Electronic Labeling and Structured Label Content

Robert Schultz

US EPA, Office of Pesticide Programs

PPDC WDL Workgroup

April 21, 2009

Current Challenges and Goals for Change

Challenges

- Multiple definitions of e-Label exist.
- Paper copies of labels and amendments must be submitted.
- Manual processes dominate the review cycle:
  - Propagating consistent label changes
  - Enforcement of standardized text
  - Hand-keying data into EPA databases
  - Searching for “me too” and past versions
  - Comparing labels
- Distribution of labels is container-based and processing requirements delay changes to printed products.

Goals of e-Label

- Structured label fields set the standard for incoming electronic data.
- Provide an e-Label Builder to support the creation of electronic labels.
- Label approval will move from a manual, paper-based process to an electronic stream of data and decisions.
- Provide the public and registrants with the latest approved and historical versions of labels online.

Benefits

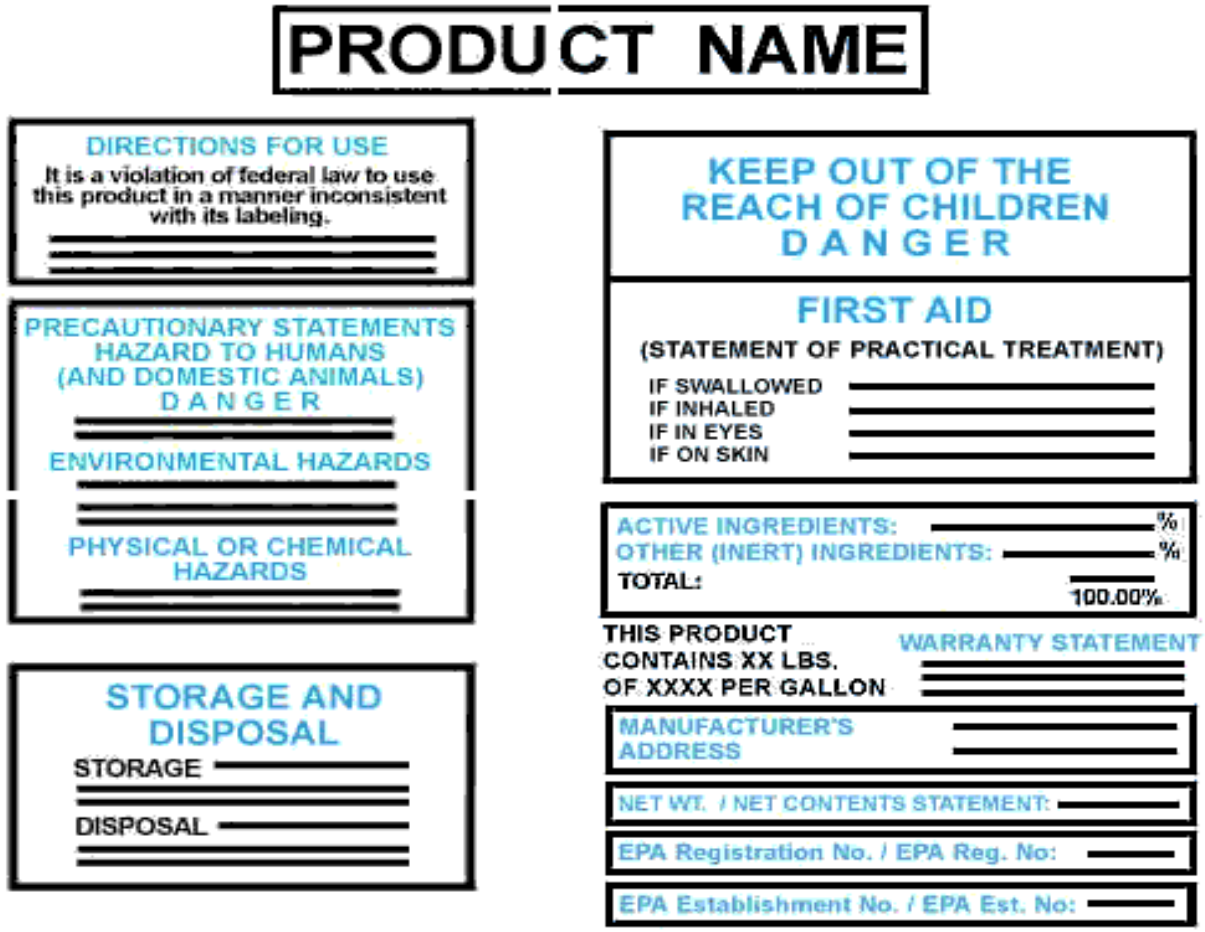
- Process labels more efficiently by allowing EPA resources to focus on critical tasks.
- Compare e-Label content against current rules, requirements, guidance and laws.
- Improve data quality, including the accuracy and completeness of data received from registrants
- Provide a level playing field for registrants.
- Automate entry into backend systems.

What is Structured Content?

- **Structured content** refers to information or content that has been broken down and classified using metadata.
- **Metadata** is "data about data"
  - "Information that describes the *content*, quality, condition, *origin*, and other characteristics of data or other pieces of information. ..."

Source: www.sdbay.sdsu.edu/glossary/index.php

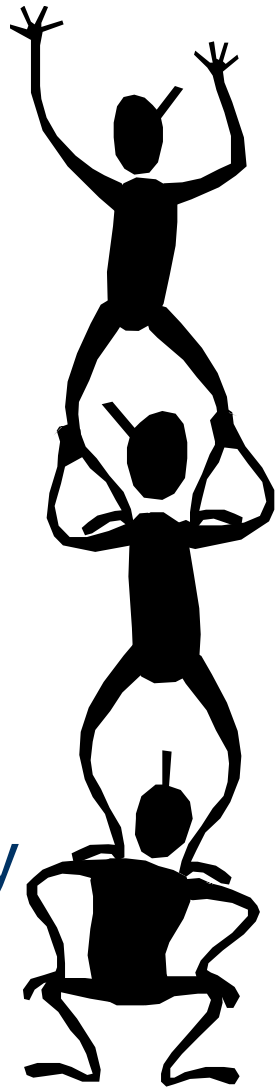
Simple Pesticide Label Structure



Source: http://www.epa.gov/pesticides/label/

OPP's Basis for Structure

- Label Review Manual
- Data fields from
  - OPPIN
  - Label Use Information System (LUIS)
- OPP Workgroup
- XML schema for submission to OPP only
- Envision additional schema for output



Content Organizational Categories

- General Information
  - overall product and company information.
- Ingredient Statement
  - details about the active ingredients and diluents.
- Precautionary Statements
  - restrictions regarding environmental, human and user safety.
- Directions for Use
  - instructions on how to mix and apply the product.
- Additional Information
  - product warranty and marketing information.
- Regulatory Information
  - EPA tracking and processing information.

Degree of structure

- Large free-text blocks
- Discrete values
- Mixed
  - Re-entry interval contained with in a text block
- Non-label information
  - Required for validation
  - LD50

Label content from discrete data

Active Ingredients:	
2,4-dichlorophenoxyacetic acid, triisopropanolamine salt	34.05%
2,4-dichlorophenoxyacetic acid, dimethylamine salt	21.97%
Other Ingredients	43.98%
Total	100.00%

Acid Equivalent: 2,4-dichlorophenoxyacetic acid – 36.5% – 3.8 lb/gal

Label content as free text

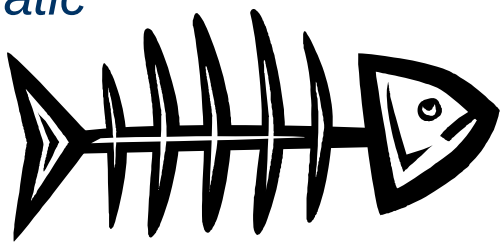
Mixing with Liquid Nitrogen Fertilizer

This product may be combined with liquid nitrogen fertilizer suitable for foliar application to accomplish broadleaf weed control and fertilization of corn, small grains, sorghum, or pastures in a single operation. Use Formula 40 in accordance with recommendations for these crops provided in this label. Use liquid fertilizer at rates recommended by the supplier or extension service specialist. Test for mixing compatibility by mixing spray ingredients in correct proportions in a clear glass jar before mixing in spray tank. A compatibility aids such as Unite or Compex may be needed in some situations. Compatibility is best with liquid fertilizer solutions containing only nitrogen. Mixing with N-P-K solutions may not be satisfactory, even with the addition of a compatibility aid. Pre-mixing Formula 40 with 1 to 4 parts water may help in situations when mixing difficulty occurs.

Fill the tank about half full with the liquid fertilizer, then add the required amount of Formula 40 with agitation.. Maintain agitation and complete filling the tank with liquid fertilizer. Apply immediately and continue spray tank agitation during application. **Do not store the spray mixture.** To avoid spray mixture compatibility problems, application during cold weather (less 40°F) is not recommended.

Non-target Organism Statement

- Label Review Manual Ch. 8, II, E
- 2. “The following statement has historically been required when a pesticide intended for outdoor use contains an active ingredient with a fish acute LC50 or aquatic invertebrate (including estuarine species such as oyster and mysid shrimp) EC50 = 1 ppm:”
  - "*This pesticide is toxic to [fish] [fish and aquatic invertebrates] [oysters/shrimp] or [fish, aquatic invertebrates, oysters and shrimp].* ”



Label content built from standard text

Environmental Hazards

This product is toxic to aquatic invertebrates and may be toxic to fish. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark except as noted on appropriate labels. Drift or runoff may adversely affect aquatic invertebrates and nontarget plants. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Application around a cistern or well may result in contamination of drinking water or groundwater.

Advantages

- Standard statements allow for more efficient review
- Level playing field across products and companies
- Facilitates mitigation
- Supports web-distributed labeling

Label content – Combined text & structured content

Agricultural Use Requirements

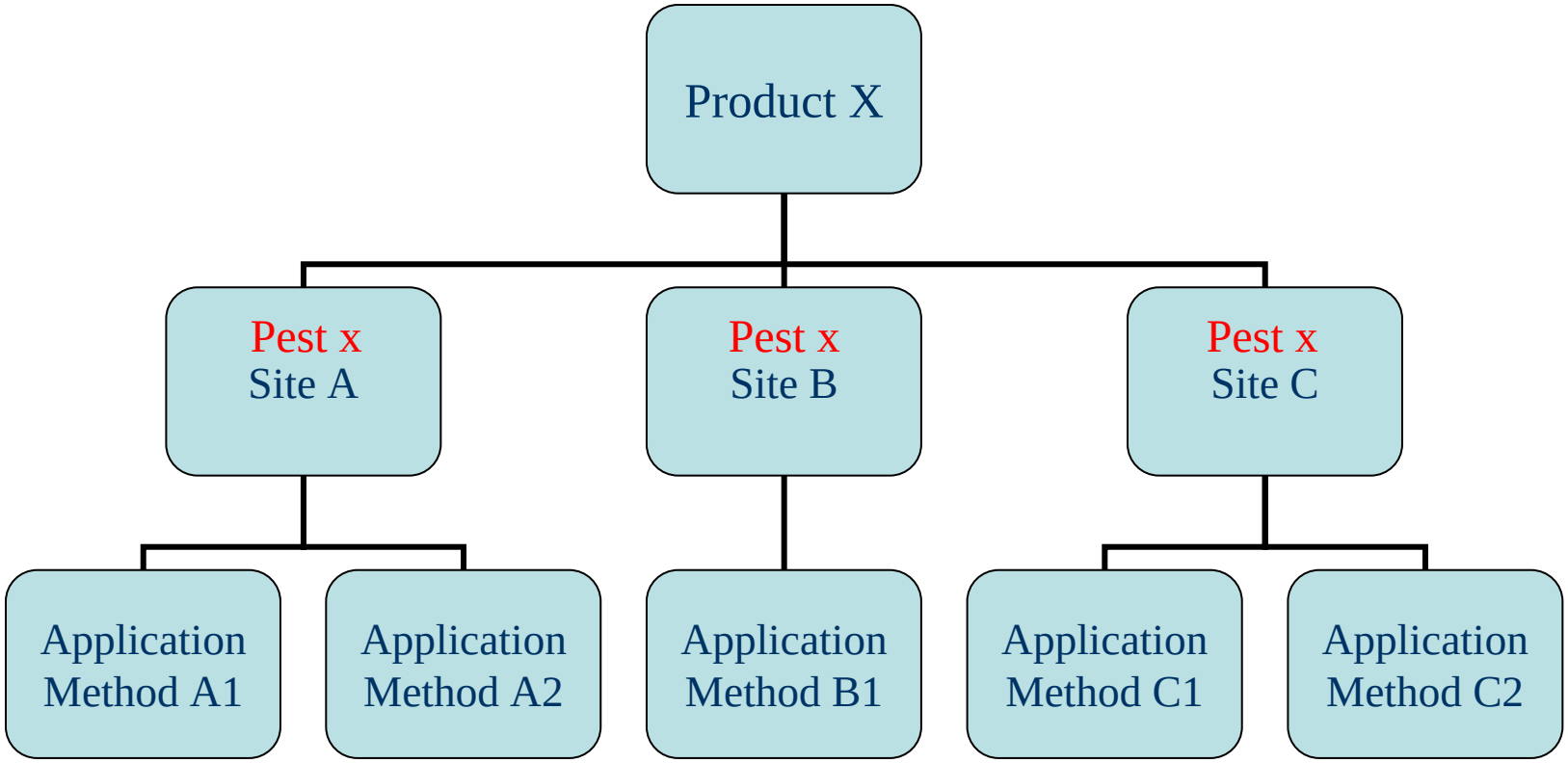
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear

Data Hierarchy



Business Rules

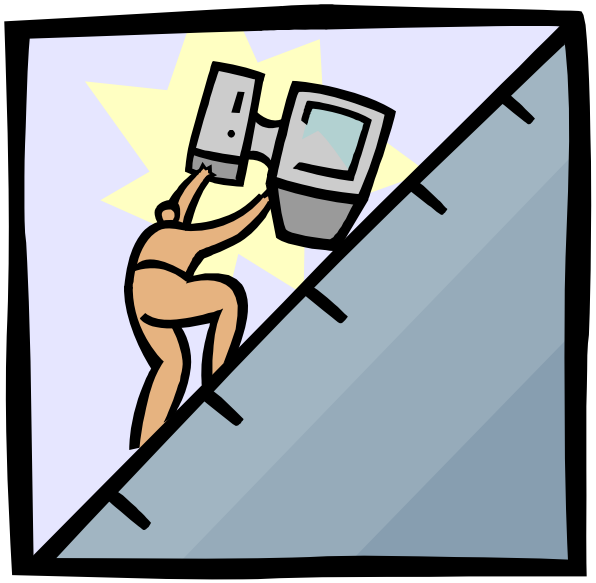
- Precautionary Statement fields' content
  - Usually based on toxic category
  - Most fields will be standardized
  - Allow the users to edit the statements.
  - Edited fields will be flagged for further review.
- Each of the major label field categories should include an extra free text field to allow registrants to enter any additional information that did not fit into the pre-defined structure.
- EPA-defined pick lists will include an "other" option
  - allows the registrant to enter a value that is not on the lists..
- EPA-defined pick lists should include both the scientific and common names where applicable.

Key Elements of e-Label Submission

- XML Schema
  - Identifies label content
  - All content would be included
  - Includes some non-label information
- PDF
  - For visual/graphic requirements

Progress

- Defined structure requirements
  - Internal OPP Workgroup
- Developed XML Schema
  - Version 1
- Defined e-Label Builder requirements
  - Based on structure



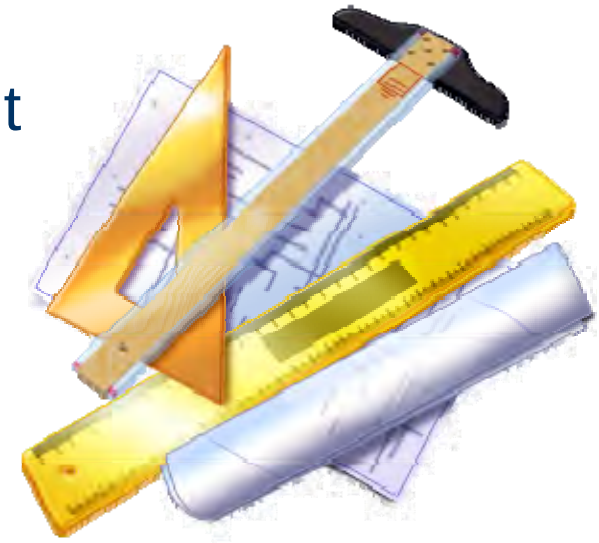
What is an XML Schema?

- Describes the structure of an XML document.
- Defines the legal building blocks of an XML document
  - defines **elements** that can appear in a document
  - defines **attributes** that can appear in a document
  - defines which elements are **child elements**
  - defines the **order** of child elements
  - defines the **number** of child elements
  - defines whether an element is **empty** or can include text
  - defines **data types** for elements and attributes
  - defines **default** and **fixed values** for elements and attributes

    - Source: http://www.w3schools.com/Schema

Data Fields

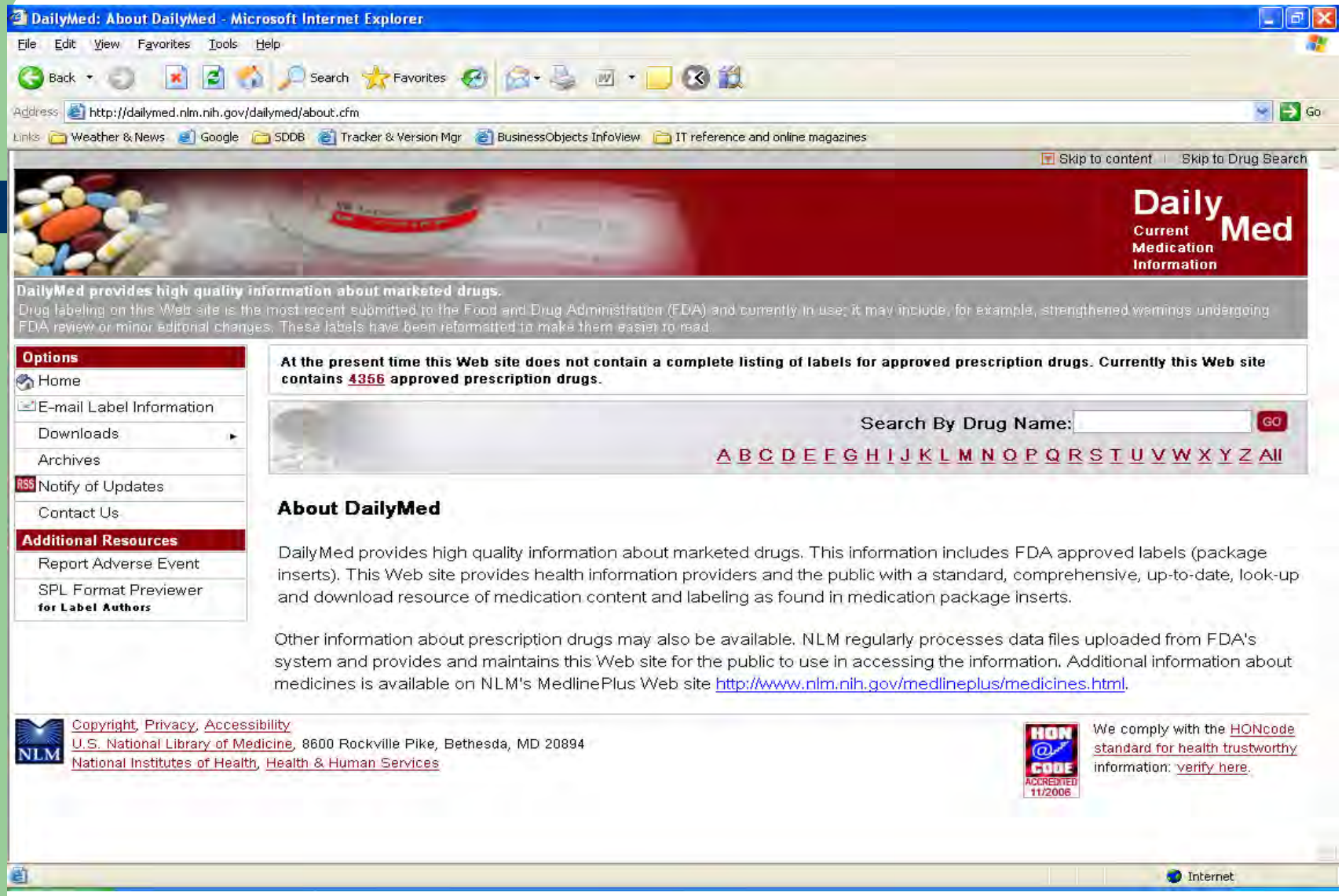
- 280 Data elements
- 7 Categories
- 34 Label sections
  - Active ingredient
  - Personal protective equipment
- 25 Subsections
  - AI name, percent
  - Respirator type, Role



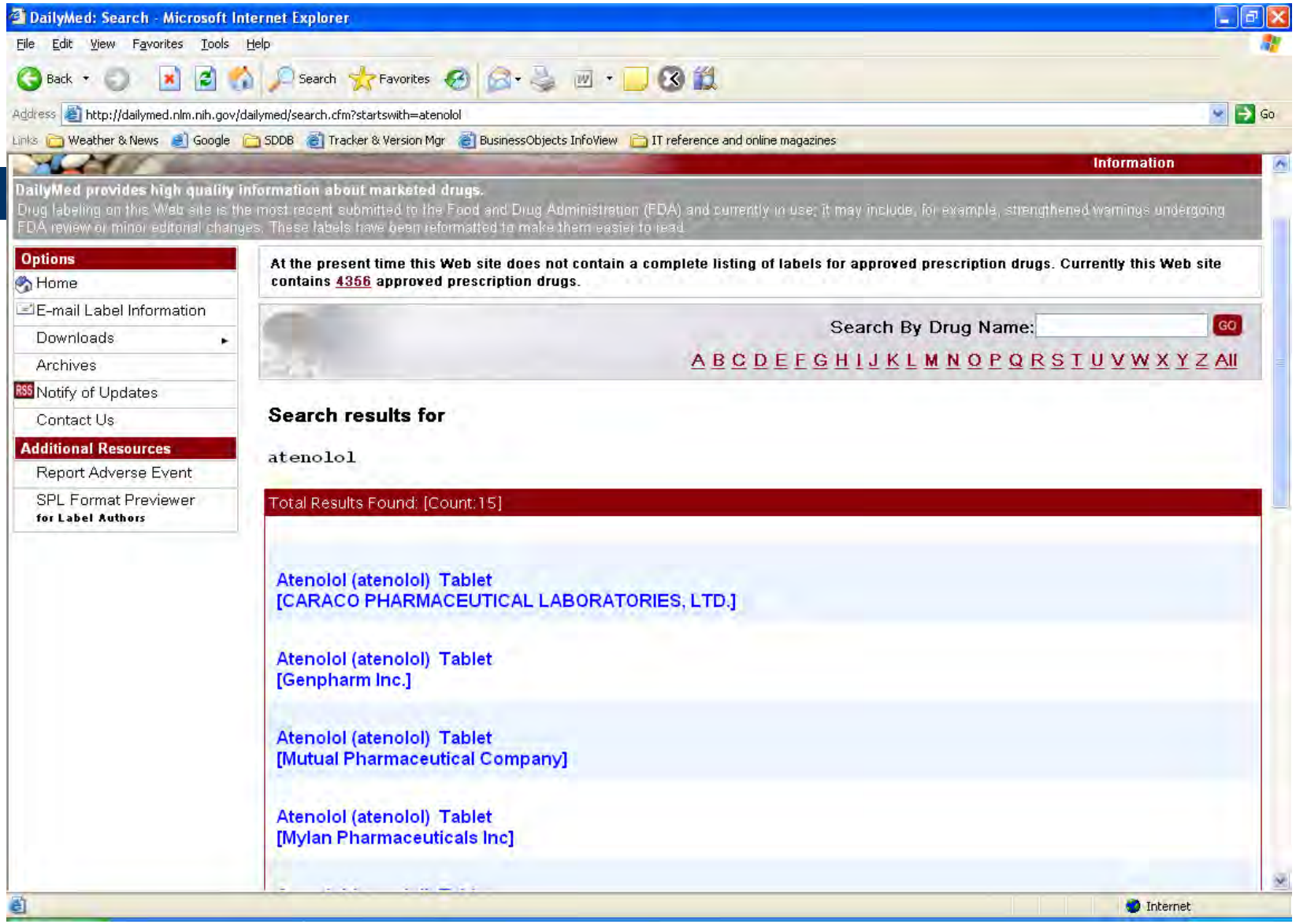
Current Thinking

- Less granularity of Use Directions
  - Application instructions too complicated
  - Maintain some discrete data
    - Site
    - Pest
    - Restrictions
    - PHI, PGI, etc.
- Alternatives to “Turbo Tax”-style for Builder
- Identify “problem” areas of labels

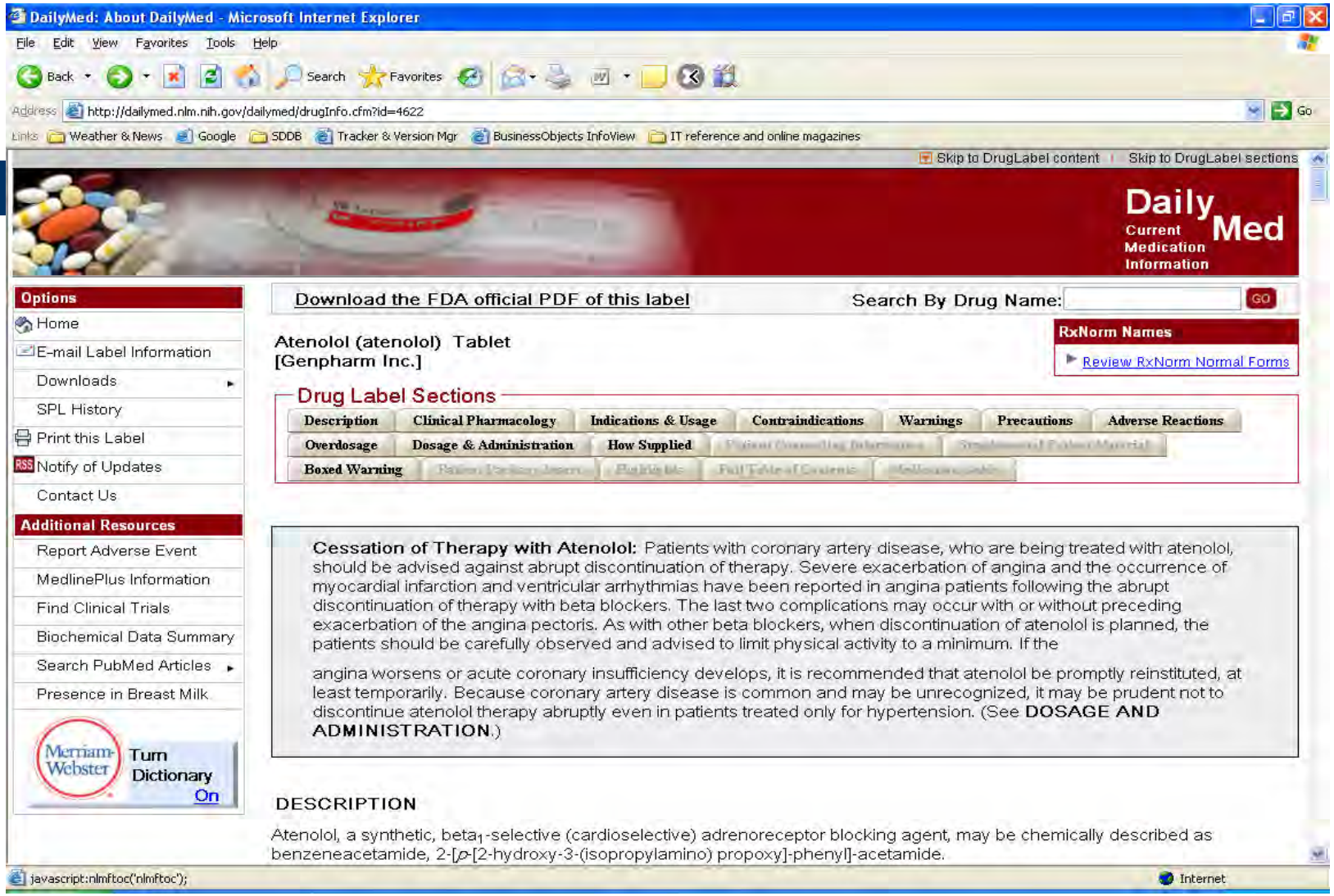
Real Life Web Label – NIH Daily Med & FDA SPL



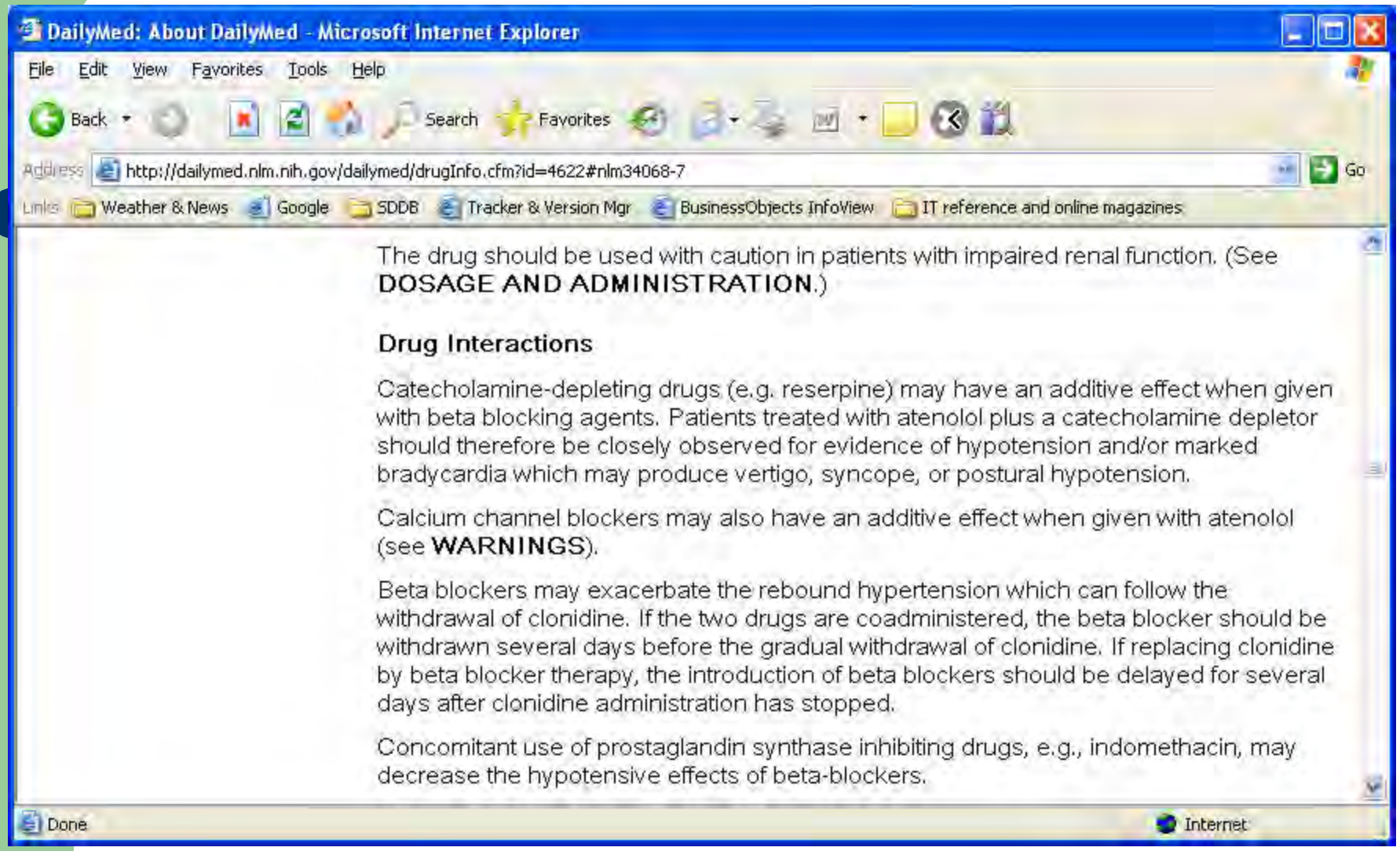
Real Life Web Label – Atenolol Search



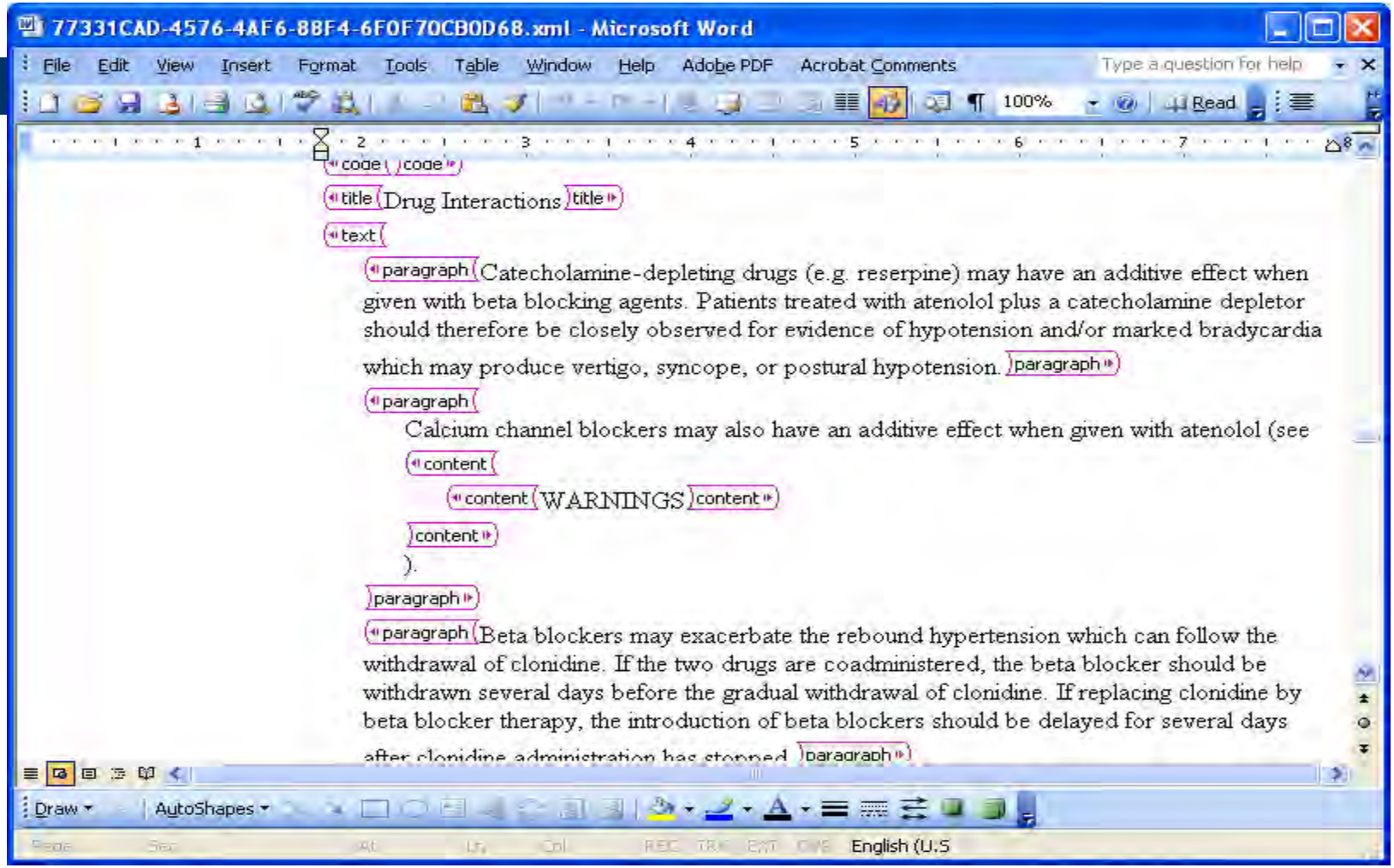
abel – Atenolol Label Content



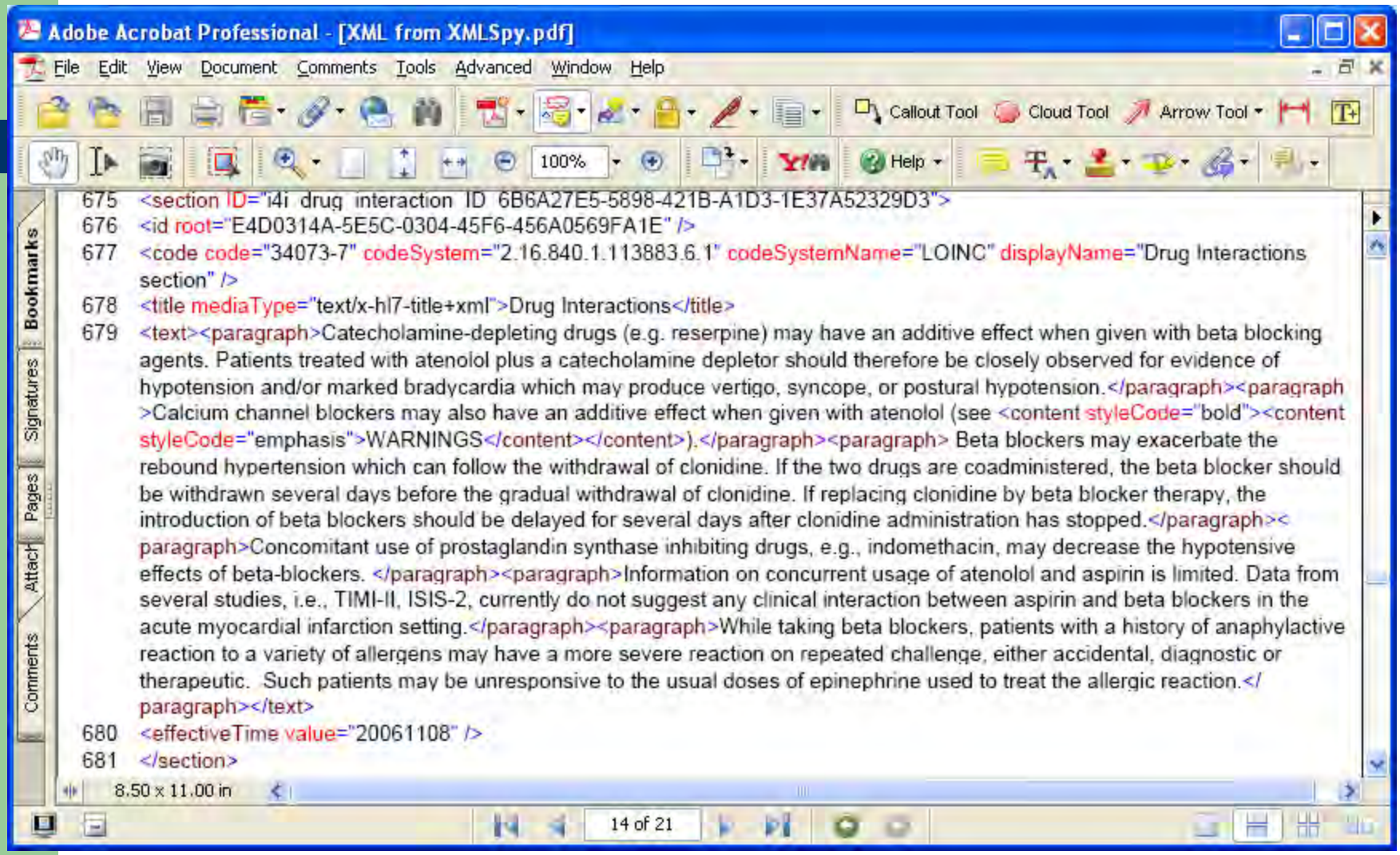
Real Life Web Label – Drug Interactions



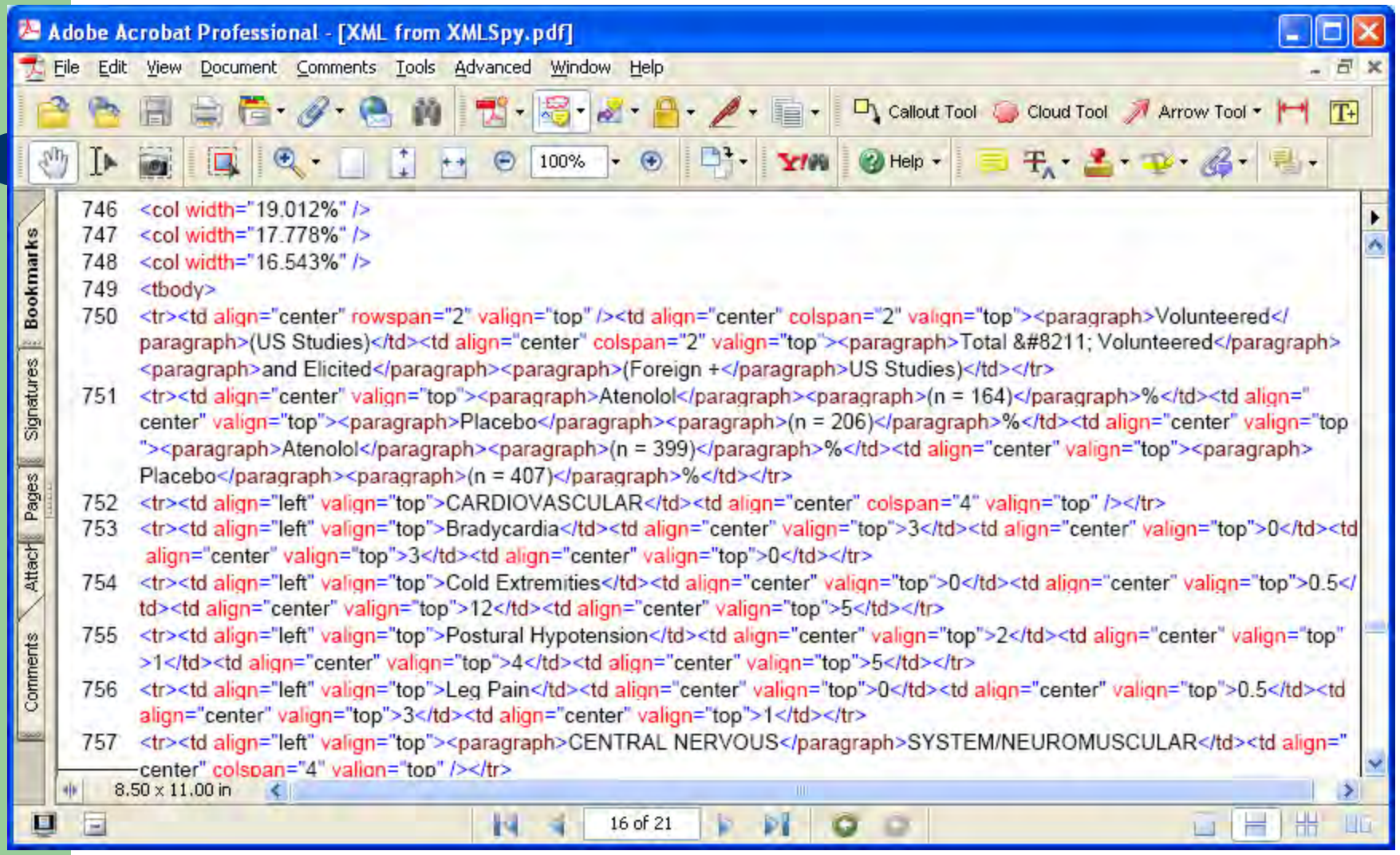
Real Life Web Label - Structuring



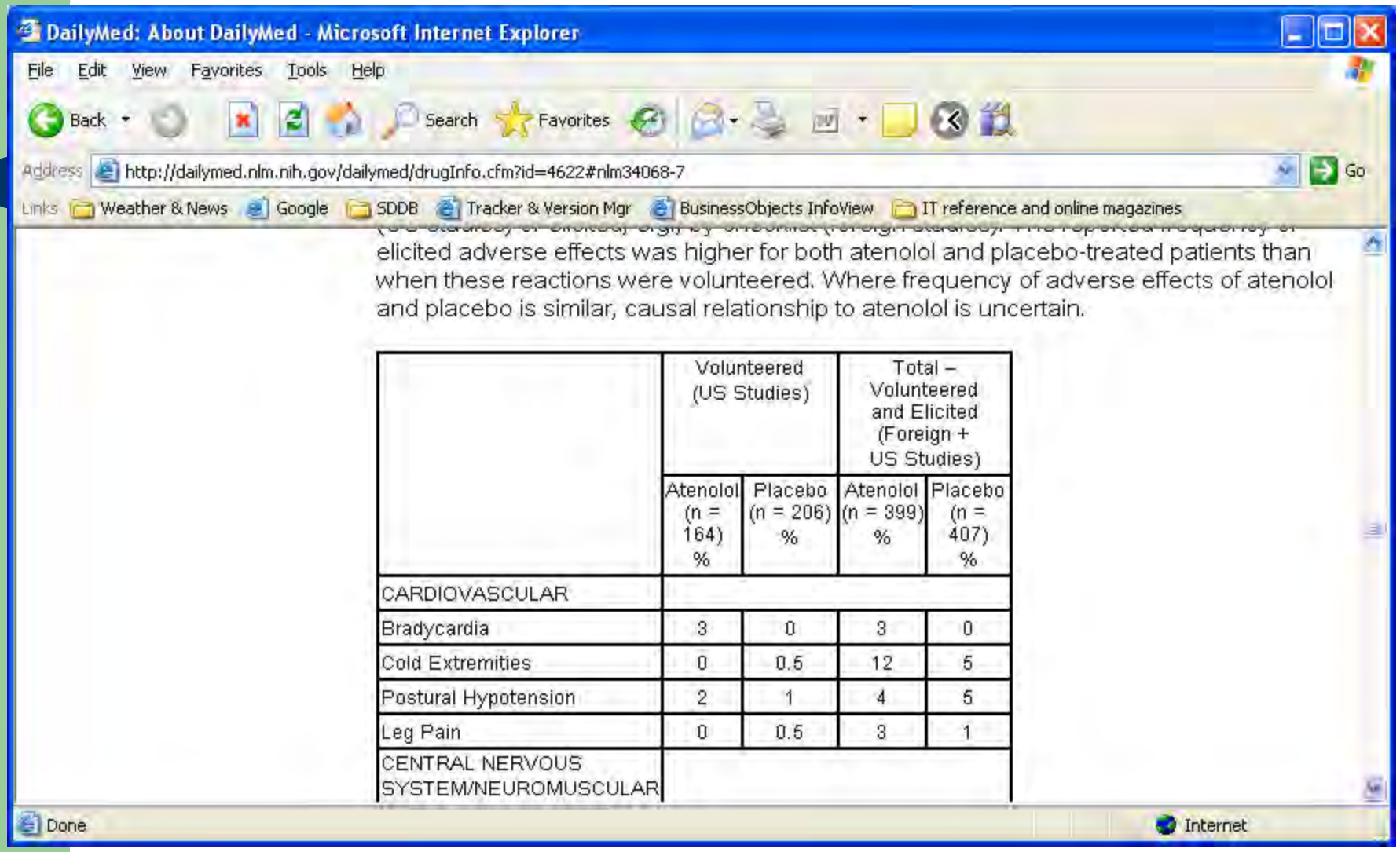
Real Life Web Label - XML



Real Life Web Label – XML Table



Real Life Web Label – Display Table



elicited adverse effects was higher for both atenolol and placebo-treated patients than when these reactions were volunteered. Where frequency of adverse effects of atenolol and placebo is similar, causal relationship to atenolol is uncertain.

	Volunteered (US Studies)		Total – Volunteered and Elicited (Foreign + US Studies)	
	Atenolol (n = 164) %	Placebo (n = 206) %	Atenolol (n = 399) %	Placebo (n = 407) %
CARDIOVASCULAR				
Bradycardia	3	0	3	0
Cold Extremities	0	0.5	12	5
Postural Hypotension	2	1	4	5
Leg Pain	0	0.5	3	1
CENTRAL NERVOUS SYSTEM/NEUROMUSCULAR				

Questions and Discussion