

# Rationale for the Current Drug Facts Label Format

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# New DFL Format

FDA was concerned about how adequately OTC labeling communicated information necessary for safe and effective use of products

- Consumers being asked to make more sophisticated decisions
- Large population of consumers of low health literacy
- Growing number of elderly consumers

# Theories guiding DFL development

- Utilize information “Chunking”
  - People tend to organize similar information together to facilitate memory
- Decrease “cognitive load”
  - Lowering memory demands should allow information to be more fully processed
- Consumers tend to rely on heuristic cues to make decisions
  - People take mental shortcuts when their attention is divided
- A less imposing label will increase consumer confidence in decision-making

# New DFL Format

- New format would include:
  - Standardized format and content
  - Headings and subheadings for navigation
  - Shortened sentences
  - Less complex terms

# Goals of New DFL Format

- Use of less complex terminology, presented in shorter sentences, within a uniformly organized structure was expected to:
  - Decrease cognitive load
  - Increase consumers' willingness and self-perceived ability to read and understand the presented material
  - New format should help consumers prioritize the importance of the presented information (e.g. warnings)

# Testing New DFL Format

- Two studies were conducted to evaluate effects of the FDA proposed format changes and to gather information on consumer preferences for label design. These studies are informally referred to as “Study A” and “Study B.”
  - Study A: “Impact of Format Elements on Comprehension of Label Information” investigated the influence of the new format and the use of highlighting on communication of important label directions and warnings.
  - Study B: “Preference for Variations in OTC Label Format” investigated consumer preferences regarding OTC label format variations and examined comprehension of various methods of communicating the relative safety and effectiveness of OTC products.

# Study A: “Impact of Format Elements on Comprehension of Label Information”



- 1,202 adult subjects participated in the study
- Conducted in 8 geographically distributed shopping malls in the U.S.
- Examined 2 levels of each of 4 independent variables
  - Label format (old vs new)
  - Drug type (cough/cold vs pain reliever)
  - Highlighting (5 concepts vs 10 concepts)
  - Attention (divided vs focused)
- Highlighting, label format, and drug type were manipulated through variations in the design of the presented label. Attention was manipulated through instructions given to the subject

# Study A: “Impact of Format Elements on Comprehension of Label Information”



- The new format labels were designed following the examples in the OTC proposed rule. Old format labels were designed using the format on the market at the time.
- All labels presented the information in the same order: Active ingredient(s), Uses/Indications, Warnings, and Directions
- Labels were developed for 2 types of products, a cough cold remedy and a pain reliever
- “Highlighting” was accomplished through bold typeface
- Half of subjects were told they would be answering questions on a food label and a drug label (divided attention) and half were told they would answer questions about only 1 label (focused attention)

# Study A: "Impact of Format Elements on Comprehension of Label Information"



**Description:** New Format, Five Highlighted Communication Objectives (Cough/Cold) Label # 258

<p><b>Active Ingredients (In Each Softgel)</b></p> <p>Ifenessine 10 mg ..... Antihistamine  Pseudoephedrine Hydrochloride 40 mg ..... Nasal Decongestant  Tromethan 35mg ..... Cough Suppressant</p> <p><b>Purposes</b></p> <p>Uses: For the temporary relief of these cold symptoms: • sneezing • runny nose • cough • nasal congestion</p>	<p><b>When Using This Product:</b></p> <ul style="list-style-type: none"> <li>■ drowsiness may occur</li> <li>■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect</li> <li>■ use caution when driving a motor vehicle or operating machinery</li> <li>■ excitability may occur, especially in children</li> </ul> <p><b>Stop Using This Product If:</b></p> <ul style="list-style-type: none"> <li>■ cough is accompanied by fever, rash or headache that lasts</li> <li>■ stomach pain occurs</li> <li>■ nervousness, dizziness or sleeplessness occur</li> <li>■ symptoms do not improve within 7 days</li> </ul> <p><b>Ask a doctor. These may be signs of a serious condition.</b></p> <p>If pregnant or breast feeding, ask a health professional before use.  <b>Keep out of reach of children.</b>  In case of overdose, get medical help right away.</p>						
<p><b>Do Not Use:</b></p> <ul style="list-style-type: none"> <li>■ if taking a monoamine oxidase inhibitor (MAOI) prescription drug (for depression, psychiatric or emotional conditions, or Parkinson's disease)</li> <li>■ for 2 weeks after stopping an MAOI drug. If uncertain about your prescription drug, ask a health professional if it contains an MAOI.</li> <li>■ during the first 4 months of pregnancy</li> </ul> <p><b>Ask A Doctor Before Use</b></p> <p><b>If You Have:</b></p> <ul style="list-style-type: none"> <li>■ heart disease</li> <li>■ excessive phlegm (mucous)</li> <li>■ glaucoma</li> <li>■ high blood pressure</li> <li>■ diabetes</li> <li>■ thyroid disease</li> <li>■ a cough that lasts from smoking, asthma or emphysema</li> <li>■ cough with fever, rash or headache that lasts</li> <li>■ a breathing problem such as emphysema or chronic bronchitis</li> <li>■ difficulty in urination due to prostate gland enlargement</li> </ul> <p><b>If You Are:</b></p> <ul style="list-style-type: none"> <li>■ taking any drugs for asthma</li> <li>■ taking sedatives or tranquilizers</li> </ul>	<p><b>Directions:</b> Do not use more than directed.</p> <table border="1"> <tr> <td>Adults and children over 12 years of age</td> <td>Take 2 softgels every 4 hours. Do not take more than 4 doses (8 softgels) in a 24-hour period.</td> </tr> <tr> <td>Children 6 to under 12 years</td> <td>Take 1 softgel every 4 hours</td> </tr> <tr> <td>Children under 6 years of age</td> <td>Should not use this product</td> </tr> </table> <p>Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).</p>	Adults and children over 12 years of age	Take 2 softgels every 4 hours. Do not take more than 4 doses (8 softgels) in a 24-hour period.	Children 6 to under 12 years	Take 1 softgel every 4 hours	Children under 6 years of age	Should not use this product
Adults and children over 12 years of age	Take 2 softgels every 4 hours. Do not take more than 4 doses (8 softgels) in a 24-hour period.						
Children 6 to under 12 years	Take 1 softgel every 4 hours						
Children under 6 years of age	Should not use this product						

**Description:** Old Format, Five Highlighted Communication Objectives (Cough/Cold) Label # 173

**Active Ingredients:** Ifenessine, 10mg (Antihistamine), Pseudoephedrine Hydrochloride, 40mg (Nasal Decongestant), Tromethan, 35mg (Cough Suppressant).

**Indications:** For the temporary relief of cold symptoms such as sneezing, runny nose, cough, or nasal congestion.

**Warnings:** Drug Interaction Precaution: *Do not use this product if you are now taking a monoamine oxidase inhibitor (MAOI) prescription medication (for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug.* If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product. Women should avoid taking this product during the early stages (first 4 months) of pregnancy. Unless directed by a physician, do not take this product if you have heart disease, cough accompanied by excessive phlegm (mucous), glaucoma, high blood pressure, diabetes, or thyroid disease. Likewise, if you have a persistent or chronic cough such as occurs with smoking, asthma, emphysema, chronic bronchitis, difficulty in urination due to enlargement of the prostate gland, are taking any drugs for the treatment of asthma, or you are taking any sedatives or tranquilizers, do not take this product unless directed by a physician. Marked drowsiness may occur while using this product. Avoid alcoholic beverages while taking this product. Alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Use caution when driving a motor vehicle or operating machinery while taking this product. This product may cause excitability, especially in children. A persistent cough or stomach pain may be a sign of a serious condition. *If cough is accompanied by fever, rash, or persistent headache, if you experience stomach pain, or if other symptoms persist or do not improve within 7 days, stop using this product and consult a physician.* If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a physician. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

**Directions:** Do not exceed recommended dosage.  
Adults and children over 12 years of age: Take 2 softgels every 4 hours, while symptoms persist, not to exceed 4 doses (8 softgels) in 24 hours, or as directed by a physician.  
Children 6 to under 12 years of age: Take 1 softgel every 4 hours.  
Children 6 years of age or under should not be permitted to take this medication.

Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).



# Study A: “Impact of Format Elements on Comprehension of Label Information”

- Subjects were presented with the label(s) they were instructed to read and were allowed as much time as they needed.
  - Each subject received only 1 drug label
- Interviewer then asked questions from a standardized questionnaire. Label was removed from view for product knowledge questions.
- Outcome measures included:
  - Product knowledge
  - Opinion ratings of label
  - Willingness to read label
  - Confidence in using label
  - Correct decision-making based on label

# Study A: “Impact of Format Elements on Comprehension of Label Information”



- Key takeaways
  - New format takes less time to read
  - New format allows better/faster simple search for information
  - Subjects preferred new format
  - More confidence in new format with divided attention
  - Subjects preferred labels with more highlighting, although results were mixed in terms of use decisions
  - When asked to recall items from label, subjects mostly recalled items in a pattern suggesting they read Directions first, followed by Uses and Warnings

# Study A: “Impact of Format Elements on Comprehension of Label Information”



- Old format never outperformed new format, but there were places where there were no differences between old and new.
- Some product knowledge scores were the same between formats
- Different scores/results based on type of drug. Cough/cold labels were more complex and scored differently than pain reliever.
  - Cough/cold did not perform differently on product use decisions between formats
  - Pain reliever in new format performed better than old format as compared to cough/cold
- Possible that number of active ingredients impacted success of new format

# Study B: “Preference for Variations in OTC Label Format”



- 904 adult subjects participated in the study
- Conducted in 8 geographically distributed shopping malls in the U.S.
- Examined 2 levels of each of 4 independent variables
  - Title (Medication Facts vs no title)
  - Order of Warnings and Directions (Warnings first vs Directions first)
  - Placement of Active Ingredients (top vs bottom)
  - Type of demarcation lines (thick vs thin)
- A cough/cold medication and sunscreen were chosen; 16 labels were developed for each drug type to incorporate all variables

# Study B: “Preference for Variations in OTC Label Format”



**Description:** Title, Thick demarcation lines, Warnings first, Active Ingredients at Top (Cough/Cold)  
Label # 696

Medication Facts							
<b>Active Ingredients (In Each Softgel)</b>	<b>Purposes</b>						
Iifenesine 10 mg ..... Antihistamine Pseudoephedrine ..... Nasal Decongestant Hydrochloride 40 mg Tromethan 35mg ..... Cough Suppressant							
<b>Uses:</b> For the temporary relief of these cold symptoms: • sneezing • runny nose • cough • nasal congestion							
<b>Do Not Use:</b> <ul style="list-style-type: none"> <li>if taking a monoamine oxidase inhibitor (MAOI) prescription drug (for depression, psychiatric or emotional conditions, or Parkinson’s disease)</li> <li>for 2 weeks after stopping an MAOI drug. If uncertain about your prescription drug, ask a health professional if it contains an MAOI.</li> <li>during the first 4 months of pregnancy</li> </ul>	<b>Warnings</b>						
<b>Ask A Doctor Before Use</b> <b>If You Have:</b> <ul style="list-style-type: none"> <li>heart disease</li> <li>glaucoma</li> <li>thyroid disease</li> <li>a cough that lasts from smoking, asthma or emphysema</li> <li>cough with fever, rash or headache that lasts</li> <li>a breathing problem such as emphysema or chronic bronchitis</li> <li>difficulty in urination due to prostate gland enlargement</li> </ul>	<b>Directions</b> Do not use more than directed. <table border="1"> <tr> <td>Adults and children over 12 years of age</td> <td>Take 2 softgels every 4 hours</td> </tr> <tr> <td>Children 6 to under 12 years</td> <td>Take 1 softgel every 4 hours</td> </tr> <tr> <td>Children under 6 years of age</td> <td>Should not use this product</td> </tr> </table>	Adults and children over 12 years of age	Take 2 softgels every 4 hours	Children 6 to under 12 years	Take 1 softgel every 4 hours	Children under 6 years of age	Should not use this product
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<b>If You Are:</b> <ul style="list-style-type: none"> <li>taking any drugs for asthma</li> <li>taking sedatives or tranquilizers</li> </ul>	<b>When Using This Product:</b> <ul style="list-style-type: none"> <li>drowsiness may occur</li> <li>alcohol, sedatives, and tranquilizers may increase the drowsiness effect</li> <li>use caution when driving a motor vehicle or operating machinery</li> <li>excitability may occur, especially in children</li> </ul>						
<b>Stop Using This Product If:</b> <ul style="list-style-type: none"> <li>cough is accompanied by fever, rash or headache that lasts</li> <li>stomach pain occurs</li> <li>nervousness, dizziness or sleeplessness occur</li> <li>symptoms do not improve within 7 days</li> </ul> <b>Ask a doctor. These may be signs of a serious condition.</b>	<b>Stop Using This Product If:</b> <ul style="list-style-type: none"> <li>cough is accompanied by fever, rash or headache that lasts</li> <li>stomach pain occurs</li> <li>nervousness, dizziness or sleeplessness occur</li> <li>symptoms do not improve within 7 days</li> </ul> <b>Ask a doctor. These may be signs of a serious condition.</b>						
If pregnant or breast feeding, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help right away.	If pregnant or breast feeding, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help right away.						
Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).							

**Description:** No Title, Thick demarcation lines, Warnings first, Active Ingredients at Top (Cough/Cold)  
Label # 881

<b>Active Ingredients (In Each Softgel)</b> Iifenesine 10 mg ..... Antihistamine Pseudoephedrine ..... Nasal Decongestant Hydrochloride 40 mg Tromethan 35mg ..... Cough Suppressant	<b>Purposes</b>						
<b>Uses:</b> For the temporary relief of these cold symptoms: • sneezing • runny nose • cough • nasal congestion							
<b>Do Not Use:</b> <ul style="list-style-type: none"> <li>if taking a monoamine oxidase inhibitor (MAOI) prescription drug (for depression, psychiatric or emotional conditions, or Parkinson’s disease)</li> <li>for 2 weeks after stopping an MAOI drug. If uncertain about your prescription drug, ask a health professional if it contains an MAOI.</li> <li>during the first 4 months of pregnancy</li> </ul>	<b>Warnings</b>						
<b>Ask A Doctor Before Use</b> <b>If You Have:</b> <ul style="list-style-type: none"> <li>heart disease</li> <li>glaucoma</li> <li>diabetes</li> <li>a cough that lasts from smoking, asthma or emphysema</li> <li>cough with fever, rash or headache that lasts</li> <li>a breathing problem such as emphysema or chronic bronchitis</li> <li>difficulty in urination due to prostate gland enlargement</li> </ul>	<b>Directions</b> Do not use more than directed. <table border="1"> <tr> <td>Adults and children over 12 years of age</td> <td>Take 2 softgels every 4 hours</td> </tr> <tr> <td>Children 6 to under 12 years</td> <td>Take 1 softgel every 4 hours</td> </tr> <tr> <td>Children under 6 years of age</td> <td>Should not use this product</td> </tr> </table>	Adults and children over 12 years of age	Take 2 softgels every 4 hours	Children 6 to under 12 years	Take 1 softgel every 4 hours	Children under 6 years of age	Should not use this product
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If pregnant or breast feeding, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help right away.	If pregnant or breast feeding, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help right away.						
Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).							

# Study B: “Preference for Variations in OTC Label Format”



- All 16 labels were presented to each subject, and they were asked to order the packages from most to least preferred.
- Subjects were asked why they made their #1 and #2 rankings
- Then subjects were asked attitude questions on 1 of the new format labels chosen at random by the interviewer and a label based on existing OTC drug format to measure preference, credibility, and readability of labels.

# Study B: “Preference for Variations in OTC Label Format”



Drug Type	Label Number	Description	Frequency	Percent
CC	241	Title, Thick demarcation lines, Directions first, Active Ingredients at bottom	75	16.5
SS	390	Title, Thick demarcation lines, Directions first, Active Ingredients at top	60	13.4
CC	147	Title, Thin demarcation lines, Directions first, Active Ingredients at bottom	60	13.2
SS	159	Title, Thick demarcation lines, Directions first, Active Ingredients at bottom	59	13.1
SS	420	Title, Thick demarcation lines, Warnings first, Active Ingredients at top	59	13.1
SS	988	Title, Thin demarcation lines, Warnings first, Active Ingredients at bottom	50	11.1

Drug Type	Label Number	Description	Frequency	Percent
CC	067	No Title, Thin demarcation lines, Directions first, Active Ingredients at top	6	1.3
CC	881	No Title, Thick demarcation lines, Warnings first, Active Ingredients at top	4	.9
SS	717	No Title, Thin demarcation lines, Directions first, Active Ingredients at top	2	.4
CC	283	No Title, Thin demarcation lines, Warnings first, Active Ingredients at top	1	.2

# Study B: “Preference for Variations in OTC Label Format”



What is it about the first label that made you prefer it the most?	N*	%
Like the layout or easy to read	200	16.7
Begins with medication facts	175	14.6
Directions first or directions then warnings	161	13.4
Warnings first or warnings then directions	119	9.9
Non-specific section mentions (e.g., has uses, directions, warnings, etc.)	114	9.5
Miscellaneous mentions (e.g., has sun alert)	113	9.4
Print size or style	96	8.0
Other	72	6.0
Thick lines	67	5.6
Active ingredients at the top	37	3.1
Directions first, active ingredients at top	21	1.8
Active ingredients at the bottom	8	0.7
Warnings first, active ingredients at top	8	0.7
Warnings first, active ingredients at bottom	5	0.4
Does not begin with medication facts	2	0.2
Thin lines	1	0.01
Don't Know	1	0.01
<b>TOTAL</b>	<b>1200</b>	<b>100</b>

\*Numbers indicate responses, not individuals

# Study B: “Preference for Variations in OTC Label Format”



- Key takeaways
  - The presence of “Medication Facts” title was the design element that had the greatest impact
  - Subjects chose their “second” label based on how closely it resembled their first choice
  - Subjects generally preferred labels with directions above warnings, active ingredients at the bottom, and thick demarcation lines

# Implications of Studies A and B

- New format demonstrated advantages over old format
  - Subjects located information on new label formats more accurately and could use that information for use related decisions
  - Subjects had more self-confidence using new format with divided attention
  - Subjects preferred a label with Title/Headings and cues for navigation (demarcation lines)
- All variables for formatting examples were not investigated. This was designed to be a starting point to provide insight on specific variables.
- Provides some direction for areas where future research is needed, e.g., more research into impact of drug type/active ingredients on comprehension

