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Structured Product Labeling and Medication Terminology

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Overview

- Medication terminology standards
- Structured Product Labeling
- FDA Systems for Supporting Medication Terminology Standards

Medication Terminology Standards

- United States collaborators
  - National Library of Medicine (NLM)
  - Department of Veterans Affairs (VA)
  - National Cancer Institute (NCI)
  - United States Adopted Names Council (USAN)
  - United States Pharmacopeia (USP)
- International collaborators
  - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- Terminology services
  - National Cancer Institute (NCI) Enterprise Vocabulary Services

FDA Medication Terminology Standards

- Ingredient
- Ingredient strength unit
- Dosage form
- Route of administration
- Package type
- Package unit
- Product
- Packaged product
- Generic drug

FDA Medication Terminology Standards

- Ingredient name
  - Authority - USAN/FDA
  - Terminology - FDA Substance Registration System
  - Example name [UNII] – ampicillin [7C782967RD], ampicillin sodium [JFN36L5S8K]
- Ingredient strength unit
  - Authority - FDA
  - Terminology - NCI Thesaurus
  - Example name [code] –milligram [C28253]
- Dosage form
  - Authority - FDA
  - Terminology – NCI Thesaurus
  - Example name [code] – tablet, chewable [C42893]

FDA Medication Terminology Standards

- Route of administration
  - Authority - FDA
  - Terminology - NCI Thesaurus
  - Example name [code] –oral [C38288]
- Package type
  - Authority - FDA
  - Terminology – NCI Thesaurus
  - Example name [code] – bottle [C43169]
- Package quantity units
  - Authority - FDA
  - Terminology – NCI Thesaurus
  - Example name [code] – tablet [C48542]

FDA Medication Terminology Standards

- Product
  - Authority - FDA
  - Terminology – FDA NDC system
  - Example name [code] – Sinemet 25/100 [0056-0650]
- Packaged product
  - Terminology – FDA NDC system
  - Example name [code] – Sinemet 25/100 bottle of 100 tablets [0056-0650-68]
- Generic drug
  - Authority - FDA
  - Example name – carbidopa – levodopa

Structured Product Labeling (SPL)

- Standard for the exchange of medication information
  - HL7 v3 standard based on Clinical Document Architecture
- SPL for drug products include:
  - Content of labeling
    - Narrative text of the labeling describing how and when to use medication
  - Drug listing data elements
    - Structured format for describing the drug product including ingredients and packaging
  - Highlights data elements
    - Structured format for describing drug indications, drug class, drug interactions and adverse reactions

Drug Listing Data Elements

- Product
  - Proprietary (brand) and nonproprietary (generic) name and code
  - Ingredient and active moiety name and code
  - Ingredient strength
  - Dosage form
  - Appearance (imprint, color, shape, size, score, coating, symbol)
  - Route of administration
  - DEA schedule
- Packaging
  - Package quantity
  - Package type and code

Highlights Data Elements

- Indication
  - Indication and limitation of use
- Pharmacological class
  - Mechanism of action, physiologic effect, chemical class
- Key interactions with drugs and foods
  - Contributing factors and consequences
- Key adverse reactions
  - Most common and most severe adverse reactions

FDA Systems Supporting Medication Terminology Standards

- FDA Substance Registration System
- Electronic Labeling Information Processing System
- Electronic Drug listing

FDA Substance Registration System (FDA SRS)

- Computer system for generating Unique Ingredient Identifier (UNII) based on:
  - Molecular structure
  - Identifying nomenclature
  - Identifying processes
- Status
  - In operation - system includes UNII for active ingredients for approved prescription drugs
- Next steps
  - Active ingredients for non prescription drugs
  - Inactive ingredients

Electronic Labeling Information Processing System (ELIPS)

- Computer system for managing Structured Product Labeling
- Status
  - In operation - importing SPL for legacy approved prescription drugs (planned completion - 12/06)
- Next steps
  - Manage SPL changes for approved prescription drugs
  - Import and manage SPL for other marketed drugs

Electronic Drug Listing (ELIST)

- Computer system for managing inventory of all drug products marketed in the United States
  - Automated drug listing services
- Status
  - In development - reengineering process from manual, paper based process to automated, electronic based process
- Next steps
  - Develop and implement automated systems
  - Update regulations

Electronic Drug Listing Next Steps

- Systems development
  - Phase 1 (ELIPS)
    - Scope – Data collection for approved prescription drugs
    - Funding – provided by the Agency for Healthcare Research and Quality (AHRQ)
    - Completed - October 2006
  - Phase 2 (ELIST)
    - Scope – drug listing process for all marketed drugs
    - Funding – AHRQ?
    - Estimated completion date with funding – Q1 2007

Electronic Drug Listing

- Regulation changes
  - Proposed rule
    - Planned proposal release – Q3 2006
  - Final rule
    - Planned final rule – Q4 2007

Estimated Timelines Based on Funding and Expedited Regulation

- Q3 2006 – Propose change in drug listing regulations
- Q4 2006 - SPL available for all approved prescription products
- Q1 2007 – Implement FDA automated drug listing service
- Q4 2007 – Final new drug listing regulations
- Q4 2008 – SPL for all marketed drug products