



Understanding Changes to Patient Labeling Requirements

MedCon Conference

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Agenda



- Evolving FDA criteria for label comprehension studies
 - What do we need to communicate?
 - When are comprehension studies needed?
 - How are they designed?
 - How are they conducted?
- Case studies
- Keys to success
- Questions

Things are changing...



- While device studies are different than drug studies...
 - Sample size
 - Combined study designs
 - Statistical analysis
- Things are evolving
 - CDRH and CDER are collaborating more often
 - Social Scientist input is being incorporated more often
 - CDRH is specifically requesting comprehension and self-selection data more often

Historically...Readability



- Ease of understanding or comprehension achieved by the style of writing. Reading involves both *decoding and comprehension*. The reader must be able to recognize (decode) the words in the medical device patient labeling as well as comprehend the meaning of the text.
 - Choice of words
 - Sequence of events
 - Organizing into sections and headings
 - Reading level no higher than 8th grade
 - Testing (pre-testing and quantitative testing)
 - Impressions and feedback (pre-testing)
 - Self-administered questionnaires or usability testing (quantitative)

CDRH Guidance on Medical Device Patient Labeling, April 19, 2001

Evolving...Comprehension



- Assesses the extent to which consumers *understand* the information on nonprescription drug product labeling and then *apply this information* when making drug product use decisions *in a hypothetical situation*.
- Label comprehension does not predict behavior.
- Recommend label comprehension evaluation in advance of actual use testing.

CDER Guidance on Label Comprehension Studies for Nonprescription Drug Products, August 2010

Historically... Minimal exterior labeling

- PDP
 - Statement of identity
 - Net quantity of contents
- Special warnings
 - E.g., Chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride
- Specific types of products have special requirements
 - Dentures (repair and refitting)
 - Impact resistant lenses in eyeglasses
 - Maximum ozone
 - Chlorofluorocarbon propellants
 - Hearing aid devices
 - Tampons
 - Latex condoms
 - Products with natural rubber

Evolving...more drug facts-like

- Purpose: Statement of identity
- Uses = Indications
- Warnings = 6-8
 1. Special: Allergy
 2. Do not use (Contraindications)
 3. Ask a doctor before use (Conditional)
 4. Ask a doctor or pharmacist before use (Conditional)
 5. When using this product (Side Effects)
 6. Stop use and ask a doctor
 7. Pregnancy
 8. Children/Overdose
- Directions – How and when to use

Drug Labeling -Drug Facts Label



PURPOSE:
ingredient, strength

USE = Indications

WARNINGS

Allergy

DNU = Contraindications

AADBU= Conditional
(medical conditions)

AADPBU= Conditional
(Drug-Drug)

**Stop Use
Warnings**

Pregnancy warning
Children/overdose

Drug Facts

Active ingredient (in each tablet)	Purpose
Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole)	Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.

Warnings

Allergy alert: Do not use if you are allergic to omeprazole.

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- cimetidine (stomach medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretroviral medicines for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush tablets.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other Information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

Inactive ingredients: glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polyorbital 80, polyvinylpyrrolidone, sodium lauryl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

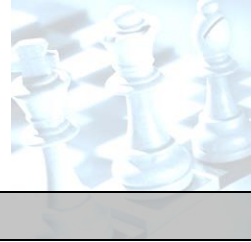
DIRECTIONS

Device Labeling - interior



- Descriptive Information
 - Purpose (indications)
 - Description of the device
 - When the product should not be used (contraindications)
 - Risks and benefits
 - Expectations of the device
 - Importance of adhering to a care regimen
- Operating Information
 - Set-up and check-out instructions
 - Operating instructions
 - Monitor activity of the device
 - Cleaning, maintenance and storage
 - Failure time and effect
 - Disposal of the device
 - Accessories
 - Troubleshooting

Other types of labeling



- Consumer Information Leaflets
 - Education
 - Tips for “Taking Charge”
- Trackers, logs
- Reference Guides
- Websites



Comprehension Testing: Designing and Conducting

Label Comprehension: Overview

- Testing the clarity of the label, not the consumer
 - Purpose, warnings and directions
- 1:1 Interviews
 - Usually 3rd party scenario questions
 - Followed by a probe to obtain the rationale
- Example: A drug intended for ages 18+
 - *Kristen is 16 years old and would like to use this device. Is it OK or not OK for her to use it?*
 - *Why do you say that?*

Label Comprehension: Iterative Process



- Qualitative: Iterative improvements
 - Test, adjust, re-test, adjust
 - Often 3 or more iterations
- Pilot
- Quantitative
- The label is the foundation of your program
 - It's worth investing time to get it right

Label Comprehension: Design



- Study Population
 - General population
 - Low literate population
 - % LL
 - REALM
- Endpoints
 - Primary endpoints: Based on a medical rationale
 - Secondary endpoints: Important, less safety risk
 - Exploratory endpoints: Important, little/no safety risk
- Judging success: # of failures

Interviews



- Well trained interviewers
- Experienced research sites
- Beyond the scenarios:
 - Additional diagnostic information
 - Demography
- Streaming and recording



Case Studies

Case Study #1



- Challenge:

Client had a laser hair removal device. Predicate existed. Goal was a full switch from professional use to over-the-counter.

Solution

*Iterative label **comprehension and self-selection** work due to concerns about proper self-selection. Two rounds of pre-testing and then a final usability study incorporating all three.*

Result: FDA cleared!

Case Study #2



- Challenge:

Automated External Defibrillator (AED) for consumer use in an emergency.

Solution

*Iterative label comprehension due to concerns about proper **comprehension in an emergency**. Two rounds of pre-testing and then a final usability study incorporating proper use (and understanding of instructions).*

Result: FDA cleared!

Case Study #3



- Challenge:

IVD device for home testing of drugs of abuse.

Solution

*Iterative label **comprehension and results interpretation** testing due to concerns about following proper procedure and interpretation of results. Two rounds of pre-testing and then a final usability study incorporating proper use and interpretation.*

Result: FDA cleared!

Keys to success



- Work with the end in mind (R2L)
- Two key questions:
 - What do you need to defend?
 - What do you want to hold in your hand after the testing is complete?
 - What is your plan if you do not get the anticipated results?
 - Mitigate
 - Re-work the labeling
 - (Sometimes both!)



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