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The Electronic Drug Label – Coming to an Information System Near You

September 8, 2010

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“Information is care”

Dr. Donald Berwick, President of the Institute for Healthcare Improvement

SPL – Structured Product Label

- An electronic document to relate product regulatory information in a standardized, structured way
  - Accurate, timely, and enhanced
    - FDA
    - Caregivers
    - Researchers, drug companies, etc.

SPL: Standards within standards within standards within…

Standards enhance communication

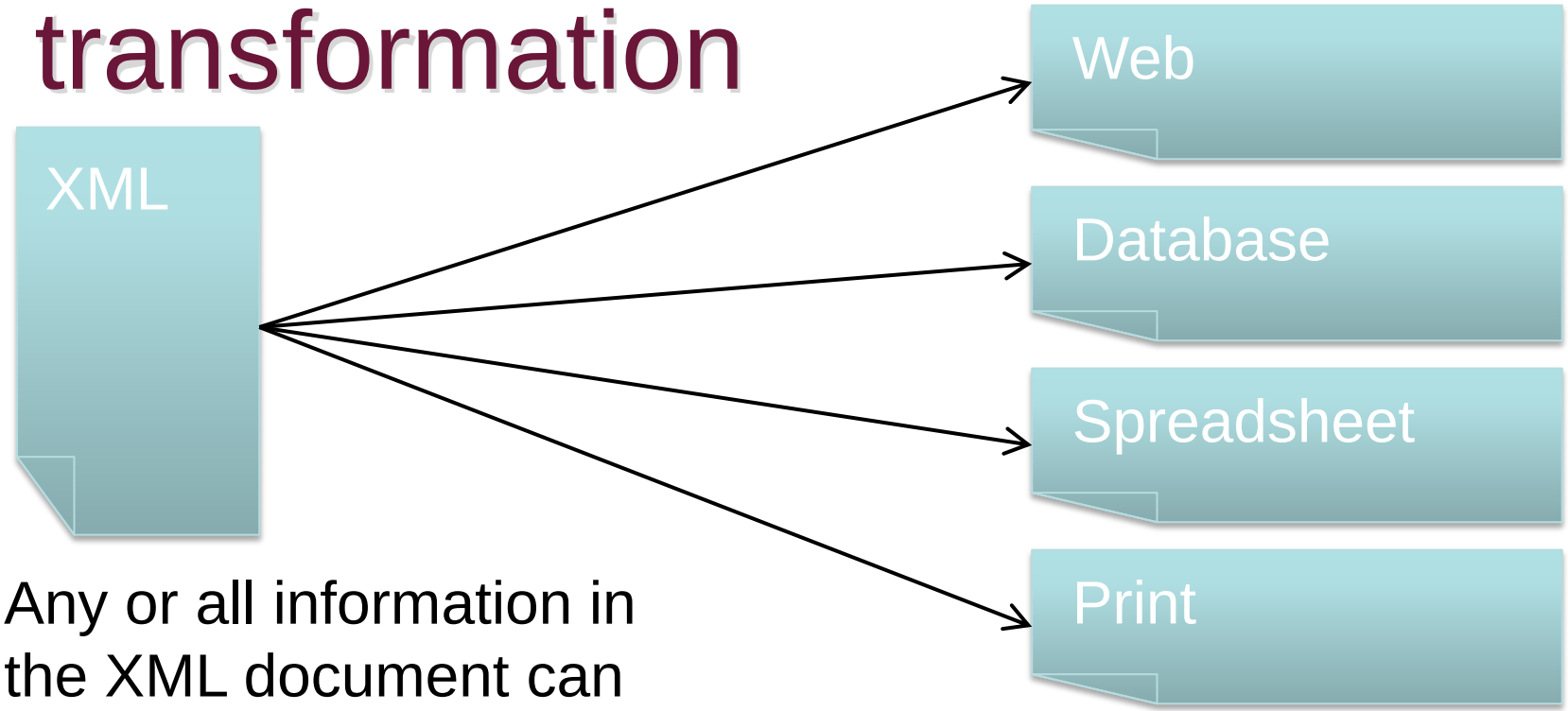
GUID

OID

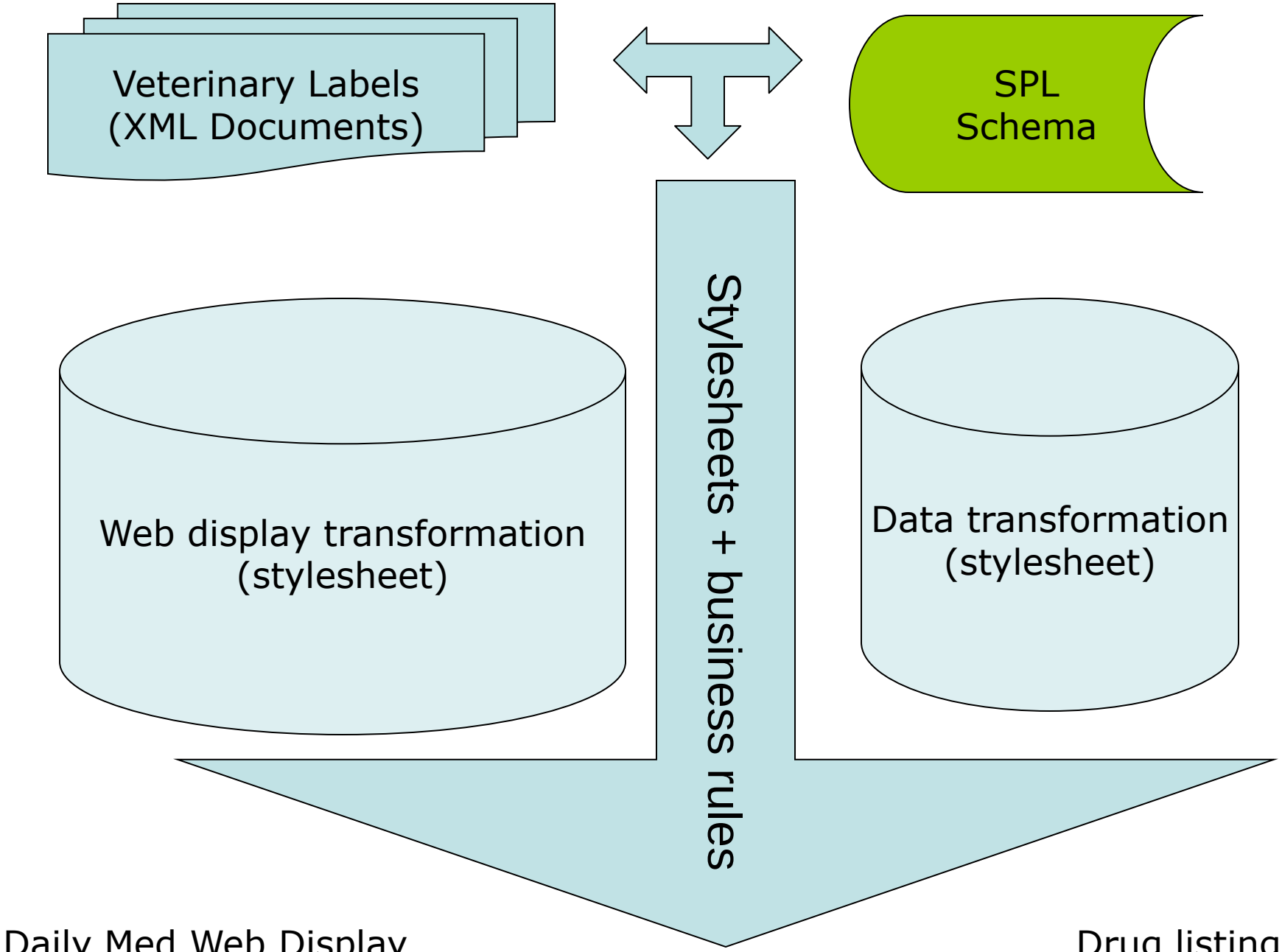
Local: model, lot, serial

INTERNATIONAL HEALTH TERMINOLOGY
STANDARDS DEVELOPMENT ORGANISATION

XML facilitates information transformation

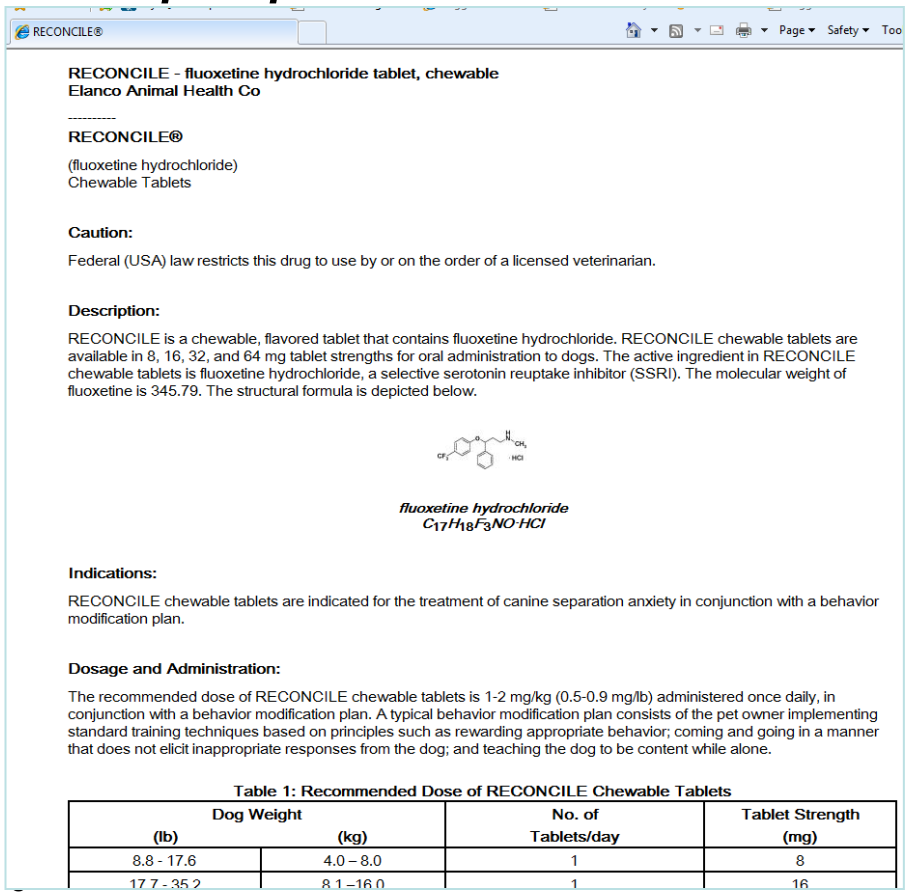


Any or all information in the XML document can be transformed (as needed)


Veterinary Labels
(XML Documents)
SPL
Schema
Stylesheets + business rules
Web display transformation
(stylesheet)
Data transformation
(stylesheet)
Daily Med Web Display
Drug listing

SPL transforms provide rules for transforming software

- *Appropriate stylesheets for viewing can be prepared for intended users*



RECONCILE®

RECONCILE - fluoxetine hydrochloride tablet, chewable
Elanco Animal Health Co

RECONCILE®

(fluoxetine hydrochloride)
Chewable Tablets

Caution:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

RECONCILE is a chewable, flavored tablet that contains fluoxetine hydrochloride. RECONCILE chewable tablets are available in 8, 16, 32, and 64 mg tablet strengths for oral administration to dogs. The active ingredient in RECONCILE chewable tablets is fluoxetine hydrochloride, a selective serotonin reuptake inhibitor (SSRI). The molecular weight of fluoxetine is 345.79. The structural formula is depicted below.

fluoxetine hydrochloride
$C_{17}H_{18}F_3NO \cdot HCl$

Indications:

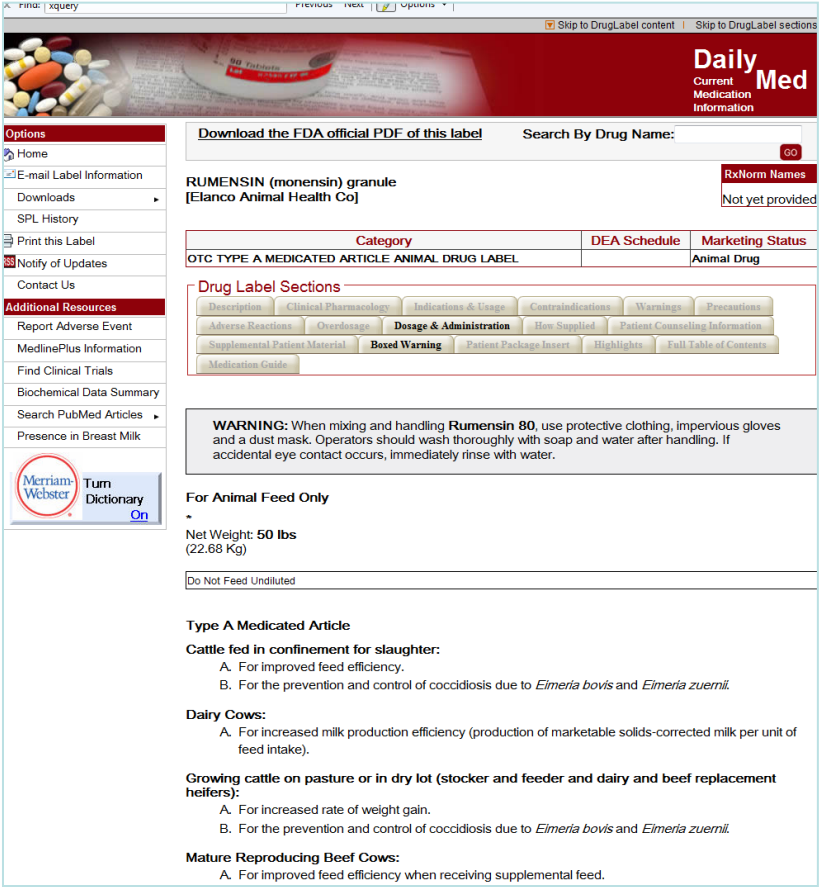
RECONCILE chewable tablets are indicated for the treatment of canine separation anxiety in conjunction with a behavior modification plan.

Dosage and Administration:

The recommended dose of RECONCILE chewable tablets is 1-2 mg/kg (0.5-0.9 mg/lb) administered once daily, in conjunction with a behavior modification plan. A typical behavior modification plan consists of the pet owner implementing standard training techniques based on principles such as rewarding appropriate behavior; coming and going in a manner that does not elicit inappropriate responses from the dog; and teaching the dog to be content while alone.

Table 1: Recommended Dose of RECONCILE Chewable Tablets

Dog Weight (lb)	Dog Weight (kg)	No. of Tablets/day	Tablet Strength (mg)
8.8 - 17.6	4.0 – 8.0	1	8
17.7 - 35.2	8.1 –16.0	1	16



Skip to DrugLabel content | Skip to DrugLabel sections

DailyMed Current Medication Information

Options
- Home
- E-mail Label Information
- Downloads
- SPL History
- Print this Label
- Notify of Updates
- Contact Us

Additional Resources
- Report Adverse Event
- MedlinePlus Information
- Find Clinical Trials
- Biochemical Data Summary
- Search PubMed Articles
- Presence in Breast Milk

Merriam-Webster Turn Dictionary On

Download the FDA official PDF of this label | Search By Drug Name: GO

RUMENSIN (monensin) granule
[Elanco Animal Health Co]

RxNorm Names: Not yet provided

Category	DEA Schedule	Marketing Status
OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG LABEL		Animal Drug

Drug Label Sections: Description | Clinical Pharmacology | Indications & Usage | Contraindications | Warnings | Precautions | Adverse Reactions | Overdosage | **Dosage & Administration** | How Supplied | Patient Counseling Information | Supplemental Patient Material | **Boxed Warning** | Patient Package Insert | Highlights | Full Table of Contents | Medication Guide

WARNING: When mixing and handling **Rumensin 80**, use protective clothing, impervious gloves and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with water.

For Animal Feed Only

Net Weight: **50 lbs**
(22.68 Kg)

Do Not Feed Undiluted

Type A Medicated Article

Cattle fed in confinement for slaughter:
A. For improved feed efficiency.
B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

Dairy Cows:
A. For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).

Growing cattle on pasture or in dry lot (stocker and feeder and dairy and beef replacement heifers):
A. For increased rate of weight gain.
B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

Mature Reproducing Beef Cows:
A. For improved feed efficiency when receiving supplemental feed.

Document meta-data enables identification

Title

Identifier

Label type code

HEARTGARD - ivermectin bar, chewable
Merial Ltd.

Heartgard Chewables for Dogs
Merial
(ivermectin)

CAUTION

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATION

For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae *(Dirofilaria immitis)* for a month (30 days) after infection.

Version

Effective time

SPL divided into label sections

Identifiers

Title

Section type code

Text

HEARTGARD - ivermectin bar, chewable
Merial Ltd.

Heartgard Chewables for Dogs
Merial
(ivermectin)

Video

Effective time

CAUTION

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Image

INDICATION

For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae *(Dirofilaria immitis)* for a month (30 days) after infection.

Highlights

Subsections

WARNING: XML CODE!

SPL label section

computer-readable info

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<component>
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      <text>
         <paragraph>
            <br/>
            <content styleCode="bold">Store at or below 25°C (77 °F),
               excursions permitted to 40 °C (104 °F).</content>
         </paragraph>
      </text>
      <effectiveTime value="20100106"/>
   </section>
</component>
```

human-readable info

Label sections rendered with FDA stylesheet

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

EXTINA® (ketoconazole) Foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. Safety and efficacy of EXTINA® Foam for treatment of fungal infections have not been established.

2 DOSAGE AND ADMINISTRATION

EXTINA® Foam should be applied to the affected area(s) twice daily for four weeks.

Hold the container upright, and dispense EXTINA® Foam into the cap of the can or other cool surface in an amount sufficient to cover the affected area(s). Dispensing directly onto hands is not recommended, as the foam will begin to melt immediately upon contact with warm skin. Pick up small amounts of EXTINA® Foam with the fingertips, and gently massage into the affected area(s) until the foam disappears. For hair-bearing areas, part the hair, so that EXTINA® Foam may be applied directly to the skin (rather than on the hair).

Avoid contact with the eyes and other mucous membranes. EXTINA® Foam is not for ophthalmic, oral or intravaginal use.

SPL increases utility of traditional content of labeling

- Links
- Color images
- Videos
- Reader assistance

FULL PRESCRIBING INFORMATION: CONTENTS*

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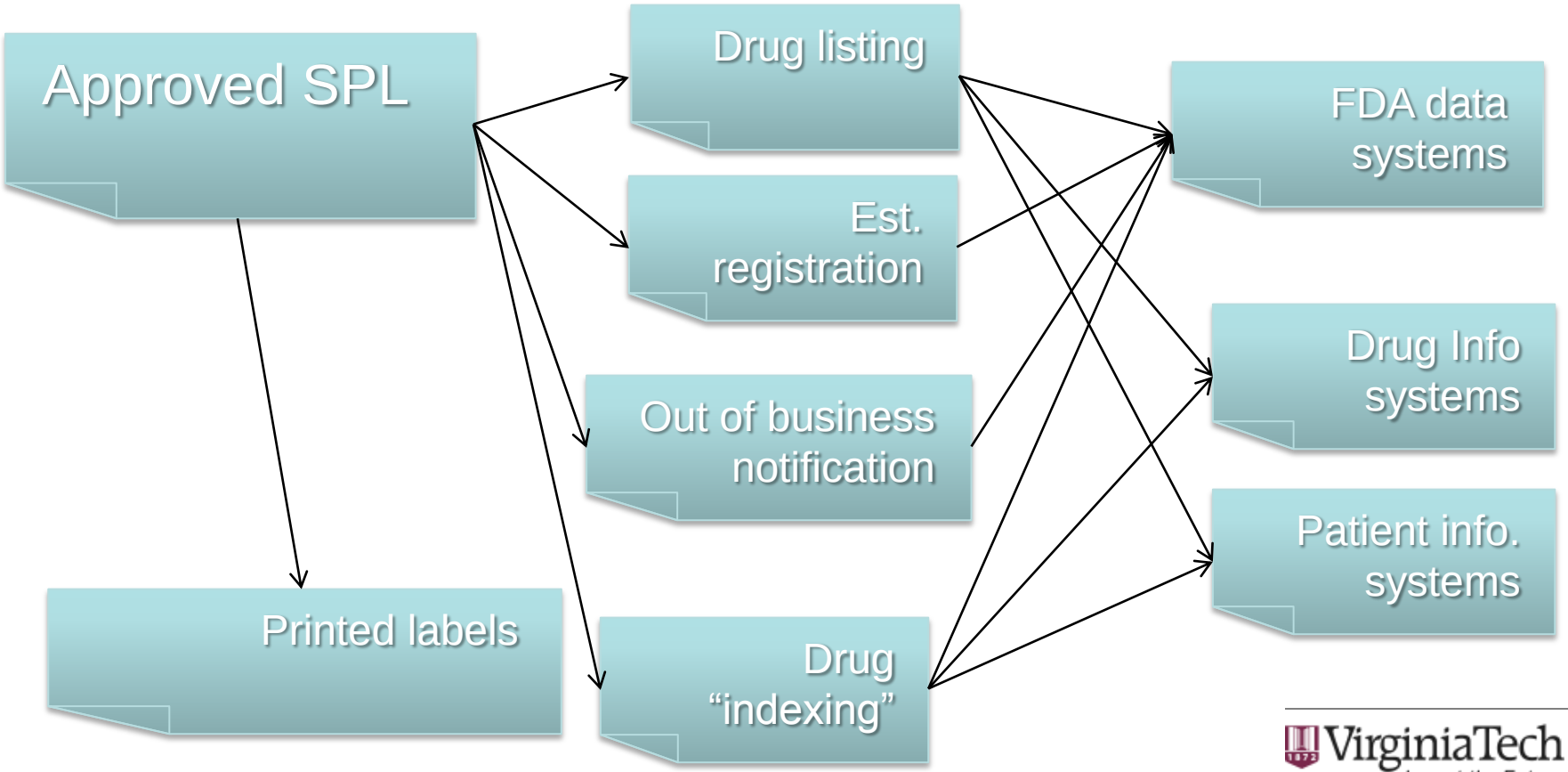
SPL improves results/outcomes when used for primary purpose of prescribing a drug

http://www.technooutlet.com/cafi176.html?source=GGAN

SPL improves information flow



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SPL contains detailed drug info

Packaging

Quantity

Dosage form

Route of administration

Approval

Product name

www.ricespharmacy.com/1648644.html

Image

Solid oral: color, shape, size, scoring, imprint

Active ingredients

Inactive ingredients

Strength

DEA Schedule

Marketing status

Indexing increases label utility

Pharmacologic class

Maximum dose

Adverse reaction

Indication

Interactions

Condition of use

Limitation of use

Are we all going to fit?

May work well….

Content of labeling

Terminologies

Schema?

May need help…

Stylesheet

Terminology subsets

Animals

Indexing by animal

Indications

Adverse reactions

Interactions

Withdrawal times

Indexing section rendered with FDA's current stylesheet

Indications and Usage

INDICATIONS		USAGE	
Indication	**Intent Of Use**	**Maximum Dose**	**Conditions & Limitations Of Use**
Infection by Dirofilaria immitis (MEDICAL PROBLEM)	PRYLX		

Conditions Of Use

Use Category	Precondition Category	Precondition	Labeling Section
Condition of use	Regulated animal	Dog	INDICATION
Condition of use	Age	≥ 6wk	INDICATION
Condition of use	Screening/monitoring test	Dirofilaria immitis Ag Bld-Ser-Psm	INDICATION

Limitations Of Use

Use Category	Precondition Category	Precondition	Labeling Section
CONTRAINDICATION	Medical Problem	Infection by Dirofilaria immitis	PRECAUTIONS

Benefits of SPL will grow over time

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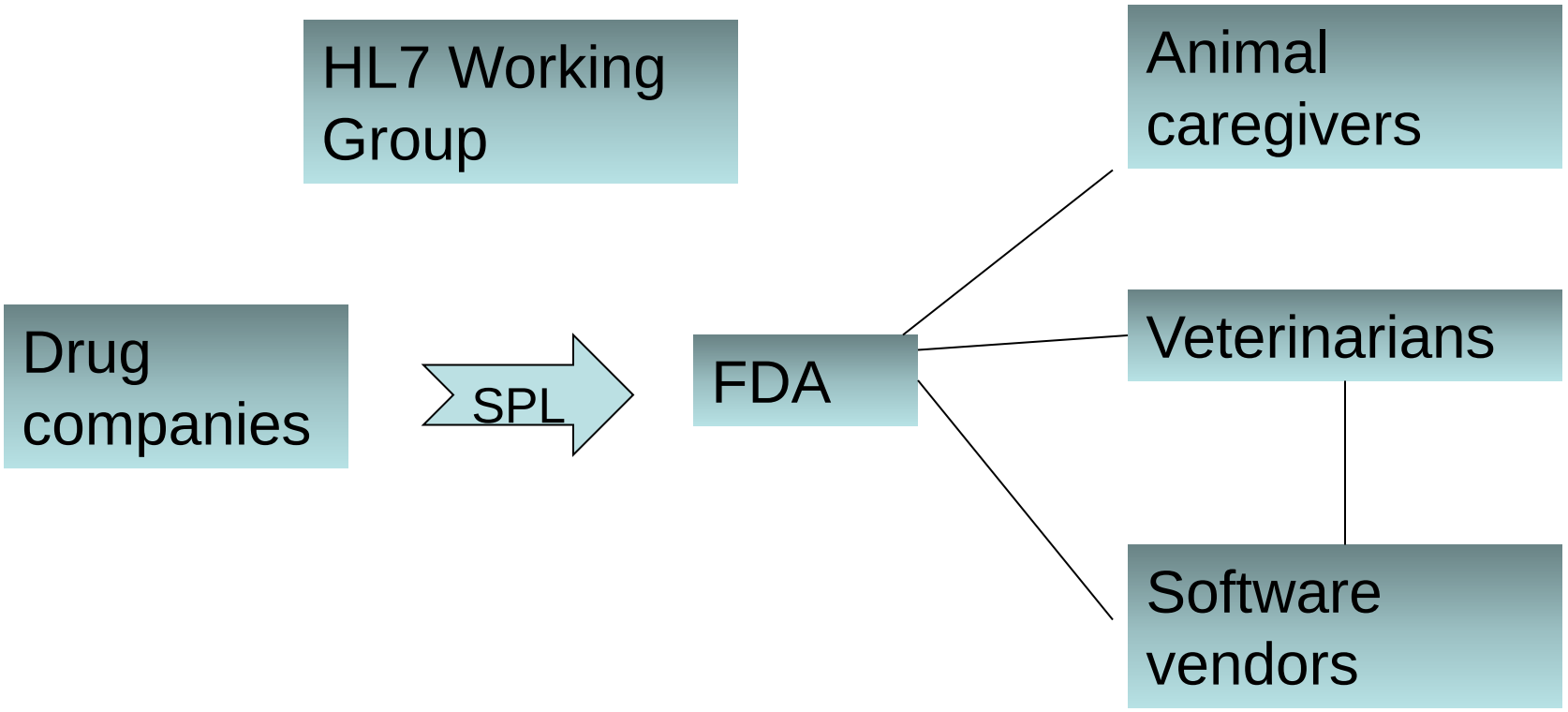
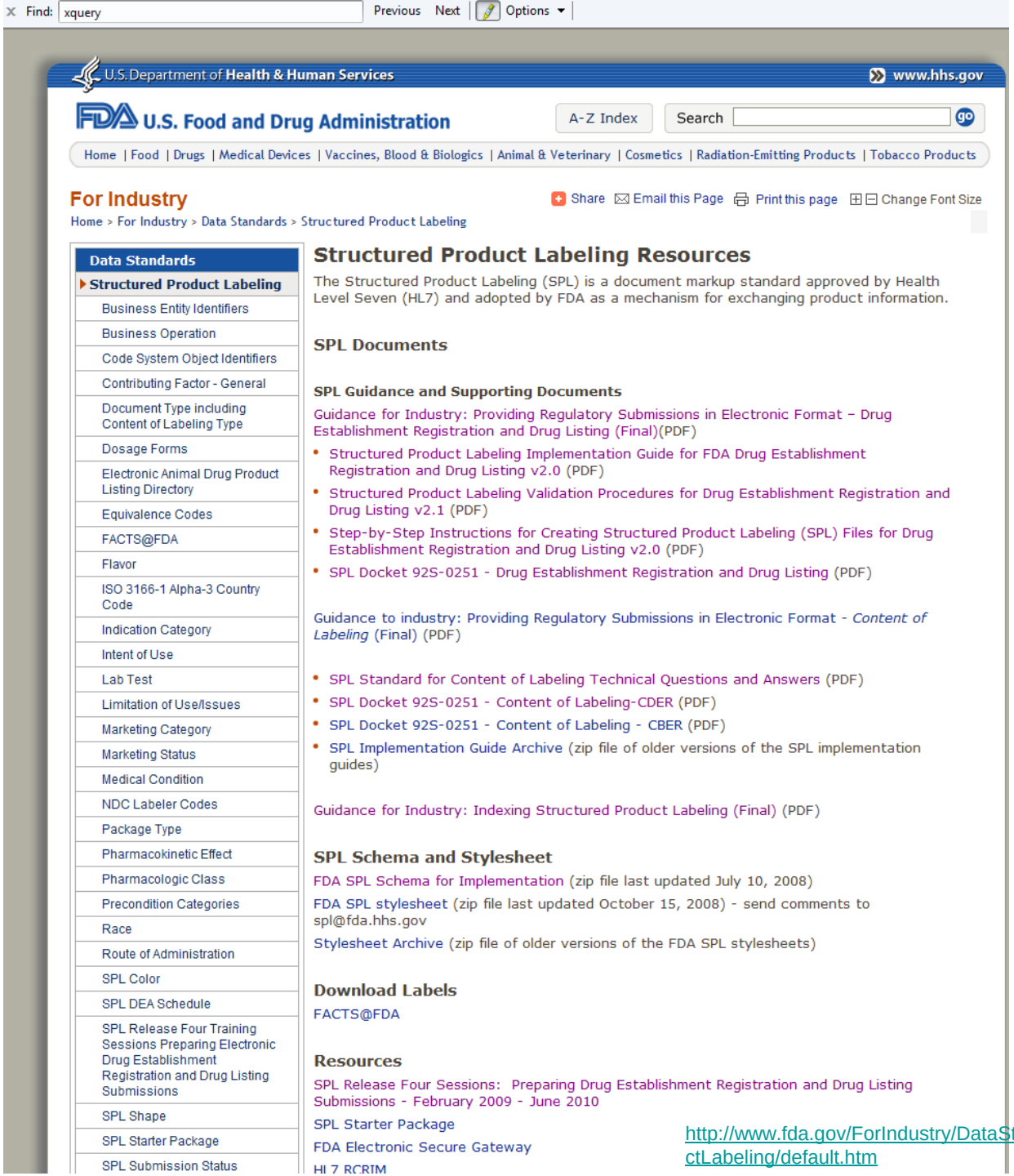
Rome wasn't built in a day

SPL implementation in phases

Drug Listing & Establishment Registration mandatory	Content of labeling mandatory	Indexing mandatory
Summer 2009	??	??

SPL involves many parties





http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

http://spl-work-group.wikispaces.com/

The more vets ask for SPLs the more likely the FDA, drug companies and vendors will provide them

http://go635254.s3.amazonaws.com/cleantechnica/files/2010/06/Demand.jpg

Questions?

http://imgs.sfgate.com/c/pictures/2010/07/29/ba-Germany_Zoo_A_0502023731.jpg

Acknowledgements

- Appreciation for funding support:
  - FDA Center for Veterinary Medicine
- Appreciation for assistance:
  - Dr. Jeff Wilcke
  - Dr. Julie Green
  - Maureen Fallon