

**Consumer Comprehension and Preference for Variations in
the Proposed Over-The-Counter Drug Labeling Format**

FINAL REPORT

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Table of Contents

| | Page |
|---|-------------|
| Acknowledgments | vi |
| Executive Summary | vii |
| Introduction | 1 |
| Impact of Format Elements on Comprehension of Label Information (Study A) | 3 |
| Design | 3 |
| Independent Variables | 4 |
| Label Format | 4 |
| Type of Drug | 4 |
| Highlighting | 4 |
| Attention | 5 |
| Participants and Method | 6 |
| Baseline Demographic Characteristics | 7 |
| Results | 9 |
| Scale Construction | 9 |
| Knowledge | 13 |
| Use of Label Information in Decisions | 14 |
| Attitudes | 14 |
| Self-Confidence | 14 |
| Involvement | 14 |
| Opinions | 15 |
| Reading Time | 15 |
| Open-Ended Responses | 15 |
| Comprehension Measures | 16 |
| Knowledge | 16 |

| | |
|---|----|
| Decision Measures | 17 |
| Search Scale | 17 |
| Average Time to Answer Search Scale Items | 18 |
| Application Scale | 18 |
| Attitude Measures | 20 |
| Preference Scale | 20 |
| Readability Scale | 21 |
| Utility Scale | 22 |
| Self-Confidence Scale | 23 |
| Personal Involvement Scale | 24 |
| Objective Involvement Scale | 24 |
| Accessibility Scale | 24 |
| Credibility Scale | 25 |
| Health Terminology Definitions | 26 |
| Discussion | 29 |
| Preference for Variations in OTC Label Format (Study B, Part 1) | 33 |
| Design | 33 |
| Participants and Method | 34 |
| Baseline Demographic Characteristics | 35 |
| Results | 36 |
| First Ranked Label | 36 |
| Open-Ended Responses | 39 |
| Label Rankings | 41 |
| Attitude Measures | 43 |
| Comprehension of Efficacy (Study B, Part 2) | 45 |
| Health Terminology Definitions | 51 |

| | |
|--|-----|
| Discussion | 54 |
| Implications | 56 |
| References | 58 |
| Appendix A: Demographic and Health Information Frequencies for Studies A and B | 63 |
| Appendix B: Label Examples, Study A | 70 |
| Appendix C: Open-ended Base Response Frequencies and Categorization Key for Study A | 75 |
| Appendix D: Factor Loadings for Opinion, Involvement, Accessibility, and Credibility Items for Study A | 81 |
| Appendix E: Label Examples, Study B | 85 |
| Appendix F: Open-Ended Base Response Frequencies and Categorization Key for Study B | 103 |
| Appendix G: Factor Loadings for Opinion Items for Study B | 110 |

| | |
|---|----|
| Table 22: Listing of Attitude Scales and Reliability | 44 |
| Table 23: Mean Difference Score for Preference Scale, Credibility Scale and Readability Scale, by Title | 45 |
| Table 24: Mean Rating for Efficacy Terms | 47 |
| Table 25: Mean Rating for Relief Terms | 48 |
| Table 26: Frequency Ratings of Efficacy Terms, by Graph | 50 |
| Table 27: Summary of Response Frequencies for Terminology Definitions | 52 |
| Table 28: Definition of Thalidomide by Age Group | 53 |

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EXECUTIVE SUMMARY

In recent years, FDA has become concerned about how adequately over-the-counter (OTC) labeling communicates information necessary for consumers to use these products safely and effectively. For example, with the advent of new categories of drugs that have switched from prescription to OTC status, consumers are being asked to make more sophisticated self-diagnostic and self-monitoring decisions. In order to provide adequate directions and safety information to potential users, the label must communicate increasingly sophisticated messages.

On February 27, 1997 (62 FR 9024), FDA proposed new regulations that would simplify the label and provide a consistent format for most OTC drugs. Several changes were proposed to simplify the label and make it easier to read. A standardized format was proposed that provided a consistent set of headings and subheadings, shortened sentences, and less complex terms for the label.

Two studies were conducted to provide an evaluation of effects of the FDA-proposed format changes on consumer comprehension of label information, and to gather information about consumer preferences for label design variations. The first study (*Impact of Format Elements on Comprehension of Label Information*) investigated the influence of the new format and the use of highlighting on the communication of important label directions and warnings. The second study (*Preference for Variations in OTC Label Format*) investigated consumer preferences regarding OTC label format variations and, secondarily, examined comprehension of various methods of communicating the relative safety and effectiveness of OTC products.

*Impact of Format Elements on Comprehension of Label Information*Design

The study examined two levels of each of four independent variables in a factorial design. The four variables were: 1) label format (old vs. new), 2) drug type (cough/cold vs. pain reliever, 3) highlighting (5 concepts vs. 10 concepts), and 4) the reader's attention (divided vs. focused). Highlighting, label format and drug type were manipulated through variations in the design of the label, while attention was manipulated through instructions given to the respondents.

Label Format: The new format labels were designed following the examples in the OTC Proposed Rule, while the old format labels were designed using the current OTC format.

Type of Drug: The stimulus materials were based on two different types of drugs, a cough/cold remedy and a pain reliever. Two types of drugs were used to provide a basis for generalizing the results beyond one type of product. Fictional names and characteristics were used to reduce potential influence due to prior exposure and recall of information about actual products.

Highlighting: The highlighting variable was designed to test the influence of this graphic design element on information communication. Highlighting was manipulated through using bold typeface for either 5 or 10 phrases.

Attention: This variable was designed to examine how the benefits of a revised OTC format might be influenced by the amount of attention paid to the label. Half of the participants were told they would answer questions about both a food and a drug label ("divided attention"), while half were told they would answer questions only about the drug label ("focused attention").

In the focused attention condition, the food label was described as reading practice.

Participants and Method

Twelve hundred and two (1,202) respondents 18 years of age and over were recruited to participate in the 30 minute study. The study was conducted in eight geographically distributed shopping malls in the United States, with approximately equal numbers of respondents at each location. Simulated OTC drug packages contained the test labels. Each respondent was given only one drug label to read. The interviewer then administered the questionnaire. Outcome measures included knowledge about the label information, opinion ratings of the label, willingness to read the label, ratings of confidence in using the label, and decision making based on the label information.

Results

Reading Time: Participants' first reading of the drug label was timed by the interviewer.

Participants spent more time reading labels in the old format than the new format (controlling for participants' baseline reading speed).

Decision Measures: These items were designed to measure participants' ability to use the label information to make decisions about the product. Four questions required relatively little mental effort (information search only), and three required greater mental effort (information application).

Searching for Label Information: For these items, the results indicated that the new format lead to more correct decisions than the old format. Participants also made more correct decisions when viewing the pain reliever label, as opposed to the cough/cold label.

Application of Label Information: These items demonstrated some complex interactions.

Participants who viewed a label with 10 highlighted objectives made more correct decisions

when their attention was focused on the label than did participants whose attention was divided. In addition, participants who read the pain reliever label made more correct decisions when it was presented in the new format, compared with presentation in the old format. There were no differences as a function of format for participants who viewed the cough/cold label.

Attitude Measures

Label Preferences: The new format pain reliever label was rated as more preferable than the old format pain reliever label, or the old format cough/cold label. Participants also preferred labels with 10 objectives highlighted to those with 5 objectives highlighted.

Label Readability: The cough/cold label with 10 highlighted objectives was rated as more readable than the cough/cold label with 5 highlighted objectives, or the pain reliever labels, regardless of highlighting. In addition, the old format pain reliever label was rated as less readable than the new format pain reliever label or the cough/cold labels, regardless of format.

Label Utility: These items were designed to measure the concept of usefulness of the label and importance of reading the label. Labels with 10 highlighted objectives were rated as having more utility than those with 5 highlighted objectives. Also, participants ranked the new format pain reliever label as having more utility than either the cough/cold or pain reliever old format labels.

Self Confidence: These items were constructed to measure participants' perceived self-confidence to use the label to perform tasks necessary to use the drug correctly. Regardless of drug type, participants in the divided attention condition rated their self-confidence higher when they viewed new format labels, compared with those who saw old format labels.

Personal Involvement: This scale measured participants' ratings of how appealing the label was, based on emotional or aesthetic terms. Participants who viewed the old format pain reliever label rated the label less aesthetically appealing than those who saw either of the new format labels or the old format cough/cold label.

Information Accessibility: In terms of how readily a reader could obtain information from the label, participants rated the presentation of information in the old format pain reliever as less accessible than the old format cough/cold label and both of the new format labels. Participants also rated the information in labels with 5 highlighted objectives as less accessible than those with 10 highlighted objectives.

Information Credibility: The cough/cold label was rated as more credible by focused attention participants who viewed the label with 10 highlighted objectives compared with those who saw the label with 5 highlighted objectives, as well as participants with divided attention who viewed the label with 10 highlighted objectives. The pain reliever label was rated as more credible by focused attention participants when it contained 10 highlighted objectives, compared to divided attention participants who viewed the label with 5 highlighted objectives.

Discussion

This study demonstrates that the new over-the-counter drug label format has advantages over the old format. The new format takes less time to read, and the new format helps people make more correct product use decisions when such decisions require a simple search for information in the label. Participants also preferred the new format to the old format, and rated the new format more favorably in terms of how readily a reader could obtain information from

the label. In addition, when their attention was divided, people felt more confident in their ability to use the new format compared to the old format.

Format interacted with type of drug on a number of measures. Participants who viewed the new format pain reliever labels made more correct product use decisions on items requiring application of label information than participants who viewed the old format pain reliever labels. Participants rated the old format pain reliever label as less preferable and less readable than the new format pain reliever label, or either version of the cough/cold label. Participants also rated the old format pain reliever label as less aesthetically appealing than the new format pain reliever label, or either the new or old cough/cold labels. Further, participants rated the new format pain reliever label as more accessible than the old format pain reliever label, or either cough/cold version. However, participants did not rate the old and new versions of the cough/cold label differently from one another on any of these measures. Finally, the new format pain reliever label was rated as having more utility than the old format pain reliever or cough/cold labels.

Labels with more highlighting were preferred to those with less highlighting. Such labels were also rated higher in terms of usefulness of the information presentation and information accessibility. Additional effects of highlighting tended to emerge only in conjunction with other variables. Given the varying pattern of interactions, it appears that the effect of highlighting on comprehension and attitudes is complex. Use of highlighting should be judiciously applied.

There were some effects due entirely to type of drug. The cough/cold labels appeared to require greater effort to read and process needed information. The information in the pain reliever labels appeared to be more amenable to searching than the cough/cold labels. In addition, participants took less time to answer the product use questions when faced with the

pain reliever labels. These effects are not unexpected, given the differences between these two products, including unequal amounts of information, different numbers of active ingredients, and different conditions treated. Given these and other unknown differences, however, it is not possible to determine the underlying causative factors.

There were some comparisons for which the new and old format did not differ, including product knowledge, ratings of how appealing the labels were rated based on functional or utilitarian aspects, and performance on product use decision items requiring application of information. In summary, the old label format did not outperform the new label format on any of the outcome measures in this study.

Preference for Variations in OTC Label Format

Design

This study examined consumer preferences for various format and graphical variations on the proposed OTC label format. The four variables examined were: 1) title (“Medication Facts” vs. no title), 2) order of warnings and directions (Warnings first vs. Directions first), 3) placement of active ingredients (top vs. bottom), and 4) type of demarcation lines (thick vs. thin). Two different drug types were used in the study: a cough/cold and a sunscreen. The factorial combination of the independent variables resulted in 16 different label designs for each of the two drug types.

Participants and Method

Nine hundred and four (904) participants 18 years of age or over were recruited to participate in the 30 minute study. The study was conducted in eight geographically distributed

shopping malls in the United States. Simulated OTC drug packages were used. All 16 package designs from either the cough/cold or the sunscreen product were laid out on a table in front of the participant. The participant was asked to order the packages from most to least preferred. Then, the participants were asked why he or she made the #1 and #2 rankings. Following the open-ended questions, each participant evaluated only one of the 16 labels (chosen randomly by the interviewer) on 12 attitude questions, and one label example which had been designed using the existing OTC drug format. These questions were designed to measure preference, credibility and readability of the label.

The second half of the session was devoted to participants' judgments of efficacy and probability terms not related to OTC label format. This section was designed to examine comprehension of various phrases designed to communicate products' relative safety and efficacy and is discussed in detail in the full report.

Results

First Ranked Label: Participants were more likely to choose labels with the title "Medication Facts" as their #1 ranked label than they were to choose those without a title.

Analysis of Label Rankings: Of the four factors examined, title had the greatest impact on participants' rankings. A secondary analysis examining the mean rankings within each factor indicated that participants ranked labels higher if they had a title, had Directions above Warnings, had thick lines, and had the active ingredients at the bottom of the label.

Attitude Measures

Participants rated a label in the new format and a label in the old format on three scales designed to measure Preference, Credibility and Readability of the label. Mean ratings of the new label

were subtracted from those of the old label to provide a difference score. Results indicated that participants rated labels with a title as more preferable, credible, and readable than those without a title. The other factors did not result in significant differences on these measures.

Discussion

The results indicate that presence of the “Medication Facts” title was the design element that had the most impact on participants’ preference ratings of the label. Participants rated the labels with the “Medication Facts” title as more credible, readable, and preferred. When examined in conjunction with the placement of the active ingredients, type of demarcation lines, and order of warnings and directions, presence of title had more impact on participants’ ratings than all other design elements combined. Although the other format variables did not have a great impact in determining rankings, respondents generally preferred labels with directions above warnings, active ingredients at the bottom, and thick demarcation lines between the sections.

Implications of these studies

The proposed OTC label format demonstrates advantages over the old format. When searching for information in the label, consumers are able to make more correct product use decisions using the new format. Consumers espouse more self-confidence in using the new format under conditions where they are not able to focus all their attention on the label. Consumers also prefer that the label be headed by a title, much like the nutrition labeling seen on food products. To a lesser extent, consumers prefer an order that features directions above warnings, active ingredients at the bottom, and thick lines between information sections.

It should be noted that these studies did not attempt to investigate the entire universe of possible format variables that might have some impact on consumers' comprehension and preference for OTC drug labels. Rather, they were designed to provide some insight into certain specific variables. As consumers become accustomed to changes in OTC labeling, new comprehension issues may arise. The results described herein should provide useful guidance for future research on these and other format issues relating to consumer comprehension of OTC labeling.

Introduction

Under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) has responsibility to assure proper labeling of prescription (Rx) and over-the-counter (OTC) drugs. Section 502 of the Act prohibits the distribution of labeling that is false or misleading or that fails to provide adequate directions for use. For OTC drugs, FDA regulations specify the need for labeling that clearly communicates important information to the consumer. For example, 21 CFR 201.5 defines “adequate directions for use” as directions under which a layperson can use a drug safely and for the purposes for which it is intended. Section 330.10 (a)(4)(v) further specifies that the label must be clear and truthful and must present product information in a fashion that will render it likely to be understood by ordinary individuals, including individuals of low comprehension, under customary conditions of purchase and use.

In recent years, FDA has become concerned about how adequately OTC labeling communicates information necessary for consumers to use these products safely and effectively. For example, with the advent of new categories of drugs that have switched from prescription to over-the-counter status, consumers are being asked to make more sophisticated self-diagnostic and self-monitoring decisions. In order to provide adequate directions and safety information to potential users, the label must communicate increasingly sophisticated messages. However, surveys that have measured population literacy levels have concluded that there are large sectors of the American population that have difficulty processing routine information (Kirsch, Jungeblut, Jenkins, and Kolstad, 1993). In addition, the elderly population, who are prime users of OTC drug products, is increasing in size. This particular segment of the population may have

greater difficulty reading the label on certain consumer products because of decreased visual functioning.

On February 27, 1997 (62 FR 9024), FDA proposed new regulations that would simplify the label and provide a consistent format for most OTC drugs. Several changes were proposed to simplify the label and make it easier to read. A standardized format was proposed that provided a consistent set of headings and subheadings (with typographical minimal standards for legibility). Sentences could be shortened by deleting certain “connecting terms” (e.g., “or,” “and,” “due to,” and “within”). Also, certain less complex terms could be used to replace technical words or phrases (e.g., replace “pulmonary” with “lung”).

FDA has asserted that a more organized label structure should improve consumer processing of the information in the label. Because there is a limit to the amount of information that people can hold in memory at one time, individuals tend to organize similar information into “chunks” to increase the amount of available space in memory and facilitate retrieval (Allen & Crozier, 1992; Miller, 1956/1994; Shiffrin & Nosofky, 1994). The use of less complex terminology, presented in shorter sentences, within a uniformly organized structure was expected to improve processing of the label in a number of ways. First, it would be expected to decrease “cognitive load.” Cognitive load is an index of the memory demands necessary to process a set of information. OTC labels that demand lower cognitive loads should be more fully processed than those that demand higher loads (Chandler and Sweller, 1991). Second, the new label formats would be expected to increase consumers’ willingness and self-perceived ability to read and understand the presented material. This is because the clearer and more structured format would be expected to make the tasks of reading and understanding the label less imposing. Research

suggests that consumers are more likely to engage in behavior they believe they can successfully complete (Wood & Bandura, 1989). Third, the new label should provide readers with clearer “signals” regarding the most important information. By helping readers prioritize the importance of the presented information, the revised labels would be expected to increase the probability that the set of information graphically identified as important is processed more completely, thereby increasing the communication of that specific information (Lorch & Lorch, 1995, 1996; Lorch, Lorch & Inman, 1993).

Two studies were conducted to provide an evaluation of effects of the FDA proposed format changes on consumer comprehension of label information, and to gather information about consumer preferences for label design variations. The first study investigated the influence of the new format and the use of highlighting on the communication of important label directions and warnings. The second study investigated consumer preferences regarding OTC label format variations and, secondarily, examined comprehension of various methods of communicating the relative safety and effectiveness of OTC products.

Impact of Format Elements on Comprehension of OTC Label Information (Study A)

This study was designed to examine the influence of label format and the use of selective highlighting on the communication of important label directions and warnings.

Design

The study examined two levels of each of four independent variables in a 2 X 2 X 2 X 2 factorial design. The four variables were:

- 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 label, while attention was manipulated through instructions given to the respondents. Copies of the stimuli can be found in Appendix B.

Independent Variables

Label Format: The new format labels were designed following the examples in the OTC Proposed Rule (62 FR 9024), while the old format labels were designed using the current OTC format. All the labels presented the information in the same order: Active Ingredients first, followed by Uses/Indications, Warnings, and Directions.

Type of Drug: The stimulus materials were based on two different types of drugs, a cough-cold remedy and a pain reliever. Two types of drugs were used to provide a basis for generalizing the results beyond one type of product. Fictional names and characteristics were used to reduce potential influence due to prior exposure and recall of information about actual products. However, the label content was based upon typical characteristics of the drug class to provide realistic stimuli. As a result, the cough/cold drug, which had three active ingredients, contained more information than the pain reliever drug, which had one active ingredient. Thus, effects of drug type may be attributable to differences in the amount of information presented to the respondent, or to other qualitative differences between the drugs.

Highlighting: The highlighting variable was designed to test the influence of graphic design emphasis on communication. It is well recognized that graphic emphasis attracts consumers' attention to information. Thus, on many labels, certain material is highlighted using

various techniques, including use of all capitals, contrasting colors, and bold typeface. However, if too much information is highlighted, the positive influence of highlighting may be reduced. Research suggests that consumers have a limited-capacity “working memory” that executes a variety of cognitive functions (Just & Carpenter, 1992, 1996). Exceeding this capacity by highlighting more information than can be effectively processed by working memory may reduce the beneficial effects of highlighting. This variable was designed to provide FDA with information about the effects of highlighting different amounts of information.

Highlighting was manipulated through the application of graphic emphasis (highlighting certain phrases through bold typeface) to either 5 or 10 “communication objectives.” To develop the test labels, a set of ten information elements (statements) important for consumers to know about each product was delineated. FDA frequently recommends this procedure to manufacturers of OTC products who are developing labels. The statements were chosen to represent different actions required on the part of the consumer (e.g., when not to use the product, when to stop using the product, when to ask a doctor before using the product). Approximately two statements were chosen from each subsection of the Warnings (i.e., Do Not Use, Ask a Doctor Before Use, Stop Using This Product If), two statements were chosen from the Directions, and one statement was chosen from Uses. Labels featuring 5 highlighted objectives included one bolded statement in each section, and labels featuring 10 highlighted objectives bolded both statements in each of the sections. The 10 objectives also served as the basis for testing participants’ knowledge about product information.

Attention: This variable was designed to examine how the benefits of a revised OTC format might be influenced by the amount of attention paid to the label. Participants were asked

to read the label for two consumer products as if they were considering purchasing the products. Each participant first read the label on a box of generic raisin bran (food product), and then read one of the sample OTC drug products. Half of the participants were told they would answer questions about both the food and the drug labels (“divided attention”), while half were told they would answer questions only about the drug label (“focused attention”). In the focused attention condition, the food label was described as reading practice.

Studies involving information processing and time of stimuli exposure have found that, when given a limited amount of time, people are more likely to rely on heuristic or peripheral cues (such as attractiveness, distinctiveness, or length) than on content when making decisions about a message (Chaiken, Liberman & Eagly, 1989; Mackie & Worth, 1989; Petty & Cacioppo, 1986). It is possible that any information-processing benefits of the revised format may be evident only under conditions of increased attentional demands. Given sufficient time and attention to a label (i.e., focused attention), consumers may be able to decode, read, and apply the information presented such that the influence of format variations is diminished. However, format variations may be more critical in helping consumers process the presented information under more realistic reading conditions (i.e., divided attention), when attentional resources are limited and they are distracted by other tasks.

Participants and Method

Twelve hundred and two (1,202) respondents 18 years of age and over were recruited to participate in the 30 minute study and were given a remuneration of \$5.00. The study was conducted in eight geographically distributed shopping malls in the United States, with

approximately equal numbers of respondents at each location. Mock-ups of prototypical OTC

boxes were designed to simulate realistic OTC drug products. After receiving instructions about which label (drug label only or drug and food label) they would be questioned, respondents were given the labels to read. Each respondent read only one drug label. Respondents could take as much time as they wanted to read the labels. Reading and response times were measured by the interviewer using a watch equipped with a second hand. The interviewer then administered the questionnaire, which was designed to measure the influence of label design on knowledge and attitudes about the OTC drug product, as well as decisions about use. Dependent variables (outcome measures) included knowledge about the product, opinion ratings of the label, willingness to read the label, ratings of confidence in using the label, and decision making based on the label information. Participant demographics were also obtained. The label was removed from view while participants answered the product knowledge items, but was returned while participants answered the remainder of the questions.

Baseline Demographic Characteristics

A summary of the study population's demographic and health characteristics is included in Appendix A. Literacy was measured using an abbreviated form of the Rapid Estimate of Adult Literacy in Medicine (REALM; Davis et al., 1991). The REALM test is designed to measure literacy by assessing reading ability for medical words commonly found on drug labels designed for consumers. However, many of the words could be considered threatening or embarrassing to certain people (e.g., testicle). Since it is difficult to distinguish a refusal to read due to embarrassment from an inability to read due to low literacy, the REALM was reduced in

size by removing some potentially threatening terms, and adding some terms of specific interest to this study: thalidomide, health professional. The resulting REALM list contained 42 words¹.

There were no differences in literacy between the groups, $F < 1.0$, $p > .60$. To provide some validation of the abbreviated REALM beyond that provided by Cronbach's alpha², a Oneway Analysis of Variance (ANOVA) was conducted on respondents' mean literacy score by education level. If the abbreviated REALM measures literacy like its longer counterpart, a pattern should emerge whereby literacy scores should increase with increasing educational level. As can be seen in Table 1, literacy scores do indeed increase by education level, $F(6, 1201) = 20.30$, $p < .001$. Respondents who have some high school education score higher on the abbreviated REALM than do participants who have a grade school education or less. Those who have completed high school or some college score higher than those who have some high school (but did not complete college), and those respondents who have completed college or graduate school score higher than those who have completed some college. Respondents who indicated they have other education beyond high school score the same on the literacy measure as respondents who have completed high school or have had some college education.

¹ Reduction of the size of the REALM is not without precedent. The original REALM contained 125 words (Davis et al., 1991), and was subsequently reduced in size by the original authors to 66 words (Davis et al., 1993).

² Reliability (as measured in this study by Cronbach's alpha), is an estimate of the amount of error variance in a particular set of items. Higher reliabilities (i.e., those that approach a score of 1.00) indicate lower variance and a higher correlation between items. Scale reliabilities of .70 and above are usually considered very good.

Table 1
Mean Literacy Score by Education Level

| Education | Mean Literacy Score |
|------------------------------------|----------------------------|
| Grade School or less | 32.7 ^a |
| Some High School | 37.2 ^b |
| Completed High School | 38.2 ^c |
| Other Education beyond High School | 39.0 ^c |
| Some College | 39.7 ^c |
| Completed College | 40.4 ^d |
| Graduate School or more | 41.1 ^d |
| Overall Mean | 39.0 |

Maximum literacy score = 42. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Results

The dependent measures were analyzed using a 2 (label format: old vs. new) X 2 (drug type: cough/cold vs. pain reliever) X 2 (highlighting: 5 concepts vs. 10 concepts) X 2 (attention: divided vs. focused) General Linear Model Analysis of Variance (GLM ANOVA). All statistical tests were conducted using an alpha level of .05. Post-hoc differences were calculated using the Least Significant Difference test (LSD).

Scale Construction

Maximum likelihood exploratory factor analysis was used to identify items for inclusion in scales³. Items that did not load on any of the extracted factors were not included in the scale.

³ Factor analysis is used to examine relationships between variables that may identify underlying constructs (or factors) in the data. These relationships may reveal that items are related to only one factor, to more than one, or to none at all. An item that loads above .400 on a given factor is typically considered salient. "Those items most clearly related to only one factor

Single scales were created by summing scores on each item and dividing by the number of items in the scale. Factor loadings for the items can be found in Appendix D. Scale composition and reliabilities can be found in Table 2.

Table 2
Listing of Scales and Reliabilities

| Scale | Items | Alpha |
|-----------|--|-------|
| Knowledge | <p><i>Cough/Cold:</i></p> <p>2a. You should stop using this product if stomach pain occurs.</p> <p>2b. A person using this drug should take no more than 10 softgels in a 24-hour period.</p> <p>2c. This product relieves nasal congestion due to the common cold.</p> <p>2d. This product relieves persistent cough from smoking.</p> <p>2e. People with heart disease should ask a doctor before taking this product.</p> <p>2f. This product can be taken with drugs used to treat depression.</p> <p>2g. This product can be given to children 8 years of age.</p> <p>2h. A person taking a drug for asthma should ask a doctor before use.</p> <p>2i. You may continue to use this product if cough is accompanied by fever or a persistent headache.</p> <p>2j. This product can be given to children under age 6.</p> <p>2k. You should stop using this product if you get a rash.</p> <p>2l. A person using this drug should not exceed 4 doses in 24 hours.</p> <p>2m. If stomach pain occurs while taking this product, you can continue to use this product as soon as the pain improves.</p> <p>2n. Women should not take this product during the <u>last</u> 5 months of pregnancy.</p> <p>2o. People with liver disease should not take this product unless directed by a physician.</p> <p>2p. People using a prescription medication to treat a mental condition should not take this product.</p> <p>2q. A person with a persistent cough from smoking should ask a doctor before use.</p> <p>2r. Women should avoid taking this product during the <u>first</u> 4 months of pregnancy.</p> <p>2s. A person with a cough that lasts from emphysema cannot use this product.</p> <p>2t. A person taking a drug for the treatment of asthma cannot use this product.</p> | .79 |

can then be recommended as a scale for the construct underlying that factor.” (Gorsuch, 1997, p. 533).

| Scale | Items | Alpha |
|-----------|--|-------|
| Knowledge | <p><i>Pain Reliever:</i></p> <p>2a. You should stop using this product if stomach pain occurs.</p> <p>2b. A person using this drug should not exceed 10 tablets in a 24-hour period.</p> <p>2c. This product does not reduce fever.</p> <p>2d. This product treats minor aches and pains associated with headache.</p> <p>2e. People taking medicines for high blood pressure should ask a doctor before taking this product.</p> <p>2f. People allergic to other pain relievers can take this product.</p> <p>2g. This product can be given to children 14 years of age.</p> <p>2h. People who consume more than 3 alcohol-containing drinks per day should ask a doctor for advice before use.</p> <p>2i. You should consult a physician before using this product if the area that hurts is red and swollen.</p> <p>2j. This product can be given to children over age 16.</p> <p>2k. You can take up to 4 tablets in 6 hours if the pain is severe.</p> <p>2l. A person using this drug should not take more than 6 tablets in 24 hours.</p> <p>2m. If stomach pain occurs while taking this product, you can continue to use this product as soon as the pain improves.</p> <p>2n. People with stomach ulcers can use this product.</p> <p>2o. People with liver disease should not take this product unless directed by a physician.</p> <p>2p. A person who is allergic to aspirin should not use this product.</p> <p>2q. This product may cause swelling and redness in the painful area.</p> <p>2r. This product may make ulcers worse.</p> <p>2s. You should not take this product within 24 hours of consuming alcohol.</p> <p>2t. A person using this product should take 2 tablets every 6 hours while symptoms persist.</p> | .81 |
| Search | <p><i>Cough/Cold:</i></p> <p>3c. Now think about another person who is taking this drug and has stomach pain. Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> <p>3e. Now think about another person who is considering taking this drug but has breathing problems. Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> <p>3g. What about a person who has just learned she is pregnant and is considering taking this product? Should she (keep taking the drug, talk to a doctor, stop taking the drug)?</p> <p>3h. What about a person who is considering taking this product but is having nervousness and difficulty sleeping? Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> | .47 |

| Scale | Items | Alpha |
|-------------|--|-------|
| Search | <p><i>Pain Reliever:</i></p> <p>3c. Now think about another person who is taking this drug and has stomach pain. Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> <p>3e. Now think about another person who is considering taking this drug but is allergic to aspirin. Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> <p>3g. What about a person who has an ulcer and is considering taking this product? Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> <p>3h. What about a person who is considering taking this product but is under a doctor's care for high blood pressure? Should this person (keep taking the drug, talk to a doctor, stop taking the drug)?</p> | .40 |
| Application | <p><i>Cough/Cold:</i></p> <p>3b. Imagine you've got a cough and are running a fever of 99 degrees. What is the maximum number of days you can take this drug?</p> <p>3d. If you took a dose of the drug at 9:00 am, according to the label, when would you take your next dose?</p> <p>3f. Imagine you have a child, age 13. How many softgels can you give the child in one dose?</p> | .26 |
| | <p><i>Pain Reliever:</i></p> <p>3b. Imagine you're taking this drug to relieve sore muscles. What is the maximum number of days you can take this drug?</p> <p>3d. Imagine you have a child, age 15. How many tablets can you give the child in one dose?</p> <p>3f. If you took a dose of the drug at 9:00 am, according to the label, when would you take your next dose?</p> | .27 |
| Preference | <p>4a. How willing would someone be to read the label?</p> <p>4c. How much do you like the format or layout of the label?</p> <p>4d. How easy is it to find information in the label?</p> <p>4i. How well organized is the format or layout of the label?</p> | .84 |
| Readability | <p>4e. How difficult is it to see each of the words printed on the label?</p> <p>4f. How difficult was it to read the label?</p> <p>4h. How confusing is the format or layout of the label?</p> | .67 |
| Utility | <p>4b. How useful is the label in helping someone decide whether or not to use the drug?</p> <p>4g. How important would it be for someone to read all the information in the label?</p> <p>4j. How easy to understand is the information in the label?</p> | .65 |

| Scale | Items | Alpha |
|-----------------------|--|-------|
| Self-Confidence | 6a. Recognize any adverse (bad) reactions. 6b. Follow the directions for taking the correct dose. 6c. Know which drugs interact with this one. 6d. Remember the warnings. 6e. Know when to stop taking the drug. 6f. Know what conditions are treated by this drug. 6g. Identify the correct dosage for a child. 6h. Tell the difference between a minor side effect and a major reaction. 6i. Identify who should not take this drug. 6j. Know when you should ask a doctor or health professional if side effects occur. | .90 |
| Personal Involvement | 5e. Exciting 5f. Appealing 5g. Fascinating 5h. Involving 5i. Interesting | .89 |
| Objective Involvement | 5a. Important 5b. Relevant 5c. Means a lot to me 5d. Valuable 5j. Needed | .86 |
| Accessibility | 7d. Using a scale from 1 to 5, where 1 means not at all and 5 means a lot, how would you say the important information in the drug label stood out? 7e. When you first read the labels, would you say your attention was focused just on the drug information label: 7f. Think about the way the information was presented in the label. Overall, how useful was the presentation? 7g. Using a scale from 1 to 5, where 1 means hard to read and 5 means easy to read, how would you rate the label? 7h. Using a scale from 1 to 5, where 1 means very hard and 5 means very easy, how easy was it to find the important information on the label? | .82 |
| Credibility | 7i. Overall, how much did you trust the information on the label? 7j. Overall, how believable was the information on the label? | .82 |

Based on the results of the factor analyses, several scales were identified. The items in these scales tended to cluster around distinct concepts and were thus grouped.

Knowledge: The use of factor analysis on dichotomous items (i.e., those scored yes vs. no) has been viewed with skepticism by some (e.g., Asher, 1997; Nunnally & Bernstein, 1994). The relatively low correlations between dichotomous items (as compared to continuous items) may

result in spurious factor identification (Asher, 1997). Therefore, the knowledge items were taken as a whole and not subjected to factor analysis.

Use of Label Information in Decisions: Four items measured participants' success at finding information in the label to answer specific questions (Search) and three items measured participants' application of information in the label to specific situations (Application).

Participants' scores on the sets of items were summed to provide a Search Measure and an Application Measure.

Attitudes: The eleven items designed to measure attitudes toward the label fell into three separate factors. The first factor tended to cluster around the concept of liking for the format or appearance of the label itself, and so the scale created from these items was named Preference. The items in the second factor tended to represent the concept of ease in reading the label and the scale thus was named Readability. The items in the third factor tended to represent the concept of usefulness of the label and importance of reading the label, and was so named Utility.

Self-Confidence: A series of ten items were constructed to measure participants' perceived self-confidence to perform tasks necessary to use the drug correctly (e.g., recognize adverse effects, identify the correct dosage). The items were based on the concept of self-efficacy, which is defined as the confidence in one's own ability to successfully complete a task (Bandura, 1986). Factor analysis indicated that these items formed a single scale, which was named Self-Confidence.

Involvement: The ten-item Personal Involvement Inventory (Zaichkowsky, 1994) was included to measure participants' involvement with the label. Involvement, as defined by Zaichkowsky (1985), is the perceived relevance of a message, "based on inherent needs, values, and interests."

Based on Zaichkowsky's work, it was hypothesized that the involvement items would separate into two separate concepts: (1) affective, or the degree to which a message is appealing based on emotional or aesthetic terms, and (2) cognitive, or the degree to which a message is appealing based on functional or utilitarian aspects (Park and Young, 1986). In this case, the "message" is the format of the label. Factor analysis of the ten involvement items revealed two factors that mirrored Zaichkowsky's affective and cognitive concepts. These scales were labeled Personal Involvement and Objective Involvement.

Opinions: Ten items were designed to measure participants' opinions about the believability and availability of information contained in the label. Two factors were extracted based on factor analysis. The first factor tended to center around the concept of how readily a reader could obtain information from the label, while the second factor tended to represent the concept of credibility of label information. The two scales derived from these items were labeled Accessibility and Credibility.

Reading Time: Participants' first reading of the drug label was timed by the interviewer. A gauge of participants' baseline reading speed, as measured by time required to answer Question 3a ("At what temperature should this drug be stored?"), was included as a covariate in this analysis. Results indicated an effect of Label Format, $F(1, 1199) = 14.57, p < .001$. Participants spent more time reading the old format ($M = 66.86$ seconds) than the new format ($M = 55.99$ seconds).

Open-Ended Responses: The drug label was removed from view after participants indicated that they had finished reading. The interviewer then asked the participant "First, tell me all the information you can remember from the drug label." These responses were

categorized according to label section (categorization key can be found in Appendix C). Table 3 reflects the categorized open-ended response frequencies. About 29% of the responses included information from the Do Not Use If section of the label. Information from the Uses section was given in 20% of the responses, and information from Dosage/Directions in 19% of the responses.

Table 3
Open-Ended Response Frequencies:
“Tell me all the information you can remember about the drug label.”

| Response Category | N* | % |
|---|-------------|------------|
| Do not use if | 1079 | 28.9 |
| Uses | 751 | 20.1 |
| Dosage/directions | 719 | 19.3 |
| Stop using if/side effects | 455 | 12.2 |
| Consult doctor before using if | 212 | 5.7 |
| Dosage form/ingredients | 206 | 5.5 |
| Promotional information/box characteristics | 158 | 4.2 |
| General warnings | 84 | 2.3 |
| Storage information | 25 | .7 |
| Nothing | 5 | .1 |
| Other | 34 | .9 |
| Don't know | 2 | .05 |
| TOTAL | 3730 | 100 |

*Numbers indicate responses, not individuals

Comprehension Measures

Knowledge: Because the True-False Knowledge items (Questions 2a-2t) were created based on the communication objectives for each of the drug labels, the questions were specific to

each drug. Therefore, Knowledge Scales were created separately for each drug. Participants received a score of “1” for a correct response, and a score of “0” for an incorrect response⁴. The outcome represents the participant’s total score on that particular scale. As mentioned previously, the drug label was not in view while participants were responding to the knowledge items.

A. Cough/Cold Drug: There were no significant effects on any of the independent variables for the Knowledge scale (all F 's < 2.0, all p 's > .20).

B. Pain Reliever Drug: There were no significant effects on any of the independent variables for the Knowledge scale (all F 's < 2.0, all p 's > .20)

Decision Measures. Items 3b-3h were designed to measure participants’ ability to use the label information to make decisions about proper use of the product. These questions differed conceptually from one another as a function of the amount of mental effort required to obtain the correct response. Therefore, they were broken down into two separate scales. As with the True-False Knowledge items, participants received a score of “1” for a correct response, and a score of “0” for an incorrect response. Participants were permitted to refer to the label while answering the decision items and the remainder of the questions.

Search Measure: Items 3c, 3e, 3g, and 3h required that participants simply locate the appropriate label information to make a decision. Results indicated main effects of Drug, $F(1, 1202) = 29.11, p < .05$, and Type of Label, $F(1, 1202) = 6.26, p < .05$. Participants who viewed the Pain Reliever label ($M = 2.43$) made more correct decisions than participants who saw the

⁴ “Don’t know” responses also received a score of “0”. Analysis of the distribution of “Don’t know” responses indicated no significant differences between groups, all F 's < .5, p 's > .5.

Cough/Cold label ($M = 2.10$), and participants who saw the new format ($M = 2.34$) made more correct decisions compared with participants who saw the old format ($M = 2.19$).

Average Time to Answer Search Scale Items: A gauge of participants' baseline reading speed, as measured by time required to answer Question 3a ("At what temperature should this drug be stored?"), was included as a covariate in this analysis to control for individual differences in reading speed. Results indicated an effect of Drug, $F(1, 1188) = 4.96, p < .05$. Participants who viewed the Cough/Cold label took more time to answer the Search items ($M = 7.10$ seconds) than participants who viewed the Pain Reliever label ($M = 6.36$ seconds). This result is not unexpected, given that the Cough/Cold label included more information overall than the Pain Reliever label.

Application Measure: Items 3b, 3d and 3f required participants to apply information from the drug label to reach a decision. Results indicated an interaction of Attention x Highlighting, $F(1, 1198) = 6.22, p < .05$, (see Table 4). Participants who viewed a label with 10 highlighted objectives made more correct decisions on the Application scale when their attention was focused on the drug label than did participants whose attention was divided. There was also an interaction of Label Format x Drug, $F(1, 1198) = 4.30, p < .05$ (see Table 5). Participants who viewed the Pain Reliever drug label made more correct decisions on the Application scale when they viewed the new format, compared with when they viewed the old format. There were no differences as a function of format for participants who saw the Cough/Cold label.

Table 4
Mean Score on Application Scale, by Attention and Highlighting

| | Attention | |
|-------------------------|-----------------------------|-----------------------------|
| | Divided (<i>SD</i>) | Focused (<i>SD</i>) |
| Highlighting: 5 | 1.59 ^{ab} (.91) | 1.57 ^{ab} (.92) |
| Highlighting: 10 | 1.45 ^a (.94) | 1.69 ^b (.93) |

Higher numbers indicate more correct decisions. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Table 5
Mean Score on Application Scale, by Label Format and Drug

| | Label Format | |
|---------------------------|-----------------------------|-----------------------------|
| | Old Format (<i>SD</i>) | New Format (<i>SD</i>) |
| Cough/Cold Drug | 1.61 ^{ab} (.94) | 1.53 ^{ab} (.93) |
| Pain Reliever Drug | 1.51 ^a (.92) | 1.65 ^b (.91) |

Higher numbers indicate more correct decisions. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Because of the relatively low aggregate reliability of the items in the Application Measure, a separate Multivariate Analysis of Variance (MANOVA) was conducted on the individual items for each drug. The results indicated a Multivariate interaction of Attention x Highlighting, $F(3, 589) = 2.80$, $p < .05$, for the Cough/Cold label. As can be seen in Table 6, participants whose attention was focused on the Cough/Cold label gave more correct answers to the question "Imagine you have a child, age 13. How many softgels can you give the child in one

dose?" when they viewed a label with 10 highlighted objectives, as opposed to 5 (Univariate $F(1, 598) = 5.61, p < .05$).

Table 6

Mean Score on Application Item "Imagine you have a child, age 13. How many softgels can you give the child in one dose?", by Attention and Highlighting: Cough/Cold

| | Attention | |
|-------------------------|-----------------------------|---------------------------|
| | Divided (SD) | Focused (SD) |
| Highlighting: 5 | .67 ^{a,b} (.47) | .57 ^b (.50) |
| Highlighting: 10 | .64 ^{a,b} (.48) | .73 ^a (.45) |

Higher numbers indicate more correct decisions. Means bearing different superscripts are significantly different at $p < .05$, LSD.

There were also main effects of Attention, $F(3, 589) = 3.49, p < .05$, and Label Format, $F(3, 589) = 4.29, p < .01$ for the Pain Reliever label. Participants gave more correct answers to the question "Imagine you're taking this drug to relieve sore muscles. What is the maximum number of days you can take this drug?" when their attention was focused on the label ($M = .54$) as opposed to divided ($M = .44$; Univariate $F(1, 598) = 6.33, p < .05$). Participants also answered this question correctly more often when they were viewing a label in the new format ($M = .56$), as compared to the old format ($M = .42$; Univariate $F(1, 598) = 12.26, p < .001$).

Attitude Measures

Preference Scale: Results indicated an interaction of Label Format x Drug, $F(1, 1187) = 15.95, p < .001$ (see Table 7). The new format Pain Reliever label was rated as more preferable than the old format Pain Reliever label, or the old format Cough/Cold label. The old format Cough/Cold label was also rated as more preferable than the old format Pain Reliever label.

There was also an effect of Highlighting, $F(1, 1187) = 6.06, p < .05$. The label with 10 highlighted objectives was rated as more preferable ($M = 6.92$) than the label with 5 highlighted objectives ($M = 6.58$).

Table 7
Mean Preference Rating, by Label Format and Drug

| | Label Format | |
|---------------------------|-----------------------------|-------------------------------|
| | Old Format (<i>SD</i>) | New Format (<i>SD</i>) |
| Cough/Cold Drug | 6.81 ^b (2.36) | 6.97 ^{b,c} (2.34) |
| Pain Reliever Drug | 6.00 ^a (2.38) | 7.22 ^c (2.20) |

Higher numbers indicate more preference. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Readability Scale: Results indicated interactions of Highlighting x Drug, $F(1, 1, 1192) = 4.81, p < .05$ (see Table 8), and Label Format x Drug, $F(1, 1192) = 4.98, p < .05$ (see Table 9). The Cough/Cold label with 10 highlighted objectives was rated as more readable than either the Cough/Cold label with 5 highlighted objectives, or the Pain Reliever label regardless of highlighting. The old format Pain Reliever label was rated as less readable than either the new format Pain Reliever label, or the Cough/Cold label, regardless of format.

Table 8
Mean Readability Rating, by Highlighting and Drug

| | Highlighting | |
|---------------------------|--|---|
| | 5 Communication Objectives (<i>SD</i>) | 10 Communication Objectives (<i>SD</i>) |
| Cough/Cold Drug | 6.05 ^a (2.47) | 6.61 ^b (2.51) |
| Pain Reliever Drug | 6.05 ^a (2.55) | 5.99 ^a (2.38) |

Higher numbers indicate more readability. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Table 9
Mean Readability Rating, by Label Format and Drug

| | Label Format | |
|---------------------------|------------------------------------|------------------------------------|
| | Old Format (<i>SD</i>) | New Format (<i>SD</i>) |
| Cough/Cold Drug | 6.20 ^b (2.52) | 6.47 ^b (2.49) |
| Pain Reliever Drug | 5.57 ^a (2.52) | 6.48 ^b (2.33) |

Higher numbers indicate more readability. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Utility Scale: There was an interaction of Label Format x Drug, $F(1, 1190) = 4.48$, $p < .05$ (see Table 10). The new format Pain Reliever label was rated as having more utility than either of the old format labels. There was also an effect of Highlighting, $F(1, 1190) = 4.34$, $p < .05$. Labels with 10 highlighted objectives were rated as having more utility ($M = 8.47$) than labels with 5 highlighted objectives ($M = 8.26$).

Table 10
Mean Utility Rating, by Label Format and Drug

| | Label Format | |
|---------------------------|-----------------------------|-------------------------------|
| | Old Format (SD) | New Format (SD) |
| Cough/Cold Drug | 8.33 ^a (1.85) | 8.38 ^{a,b} (1.69) |
| Pain Reliever Drug | 8.14 ^a (1.76) | 8.61 ^b (1.56) |

Higher numbers indicate more utility. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Self-Confidence Scale: Results indicated an interaction of Label Format x Attention, $F(1, 1181) = 5.90$, $p < .05$ (see Table 11). Participants in the divided attention condition rated their self-confidence for using the label as higher when they viewed the new format, compared to those who saw old format.

Table 11
Mean Self-Confidence Score, by Type of Label and Attention

| | Label Format | |
|--------------------------|-------------------------------|-------------------------------|
| | Old Format (SD) | New Format (SD) |
| Divided Attention | 7.89 ^a (1.94) | 8.34 ^b (1.57) |
| Focused Attention | 8.15 ^{a,b} (1.69) | 8.12 ^{a,b} (1.72) |

Higher numbers indicate more self-confidence. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Personal Involvement Scale: Results indicated an interaction of Label Format x Drug, $F(1, 1197) = 3.98, p < .05$ (see Table 12). Participants who viewed the old format Pain Reliever label rated themselves as less personally involved than those who saw either of the new format labels or the old format Cough/Cold label.

Table 12
Mean Personal Involvement Score, by Label Format and Drug

| | Label Format | |
|---------------------------|-----------------------------|-----------------------------|
| | Old Format (SD) | New Format (SD) |
| Cough/Cold Drug | 4.84 ^b (2.71) | 4.84 ^b (2.65) |
| Pain Reliever Drug | 4.33 ^a (2.44) | 4.94 ^b (2.70) |

Higher numbers indicate more personal involvement. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Objective Involvement Scale: There were no significant effects for the Objective Involvement scale (all F 's < 3.7 , all p 's $> .05$).

Accessibility Scale: Results indicated an interaction of Label Format x Drug, $F(1, 1199) = 5.63, p < .05$ (see Table 13). The presentation of information in the old format Pain Reliever label was rated as less accessible than the old format Cough/Cold label and both drug types in the new format. The presentation of information in the new format Pain Reliever label was rated as most accessible. There was also an effect of Highlighting, $F(1, 1199) = 4.45, p < .05$. The presentation of information in labels with 5 highlighted objectives was rated as less accessible ($M = 3.85$) than labels with 10 highlighted objectives ($M = 3.96$).

Table 13
Mean Accessibility Rating, by Label Format and Drug

| | Label Format | |
|---------------------------|----------------------------|------------------------------|
| | Old Format (SD) | New Format (SD) |
| Cough/Cold Drug | 3.90 ^b (.88) | 3.98 ^{b,c} (.85) |
| Pain Reliever Drug | 3.72 ^a (.93) | 4.04 ^c (.83) |

Higher numbers indicate more accessibility. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Credibility Scale: There was a three-way interaction of Attention x Highlighting x Drug for label credibility, $F(1, 1199) = 5.42$, $p < .05$ (see Table 14). The Cough/Cold label was rated as more credible by focused attention participants who viewed the label with 10 highlighted objectives compared with those who saw the label with 5 highlighted objectives, as well as participants with divided attention who viewed the label with 10 highlighted objectives. The Pain Reliever label was rated as more credible by focused attention participants who saw the label with 10 highlighted objectives, compared with divided attention participants who saw the label with 5 highlighted objectives.

Table 14
Mean Credibility Rating, by Attention, Highlighting and Drug

| | Cough/Cold | | Pain Reliever | |
|-------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | Divided Attention (<i>SD</i>) | Focused Attention (<i>SD</i>) | Divided Attention (<i>SD</i>) | Focused Attention (<i>SD</i>) |
| Highlighting: 5 | 4.16 ^{a,b} (.87) | 4.03 ^a (.94) | 4.15 ^{a,c} (.97) | 4.26 ^{b,c} (.89) |
| Highlighting: 10 | 4.06 ^{a,c} (.94) | 4.35 ^b (.73) | 4.26 ^{b,c} (.79) | 4.31 ^{b,d} (.85) |

Higher numbers indicate more credibility. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Health Terminology Definitions

Respondents were asked to define each of six health terms “as if you saw it in a dictionary”: “effectiveness,” “health professional,” “placebo,” “symptom,” “temporary,” and “thalidomide.” There have been questions raised concerning how many consumers can successfully define these terms. Although “health professional” is not a term commonly found in a dictionary, the question was worded with reference to a dictionary to increase the likelihood that participants would give what they perceived to be an objective, shared definition. Responses were scored 0 (incorrect), 1 (partially correct) or 2 (correct), based on their correspondence with the definition found in the Merriam-Webster (1993) and American Heritage (1976) dictionaries. As can be seen in Table 15, 85% of the respondents provided a correct or partially correct definition of “effectiveness,” 97% provided a correct/partially correct definition of “health professional,” and 95% provided a correct/partially correct definition of “temporary.” On the other hand, 74% of the respondents provided a correct/partially correct definition of “symptom,” 43% provided a correct/partially correct definition of “placebo,” and only 33% provided a correct

definition of “thalidomide.” This last result is of interest, given the history of Thalidomide and the possibility, at the time this study was conducted, that it would be reintroduced into the marketplace⁵. To examine the possibility that this lack of knowledge or familiarity with the term was due to the age of the respondents, a separate analysis was performed, comparing respondents who were age 45 and over to those who were under age 45. As can be seen in Table 16, the results indicated that a larger percentage of adults age 45 and over (58%) were able to correctly (or acceptably) define thalidomide, compared to adults under age 45 (23%; $X^2(1, N = 1202) = 81.68, p < .001$).

Table 15
Summary of Response Frequencies for Terminology Definitions

| Term | Response Score | N | % |
|----------------------------|-----------------------|----------|----------|
| Effectiveness | Correct | 959 | 79.8 |
| | Partially Correct | 62 | 5.2 |
| | Incorrect | 181 | 15.1 |
| Health Professional | Correct | 1068 | 88.9 |
| | Partially Correct | 97 | 8.1 |
| | Incorrect | 37 | 3.1 |

⁵ Thalidomide was marketed in Europe and Canada as a sedative during the 1950's and 1960's. Its use in pregnant women was associated with severe, debilitating birth defects. On July 16, 1998, Thalidomide was approved for marketing in the U.S. for treatment for erythema nodosum leprosum (ENL), a complication of leprosy. As part of its approval, a strict and extensive distribution and tracking system for the drug has been initiated by the manufacturer, Celgene Inc. (FDA Talk Paper, 1997; Marwick, 1997).

| Term | Response Score | N | % |
|--------------------|-----------------------|----------|----------|
| Placebo | Correct | 397 | 33.0 |
| | Partially Correct | 116 | 9.7 |
| | Incorrect | 689 | 57.3 |
| Symptom | Correct | 475 | 39.5 |
| | Partially Correct | 414 | 34.4 |
| | Incorrect | 313 | 26.0 |
| Temporary | Correct | 1086 | 90.3 |
| | Partially Correct | 57 | 4.7 |
| | Incorrect | 59 | 4.9 |
| Thalidomide | Correct | 195 | 16.2 |
| | Partially Correct | 202 | 16.8 |
| | Incorrect | 805 | 67.0 |

Table 16
Definition of Thalidomide by Age Group

| | Thalidomide Definition | |
|-------------------------|-------------------------------|------------------|
| | Correct/Acceptable | Incorrect |
| Age 18-44 | n=167 (23.1%) | n=557 (69.2%) |
| Age 45 and above | n=230 (57.9%) | n=248 (30.8%) |

Discussion

This study demonstrates that the new over-the-counter drug label format has advantages over the old format. Compared to the old format, the new format takes less time to read. In terms of actual performance, the new format helps people make more correct product use decisions than the old format, when such decisions require a simple search for information in the label. Participants also preferred the new format to the old format, and rated the new format more favorably in terms of how readily a reader could obtain information from the label. In addition, when their attention was divided, people felt more confident in their ability to use the new format compared to the old format. As discussed previously, consumers are more likely to engage in behavior they believe they can successfully complete. Thus, consumers who face multiple tasks may be more likely to read labels written in the new format, because they are more confident of their ability to decipher and use the information in the label. This confidence may increase the number of consumers who read OTC drug labels in whole or in part, thereby increasing the likelihood that the important information on the label will be delivered. An unread drug label will not impart information, regardless of how well-written the information, or how understandably and artfully presented.

Format interacted with type of drug on a number of measures. Participants who viewed the new format pain reliever labels made more correct product use decisions on items requiring application of label information than participants who viewed the old format pain reliever labels. Participants rated the old format pain reliever label as less preferable and less readable than the new format pain reliever label, or either version of the cough/cold label. Participants also reported lower personal involvement when they viewed the old format pain reliever label,

compared to the new format pain reliever, or either the new or old cough/cold labels. In terms of accessibility of information, participants rated the new format pain reliever label as more accessible than the old format pain reliever label, or either cough/cold version. However, it is important to note that participants did not rate the old and new versions of the cough/cold label differently from one another on any of these measures. Lastly, the new format pain reliever label was rated as having more utility than the old format pain reliever or cough/cold labels.

Labels with more highlighting were preferred to those with less highlighting. Labels with more highlighted elements, compared to those with less highlighted elements, were also rated higher in terms of usefulness of the presentation of information, and accessibility of the information. Additional effects of highlighting tended to emerge only in conjunction with other variables. When viewing labels with 10 highlighted elements, participants who could focus their attention on the label made more correct product use decisions requiring application of label information than participants whose attention was divided. Participants who could focus on the label also rated it as more readable when there was more highlighting, as opposed to less.

Interactions of highlighting by type of drug were observed in a number of cases. The cough/cold label with 10 highlighted objectives was rated as more readable than the cough/cold label with 5 highlighted objectives, or either highlighted versions of the pain reliever label. For the cough/cold label, participants who could focus on the label rated those labels with more highlighting as more credible than participants whose attention was divided. Within the focused attention group, cough/cold labels with more highlighting were rated as more credible than cough/cold labels with less highlighting. A different pattern was observed for the pain reliever drug. The credibility ratings from participants whose attention was focused was higher for labels

with more highlighting compared to those for labels with less highlighting from participants whose attention was divided. Given the varying pattern of interactions, it appears that the effect of highlighting on comprehension and attitudes is complex. Use of highlighting should be judiciously applied.

There were some effects due entirely to type of drug. The cough/cold labels appeared to require greater effort to read and process needed information. Specifically, the results suggest that the pain reliever labels were easier to search for information (i.e., participants made more correct decisions) than were the cough/cold labels. Those who read the cough/cold labels also took more time to answer the product use questions than those who saw the pain reliever labels. These effects are not unexpected, given differences between these two products, including the unequal amounts of label information, differences in the number of active ingredients, and different conditions treated. Given these and other unknown differences, however, it is not possible to determine from the current results the causative underlying factors involved.

In this study, the old label format never outperformed the new label format. There were, however, some comparisons for which the new and old format did not differ. Participants did not differ in their product knowledge scores whether they read the label in the old or the new format. Participants who read the cough/cold label did not perform differently between the new and old format on product use decision items that required application of label information to hypothetical situations. It is possible that these results may be due to the peculiarities of the cough/cold label, rather than any lack of benefit from the new format. Perhaps the effects of the new format are stronger among products with fewer active ingredients. Further research is needed to provide insight into this question.

When asked to recall everything they could about the label, respondents mostly recalled information from the Do Not Use If section, followed by information from the Uses and Directions sections. This pattern of remembering suggests a recency effect, in which participants are most easily able to remember that which they have last read. If this is the case, it suggests that respondents are reading the directions first, followed by uses and warnings. This finding contrasts with those of Vigilante and Wogalter (1997), who found that consumers generally prefer and expect OTC drug labels to be constructed as: 1) uses, 2) warnings, and 3) directions. It is possible that while the Vigilante and Wogalter findings may reflect preferences, actual reading order may be somewhat different.

The majority of respondents can define the terms “efficacy,” “health professional,” “temporary,” and, to a lesser extent, “symptom.” However, the majority of respondents cannot define terms such as “placebo” and “thalidomide.” Younger respondents (under age 45) are less able to define thalidomide than older respondents. Lack of comprehension of the term “placebo” is puzzling. Perhaps use of the term has become commonplace, but the corresponding definition has not accompanied it. It could be worthwhile to provide some explanation of “placebo” when used in labeling.

Preference for Variations in OTC Label Format (Study B)

This study was designed to investigate consumer preferences for various format and graphical variations on the proposed OTC label format. Research on OTC label order preferences by Vigilante and Wogalter (1997) found that consumers generally prefer an order that consists of indications first, followed by personal hazard information (including warnings) and directions, active and inactive ingredients, with storage instructions and manufacturer information at the end. However, for emergency situations, the preferred order is somewhat different; personal hazard information moves up, followed by directions, indications, and active ingredients. It is important to include both performance and preference measures in format evaluation (Levy, Fein & Schucker, 1992).

Design

The study examined two levels of each of four independent variables in a 2 X 2 X 2 X 2 factorial design. The four variables were:

- 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)

Two different drug types were used in the study; a cough/cold drug and a sunscreen. The factorial combination of the independent variables resulted in 16 different label designs for each of the two drug types. The label designs can be found in Appendix E.

The second half of the session was devoted to participants' judgements of efficacy and probability terms. This section was designed to examine participants' comprehension of various methods of communicating the relative safety and efficacy of certain products and is discussed later in more detail. Finally, participants were administered the abbreviated REALM (as described previously) and asked a series of demographic questions.

Baseline Demographic Characteristics

A summary of the study population's demographic and health characteristics is included in Appendix A. A Oneway ANOVA was conducted on respondents' mean literacy score by education level. As can be seen in Table 17, and similar to the pattern found in Study A, literacy scores increased with increasing education, $F(6, 903) = 25.04, p < .001$. Respondents who have some high school education or who have completed high school scored higher on the abbreviated REALM than did participants who have a grade school or less education. Those who have some college or have completed college scored higher than those who have some high school or who have completed high school, and those respondents who have had graduate school or more scored higher than those who have some college. Respondents who indicate they have other education beyond high school scored the same on the literacy measure as respondents who have some college education, have completed college or have graduate school or higher education.

Table 17
Mean Literacy Score by Education Level

| Education Level | Mean Literacy Score |
|------------------------------------|---------------------|
| Grade School or less | 28.3 ^a |
| Some High School | 36.6 ^b |
| Completed High School | 37.0 ^b |
| Other Education beyond High School | 39.8 ^{c,d} |
| Some College | 39.5 ^c |
| Completed College | 40.3 ^{c,d} |
| Graduate School or more | 41.2 ^d |
| Overall Mean | 38.4 |

Maximum literacy score = 42. Means bearing different superscripts are significantly different at $p < .05$, LSD.

Results

First Ranked Label: Table 18 presents a summary of the first ranked labels for both the Cough/Cold (CC) and Sunscreen (SS) products. The frequencies in Table 18 indicate that participants were more likely to choose labels with the title "Medication Facts" as their #1 ranked label than those labels without a title. Visual inspection of the label rankings was not illuminating with regard to the other format variables, so rankings were subjected to statistical analysis.

Table 18
First Ranked Label

| 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 |
| CC | 576 | Title, Thick demarcation lines, Warnings first, Active Ingredients at bottom | 46 | 10.1 |
| CC | 687 | Title, Thick demarcation lines, Warnings first, Active Ingredients at top | 46 | 10.1 |
| CC | 500 | Title, Thick demarcation lines, Directions first, Active Ingredients at top | 42 | 9.2 |
| SS | 227 | Title, Thick demarcation lines, Warnings first, Active Ingredients at bottom | 41 | 9.1 |
| SS | 216 | Title, Thin demarcation lines, Directions first, Active Ingredients at bottom | 39 | 8.7 |
| SS | 301 | Title, Thin demarcation lines, Directions first, Active Ingredients at top | 38 | 8.5 |
| CC | 130 | Title, Thin demarcation lines, Warnings first, Active Ingredients at bottom | 38 | 8.4 |

| Drug Type | Label Number | Description | Frequency | Percent |
|------------------|---------------------|---|------------------|----------------|
| CC | 696 | Title, Thick demarcation lines, Warnings first, Active Ingredients at top | 36 | 7.9 |
| SS | 145 | Title, Thin demarcation lines, Warnings first, Active Ingredients at top | 33 | 7.3 |
| CC | 325 | Title, Thin demarcation lines, Warnings first, Active Ingredients at top | 27 | 5.9 |
| CC | 827 | No Title, Thick demarcation lines, Directions first, Active Ingredients at bottom | 19 | 4.2 |
| CC | 680 | No Title, Thin demarcation lines, Warnings first, Active Ingredients at bottom | 18 | 4.0 |
| CC | 786 | No Title, Thick demarcation lines, Warnings first, Active Ingredients at bottom | 14 | 3.1 |
| SS | 177 | No Title, Thin demarcation lines, Warnings first, Active Ingredients at bottom | 12 | 2.7 |
| CC | 904 | No Title, Thick demarcation lines, Directions first, Active Ingredients at top | 12 | 2.6 |
| CC | 611 | No Title, Thin demarcation lines, Directions first, Active Ingredients at bottom | 11 | 2.4 |
| SS | 207 | No Title, Thick demarcation lines, Directions first, Active Ingredients at bottom | 11 | 2.4 |
| SS | 209 | No Title, Thin demarcation lines, Directions first, Active Ingredients at bottom | 10 | 2.2 |
| SS | 452 | No Title, Thick demarcation lines, Directions first, Active Ingredients at top | 10 | 2.2 |
| SS | 701 | No Title, Thick demarcation lines, Warnings first, Active Ingredients at bottom | 10 | 2.2 |
| SS | 851 | No Title, Thin demarcation lines, Warnings first, Active Ingredients at top | 8 | 1.8 |
| SS | 203 | No Title, Thick demarcation lines, Warnings first, Active Ingredients at top | 7 | 1.6 |

| 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 |

Note: Percentages for Cough/Cold (CC) rankings are based on 455 responses, while percentages for Sunscreen (SS) rankings are based on 449 responses.

Open-Ended Responses: After ranking the 16 labels, respondents were asked “What was it about the first label that made you prefer it the most?” Table 19 reflects the categorized open-ended response frequencies (categorization keys are in Appendix F). The results show that “Like the layout or easy to read” was mentioned in 16.7% of the responses, while “Begins with medication facts” was mentioned in 14.6% of the responses, and “Directions first, or directions then warnings” was mentioned in 13.4% of the responses.

Participants were then asked “What was it about the second label that made you prefer it second most?” Table 20 reflects the categorized open-ended response frequencies for this question. Participants mentioned “Nearly the same as the first or no real difference” in 26.0% of the responses, while “Warnings first, active ingredients at bottom” was mentioned in 13.3% of the responses. Apparently, participants chose the second ranked label primarily for its similarity to the first ranked label.

Table 19
 Open-Ended Response Frequencies:
 “What is it about the first label that made you prefer it the most?”

| 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 |
| TOTAL | 1200 | 100 |

*Numbers indicate responses, not individuals

Table 20
 Open-Ended Response Frequencies:
 “What is it about the second label that made you prefer it the second most?”

| What is it about the second label that made you prefer it second most? | N* | % |
|--|-------------|------------|
| Nearly the same as the first or no real difference | 323 | 26.0 |
| Warnings first, active ingredients at bottom | 165 | 13.3 |
| Directions first or directions then warnings | 100 | 8.1 |
| Other | 99 | 8.0 |
| Miscellaneous mentions (e.g., has sun alert) | 92 | 7.4 |
| Non-specific section mentions (e.g., has uses, directions, warnings, etc.) | 91 | 7.3 |
| Warnings first or warnings then directions | 83 | 6.7 |
| Warnings first, active ingredients at top | 74 | 6.0 |
| Begins with medication facts | 72 | 5.8 |
| Thin lines | 57 | 4.6 |
| Thick lines | 50 | 4.0 |
| Print size or style | 9 | 0.7 |
| Not exactly the format I prefer | 8 | 0.6 |
| Does not begin with medication facts | 5 | 0.4 |
| Active ingredients at the bottom | 5 | 0.4 |
| Active ingredients at the top | 4 | 0.3 |
| Like the layout or easy to read | 2 | 0.2 |
| Directions first, active ingredients at top | 1 | 0.08 |
| Don't Know | 1 | 0.08 |
| TOTAL | 1241 | 100 |

*Numbers indicate responses, not individuals

Label Rankings: A conjoint analysis was performed on participants' rankings of the 16 labels.

Conjoint analysis simultaneously weighs different features of multiple variables. This type of

analysis allows for a determination of the relative importance of each particular attribute of a variable, in addition to the level at which each attribute is preferred (SPSS Categories, 1994). By using the participants' rankings of the labels, we simultaneously examined the relative impact of title ("Medication Facts" or none), order of warnings and directions (Warnings or Directions first), placement of active ingredients (top or bottom), and demarcation lines (thick or thin). Results indicated that, of the four factors examined, title had the greatest impact on rankings, with a utility range⁷ from -1.83 for no title and 1.83 for the "Medication Facts" title. The effect of the other three variables was not significant; utility range for active ingredients, .19 for bottom placement, -.19 for top placement; utility range for warnings and directions, .32 for directions first and -.32 for warnings first; and utility range for demarcation lines, -.15 for thin lines and .15 for thick lines. These results clearly indicate that the presence of a title was the most important factor in determining participants' preference rankings. A secondary analysis was performed using the Wilcoxon Signed Ranks test (used to compare mean (average) ranks across independent variables). Mean ranks for each type of label from the Wilcoxon test are in Table 21. Results confirmed the conjoint analysis with regard to title. Labels with the "Medication Facts" title were more preferred compared to labels with no title, $Z = -20.72$, $p < .001$. In addition, labels with active ingredients at the bottom were more preferred to those with active ingredients at the top, $Z = -4.59$, $p < .001$; labels with thick lines were more preferred to those with thin lines, $Z = -4.70$, $p < .001$; and labels with directions presented first were more preferred

⁷ The Conjoint procedure estimates "part-worths" for each factor level. Part-worth scores indicate the influence of each factor on the participants' preference for a particular combination of variables. They are computed through a set of regressions on the participants' label rankings. The utility score (or range) is the sum of all the part-worth scores (SPSS Categories, 1994).

to those with warnings presented first, $Z = -4.90$, $p < .001$. Although all these differences were statistically significant, the magnitude of the difference for the title variable was much greater.

Table 21
Mean Label Ranks by Format Element

| Format Element | Mean Rank | SD |
|------------------------------|------------------|-----------|
| Medication Facts Title | 6.67 | 1.95 |
| No Title | 10.33 | 1.95 |
| Thick Lines | 8.35 | .94 |
| Thin Lines | 8.65 | .94 |
| Directions first | 8.18 | 1.97 |
| Warnings first | 8.82 | 1.97 |
| Active Ingredients at bottom | 8.31 | 1.31 |
| Active Ingredients at top | 8.69 | 1.31 |

A lower mean rank indicates a greater preference.

Attitude Measures: The 12 attitude questions for the new format and old (existing) format label were subjected to separate maximum likelihood factor analyses. Results of both factor analyses indicated a three factor solution (factor loadings for each of the items are in Appendix G). Based on the factor loadings, three scales were constructed from the items. As in Study A, the items in the first factor tended to cluster around the concept of liking for the format or appearance of the label itself, and so the scale created from these items was named Preference. The items in the second factor tended to represent the concept of credibility or believability of the information in the label, and therefore was named Credibility. The remaining items tended to represent the concept of ease in reading the label and the scale thus was named Readability. Reliabilities and

items for each scale are presented in Table 22. Two items (“How important would it be for someone to read all the information on the label?” and “How biased is the information in the label?”) did not load above .400 on any of the factors and were subsequently dropped from analysis. The alphas for each of the constructed scales indicate that they have good reliability (refer to Footnote #3 for a detailed explanation of alpha level and reliability).

Table 22
Listing of Attitude Scales and Reliabilities

| Scale | Items | Alpha (new label) | Alpha (old label) |
|-------------|--|-------------------------|-------------------------|
| Preference | 2c. How much do you like the format or layout of the label? 2d. How easy is it to find information in the label? 2i. How well organized is the format or layout of the label? 2b. How useful is the label in helping someone to decide whether or not to use the drug? 2a. How willing would someone be to read the label? | .85 | .88 |
| Credibility | 2j. How much do you trust the information in the label? 2k. How confident would you be relying on the information in the label? 2e. How believable is the information on the label? | .86 | .91 |
| Readability | 2h. How confusing is the format or layout of the label? 2f. How difficult was it to read the label? | .65 | .70 |

For each of the scales, a difference score was computed by subtracting the mean of the items measuring opinions of the old format from the mean of the items measuring opinions of the new format. This difference score was then used in a 2 x 2 x 2 x 2 Multivariate Analysis of Variance (MANOVA). All analyses were conducted using an alpha of .05. Results indicated a multivariate main effect of title, $F(1, 872) = 12.55, p < .001$. As can be seen in Table 23, participants rated the new format label versions with the “Medication Facts” title as more preferred, Univariate $F(1, 890) = 37.62, p < .001$, more credible, Univariate $F(1, 890) = 13.65,$

$p < .001$, and more readable, Univariate $F(1, 890) = 9.39$, $p < .005$, than the new format labels without a title.

Table 23
Mean Difference Score for Preference Scale, Credibility Scale and Readability Scale, by Title

| | Title | |
|-------------------|--------------------------|----------------|
| | Medication Facts (SD) | None (SD) |
| Preference Scale | 3.83 (2.85) | 2.63 (2.63) |
| Credibility Scale | 1.85 (2.58) | 1.25 (2.32) |
| Readability Scale | 3.40 (3.93) | 2.63 (3.44) |

Higher numbers indicate more preference, credibility and readability, respectively.

Comprehension of Efficacy Information

The second half of the study was designed to investigate participants' comprehension of various verbal and graphic representations of drug effectiveness. As the number of OTC products grows, consumers are being presented with more complex representations of drug effectiveness. One example of this is the inclusion in package inserts of graphs depicting drug activity in comparison to placebo rate. "[A] graph reader must do two things. First, the reader must mentally represent the objects in the graph in only a certain way...Second, the graph reader must remember or deduce which aspects of the visual constituents of the graph stand for which of the mathematical scales that the graph is trying to communicate" (Pinker, 1990, p. 75).

Consumers must often reconcile this information with traditional verbal descriptions of

effectiveness (e.g., moderate pain relief). The reactions of consumers to different representations of efficacy may provide some insight into the different cognitive processes involved in their interpretation (Day, 1988). This segment the study was designed to investigate consumer ratings of both graphical and verbal depictions of drug efficacy, and determine the amount of correspondence between these ratings.

In the first task, participants were asked to rate two sets of 7 descriptive phrases designed to communicate differing levels of effectiveness. This task was designed to determine whether participants would distinguish between relatively subtle differentiations in the language used to describe efficacy. For the first set of terms (“completely effective,” “frequently effective,” “generally effective,” “minimally effective,” “moderately effective,” “occasionally effective,” and “usually effective”), the instructions read, “I’m going to give you a list of phrases that describe how likely a particular over-the-counter drug might work in a group of people. Out of 10 people, if a drug was described this way, for how many would you expect it to work?” (0 = nobody, 10 = everybody). Paired t-tests were conducted on the means. Table 24 presents the means for these terms.

Table 24
Mean Rating for Effectiveness Terms

| Term | Mean | SD |
|------------------------|-------------------|-----------|
| Completely effective | 7.73 ^a | 2.25 |
| Frequently effective | 5.83 ^b | 2.42 |
| Usually effective | 5.83 ^b | 2.38 |
| Moderately effective | 5.80 ^b | 1.86 |
| Generally effective | 5.77 ^b | 2.14 |
| Occasionally effective | 4.38 ^c | 2.57 |
| Minimally effective | 3.36 ^d | 2.64 |

Means bearing different superscripts are significantly different at $p < .001$.

The results indicate that participants did not differentiate between the terms “frequently effective,” “usually effective,” “generally effective,” and “moderately effective”; that is, products using these descriptive words were rated as equal in their effectiveness. Participants did distinguish between the other three terms, rating “completely effective” as the term with the highest proportion of population efficacy (approximately 7.7 out of 10, or 77% out of 100 people) and “minimally effective” as the term with the lowest proportion of population efficacy (approximately 3.4 out of 10, or 34% out of 100 people).

For the second set of terms (“complete relief,” “frequent relief,” “general relief,” “minimal relief,” “moderate relief,” “occasional relief,” and “usual relief”), the instructions read, “I’m going to give you a list of phrases that could be used to describe the effectiveness a particular over-the-counter drug might have. If a drug was described as having this characteristic, how effective do you think it would be on a scale from 0 to 10, where 0 means not

at all effective and 10 means extremely effective?” As can be seen in Table 25, participants made more distinctions among terms describing relief, as compared to efficacy. Respondents did not differentiate between “frequent relief” and “general relief,” indicating that they believed products using these two terms would be equal in their relief. As with the first set of terms, “complete relief” was rated as giving the highest proportion of effectiveness (8.6 out of 10, or 86%) and “minimal relief” was rated as the lowest (3.2 out of 10, or 32%).

Table 25
Mean Rating for Relief Terms

| Term | Mean | SD |
|-------------------|-------------------|-----------|
| Complete relief | 8.63 ^a | 1.87 |
| Frequent relief | 5.83 ^b | 2.24 |
| General relief | 5.82 ^b | 1.73 |
| Usual relief | 5.64 ^c | 2.25 |
| Occasional relief | 5.41 ^d | 1.93 |
| Moderate relief | 5.01 ^e | 1.80 |
| Minimal relief | 3.20 ^f | 2.23 |

Means bearing different superscripts are significantly different at $p < .05$.

To investigate participants’ comprehension of graphically presented efficacy information, four bar graphs were created, varying the rate of effectiveness for both the active drug (called CORZIL) and placebo. The efficacy rates represented in the graphs were: 1) Corzil 50%, Placebo 10%, 2) Corzil 50%, Placebo 30%, 3) Corzil 80%, Placebo 10%, and 4) Corzil 80%, Placebo 30%. Participants were asked to choose one term from a list that they felt best represented how well the drug worked. Since part of the purpose of this task was to investigate

participants' understanding of the concept and term placebo, no further clarification was provided as to which bar on the graph (Corzil or Placebo) was the drug. The terms provided were: "completely effective," "moderately effective," "generally effective," "occasionally effective," "minimally effective," "frequently effective," and "usually effective." Based on the ratings of the efficacy terms, it might be expected that participants would describe the effectiveness of the drug in graphs 1 and 2 using terms previously rated as describing effectiveness in approximately 50% of the population (frequently, moderately, usually or generally effective). Similarly, based on the mean ratings in Table 25, the effectiveness of the drug in graphs 3 and 4 should be described as "completely effective" (rated as effective in 77% of the population). Table 26 presents a table of efficacy frequencies, by graph. For graphs 1 and 2, participants tended to describe the drug as "moderately effective" (35% and 32%, respectively). However, for graphs 3 and 4, participants described the drug as "generally effective" (41% and 41%, respectively). Placebo rate (10% or 30%) did not appear to impact participants' ratings of drug effectiveness.

Table 26
Frequency Ratings of Efficacy Terms, by Graph

| Efficacy Term | Graph 1 | | Graph 2 | | Graph 3 | | Graph 4 | |
|------------------------|------------------------|-------------|------------------------|-------------|------------------------|-------------|------------------------|-------------|
| | Corzil 50 / Placebo 10 | | Corzil 50 / Placebo 30 | | Corzil 80 / Placebo 10 | | Corzil 80 / Placebo 30 | |
| | N | % | N | % | N | % | N | % |
| Completely Effective | 43 | 4.8% | 43 | 4.8% | 159 | 17.6% | 100 | 11.1% |
| Moderately Effective | 314 | 34.7% | 292 | 32.3% | 112 | 12.4% | 156 | 17.3% |
| Generally Effective | 149 | 16.5% | 132 | 14.6% | 371 | 41.0% | 373 | 41.3% |
| Occasionally Effective | 178 | 19.7% | 205 | 22.7% | 49 | 5.4% | 64 | 7.1% |
| Minimally Effective | 93 | 10.3% | 136 | 15.0% | 32 | 3.5% | 23 | 2.5% |
| Frequently Effective | 66 | 7.3% | 42 | 4.6% | 115 | 12.7% | 115 | 12.7% |
| Usually Effective | 48 | 5.3% | 47 | 5.2% | 57 | 6.3% | 67 | 7.4% |
| Don't Know | 9 | 1.0% | 3 | 0.3% | 5 | 0.6% | 2 | 0.2% |
| Refused | 4 | 0.4% | 3 | 0.3% | 4 | 0.4% | 3 | 0.3% |
| Total | 904 | 100% | 903 | 100% | 904 | 100% | 903 | 100% |

Health Terminology Definitions

As in Study A, respondents were asked to define six health terms “as if you saw it in a dictionary”: “effectiveness,” “health professional,” “placebo,” “symptom,” “temporary,” and “thalidomide.” Responses were scored 0 (incorrect), 1 (partially correct) or 2 (correct). As can be seen in Table 27, 87% of the respondents provided a correct or partially correct definition of “effectiveness,” 95% provided a correct/partially correct definition of “health professional,” and 93% provided a correct/partially correct definition of “temporary.” Similar to the pattern seen in Study A, 76% of the respondents provided a correct/partially correct definition of “symptom,” 41% provided a correct/partially correct definition of “placebo,” and only 31% provided a correct definition of “thalidomide.” A separate analysis was performed on this last term comparing respondents who were age 45 and over to those who were under age 45. Table 28 presents the breakdown of thalidomide definition accuracy by age. The results indicate that a significantly greater proportion of respondents age 45 and over can correctly or acceptably define the term “thalidomide” (49.2%) compared to respondents under age 45 (21.7%; $X^2(1, N = 904) = 72.49, p < .001$). This is consistent with the findings from Study A indicating that the younger population are those who are least knowledgeable about it.

Table 27
Summary of Response Frequencies for Terminology Definitions

| Term | Response Score | N | % |
|----------------------------|-----------------------|----------|----------|
| Effectiveness | Correct | 709 | 78.4 |
| | Partially Correct | 78 | 8.6 |
| | Incorrect | 117 | 12.9 |
| Health Professional | Correct | 731 | 80.9 |
| | Partially Correct | 125 | 13.8 |
| | Incorrect | 48 | 5.3 |
| Placebo | Correct | 262 | 29.0 |
| | Partially Correct | 107 | 11.8 |
| | Incorrect | 535 | 59.2 |
| Symptom | Correct | 367 | 40.6 |
| | Partially Correct | 319 | 35.3 |
| | Incorrect | 218 | 24.1 |
| Temporary | Correct | 777 | 86.0 |
| | Partially Correct | 67 | 7.4 |
| | Incorrect | 60 | 6.6 |
| Thalidomide | Correct | 132 | 14.6 |
| | Partially Correct | 152 | 16.8 |
| | Incorrect | 620 | 68.6 |

Table 28
Definition of Thalidomide by Age Group

| | Thalidomide Definition | |
|-------------------------|-------------------------------|------------------|
| | Correct/Acceptable | Incorrect |
| Age 18-44 | n=127 (21.7%) | n=458 (78.3%) |
| Age 45 and above | n=157 (49.2%) | n=162 (50.8%) |

Discussion

The results indicate that presence of the “Medication Facts” title was the design element that had the most impact on participants’ preference ratings of the label. When asked “What was it about the first label that made you prefer it the most?” respondents most frequently indicated that “liking for the format/easy to read” and “begins with Medication Facts” were their reasons for choosing the first ranked label. Responses to “What was it about the second label that made you prefer it second most?” indicated that respondents generally chose their second ranked label for its similarity to the first ranked label. Participants rated the labels with the “Medication Facts” title as more credible, readable, and preferred. When examined in conjunction with the placement of the active ingredients, type of demarcation lines, and order of warnings and directions, presence of title had more impact on participants’ ratings than all other design elements combined. Although the other format variables did not have a great impact in determining rankings, respondents generally preferred labels with directions above warnings, active ingredients at the bottom, and thick demarcation lines between the sections.

The results for Part 2 of Study B indicated that participants tended to group certain descriptors of effectiveness when asked to rate the likelihood of a particular drug working in ten people. Participants rated “frequently effective,” “usually effective,” “generally effective,” and “moderately effective” as approximately equal to one another in terms of their population efficacy. On the other hand, respondents clearly distinguished between “completely effective,” rated as representing the highest population efficacy, “minimally effective,” rated as the lowest, and “occasionally effective” falling in between. It is interesting to note that the one term that might be construed to represent 100% effectiveness (i.e., completely effective) was only rated to

be 77% effective in the population. It is possible that either consumers have become jaded with regard to advertised claims of effectiveness, or they are demonstrating a sophisticated understanding of the rate of therapeutic effect. One wonders what efficacy term, if any, would have to be employed to get a rating of full confidence.

Compared with efficacy descriptors, however, participants demonstrated more distinction among terms describing relief. In order of rated relief, respondents scored “complete relief” as the highest, followed by “frequent” and “general relief,” “usual relief,” “occasional relief,” “moderate relief,” and “minimal relief.” Respondents did not differentiate between “frequent relief” and “general relief,” indicating that they believed products using these two terms would be equal in relief. As with the first set of terms, the greatest differences were shown between “complete relief” and “minimal relief.”

Graphical representations of effectiveness do not appear to correspond to written representations. Participants who viewed graphs in which the drug was represented as 50% effective tended to choose the term “moderately effective” to describe the drug. When the drug was graphically displayed as 80% effective, however, participants tended to choose the term “generally effective” to describe it. Placebo rate did not appear to affect participants’ ratings of drug effectiveness. Regardless of whether the placebo rate was presented as 10% or 30%, participants did not use different terms to refer to drug effectiveness. Participants tended to describe the effectiveness of the drug in graphs 1 and 2 (50% effective) as “moderately effective,” but did not differentiate between the terms “moderately” and “generally effective” in the first task. This may indicate that participants are more likely to distinguish among efficacy terms when the information is presented graphically rather than verbally. It appears that there is

not much consistency between graphical and visual interpretations of effectiveness. Although the depiction of 50% drug efficacy could be interpreted as corresponding to its verbal component, the 80% effectiveness rate did not correspond to previous term ratings (in this case, complete efficacy). It is possible that the terms used to describe efficacy in this study were not sufficiently subtle to pick up the participants' conceptualization of the concept.

A majority of respondents were able to define the terms "temporary," "health professional," "effectiveness," and "symptom" correctly/acceptably. However, a majority of respondents could not define the terms "placebo" or "thalidomide." Consistent with the previous findings in Study A, younger respondents are less able to define thalidomide than older respondents.

Implications of Studies A and B

The proposed OTC label format demonstrates advantages over the old format. When searching for information in the label, consumers are able to make more correct product use decisions using the new format. Consumers espouse more self-confidence in using the new format under conditions where they are not able to focus all their attention on the label. Consumers also prefer that the label be headed by a title, much like the nutrition labeling seen on food products. To a lesser extent, consumers prefer an order that features directions above warnings, active ingredients at the bottom, and thick lines between information sections.

It should be noted that these studies did not attempt to investigate the entire universe of possible format variables that might have some impact on consumers' comprehension and preference for OTC drug labels. Rather, they were designed to provide some insight into certain specific variables. As consumers become accustomed to changes in OTC labeling, new

comprehension issues may arise. The results described herein should provide useful guidance for future research on these and other format issues relating to consumer comprehension of OTC labeling.

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Appendix A

Demographic Frequencies

| Variable | Category | Study A | | Study B | |
|----------------|------------------|---------|------|---------|------|
| | | N | % | N | % |
| Interview Site | Philadelphia, PA | 151 | 12.6 | 112 | 12.4 |
| | Birmingham, AL | 148 | 12.3 | 113 | 12.5 |
| | Cleveland, OH | 151 | 12.6 | 112 | 12.4 |
| | Chicago, IL | 151 | 12.6 | 113 | 12.5 |
| | Dallas, TX | 150 | 12.5 | 111 | 12.3 |
| | Denver, CO | 150 | 12.5 | 118 | 13.1 |
| | Los Angeles, CA | 151 | 12.6 | 112 | 12.4 |
| | Seattle, WA | 150 | 12.6 | 113 | 12.5 |
| | <i>TOTAL</i> | 1202 | 100 | 904 | 100 |
| Gender | Female | 599 | 49.8 | 452 | 50.0 |
| | Male | 603 | 50.2 | 452 | 50.0 |
| | <i>TOTAL</i> | 1202 | 100 | 904 | 100 |
| Age | 18-24 | 266 | 22.1 | 249 | 27.5 |
| | 25-34 | 221 | 18.4 | 170 | 18.8 |
| | 35-44 | 237 | 19.7 | 166 | 18.4 |
| | 45-54 | 192 | 16.0 | 137 | 15.2 |
| | 55-64 | 135 | 11.2 | 100 | 11.1 |
| | 65+ | 151 | 12.6 | 82 | 9.1 |
| | <i>TOTAL</i> | 1202 | 100 | 904 | 100 |

| Variable | Category | Study A | | Study B | |
|----------------|------------------------------------|---------|------|---------|------|
| | | N | % | N | % |
| Ethnicity | Black/Non-Hispanic | 297 | 24.7 | 261 | 28.9 |
| | Hispanic | 69 | 5.7 | 53 | 5.9 |
| | Asian/Pacific Islander | 24 | 2.0 | 13 | 1.4 |
| | White/Non-Hispanic | 774 | 64.4 | 555 | 61.4 |
| | Indian or Alaskan Native | 9 | 0.7 | 7 | 0.8 |
| | Other | 24 | 2.0 | 15 | 1.7 |
| | Don't Know/Refused | 5 | 0.4 | 0 | 0 |
| | <i>TOTAL</i> | 1202 | 100 | 904 | 100 |
| Marital Status | Married | 457 | 38.0 | 347 | 38.4 |
| | Separated | 43 | 3.6 | 31 | 3.4 |
| | Divorced | 132 | 11.0 | 108 | 11.9 |
| | Widowed | 78 | 6.5 | 50 | 5.5 |
| | Never Married | 489 | 40.7 | 366 | 40.5 |
| | Don't Know/Refused | 3 | 0.2 | 2 | 0.2 |
| | <i>TOTAL</i> | 1202 | 100 | 904 | 100 |
| Education | Grade School or less | 18 | 1.5 | 15 | 1.7 |
| | Some High School | 129 | 10.7 | 105 | 11.6 |
| | Completed High School | 384 | 31.9 | 295 | 32.6 |
| | Some College | 334 | 27.8 | 248 | 27.4 |
| | Completed College | 193 | 16.1 | 144 | 15.9 |
| | Graduate School or more | 87 | 7.2 | 64 | 7.1 |
| | Other Education beyond High School | 55 | 4.6 | 33 | 3.7 |
| | Don't Know/Refused | 2 | 0.2 | 0 | 0 |
| | <i>TOTAL</i> | 1202 | 100 | 904 | 100 |

| Variable | Category | Study A | | Study B | |
|--------------|------------------------------------|---------|------|---------|------|
| | | N | % | N | % |
| Profession | Professional/Technical | 224 | 18.6 | 171 | 18.9 |
| | Manager/Administrator | 109 | 9.1 | 69 | 7.6 |
| | Sales Worker | 103 | 8.6 | 73 | 8.1 |
| | Clerical | 78 | 6.5 | 51 | 5.6 |
| | Craft | 17 | 1.4 | 14 | 1.5 |
| | Operatives (except Transportation) | 10 | 0.8 | 9 | 1.0 |
| | Transport Operatives | 16 | 1.3 | 8 | 0.9 |
| | Laborer | 85 | 7.1 | 89 | 9.8 |
| | Service Worker | 75 | 6.2 | 77 | 8.5 |
| | Farmer/Farm Manager | 1 | 0.1 | 1 | 0.1 |
| | Retired | 173 | 14.4 | 87 | 9.6 |
| | Housewife | 94 | 7.8 | 54 | 5.8 |
| | Student | 86 | 7.2 | 97 | 10.7 |
| | Unemployed | 89 | 7.4 | 82 | 9.1 |
| | Military | 22 | 1.8 | 15 | 1.7 |
| | Don't Know/Refused | 20 | 1.7 | 9 | 1.0 |
| <i>TOTAL</i> | | 1202 | 100 | 904 | 100 |

| Variable | Category | Study A | | Study B | |
|----------------------------|----------------------|---------|------|---------|------|
| | | N | % | N | % |
| Total Family Income | Under \$25,000 | 290 | 24.1 | 231 | 25.6 |
| | \$25,000 to \$29,999 | 169 | 14.1 | 145 | 16.0 |
| | \$30,000 to \$34,999 | 137 | 11.4 | 90 | 10.0 |
| | \$35,000 to \$39,999 | 95 | 7.9 | 78 | 8.6 |
| | \$40,000 to \$49,999 | 119 | 9.9 | 87 | 9.6 |
| | \$50,000 to \$59,999 | 82 | 6.8 | 70 | 7.7 |
| | \$60,000 to \$74,999 | 69 | 5.7 | 62 | 6.9 |
| | \$75,000 and over | 89 | 7.4 | 72 | 8.0 |
| | Don't Know/Refused | 152 | 12.6 | 69 | 7.6 |
| | <i>TOTAL</i> | | 1202 | 100 | 904 |

Health Information

| Variable | Category | Study A | | Study B | |
|---|---------------------|---------|------|---------|------|
| | | N | % | N | % |
| In general, would you say your health is: | Excellent | 297 | 24.7 | 245 | 27.1 |
| | Very Good | 393 | 32.7 | 329 | 36.4 |
| | Good | 344 | 28.6 | 241 | 26.7 |
| | Fair | 138 | 11.5 | 75 | 8.3 |
| | Poor | 28 | 2.3 | 14 | 1.5 |
| | Don't Know/Refused | 2 | 0.2 | 0 | 0 |
| | <i>TOTAL</i> | | 1202 | 100 | 904 |
| Are you being treated for any of these medical conditions? | None | 856 | 71.2 | 629 | 69.6 |
| | Heart Disease | 21 | 1.7 | 20 | 2.2 |
| | High Blood Pressure | 87 | 7.2 | 67 | 7.4 |
| | Asthma | 46 | 3.8 | 34 | 3.8 |
| | Depression | 35 | 2.9 | 24 | 2.7 |
| | High Cholesterol | 30 | 2.5 | 15 | 1.7 |
| | Stomach Ulcers | 15 | 1.2 | 13 | 1.4 |
| | Emphysema | 2 | 0.2 | 1 | 0.1 |
| | Multiple Conditions | 101 | 8.4 | 46 | 5.1 |
| | Don't Know/Refused | 9 | 0.7 | 55 | 6.1 |
| | <i>TOTAL</i> | | 1202 | 100 | 904 |

| Variable | Category | Study A | | Study B | |
|---|---------------------|---------|------|---------|------|
| | | N | % | N | % |
| How often have you purchased an over-the-counter cough/cold drug in the past six months? | Zero times | 473 | 39.4 | 342 | 37.8 |
| | One-Two times | 497 | 41.3 | 398 | 44.0 |
| | Three-Four times | 149 | 12.4 | 104 | 11.5 |
| | Five-Six times | 48 | 4.0 | 32 | 3.5 |
| | Seven or more times | 31 | 2.6 | 28 | 3.1 |
| | Don't Know/Refused | 4 | 0.3 | 0 | 0 |
| | <i>TOTAL</i> | | 1202 | 100 | 904 |
| How often have you purchased an over-the-counter pain reliever drug in the past six months? | Zero times | 370 | 30.8 | 260 | 28.8 |
| | One-Two times | 520 | 43.3 | 402 | 44.5 |
| | Three-Four times | 175 | 14.6 | 136 | 15.0 |
| | Five-Six times | 79 | 6.6 | 54 | 6.0 |
| | Seven or more times | 56 | 4.7 | 51 | 5.6 |
| | Don't Know/Refused | 2 | 0.2 | 1 | 0.1 |
| | <i>TOTAL</i> | | 1202 | 100 | 904 |
| How often have you purchased an over-the-counter sunscreen in the past six months? | Zero times | 747 | 62.1 | 561 | 62.1 |
| | One-Two times | 370 | 30.8 | 280 | 31.0 |
| | Three-Four times | 57 | 4.7 | 43 | 4.8 |
| | Five-Six times | 14 | 1.2 | 15 | 1.7 |
| | Seven or more times | 10 | 0.8 | 5 | 0.6 |
| | Don't Know/Refused | 4 | 0.3 | 0 | 0 |
| | <i>TOTAL</i> | | 1202 | 100 | 904 |

Appendix B

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

| | | | | | | | | |
|---|--|---|--|--|------------------------------|------------------------------|-------------------------------|-----------------------------|
| <p>Active Ingredients (in Each Softgel) Benesine 10 mg Antihistamine Pseudoephedrine Nasal Decongestant Hydrochloride 40 mg Tromethan 35mg Cough Suppressant</p> <p>Uses: For the temporary relief of these cold symptoms: • sneezing • runny nose • cough • nasal congestion</p> | <p>Purposes</p> | <p>When Using This Product:</p> <ul style="list-style-type: none"> ■ drowsiness may occur ■ avoid alcohol ■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect ■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children <p>Stop Using This Product If:</p> <ul style="list-style-type: none"> ■ cough is accompanied by fever, rash or headache that lasts ■ stomach pain occurs ■ nervousness, dizziness or sleeplessness occur ■ symptoms do not improve within 7 days <p>Ask a doctor. These may be signs of a serious condition.</p> <p>If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help right away.</p> | | | | | | |
| <p>Warnings</p> <p>Do Not Use:</p> <ul style="list-style-type: none"> ■ if taking a monoamine oxidase inhibitor (MAOI) prescription drug (for depression, psychiatric or emotional conditions, or Parkinson's disease) ■ for 2 weeks after stopping an MAOI drug. If uncertain about your prescription drug, ask a health professional if it contains an MAOI. ■ during the first 4 months of pregnancy <p>Ask A Doctor Before Use If You Have:</p> <ul style="list-style-type: none"> ■ heart disease ■ excessive phlegm (mucous) ■ glaucoma ■ high blood pressure ■ diabetes ■ thyroid disease ■ a cough that lasts from smoking, asthma or emphysema ■ cough with fever, rash or headache that lasts ■ a breathing problem such as emphysema or chronic bronchitis ■ difficulty in urination due to prostate gland enlargement <p>If You Are:</p> <ul style="list-style-type: none"> ■ taking any drugs for asthma ■ taking sedatives or tranquilizers | | <p>Directions: 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: New Format, Ten Highlighted Communication Objectives (Cough/Cold)
Label # 072**

| | | | | | | | | |
|---|--|---|--|--|------------------------------|------------------------------|-------------------------------|-----------------------------|
| <p>Active Ingredients (in Each Softgel) Benesine 10 mg Antihistamine Pseudoephedrine Nasal Decongestant Hydrochloride 40 mg Tromethan 35mg Cough Suppressant</p> <p>Uses: For the temporary relief of these cold symptoms: • sneezing • runny nose • cough • nasal congestion</p> | <p>Purposes</p> | <p>When Using This Product:</p> <ul style="list-style-type: none"> ■ drowsiness may occur ■ avoid alcohol ■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect ■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children <p>Stop Using This Product If:</p> <ul style="list-style-type: none"> ■ cough is accompanied by fever, rash or headache that lasts ■ stomach pain occurs ■ nervousness, dizziness or sleeplessness occur ■ symptoms do not improve within 7 days <p>Ask a doctor. These may be signs of a serious condition.</p> <p>If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help right away.</p> | | | | | | |
| <p>Warnings</p> <p>Do Not Use:</p> <ul style="list-style-type: none"> ■ if taking a monoamine oxidase inhibitor (MAOI) prescription drug (for depression, psychiatric or emotional conditions, or Parkinson's disease) ■ for 2 weeks after stopping an MAOI drug. If uncertain about your prescription drug, ask a health professional if it contains an MAOI. ■ during the first 4 months of pregnancy <p>Ask A Doctor Before Use If You Have:</p> <ul style="list-style-type: none"> ■ heart disease ■ excessive phlegm (mucous) ■ glaucoma ■ high blood pressure ■ diabetes ■ thyroid disease ■ a cough that lasts from smoking, asthma or emphysema ■ cough with fever, rash or headache that lasts ■ a breathing problem such as emphysema or chronic bronchitis ■ difficulty in urination due to prostate gland enlargement <p>If You Are:</p> <ul style="list-style-type: none"> ■ taking any drugs for asthma ■ taking sedatives or tranquilizers | | <p>Directions: 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: Iphenesine, 10mg (Antihistamine), Pseudoephedrine Hydrochloride, 40mg (Nasal Decongestant), Tromethaphan, 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).

**Description: Old Format, Ten Highlighted Communication Objectives (Cough/Cold)
Label # 753**

Active Ingredients: Iphenesine, 10mg (Antihistamine), Pseudoephedrine Hydrochloride, 40mg (Nasal Decongestant), Tromethaphan, 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).

Description: New Format, Five Highlighted Communication Objectives (Pain Reliever)
 Label # 162

| Active Ingredient (In Each Tablet) | Purpose |
|--|---|
| Moraprotin 12.5 mg..... | Pain Reliever |
| Uses: For the temporary relief of minor aches and pains from: • common cold • headache • muscular aches • arthritis. Temporarily reduces fever. | |
| Warnings | |
| Do Not Use: | |
| <ul style="list-style-type: none"> • if you have had an allergic reaction (such as asthma, swelling, shock or hives) to aspirin or other pain relievers. It may cause a similar reaction. • if you have ulcers or holes in the stomach lining. It may make this condition worse. • with any other pain reliever/fever reducer • for more than 3 days for fever • for more than 10 days for pain • during the last 3 months of pregnancy. It may cause problems in the unborn child or complications during delivery. | |
| Ask A Doctor Before Use It: | |
| <ul style="list-style-type: none"> • you are taking any drugs for high blood pressure • the painful area is red or swollen • you generally consume 3 or more alcohol-containing drinks per day | |
| Stop Using This Product It: | |
| <ul style="list-style-type: none"> • stomach pain occurs • symptoms continue or worsen • new or unexpected symptoms occur | |
| <p>Ask a doctor. These may be signs of a serious condition.</p> <p>If pregnant or breast feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>In case of overdose, get medical help right away.</p> | |
| Directions: | |
| Take with a full glass of water or other liquid. | |
| Adults and children 16 years of age and over | Take 2 tablets every 6 hours until pain goes away. Do not take more than 2 tablets in any 6 hour period or 6 tablets in any 24 hour period. |
| Children under 16 years of age | Do not use this product |
| Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F). | |

Description: New Format, Ten Highlighted Communication Objectives (Pain Reliever)
 Label # 085

| Active Ingredient (In Each Tablet) | Purpose |
|--|---|
| Moraprotin 12.5 mg..... | Pain Reliever |
| Uses: For the temporary relief of minor aches and pains from: • common cold • headache • muscular aches • arthritis. Temporarily reduces fever. | |
| Warnings | |
| Do Not Use: | |
| <ul style="list-style-type: none"> • if you have had an allergic reaction (such as asthma, swelling, shock or hives) to aspirin or other pain relievers. It may cause a similar reaction. • if you have ulcers or holes in the stomach lining. It may make this condition worse. • with any other pain reliever/fever reducer • for more than 3 days for fever • for more than 10 days for pain • during the last 3 months of pregnancy. It may cause problems in the unborn child or complications during delivery. | |
| Ask A Doctor Before Use It: | |
| <ul style="list-style-type: none"> • you are taking any drugs for high blood pressure • the painful area is red or swollen • you generally consume 3 or more alcohol-containing drinks per day | |
| Stop Using This Product It: | |
| <ul style="list-style-type: none"> • stomach pain occurs • symptoms continue or worsen • new or unexpected symptoms occur | |
| <p>Ask a doctor. These may be signs of a serious condition.</p> <p>If pregnant or breast feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>In case of overdose, get medical help right away.</p> | |
| Directions: | |
| Take with a full glass of water or other liquid. | |
| Adults and children 16 years of age and over | Take 2 tablets every 6 hours until pain goes away. Do not take more than 2 tablets in any 6 hour period or 6 tablets in any 24 hour period. |
| Children under 16 years of age | Do not use this product |
| Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F). | |

Description: Old Format, Five Highlighted Communication Objectives (Pain Reliever)
Label # 326

Active Ingredient: Moraprofen, 12.5mg (Pain Reducer).
Indications: For the temporary relief of minor aches and pains associated with the common cold, headache, muscular aches, for the minor pain of arthritis, and for the reduction of fever.
Warnings: Do not take this product if you have had a severe allergic reaction to aspirin, e.g. — asthma, swelling, shock, or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin. Moraprofen could cause similar reactions in patients allergic to other pain relievers/fever reducers. Do not take this product if you have stomach ulcers or perforations in the stomach lining, as the use of this or similar products may be associated with an aggravation of gastrointestinal (stomach) problems. Do not use this product with any other pain reliever/fever reducer. Do not take this product for more than 3 days for fever, or for more than 10 days for pain. IT IS ESPECIALLY IMPORTANT NOT TO USE MORAPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY. As with aspirin and acetaminophen, if you are taking any prescription medicines to treat high blood pressure or if the painful area is red or swollen, do not take this product without first discussing it with your doctor. If you generally consume 3 or more alcohol-containing drinks per day, you should talk to your doctor for advice on when and how you should take Imprint or other pain relievers. If you experience stomach pain, if symptoms continue or worsen, or if you experience any new or unexpected symptoms, stop using this product and consult a physician. These could be signs of a serious illness. 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: Take with a full glass of water or other liquid. Adults and children 16 years of age and older: Take 2 tablets every 6 hours while symptoms persist, not to exceed 6 tablets in 24 hours unless directed to do so by a physician. Children under 16 years of age: Do not give this product to children under 16 years of age, or permit them to take it.
Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).

Description: Old Format, Ten Highlighted Communication Objectives (Pain Reliever)
Label # 369

Active Ingredient: Moraprofen, 12.5mg (Pain Reducer).
Indications: For the temporary relief of minor aches and pains associated with the common cold, headache, muscular aches, for the minor pain of arthritis, and for the reduction of fever.
Warnings: Do not take this product if you have had a severe allergic reaction to aspirin, e.g. — asthma, swelling, shock, or hives, because even though this product contains no aspirin or salicylates, cross-reactions may occur in patients allergic to aspirin. Moraprofen could cause similar reactions in patients allergic to other pain relievers/fever reducers. Do not take this product if you have stomach ulcers or perforations in the stomach lining, as the use of this or similar products may be associated with an aggravation of gastrointestinal (stomach) problems. Do not use this product with any other pain reliever/fever reducer. Do not take this product for more than 3 days for fever, or for more than 10 days for pain. IT IS ESPECIALLY IMPORTANT NOT TO USE MORAPROFEN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY. As with aspirin and acetaminophen, if you are taking any prescription medicines to treat high blood pressure or if the painful area is red or swollen, do not take this product without first discussing it with your doctor. If you generally consume 3 or more alcohol-containing drinks per day, you should talk to your doctor for advice on when and how you should take Imprint or other pain relievers. If you experience stomach pain, if symptoms continue or worsen, or if you experience any new or unexpected symptoms, stop using this product and consult a physician. These could be signs of a serious illness. 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: Take with a full glass of water or other liquid. Adults and children 16 years of age and older: Take 2 tablets every 6 hours while symptoms persist, not to exceed 6 tablets in 24 hours unless directed to do so by a physician. Children under 16 years of age: Do not give this product to children under 16 years of age, or permit them to take it.
Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).



Appendix C



Study A: Open-Ended Base Response Frequencies and Categorization Key: "Tell me everything you can remember about the label"

| Response | N | % |
|---|-----|------|
| do not use during pregnancy (D) | 152 | 12.6 |
| use for colds (C) | 124 | 10.3 |
| children <16 may not use (T) | 123 | 10.2 |
| do not use if ulcers/holes in stomach (D) | 119 | 9.9 |
| use for pain relief (C) | 107 | 8.9 |
| do not use if high blood pressure (D) | 103 | 8.6 |
| directions/dosage/dosage info (unspec) (T) | 89 | 7.4 |
| nasal decongestant (C) | 83 | 6.9 |
| do not use if asthma (D) | 82 | 6.8 |
| do not exceed max dose of 8 in 24 hrs (CC)/6 in 24 hrs (PR) (T) | 81 | 6.7 |
| adults/+16 may take 2/2 tablets/gelcaps every 6 hrs. (T) | 78 | 6.5 |
| drowsiness (F) | 77 | 6.4 |
| list of ingredients (unspec) (X) | 75 | 6.2 |
| do not use if taking other medications/pain relievers (D) | 73 | 6.1 |
| do not use if allergy to aspirin (D) | 72 | 6.0 |
| avoid alcohol when using medication (F) | 68 | 5.7 |
| use for flu (C) | 65 | 5.4 |
| do not use if heart disease/condition (D) | 61 | 5.1 |
| consult with doctor before using (unspec) (E) | 60 | 5.0 |
| children <6 may not use (T) | 59 | 4.9 |
| incorrect spec. dosage recall (T) | 59 | 4.9 |
| warnings (unspec) (G) | 55 | 4.6 |
| do not use if last 3 mos. of pregnancy (D) | 54 | 4.5 |

| Response | N | % |
|--|----|-----|
| softgel cap/tablet (X) | 50 | 4.2 |
| antihistamine (C) | 50 | 4.2 |
| do not use if stomach pain (D) | 49 | 4.1 |
| use for headaches (C) | 49 | 4.1 |
| use for minor aches/pains (C) | 48 | 4.0 |
| consult doctor before using if pregnancy (E) | 45 | 3.7 |
| do not use during first 4 mos. of pregnancy (D) | 45 | 3.7 |
| do not use if using anti-depressants (D) | 43 | 3.6 |
| don't drive/operate machinery/operate with care due to side effects when using (F) | 42 | 3.5 |
| warnings/statements you should not use the product (unspec) (D) | 41 | 3.4 |
| adults/age 12+ may take 2/2 gelcaps/tablets every 4 hrs. (T) | 41 | 3.4 |
| stop using/call doctor if stomach pain (F) | 41 | 3.4 |
| use for coughing (C) | 40 | 3.3 |
| gives max days to be taken/7 days (CC)/3 days if fever (PR)/10 days if pain (PR) (T) | 39 | 3.2 |
| stop using/call doctor if symptoms persist (F) | 38 | 3.2 |
| contains Moraprofen (X) | 38 | 3.2 |
| do not use if using MAOI for depression/Parkinson's (D) | 38 | 3.2 |
| take 2/2 gelcaps/tablets every 4 hrs. (T) | 36 | 3.0 |
| other | 34 | 2.8 |
| take with full glass of water (T) | 33 | 2.7 |
| cough suppressant (C) | 32 | 2.7 |
| \$2.00 rebate (A) | 31 | 2.6 |
| keep out of reach of children (G) | 28 | 2.3 |
| do not use if allergies/allergic reactions (unspec) (D) | 27 | 2.2 |
| contains 100 tablets (A) | 27 | 2.2 |

| Response | N | % |
|---|----|-----|
| use for runny nose/eyes (C) | 27 | 2.2 |
| stop using/call doctor if rash (F) | 26 | 2.2 |
| contains 24 gelcaps (A) | 26 | 2.2 |
| what it is used for/usage/what symptoms it relieves (unspec) (C) | 25 | 2.1 |
| other spec. reasons to consult doctor (E) | 25 | 2.1 |
| do not use if diabetes (D) | 25 | 2.1 |
| other spec. warnings/statements you should not use product (D) | 24 | 2.0 |
| consult doctor before using if heart disease (E) | 24 | 2.0 |
| other spec. uses/symptoms relieved (C) | 23 | 1.9 |
| children 6-12 may take 1/2 gelcap/tablet every 4 hrs. (T) | 23 | 1.9 |
| other spec. ingredients (X) | 23 | 1.9 |
| consult doctor before using if high blood pressure/use of drugs for HBP (E) | 22 | 1.8 |
| may experience side effects (unspec) (F) | 22 | 1.8 |
| use for arthritis (C) | 22 | 1.8 |
| reasons to stop using/taking medication/consult doctor (unspec) (F) | 22 | 1.8 |
| use for reduces fever (C) | 22 | 1.8 |
| other spec. reasons to stop using/taking medication/consult doctor (F) | 21 | 1.7 |
| use for sneezing (C) | 20 | 1.7 |
| dosage for adults/children (T) | 20 | 1.7 |
| do not give to children under 12 (T) | 20 | 1.7 |
| stop using/call doctor if allergic reactions (unspec) (F) | 20 | 1.7 |
| contains 12/12.5 mg of medication/Moraprofen (X) | 20 | 1.7 |
| stop using/call doctor if fever (F) | 20 | 1.7 |
| Imprit (A) | 20 | 1.7 |
| do not use if nursing/breast feeding (D) | 19 | 1.6 |

| Response | N | % |
|--|----|-----|
| Corzil (A) | 17 | 1.4 |
| stop using/call doctor if persistent cough (F) | 17 | 1.4 |
| consult doctor before using if regular use of alcohol/drugs (E) | 16 | 1.3 |
| multi-symptoms (unspec) (C) | 14 | 1.2 |
| stop using/call doctor if swelling/inflammation (F) | 14 | 1.2 |
| dizziness (F) | 13 | 1.1 |
| do not use if problems with alcohol/3+ alcoholic beverages per day (D) | 16 | 1.3 |
| box color (A) | 11 | 0.9 |
| consult doctor before using if taking other medications (E) | 11 | 0.9 |
| for daytime use (A) | 10 | 0.8 |
| other spec. directions/dosage mentions (T) | 10 | 0.8 |
| room temperature (B) | 9 | 0.7 |
| do not use if you smoke/have cough due to smoking (D) | 9 | 0.7 |
| consult doctor before using if asthma (E) | 9 | 0.7 |
| may cause excitability/nervousness (F) | 8 | 0.7 |
| do not use if glaucoma (D) | 8 | 0.7 |
| take as prescribed/do not exceed recommended dosage (T) | 8 | 0.7 |
| safety-sealed (A) | 8 | 0.7 |
| contains no aspirin/non-aspirin (A) | 7 | 0.6 |
| do not use if thyroid problem/thyroid disease (D) | 7 | 0.6 |
| do not use if area is red/swollen (D) | 6 | 0.5 |
| do not use if emphysema (D) | 6 | 0.5 |
| other spec. side effects (F) | 6 | 0.5 |
| temperature for storage of medication (unspec) (B) | 6 | 0.5 |
| 20-25 degrees Celsius (B) | 5 | 0.4 |

| Response | N | % |
|--|---|-----|
| other spec. temperatures for storage of medication (B) | 5 | 0.4 |
| nothing/nothing more | 5 | 0.4 |
| don't know | 2 | 0.2 |
| other spec. warnings (G) | 1 | 0.1 |
| contains no aspirin/non-aspirin (A) | 1 | 0.1 |

Classification Key

(D) Do not use if

(C) Uses

(T) Dosage/directions

(F) Stop using if/side effects

(E) Consult doctor before using if

(X) Dosage form/ingredients

(A) Promotional information/box characteristics

(G) General warnings

(B) Storage information

Other

Appendix D

Study A: Factor Loadings for Opinion Items

| Item | Factor | | |
|---|--------|-------|------|
| | 1 | 2 | 3 |
| 4c. How much do you like the format or layout of the label? | .779 | | |
| 4d. How easy is it to find information in the label? | .719 | | |
| 4a. How willing would someone be to read the label? | .546 | | |
| 4i. How well organized is the format or layout of the label? | .488 | | |
| 4f. How difficult was it to read the label? | | -.922 | |
| 4e. How difficult is it to see each of the words printed on the label? | | -.505 | |
| 4h. How confusing is the format or layout of the label? | | -.410 | |
| 4j. How easy to understand is the information in the label? | | | .579 |
| 4g. How important would it be for someone to read all the information on the label? | | | .521 |
| 4b. How useful is the label in helping someone decide whether or not to use the drug? | | | .414 |

Item 4k was not included in the scale because it did not load greater than .400 on any of the factors.

Study A: Factor Loadings for Involvement Items

| Item | Factor | |
|-----------------------|--------|------|
| | 1 | 2 |
| 5g. Fascinating | .912 | |
| 5e. Exciting | .859 | |
| 5f. Appealing | .821 | |
| 5i. Interesting | .674 | |
| 5h. Involving | .602 | |
| 5a. Important | | .804 |
| 5d. Valuable | | .777 |
| 5b. Relevant | | .743 |
| 5c. Means a lot to me | | .719 |
| 5j. Needed | | .647 |

Study A: Factor Loadings for Accessibility and Credibility Items

| Item | Factor | |
|---|--------|-------|
| | 1 | 2 |
| 7h. How easy was it to find the important information on the label? | .819 | |
| 7d. How would you say the important information in the drug label stood out? | .757 | |
| 7g. How would you rate the label [for reading]? | .748 | |
| 7f. Overall, how useful was the presentation [of the information in the label]? | .659 | |
| 7e. When you first read the label, would you say your attention was focused just on the drug information label: | .465 | |
| 7j. Overall, how believable was the information in the label? | | -.894 |
| 7i. Overall, how much did you trust the information in the label? | | -.796 |

Items 7a, 7b, and 7c were not included in the scale because it did not load greater than .400 on any of the factors.