

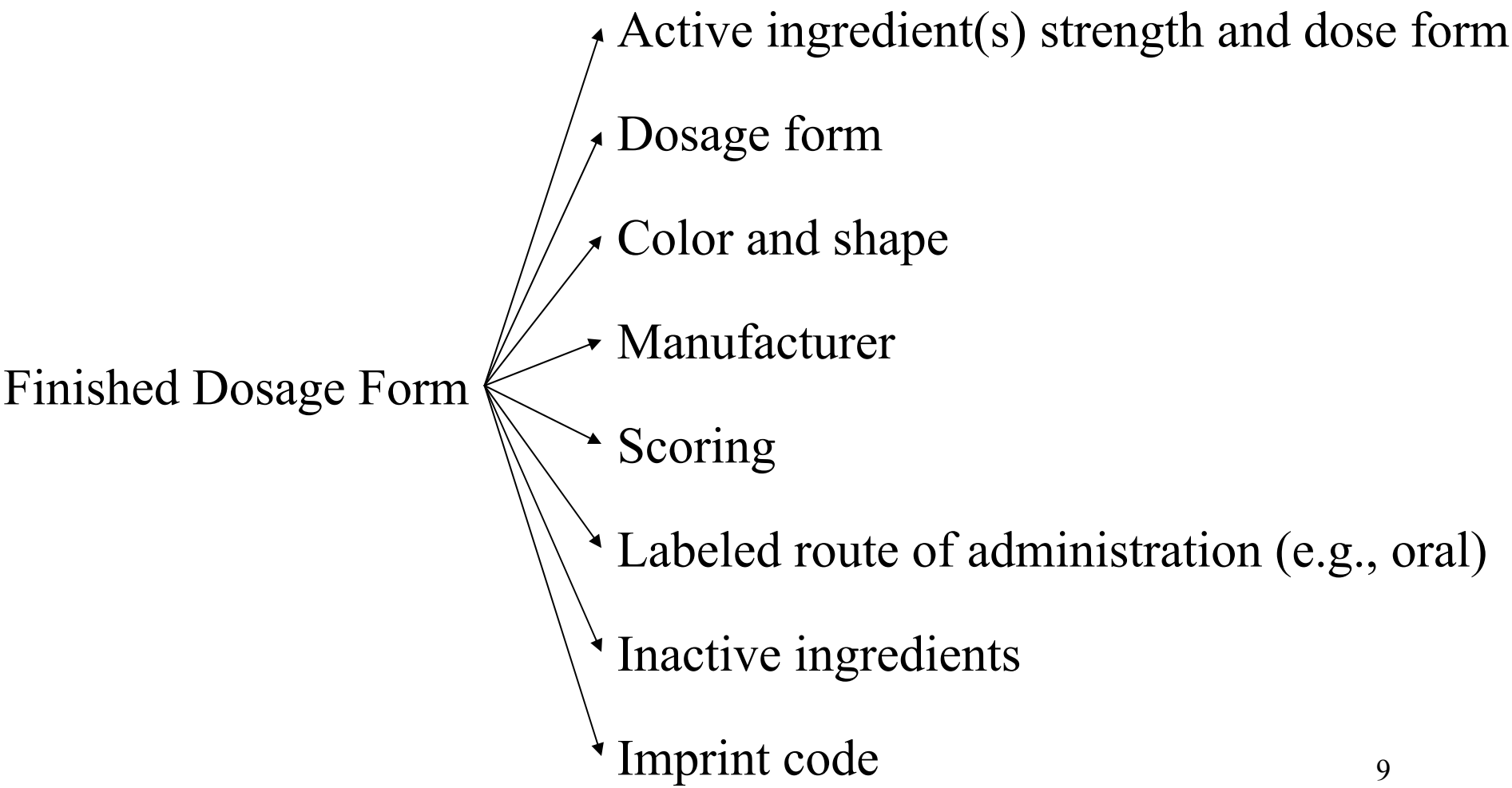
**Labeling**

- Boxed warning
- Indications and Usage
- Dosage and Administration
- How Supplied
- Contraindications
- Warnings and Precautions
- Drug Interactions
- Pregnancy
- Labor and delivery

- Lactating women
- Pediatric use
- Geriatric use
- Adverse reactions
- Drug abuse
- Overdosage
- Description

- Mechanism of action
- Pharmacodynamics
- Pharmacokinetics
- Other pharmacology
- Carcinogenicity
- Animal toxicology
- Clinical studies
- Patient counseling
- References

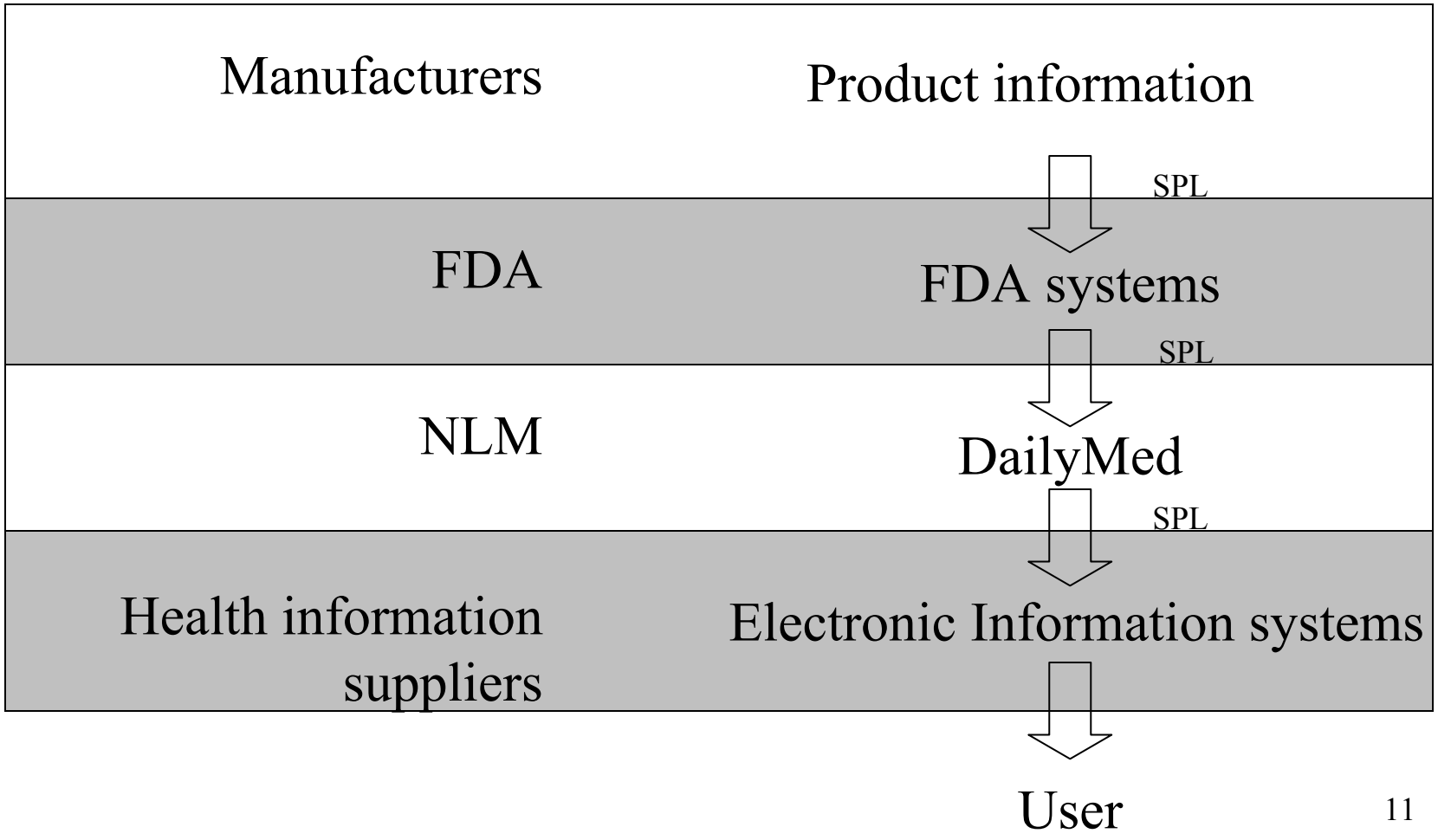
# SPL Data Elements



# DailyMed Initiative

- Electronic repository of product information
  - Up to date
  - Reliable
  - Free
- Supported by National Library of Medicine
  - Information available for download into computer systems

# Information Flow



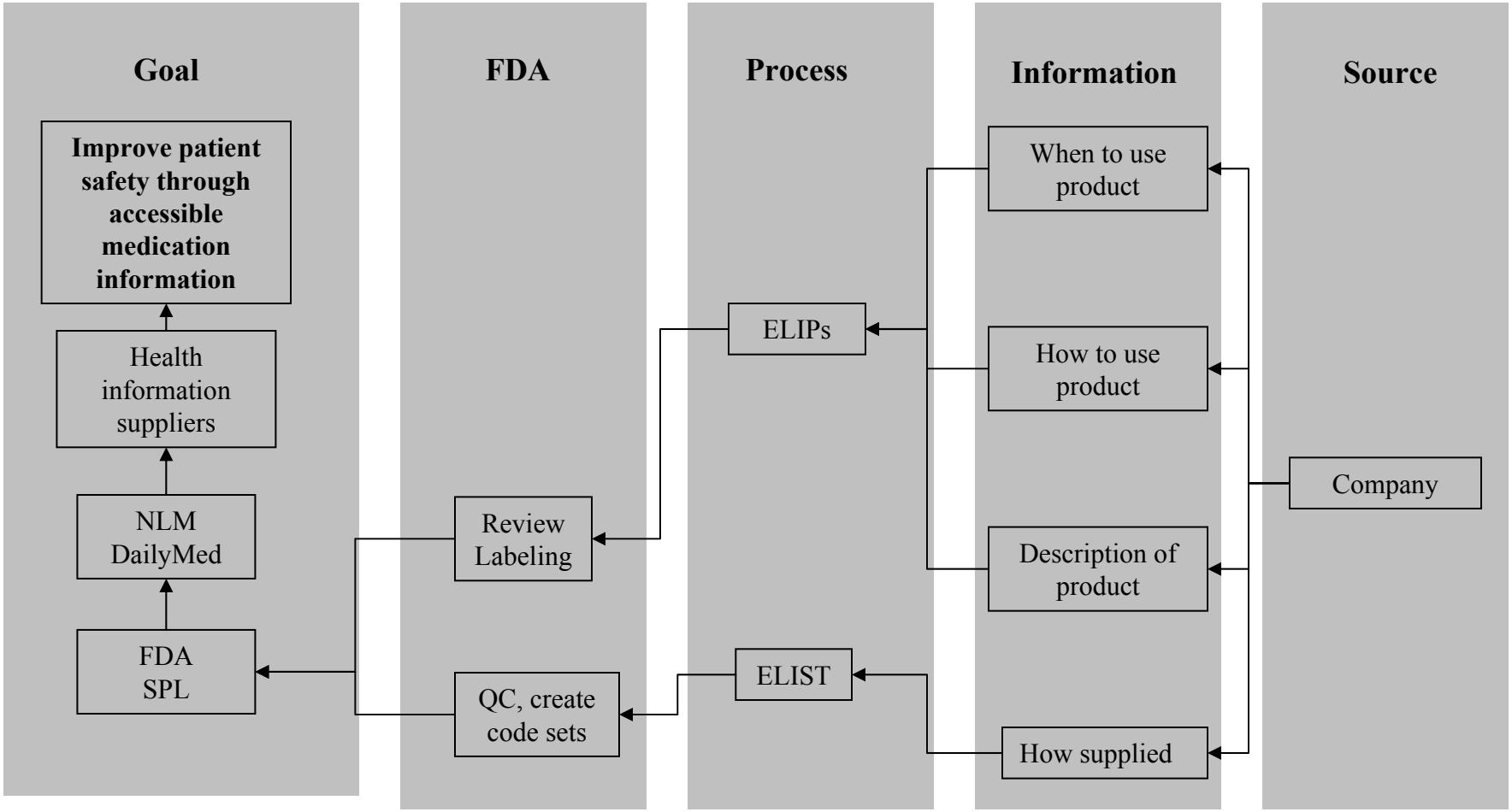
# Structured Product Labeling Project

- Create environment to
  - Receive and store information from companies
    - Labeling
    - Listing information
  - Retrieve, review, compare, edit and approve changes to labeling
  - Support terminology standards
  - Generate drug code sets,
  - Export up to date SPL to DailyMed repository

# Systems

- Electronic Labeling Information Processing System (ELIPs)
  - Content of product label
- FDA Unified Registration and Listing System (FURLS)
  - Food Facility Registration Module (FFRM)
    - Information on food facilities and products
  - Drug Facility Registration Module (DFRM)
    - Information on drug facilities
  - Electronic Listing system (eLIST)
    - Drug product code sets
- Substance Registration System (SRS)
  - Ingredient terminology and code set

# SPL for Patient Safety



# Project Phases Transition

- Content of Labeling from PDF to SPL
  - Begin – June 2004
  - Completed – July 2005
  - Regulations - ELR
  - Standards - SPL
  - Systems – EDR

# Project Phases
# SPL for Prescription Drugs

- Availability of SPL for approved prescription drugs
  - Begin – July 2005
  - Complete – July 2006
  - Regulations - ELR, PLR*
  - Standards - SPL, UNII*, Medication Terminology*
  - Systems – ELIPs, SRS*

*not required for completion

# Project Phase
# SPL for All Drugs

- Availability of SPL for all drugs
  - Begin – 2006
  - Complete – 2007
  - Regulations - DLR
  - Standards - DPC, NDC
  - Systems - eLIST, DFRM