FDA Support for Electronic Prescribing - Status

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Update

- Proposed Changes to the FDA Drug Listing Regulation
- Distributing NDC Information
  - National Drug Code (NDC) Directory
  - Structured Product Labeling (SPL)
- FDA Medication Information, Identifiers and Terminology
- Future Initiatives

Federal Medication Terminology Collaboration

- Food and Drug Administration
  - Drug model - Structured Product Labeling
  - Terminology – Product codes, ingredient identifiers, dosage forms, routes of administration, units of measure
  - Process - Source of new product information through Structured Product Labeling
- National Library of Medicine
  - Drug model – RxNorm
  - Terminology – Clinical drug
  - Process - Link clinical drug to NDC and distribution of Structured Product Labeling through DailyMed
- Department of Veterans Affairs/Veterans Health Administration
  - Drug model – National Drug File Reference Terminology (NDF-RT)
  - Terminology – Pharmacological class (MoA, physiologic effect, structural class), VA/KP Problem List
  - Process – Link RxNorm, NDC and NDF-RT
- National Cancer Institute
  - Terminology – NCI Thesaurus source for FDA terminology
  - Process – NCI Enterprise Vocabulary Services, source for terminologies through NCI Terminology Browser
- Agency for Healthcare Quality and Research
  - Process - Project support and funding

Proposed Changes to the FDA Drug Listing Regulation

- Federal Register -August 29, 2006 (vol. 71, No. 167) Docket 2005N-0403
  - Central assignment of NDC number
    - Move from manufacture assignment to FDA assignment of NDC
  - Automate Drug Registration and Listing
    - Move from manual/paper process to automated/electronic process
  - Products
    - Human and animal drugs and biologics
- Status
  - Comments on the proposed rule due over the next 3 to 4 months
  - Publish final rule – dependent on comments and sign off process
  - Industry has 9 months to update listing after final rule issues

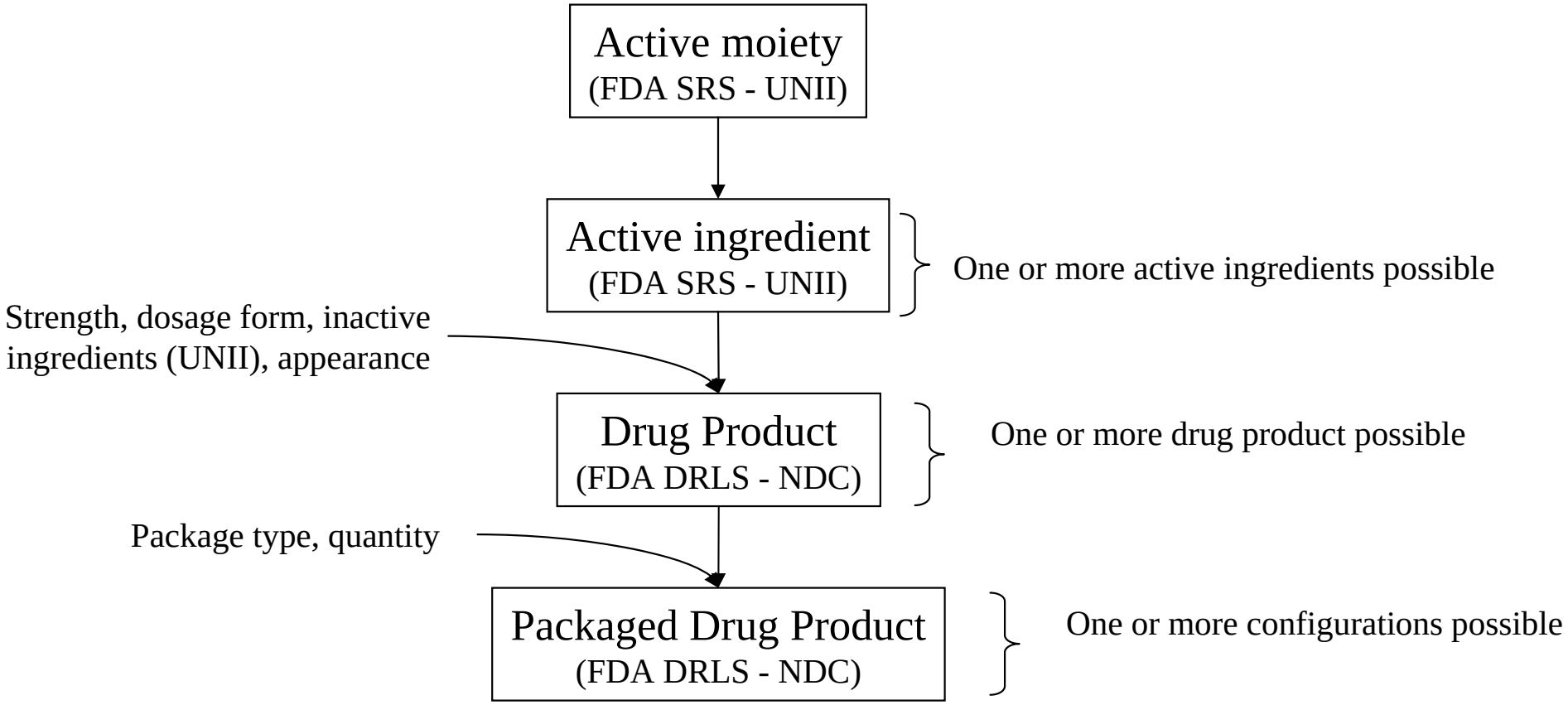
Distributing NDC Information

- FDA National Drug Code (NDC) Directory would contain the definitive list of valid codes
- SPL would be the method for electronically distributing up to date information at the products level
  - Structured Product Labeling contains
    - Content of labeling
    - Drug Listing Data Elements
  - Status
    - 2006 - SPL for approved prescription innovator drugs
    - 2007 to 2010 - Maintain up to date SPL for marketed drug products (human and animal) (timing dependent on regulation changes)

Drug Listing Information

- Product
  - Proprietary and nonproprietary name and code (FDA DRLS)
  - Ingredients
    - Active and inactive ingredient and active moiety name and code (Unique Ingredient Identifier (UNII) from FDA SRS)
    - Active and inactive ingredient strength (NCI Thesaurus, 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 code (FDA DRLS)

Medication Identifiers Summary



FDA Medication Identifiers

- Ingredient names and identifiers
- Product names and codes
- Packaged drug product codes

Ingredient

- Definition
  - Substance that make up the product [Active moiety - active ingredient without counter ion]
- Ingredient name
  - Example – Oxycodone hydrochloride (active moiety – oxycodone)
- Unique Ingredient Identifier (UNII) – source - FDA Substance Registration System
  - Examples
    - Oxycodone hydrochloride – UNII - C1ENJ2TE6C
    - Oxycodone – UNII - CD35PMG570
    - Acetaminophen – UNII - 362O9ITL9D
    - Peanut – UNII - QE1QX6B99R
    - Milk – UNII - 917J3173FT
    - Citronella oil – H711OZ709T
- Status
  - 2006 – UNII for active ingredients in approved prescription drugs, food ingredients from the VA food allergy list, most botanicals and some inactive ingredients,
  - 2007 to 2010 – Maintain UNII for new products and add UNII for active ingredients for other products such as OTC, biologics, animal drugs) and many inactive ingredients in marketed drug products (dependent on regulation changes)

Drug Product

- Definition
  - Drug product defined by active ingredients, strength, manufactured dosage form, inactive ingredients, specific appearance of the dosage form, proprietary name, manufacturer and distributor. A drug product may include two or more drug products in the same package (example - oral contraceptives).
- Product names
  - Proprietary name – example – Tylox
  - Non proprietary name – example - oxycodone hydrochloride and acetaminophen
- Product code – source - FDA Drug Registration and Listing System (DRLS)
  - Example – product code = 0045-0526 - Tylox capsules with 5 mg of oxycodone and 500 mg of acetaminophen and inactive ingredients… from Ortho – McNeil
- Status
  - 2006 – Most prescription drugs in National Drug Code (NDC) Directory, SPL with drug product codes for approved prescription innovator drugs
  - 2007 to 2010 – Maintain up to date SPL with drug product codes for marketed drug products (human and animal) (dependent on regulation changes)

Packaged Drug Product

- Definition
  - Includes the drug product, packaging and product quantity
- National Drug Code (NDC) – source - FDA Drug Registration and Listing System (DRLS)
  - Example
    - Tylox 100 capsules in a bottle – 0045-0526-60
    - Tylox 100 capsules in a blister pack – 0045-0526-79
- Status
  - 2006 – Most prescription drugs in National Drug Code (NDC) Directory and SPL with packaged drug product codes for approved prescription innovator drugs
  - 2007 to 2010 – Maintain up to date SPL with packaged drug product codes for marketed drug products (human and animal) (dependent on regulation changes)

Medication Terminology

- Manufactured dosage form
- Route of administration
- Units of measure
- Appearance
- Package type

Manufactured Dosage Form

- Definition
  - way of identifying the drug product in its physical form.
- Source – NCI Thesaurus
  - Examples
    - Tablet, orally disintegrating – C42999
    - Powder, for suspension – C42975
    - Injection, solution – C42956
- Status
  - Available in NCI Thesaurus

Route of Administration

- Definition
  - the path by which a particular drug product is introduced on or into the body.
- Source – NCI Thesaurus
  - Examples
    - Oral – C38286
    - Intramuscular – C28161
    - Intrathecal – C38267
- Status
  - Available in NCI Thesaurus

Unit of Measure

- Definition
  - Amount of an ingredient in a unit of a drug product.
- Source – NCI Thesaurus and Unified Code for Units of Measure (UCUM)
  - Examples
    - Milligram [C28253][mg] per tablet [C48542]
    - Milliliter [C28254][mL] per spray [C48537]
- Status
  - Available in NCI Thesaurus and UCUM

Appearance

- Definition
  - Color, shape, size, coating, scoring, symbol, imprint code of drug product with a solid manufactured dosage form
- Source – NCI Thesaurus for colors and shapes
  - Examples
    - White – C48325
    - Round – C48348
- Status
  - Available in NCI Thesaurus

Package Type

- Definition
  - Container or wrapping in which any drug product is enclosed for use in the delivery or display of such commodities to retail purchasers.
- Source – NCI Thesaurus
  - Examples
    - BOTTLE – C43169
    - DIALPACK – C43191
- Status
  - Available in NCI Thesaurus

Potential Future Initiatives

- Additional Data Elements
  - Highlights Data Elements
  - Other drug product data elements
    - NCPDP Billing Units
- SPL for other products
  - Medical Devices
    - Device listing data elements
  - Dietary supplements
    - Supplement facts data elements
  - Foods
    - Nutrition facts data elements
  - Others

Highlights Data Elements (1 of 2)

- Indication
  - Intent of use and indication
    - [treatment for migraine] [prophylaxis for stroke]
- Usage
  - Maximum dose
    - [2500 mg per day]
  - Conditions of use
    - Adjunct - [Use with aspirin]
    - Screening or monitoring test - [Absolute neutrophil count]
    - Patient characteristic – [Use in children under the age of 6]
  - Limitations of use
    - Contraindication, use with caution, dose modification, little of no information, second line treatment, duration of use, conditional approval – [contraindicated in women] [dose modification for patients with renal impairment]

Highlights Data Elements (2 of 2)

- Interactions
  - Contributing factor and consequence
    - [use with Dilantin has a consequence of increasing drug levels] [use with MAOI has a consequence of malignant hypertension]
- Adverse reactions
  - Consequence
    - [adverse reactions includes nausea]
- Pharmacological class
  - Mechanism of action, physiologic effect and/or structural class
    - [Adrenergic Agonists] [Coronary Arterial Vasodilation] [Ergot Alkaloids]

FDA Data Standards Council References

- Terminology

http://www.fda.gov/oc/datacouncil/spl.html

- Stylesheet

http://www.fda.gov/oc/datacouncil/stylesheets/spl/spl.xsl

- Schema

http://www.fda.gov/oc/datacouncil/schemas/spl.xsd