



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

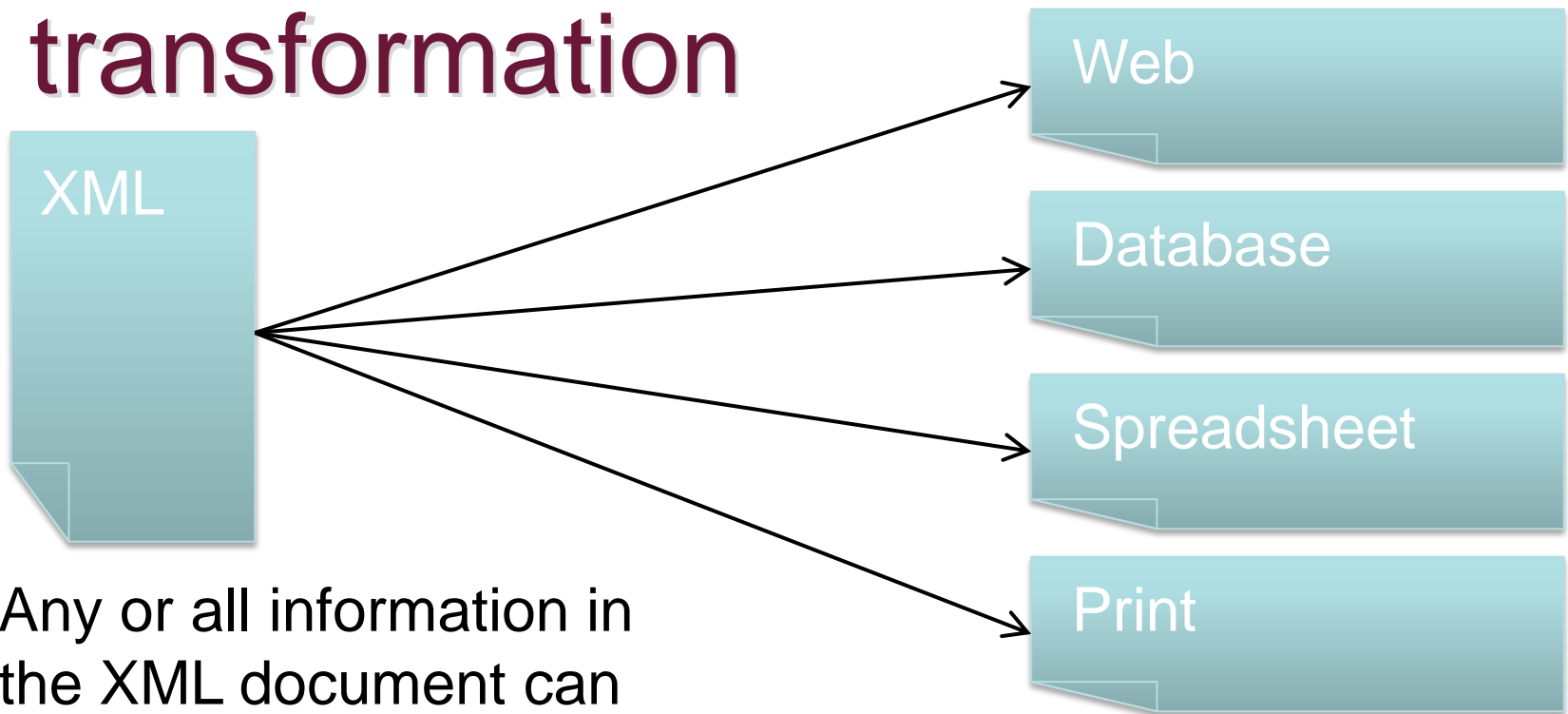
OID



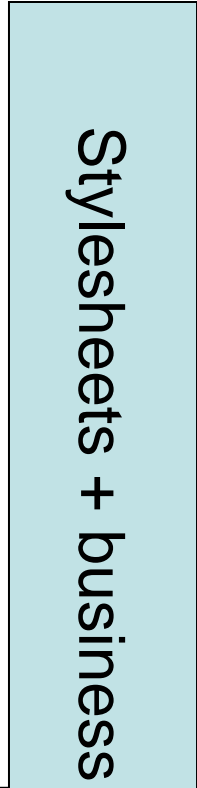
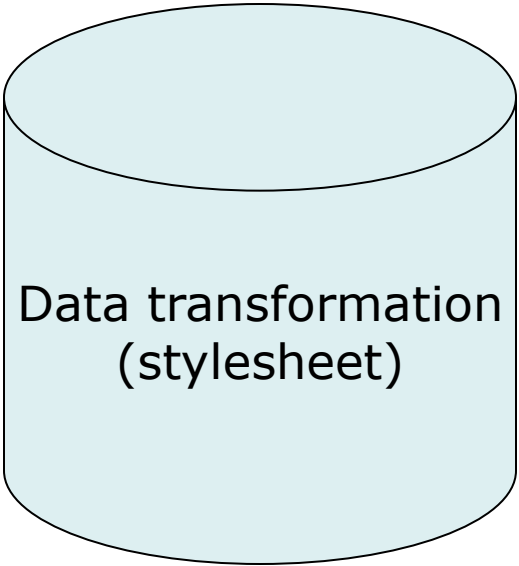
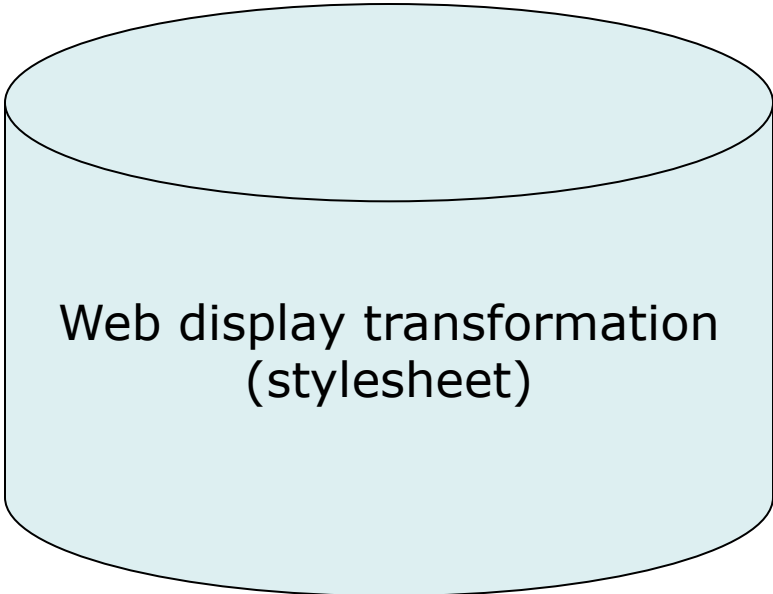
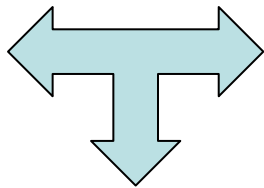
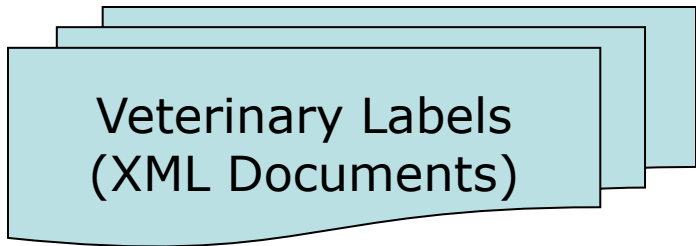
Local:
model, lot,
serial



XML facilitates information transformation



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

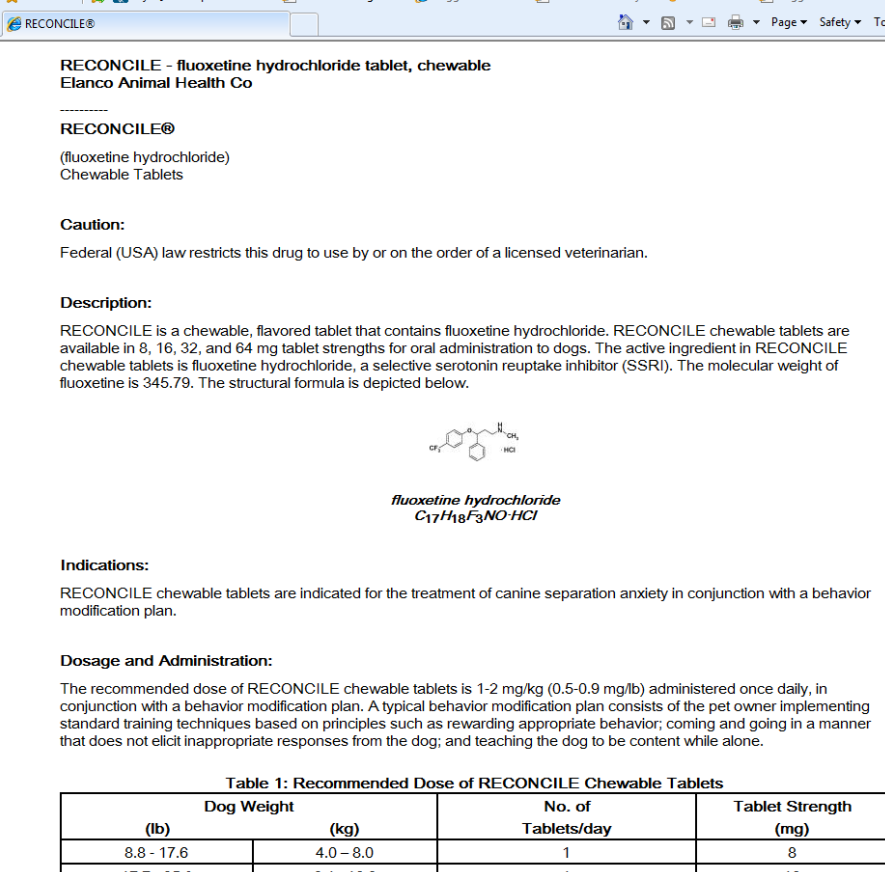


Daily Med Web Display

Drug listing

SPL transforms provide rules for transforming software

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




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.



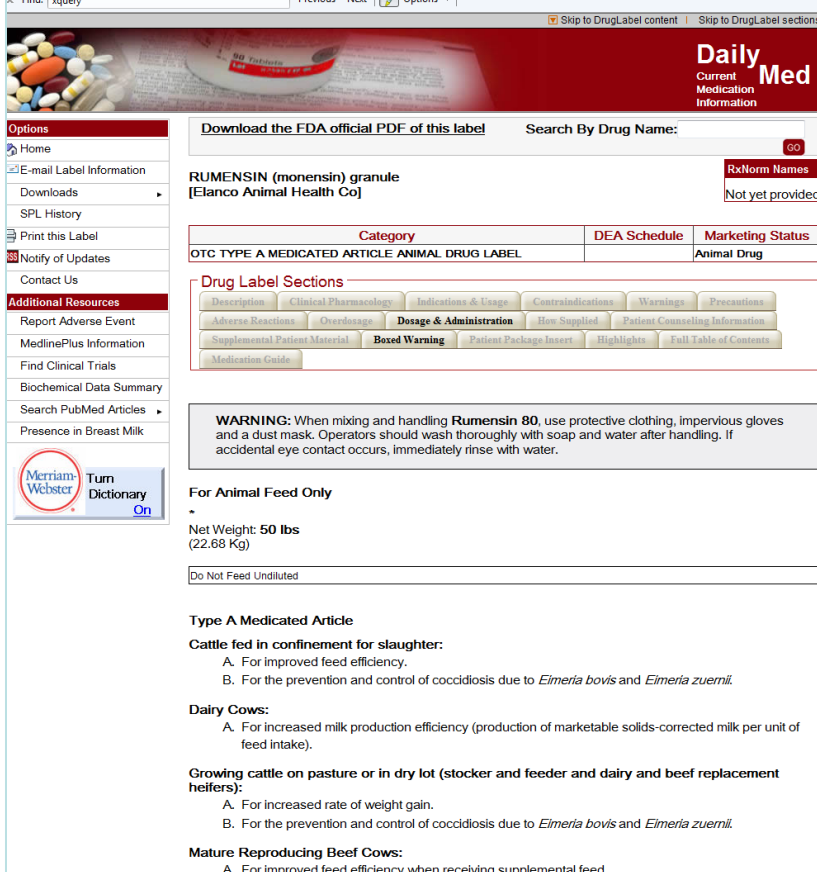
fluoxetine hydrochloride
 $C_{17}H_{18}F_3NO \cdot HCl$

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



RUMENSIN (monensin) granule
 (Elanco Animal Health Co)

Category
 OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG LABEL

DEA Schedule
 Not yet provided

Marketing Status
 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

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.

Label
type code

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

CAUTION

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

Effective
time

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

```
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  <section>
    <id root="1c76d902-d418-4e35-a7a9-2f52395b3cd2"/>
    <code code="44425-7" codeSystem="2.16.840.1.113883.6.1"
      displayName="STORAGE AND HANDLING SECTION"/>
    <title>STORAGE CONDITIONS</title>
    <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>
```

computer-readable info

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

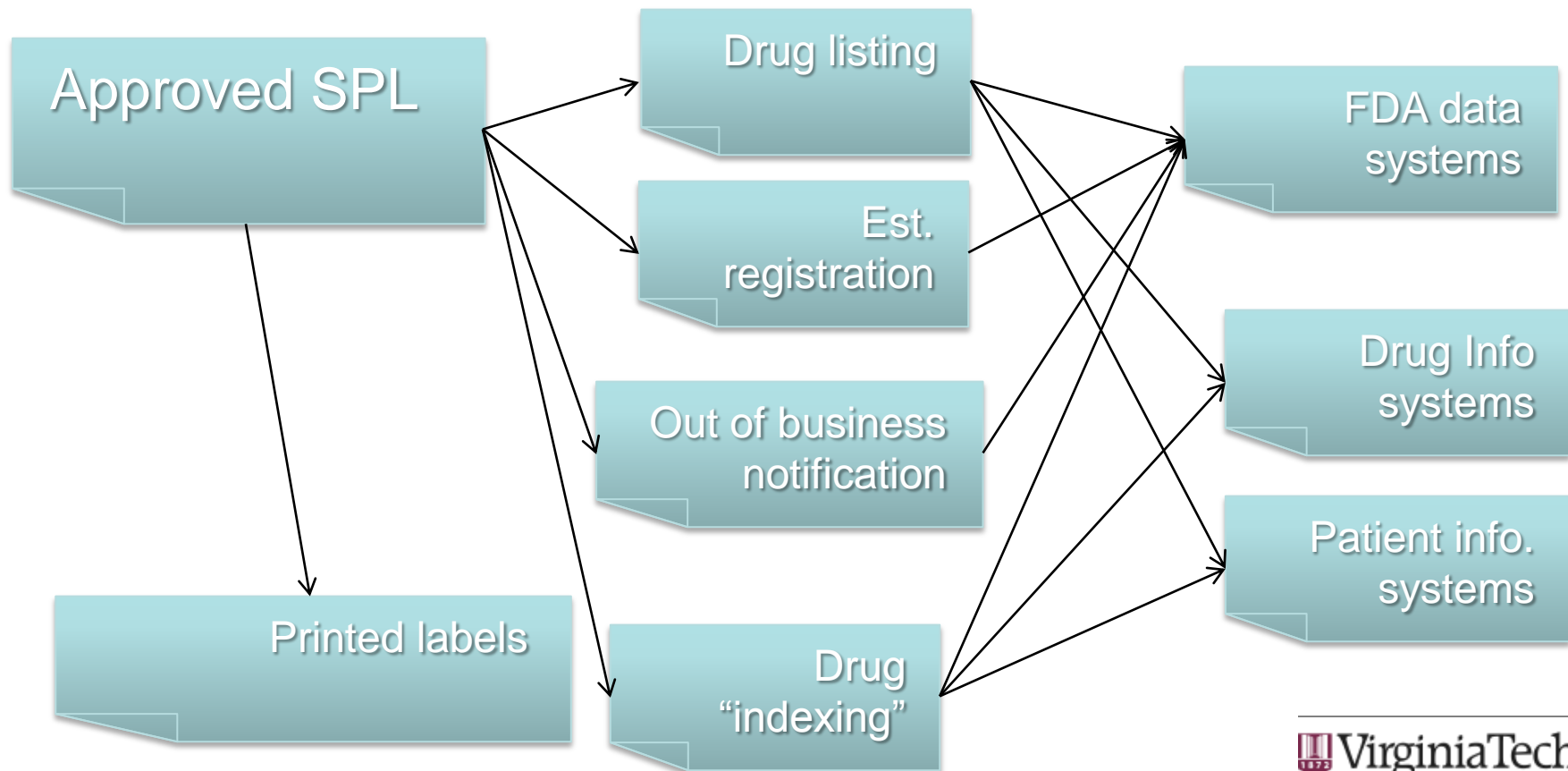
FULL PRESCRIBING INFORMATION: CONTENTS*

- 1 INDICATIONS AND USAGE
- 2 DOSAGE AND ADMINISTRATION
- 3 DOSAGE FORMS AND STRENGTHS
- 4 CONTRAINDICATIONS
- 5 WARNINGS AND PRECAUTIONS
 - 5.1 Contact Sensitization
 - 5.2 Flammable Contents
 - 5.3 Systemic Effects

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



SPL improves information flow



SPL contains detailed drug info

Packaging

Product name

Active ingredients

Quantity

Inactive ingredients

Dosage form

Strength

Route of administration

DEA Schedule

Approval

Image

Marketing status



www.ricespharmacy.com/1648644.html

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

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 <i>Dirofilaria immitis</i> (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	<i>Dirofilaria immitis</i> Ag Bld-Ser-Psm	INDICATION
			Limitations Of Use			
			Use Category	Precondition Category	Precondition	Labeling Section
			CONTRAINDICATION	Medical Problem	Infection by <i>Dirofilaria immitis</i>	PRECAUTIONS

Benefits of SPL will grow over time



Rome wasn't built in a day





SPL implementation in phases

Drug Listing &
Establishment
Registration
mandatory

Content of
labeling
mandatory

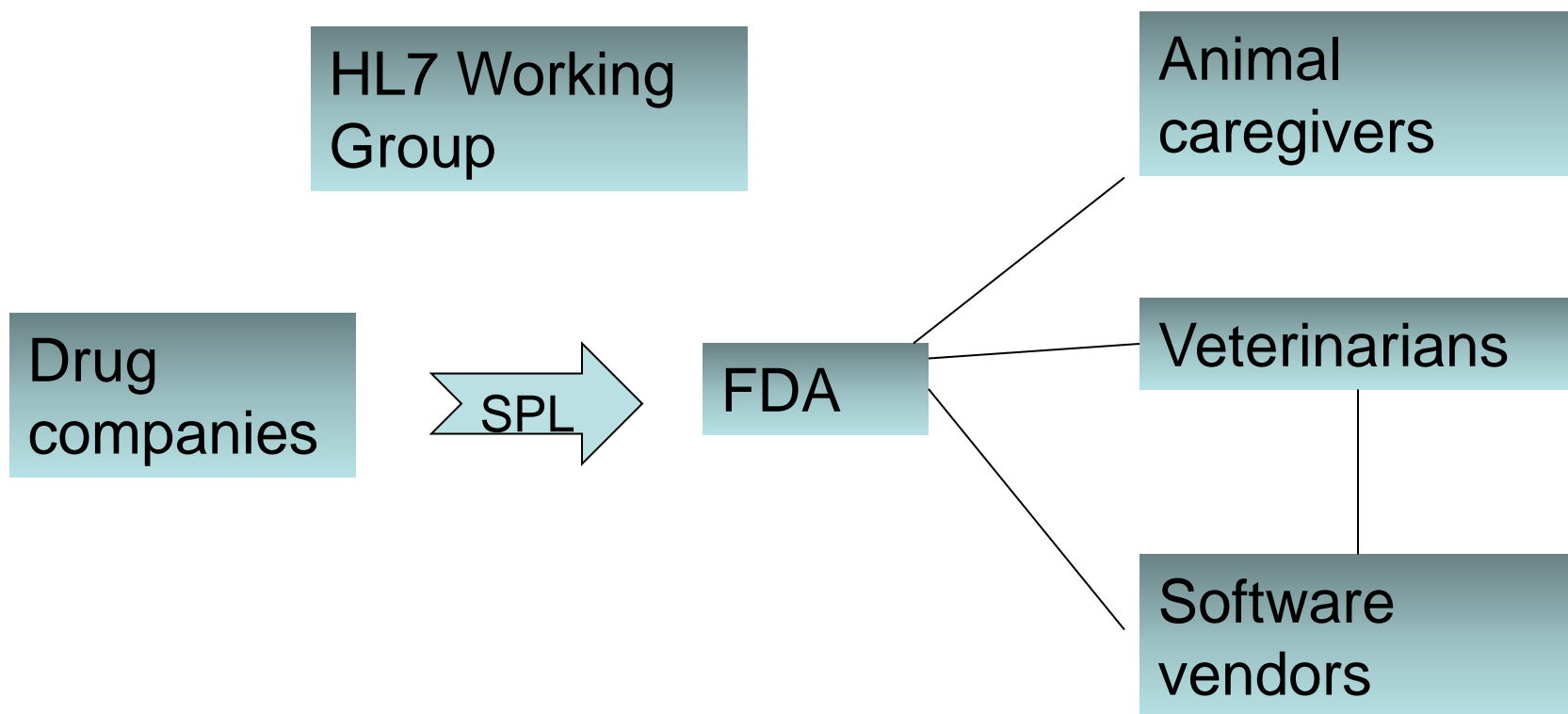
Indexing
mandatory

Summer
2009

??

??

SPL involves many parties



For Industry

Share Email this Page Print this page Change Font Size

Home > For Industry > Data Standards > Structured Product Labeling

Data Standards

Structured Product Labeling

Table listing various data standards such as Business Entity Identifiers, Business Operation, Code System Object Identifiers, etc.

Structured Product Labeling Resources

The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information.

SPL Documents

SPL Guidance and Supporting Documents

Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Drug Establishment Registration and Drug Listing (Final)(PDF)

- List of documents including Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v2.0 (PDF), Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v2.1 (PDF), etc.

Guidance to industry: Providing Regulatory Submissions in Electronic Format - Content of Labeling (Final) (PDF)

- List of documents including SPL Standard for Content of Labeling Technical Questions and Answers (PDF), SPL Docket 92S-0251 - Content of Labeling-CDER (PDF), etc.

Guidance for Industry: Indexing Structured Product Labeling (Final) (PDF)

SPL Schema and Stylesheet

FDA SPL Schema for Implementation (zip file last updated July 10, 2008)
FDA SPL stylesheet (zip file last updated October 15, 2008) - send comments to spl@fda.hhs.gov
Stylesheet Archive (zip file of older versions of the FDA SPL stylesheets)

Download Labels

FACTS@FDA

Resources

SPL Release Four Sessions: Preparing Drug Establishment Registration and Drug Listing Submissions - February 2009 - June 2010
SPL Starter Package
FDA Electronic Secure Gateway
HI 7 RCRIM

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

Actions

- Join this Wiki
- Recent Changes
- Manage Wiki
- Search

Navigation

- Home**
- All pages of this SPL Wiki**
- Documents and References
 - Training and Seminars
 - Industry Survey

All Groups/ Subteams

FAQs / Q and As

- DUNS Number FAQ
- FAQ
- PLR FAQ
- UNII Codes FAQ
- VetMed FAQ
- Biologics Q-and-A
- Drug Element Q&A
- Drug Listing Q&A
- Image Issues
- Ingredients
- PLR
- PLR Recent Major Changes

New Materials and Updates

Wikispaces : SPL-work-group - all changes home · re: Two Tablets

Thank You!

Generous donations from Intagras, Inc. and i4i have enabled us to suppress the advertising from scrolling on the right side. This valuable screen space is now available for more SPL Working group information. This acknowledgement does not constitute an endorsement of any particular vendor.

Important Note: Please join [wikispaces](#) (it's free!) so that you can participate in discussions. You do not need to specifically join the SPL Working Group WIKI unless you want to help edit the WIKI.

[HL7 Information on SPL](#)

[FDA Documents](#) / [Training & Training Notes](#) / [SPL eBooks](#) / [eCards](#) / [SPL Pathways Training](#) / [Validation Alerts](#) /

[Introduction to SPL](#) / [Abbreviations](#) / [Glossary](#) / [Recent Changes on this Wiki](#) / [Calendar of Events](#) /

[\[new!\] SPL Working Group](#) / [Vendors](#) /

Other Useful Websites:

[Registered Establishments](#) [DFARS] / [FDA Data Council](#) / [DailyMed Site](#) / [Drugs @ FDA](#)

[Pragmatics Validator](#)

New!! [if validator is down, send an e-mail to spl@pragmaticdata.com]

[26-Mar-2010]

!! When the Pragmatic Data Validator Lite tool is down, send an e-mail to spl@pragmaticdata.com instead of spl@fda.hhs.gov !!

[19-Mar-2010]

National Library of Medicine has updated its DailyMed website to display the Category (product type), DEA schedule (if applicable) and marketing category (i.e., NDA or ANDA) directly below the SPL header.

====**FDA REMINDER!** [05-Mar-2010] Please ensure that all of the data provided in SPL files submitted to register drug establishments and list drug products is **accurate**. 1. Ensure that **application numbers are accurate** and that the numbers are not transposed. 2. Check the addresses in your Establishment Registration SPL documents to ascertain that the information is correct 3. Remember that **SPL authors** now determine the date which the listing SPL documents can be released to the public. Check the marketing start date to ensure that **you agree** that the listing SPL file can be **released** on that date. ----

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[16-Feb-2010]

eBook for [Common Technical Errors](#) (eBook #14)

[15-Feb-2010]

Structured Product Labeling, Release 5

During the HL7 Working Group Meeting in January 2010, a new project was started that will extend the Structured Product Labeling (SPL) standard to the next release (R5) for the support of medical devices. [More information here.](#)

Controlled vocabulary lists for countries without postal codes, countries and ntvals - [links here](#)

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



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





Questions?



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



Acknowledgements

- Appreciation for funding support:
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 - Dr. Jeff Wilcke
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