

# Electronic Labeling and Structured Label Content

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Office of Pesticide Programs

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# 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. ...”
    - [www.sdbay.sdsu.edu/glossary/index.php](http://www.sdbay.sdsu.edu/glossary/index.php)

# Simple Pesticide Label Structure

## PRODUCT NAME

<b>DIRECTIONS FOR USE</b> It is a violation of federal law to use this product in a manner inconsistent with its labeling. _____ _____	<b>KEEP OUT OF THE REACH OF CHILDREN DANGER</b>
<b>PRECAUTIONARY STATEMENTS HAZARD TO HUMANS (AND DOMESTIC ANIMALS) DANGER</b> _____ _____ <b>ENVIRONMENTAL HAZARDS</b> _____ _____ <b>PHYSICAL OR CHEMICAL HAZARDS</b> _____ _____	<b>FIRST AID</b> (STATEMENT OF PRACTICAL TREATMENT)  IF SWALLOWED _____ IF INHALED _____ IF IN EYES _____ IF ON SKIN _____
<b>STORAGE AND DISPOSAL</b>  STORAGE _____ _____ DISPOSAL _____ _____	<b>ACTIVE INGREDIENTS:</b> _____ % <b>OTHER (INERT) INGREDIENTS:</b> _____ % <b>TOTAL:</b> _____ 100.00%  <b>THIS PRODUCT</b> _____ <b>WARRANTY STATEMENT</b> <b>CONTAINS XX LBS.</b> _____ <b>OF XXXX PER GALLON</b> _____ <b>MANUFACTURER'S</b> _____ <b>ADDRESS</b> _____ <b>NET WT. / NET CONTENTS STATEMENT:</b> _____ <b>EPA Registration No. / EPA Reg. No:</b> _____ <b>EPA Establishment No. / EPA Est. No:</b> _____

# 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
  - Discrete data value contained within 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

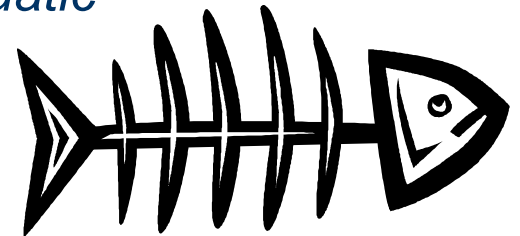
## Mixing with Liquid Nitrogen Fertilizer

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**

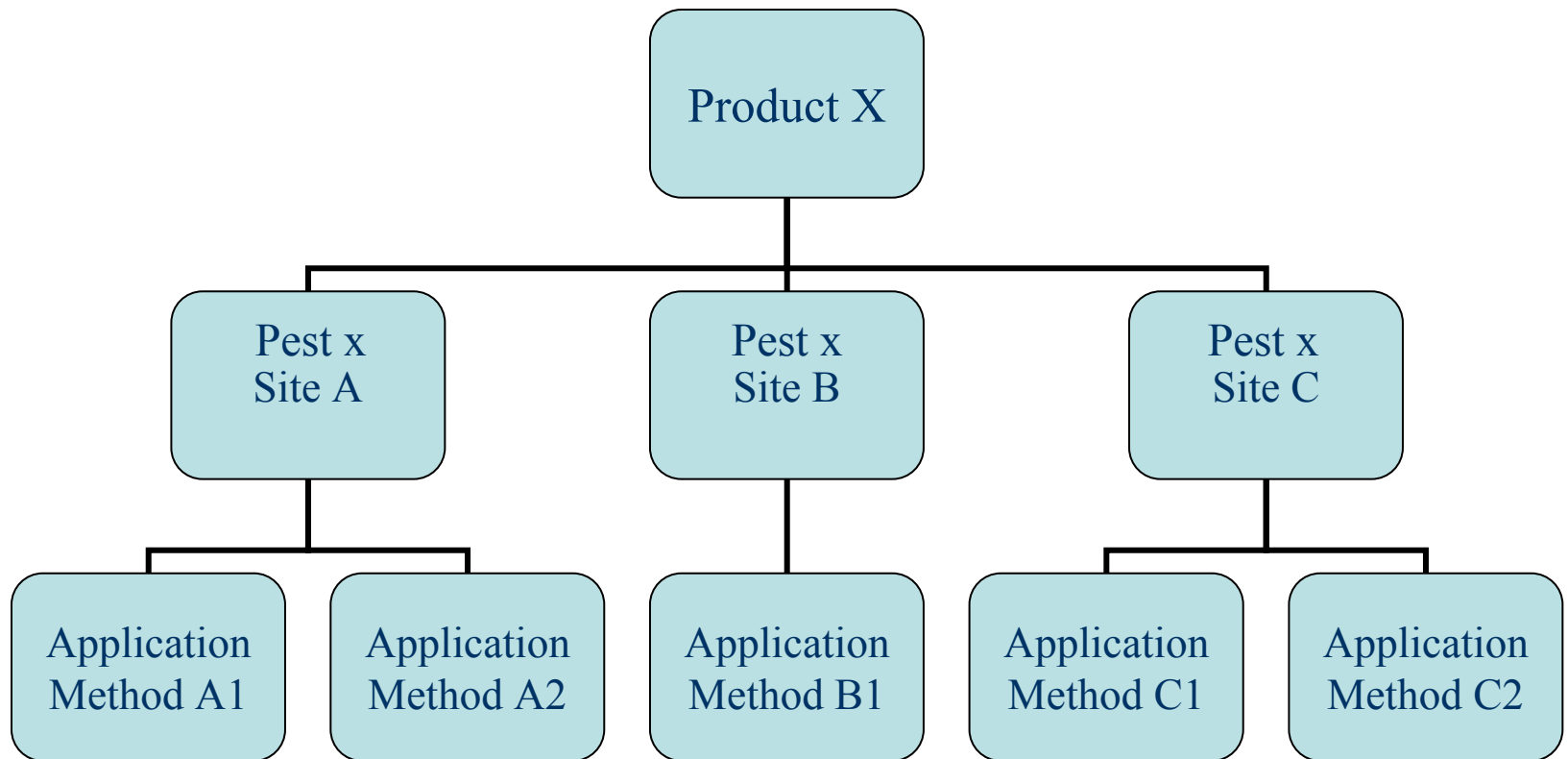
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements 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
- PDF
  - For visual/graphic requirements



# Real Life Web Label – NIH Daily Med & FDA SPL

DailyMed: About DailyMed - Microsoft Internet Explorer

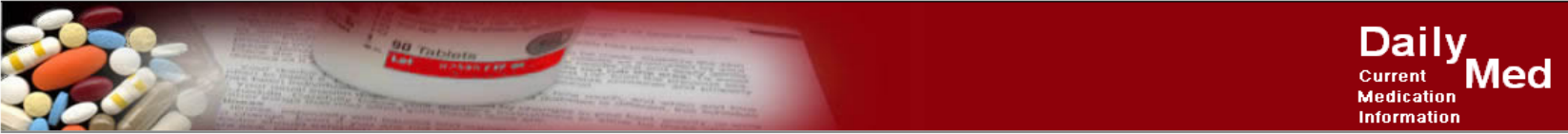
File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites RSS Feeds Print Mail

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Skip to content Skip to Drug Search



**Daily Med**  
Current Medication Information

**DailyMed provides high quality information about marketed drugs.**  
Drug labeling on this Web site is the most recent submitted to the Food and Drug Administration (FDA) and currently in use; it may include, for example, strengthened warnings undergoing FDA review or minor editorial changes. These labels have been reformatted to make them easier to read.

**Options**

- Home
- E-mail Label Information
- Downloads
- Archives
- RSS** Notify of Updates
- Contact Us

**Additional Resources**

- Report Adverse Event
- SPL Format Previewer for Label Authors

**At the present time this Web site does not contain a complete listing of labels for approved prescription drugs. Currently this Web site contains **4356** approved prescription drugs.**


Search By Drug Name:  **GO**


**A B C D E F G H I J K L M N O P Q R S T U V W X Y Z All**

**About DailyMed**

DailyMed provides high quality information about marketed drugs. This information includes FDA approved labels (package inserts). This Web site provides health information providers and the public with a standard, comprehensive, up-to-date, look-up and download resource of medication content and labeling as found in medication package inserts.

Other information about prescription drugs may also be available. NLM regularly processes data files uploaded from FDA's system and provides and maintains this Web site for the public to use in accessing the information. Additional information about medicines is available on NLM's MedlinePlus Web site <http://www.nlm.nih.gov/medlineplus/medicines.html>.

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Internet

# Real Life Web Label – Atenolol Search

**DailyMed: Search - Microsoft Internet Explorer**

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Address <http://dailymed.nlm.nih.gov/dailymed/search.cfm?startswith=atenolol> Go

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**Information**

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Search By Drug Name:  **GO**

**A B C D E F G H I J K L M N O P Q R S T U V W X Y Z All**

**Search results for**  
**atenolol**

**Total Results Found: [Count:15]**

- Atenolol (atenolol) Tablet**  
**[CARACO PHARMACEUTICAL LABORATORIES, LTD.]**
- Atenolol (atenolol) Tablet**  
**[Genpharm Inc.]**
- Atenolol (atenolol) Tablet**  
**[Mutual Pharmaceutical Company]**
- Atenolol (atenolol) Tablet**  
**[Mylan Pharmaceuticals Inc]**

Internet



# Real Life Web Label – Atenolol Label Content

DailyMed: About DailyMed - Microsoft Internet Explorer

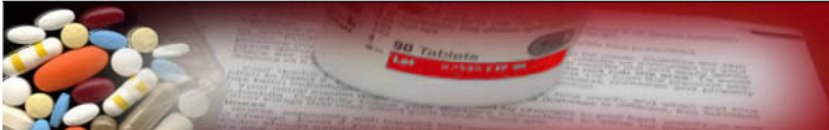
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Skip to DrugLabel content Skip to DrugLabel sections




**Daily Med**  
Current Medication Information

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- 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

 Turn Dictionary On

[Download the FDA official PDF of this label](#)

Search By Drug Name:  GO

**RxNorm Names**

[Review RxNorm Normal Forms](#)

**Atenolol (atenolol) Tablet**  
[Genpharm Inc.]

**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		

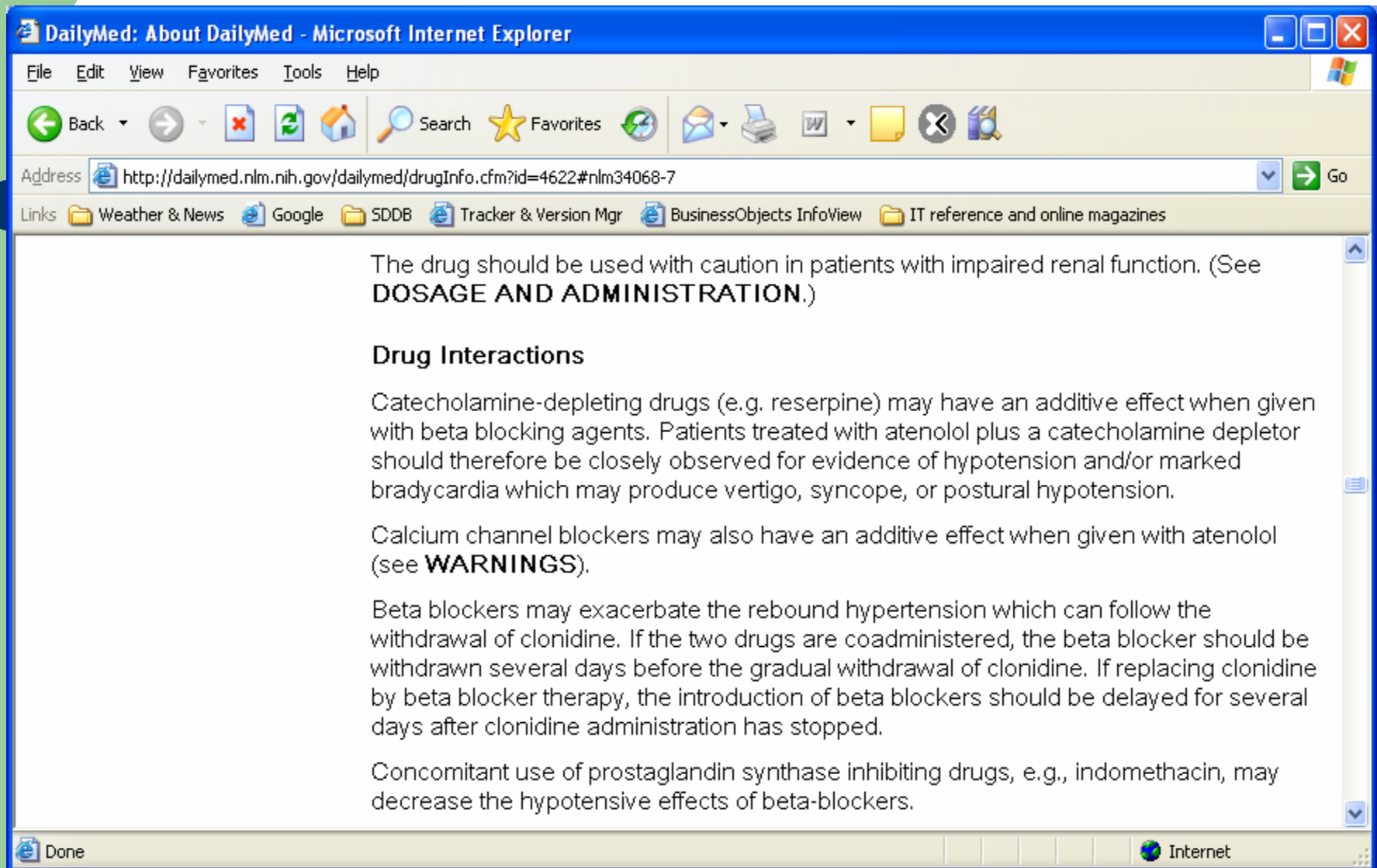
**Cessation of Therapy with Atenolol:** Patients with coronary artery disease, who are being treated with atenolol, should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported in angina patients following the abrupt discontinuation of therapy with beta blockers. The last two complications may occur with or without preceding exacerbation of the angina pectoris. As with other beta blockers, when discontinuation of atenolol is planned, the patients should be carefully observed and advised to limit physical activity to a minimum. If the angina worsens or acute coronary insufficiency develops, it is recommended that atenolol be promptly reinstituted, at least temporarily. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue atenolol therapy abruptly even in patients treated only for hypertension. (See **DOSAGE AND ADMINISTRATION**.)

**DESCRIPTION**

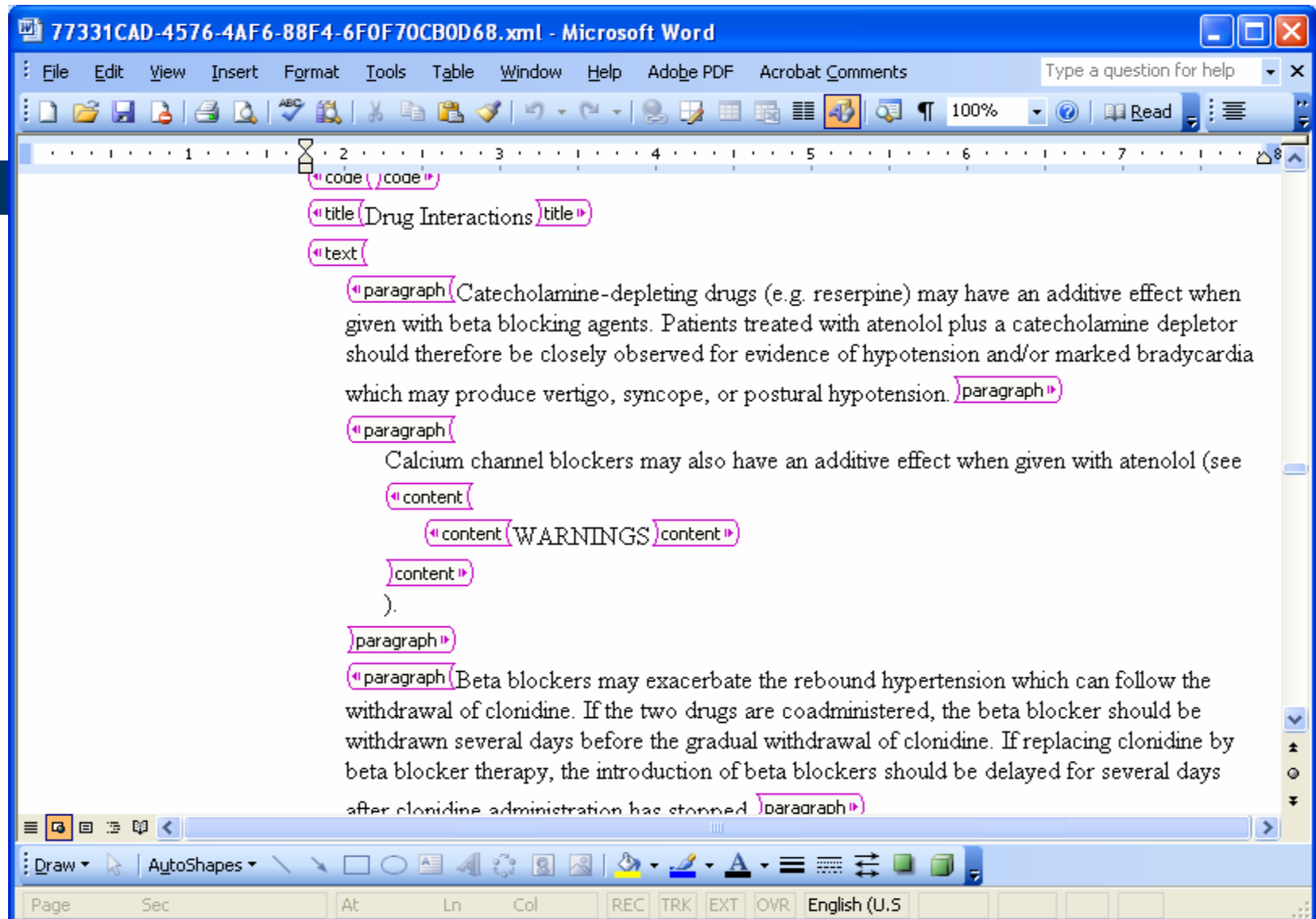
Atenolol, a synthetic, beta<sub>1</sub>-selective (cardioselective) adrenoreceptor blocking agent, may be chemically described as benzeneacetamide, 2-[p-[2-hydroxy-3-(isopropylamino) propoxy]-phenyl]-acetamide.

javascript:nlmftoc("nlmftoc"); Internet

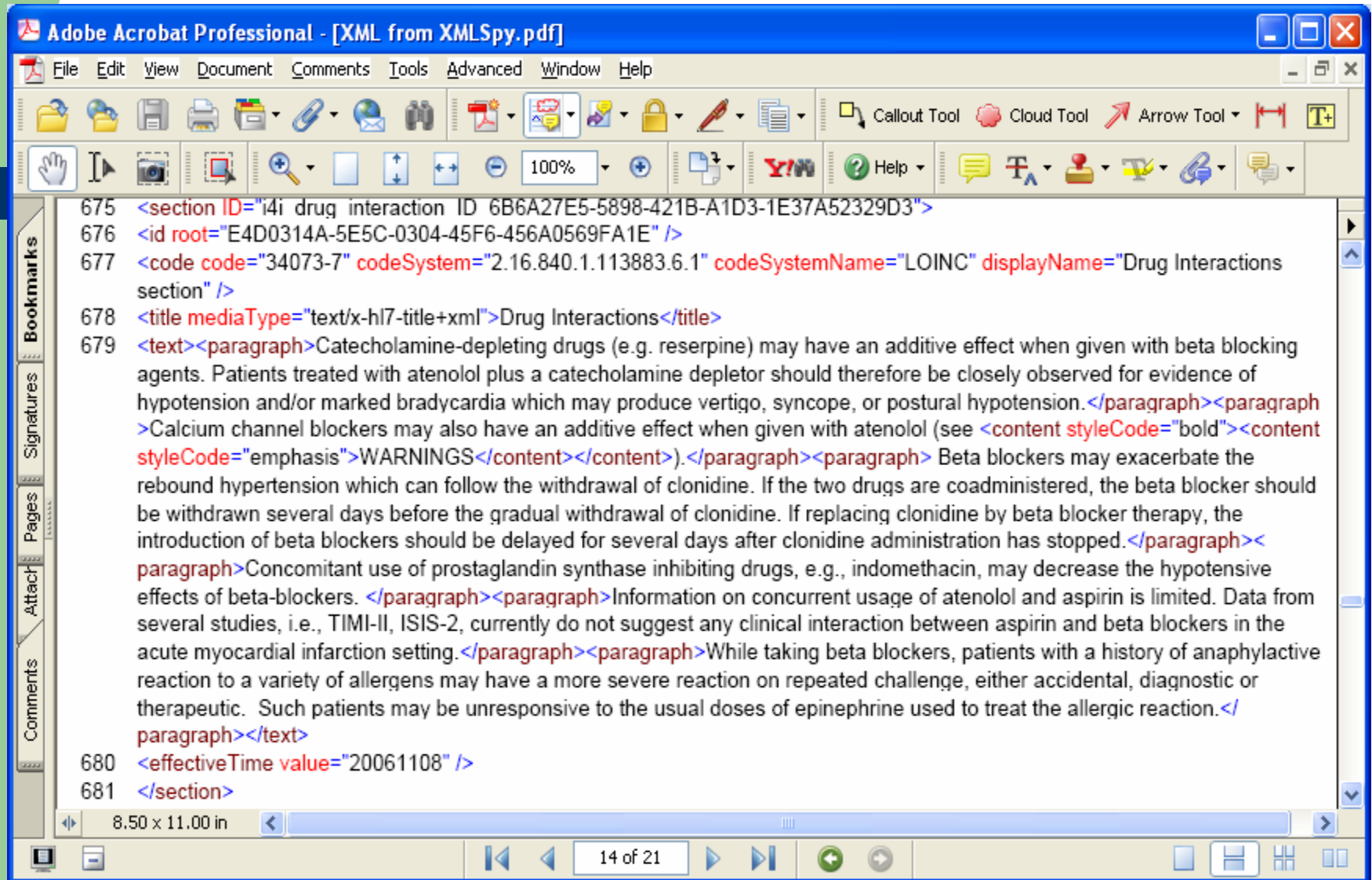
# Real Life Web Label – Drug Interactions



# Real Life Web Label - Structuring



# Real Life Web Label - XML



# Real Life Web Label – XML Table

The screenshot shows the Adobe Acrobat Professional interface with the file '[XML from XMLSpy.pdf]'. The main content area displays XML code for a table, with line numbers 746 through 757 on the left. The XML code defines a table with columns for medical conditions and their associated statistics. The table structure is as follows:

CARDIOVASCULAR	Bradycardia	Cold Extremities	Postural Hypotension	Leg Pain	CENTRAL NERVOUS SYSTEM/NEUROMUSCULAR
Volunteered (US Studies)	Total &#8211; Volunteered and Elicited (Foreign + US Studies)	Atenolol (n = 164)	Placebo (n = 206)	Atenolol (n = 399)	Placebo (n = 407)
3	0	0.5	12	5	
2	1	4	5	3	1
CENTRAL NERVOUS SYSTEM/NEUROMUSCULAR					

The XML code is as follows:

```
746 <col width="19.012%" />
747 <col width="17.778%" />
748 <col width="16.543%" />
749 <tbody>
750 <tr><td align="center" rowspan="2" valign="top" /><td align="center" colspan="2" valign="top"><paragraph>Volunteered</paragraph>(US Studies)</td><td align="center" colspan="2" valign="top"><paragraph>Total &#8211; Volunteered</paragraph>and Elicited</td><td align="center" colspan="2" valign="top"><paragraph>(Foreign +</paragraph>US Studies)</td></tr>
751 <tr><td align="center" valign="top"><paragraph>Atenolol</paragraph><paragraph>(n = 164)</paragraph>%</td><td align="center" valign="top"><paragraph>Placebo</paragraph><paragraph>(n = 206)</paragraph>%</td><td align="center" valign="top"><paragraph>Atenolol</paragraph><paragraph>(n = 399)</paragraph>%</td><td align="center" valign="top"><paragraph>Placebo</paragraph><paragraph>(n = 407)</paragraph>%</td></tr>
752 <tr><td align="left" valign="top">CARDIOVASCULAR</td><td align="center" colspan="4" valign="top" /></tr>
753 <tr><td align="left" valign="top">Bradycardia</td><td align="center" valign="top">3</td><td align="center" valign="top">0</td><td align="center" valign="top">3</td><td align="center" valign="top">0</td></tr>
754 <tr><td align="left" valign="top">Cold Extremities</td><td align="center" valign="top">0</td><td align="center" valign="top">0.5</td><td align="center" valign="top">12</td><td align="center" valign="top">5</td></tr>
755 <tr><td align="left" valign="top">Postural Hypotension</td><td align="center" valign="top">2</td><td align="center" valign="top">1</td><td align="center" valign="top">4</td><td align="center" valign="top">5</td></tr>
756 <tr><td align="left" valign="top">Leg Pain</td><td align="center" valign="top">0</td><td align="center" valign="top">0.5</td><td align="center" valign="top">3</td><td align="center" valign="top">1</td></tr>
757 <tr><td align="left" valign="top"><paragraph>CENTRAL NERVOUS</paragraph>SYSTEM/NEUROMUSCULAR</td><td align="center" colspan="4" valign="top" /></tr>
```

# Real Life Web Label – Display Table

DailyMed: About DailyMed - Microsoft Internet Explorer

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Address <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=4622#nml34068-7> Go

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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				

Done Internet

# OPP's Basis for Structure

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



# Questions and Discussion

