August 6, 1997

Supporting Statement

Evaluation of Statement of Identity Placement and Alcohol Warnings for Over-the-Counter (OTC) Drugs

A. Justification

A1. Necessity for the Information Collection

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) has responsibility to assure proper labeling of prescription and 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 Section 201 defines "adequate directions of use" as directions under which a layperson can use a drug safely and for the purposes for which it is intended. 21 CFR Section 330.10(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 people with low comprehension ability, under customary conditions of purchase and use.

In recent years, FDA has become concerned about the adequacy of OTC labeling. For example, with the advent of new categories of Rx-to-OTC switch drugs, consumers are being asked to provide more sophisticated self-diagnostic and self-monitoring evaluations. 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). The elderly population, as prime users of OTC products, is increasing in size. However, because of decreasing visual functioning, this segment may have greater difficulty reading the label on certain consumer products.

In February, 1997, FDA proposed new regulations that would simplify the label for most OTC drugs and provide a consistent format for these products. 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 jargonistic phraseology (e.g., replace "pulmonary" with "lung"). In the Federal Register of May 23, 1997, FDA announced four studies to measure communication aspects of the revised OTC labels. Two of these studies (Studies A and B) have been previously submitted to OMB. The present supporting statement focuses on the remaining two studies.

The purpose of the two studies described in this statement is to provide an evaluation of two specific OTC labeling issues. One study (Study C) will investigate the influence of variations in the form and placement of the Statement of Identity (SOI) for OTC products. The other study (Study D) will investigate the specificity and framing of the wordings for the Alcohol Warning included in oral analgesics. Both studies will utilize shopping mall intercepts to recruit subjects. Eligible participants will be recruited in eight geographically dispersed malls serving a variety of socioeconomic classes. Recruited subjects will be screened for their ability to read English, visually process the label (have reading glasses available if necessary) and age (over 18 years old). They will be asked to participate in a study being conducted for the Food and Drug Administration that lasts no more than 30 minutes.

Study C: Form and Placement of the Statement of Identity (SOI)

OTC products are identified by three possible "names": the brand name (Tylenol), the statement of pharmacological activity (pain reliever), and the active ingredient(s) (AI) (acetaminophen). The brand name is important in the marketing of consumer products. Not only do these names convey a unique identification of the product, they also become "associated" with the product attributes that "position" the product in the market and distinguish competing products from each other. The statement of pharmacological activity is important because it informs consumers about the correct uses for a product. The active ingredients list is important because it informs consumers of the chemical contents and permits consumers to make judgments on the basis of specific active ingredients in addition to or as opposed to other product attributes.

Each of these three names are usually listed on the front or principle display panel (PDP) for OTC single ingredient products. However, for combination or mixture products, only the brand name and statement of activity are usually listed on the PDP. FDA regulations specify that the SOI of an OTC drug product must be prominently shown on the PDP. For single ingredient products, the SOI is composed of the ingredient name followed by an accurate statement of the pharmacological category or the intended action of the drug. For combination OTC products, FDA regulations (201.61b) state that the SOI listing requirement may be satisfied if the general pharmacological actions of the mixture (in terms meaningful to the layman) are displayed in conjunction with the most prominent listing of the brand name of the product. Active ingredients must be displayed on the back panel of the product in all instances.

Recently, there has been a difference of opinion about the placement of the active ingredient (AI) information on combination OTC products. Some have argued that AIs should be listed on the PDP so that consumers would have ready access to that information at the time of purchase. This would prompt or more readily permit consumers to make product decisions on the basis of product ingredients. Others have argued that such information is readily available for consumers who simply examine the back panel and that listing all of the AIs for combination OTC products would distract from the overall communication of product identity, make the package unattractive, or lessen the communication of other information listed on the PDP.

Decision Processes: One may hypothesize that the major advantage of listing the AI's on the front panel is that consumers will be able to compare active ingredients among competing products more easily. This could increase consumers' reliance on AI's as decision criteria for purchase. On the other hand, some may argue that consumers can utilize AI's, if they wish, simply by looking at the products back panel. Further, listing the AI's on the PDP may distract from conveyance of other information on the panel, making it more difficult for manufacturers to communicate product differences and advantages through "product positioning" information.

Consumers may process AI label information on the PDP using two basic decision making processes. On the one hand, they may include the AI information as part of a systematic decision process. Here, consumers integrate the AI information along with other information about the product in an effortful and careful process. For example, they may seek to determine if the ingredients listed are appropriate for the conditions they seek to treat. On the other hand, they may use AI's as a "signal" that is processed more superficially as part of a "judgment heuristic" that forms the basis for a purchase decision. Judgment heuristics allow individuals to make simple, quick decisions requiring little effort. In this heuristic process, information on the product is unsystematically analyzed (Chaiken and Maheswaran, 1994; Petty, Cacioppo and Schumann, 1983). For example, instead of carefully considering the effect of the individual AI's on their symptoms, they would rely on the "signal value" of the AI list to form impressions and make decisions (e.g., the more AI's the more potent the medicine, the more value for their money). Thus, while listing the AI's on the PDP may allow the consumer to make systematic comparisons, it may also increase the use of AI's as a cue for heuristic decision making.

Purpose: The purpose of Study C is to investigate consumers' perceptions, processing and evaluation of the placement of active ingredient information on the front and/or back portion of the product package.

Stimuli: The study will utilize two placements (P) for the AI's. For both conditions the brand name and pharmacological activity name will be placed on the PDP and the active ingredients list will be placed on the back panel. For the second placement, however, the active ingredients will be placed on both the front and back panel. The table below displays the two placements:

Placement	Brand Name	Pharmacologic Activity	Active Ingredients
1	Front	Front	Back
2	Front	Front	Front & Back

These placements will be replicated for two drug classes (DC) that have multi-ingredient brands: analgesics and cough-cold products.

For each of these product classes, packaging will be created. The brand name section of the label will be "blanked" out on all of the packages. The packages will contain three

different product claims (PC) (i.e., for cough-cold product: "fast acting," "long lasting," and "strong medicine"; for the analgesic product: "doctor recommended," effective relief," and "powerful formula"). This will be crossed factorially with a variable number of active ingredients (NAI's). This variable will be composed of three levels, either 2 or 3 or 4 active ingredients (see Appendix A for back panel mock-ups with AI's listed) . The product claims are chosen to provide "selling points" that are conceptually unrelated to the symptom conditions treated by the AIs'. In summary, 36 stimuli will be created, factorially combining 3 PC's, 3 NAI's, 2 DC's, and 2 P's for the AIs'[1].

Design: Although many stimuli will be created, the number of stimuli presented to any research participant will be limited. In order to assure that there will be no confounding of PC and AI, we will use a Latin square design to select the stimulus set shown to respondents. This design will assure that the influence of PC's and NAI's is counterbalanced in the presentation to research participants (see Appendix A for a description the Latin square design for stimulus selection). Participants will view one stimulus set for each drug classes, with order of presentation randomized. Half the subjects will see stimuli using P1 and half P2 (see above table). PC and NAI will be within subject factors, and DC and P will be between subject factors.

The complexity of this design is predicated by the number of possible factors that may influence product selection decisions (e.g., PC's, NAI's). The important question for FDA is how the placement of the AI (on the front and/or back panel) influences appropriate product selection. Therefore, the primary analytical model will be a 2 (P) X 3 (stimulus set chosen from the latin square) X 3 (scenario read) ANOVA. All of these variables are between-subject, resulting in 18 cells for the analysis. Additional analyses, exploring the influence of the other factors manipulated in the study will be of secondary interest.

Procedure: Research participants will be brought into a room that contains a mocked-up display of the OTC pharmaceutical section of a pharmacy that has these two drug classes. For each drug class, there will be three packages displayed, with a the brand name blackened and a product claim prominently displayed in a "banner" diagonally placed on the PDP. For each of the drug classes, participants will be asked to pretend that they are interested in purchasing a single product and then answer questions about their selection. One of three specific scenarios will be presented at random to each participant. The scenario will provide participants with a set of

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[1] The following is a listing of the abbreviations used in this section:

AI = active ingredients
NAI = number of active ingredients
DC = drug class
PC = product claim
P = placement of AIs
PDP = principle display panel

symptoms to be treated by the selected medication. Each scenario is constructed so that only one of the products displayed treats the symptom constellation without superfluous ingredients.

Respondents will be asked to make a purchase decision, selecting one package among those presented. They will be permitted to inspect the drug cartons as displayed. The inspection practices will be recorded by the interviewer. This procedure will be repeated for each of the drug classes, counterbalancing the order of the classes assigned.

Measures: After completing the purchase simulation for both products, participants will be asked a series of questions about the purchase scenarios via a structured questionnaire (see Appendix B for a copy of the questionnaire). First, participants will be asked what factors influenced their decisions in an open-ended fashion. Any reference to the package design, ingredients, or pharmacological activity will be coded, as will mentions of the product claims.

Respondents will be asked to compare the three package designs within each drug class. Any references to the ease of reading, consumer friendliness, "neatness," or other evaluation of the package will be recorded. More specific codes will be established empirically. Respondents will also be asked to describe the "advantage or benefit" of each product as a means of assessing the degree to which the number or placement of AIs influence product perceptions.

Questionnaire scales will also measure: (1) the decision making process (systematic processes or heuristics) used to make the product selection, and (2) preferences in package design. Measures of consumer literacy and demographic questions will be included.

For each of the questions, research participants will be able to view the display with the drug products present.

Number of Research Participants: Approximately 216 participants in total will be used in this study. To assure that participants are appropriate candidates, they will be screened to assure that they are over 18 years of age and can read English.

Study D: Specificity and Framing of the Alcohol Warning

OTC analgesic products contain a warning for consumers informing them about concerns when consuming considerable amounts of alcoholic beverages. The current warning, which is required for Aleve (Naproxen Sodium), is: "Alcohol Warning: If you generally consume three or more alcohol-containing drinks per day, you should consult your physician for advice on when and how you should take Aleve and other pain relievers".

Analyses of consumer warnings suggests that a complete warning should contain four elements: a signal word or phrase (e.g., "alcohol warning"), a statement of dangerous behavior (e.g., generally consuming more than three alcohol-containing drinks), possible negative outcomes (e.g., what health problems could occur), and a way to remedy the concerns (e.g., consult the

physician). While the current warning has several of these elements, it does not contain all of these elements. The phrasing of information in these elements is also a concern.

The purpose of Study D is to investigate how various methods of phrasing information in the alcohol warning influences consumers' perception of the product's risk. To understand how variations in the warning message communicate this risk, a number of "risk communication factors" will be varied simultaneously. First, the specificity of the risk outcome may be varied. It is possible to describe this risk outcome in a general fashion (e.g., health problems) or to specify the nature of the specific risk outcome (e.g., increased risk of internal bleeding or increased risk of liver damage). Second, the description of the amount of alcohol consumed can be stated in terms of varying the number of alcohol-containing drinks per day (e.g, 2, 3 or 4 drinks per day). Third, the frequency with which such behavior is exhibited can be variously discussed (e.g., generally, usually, or frequently).

These descriptors of specificity, quantity and frequency provide consumers with various notions of the risk associated with consuming alcohol beverages and concomitant use of certain pain relievers. Studies of prescription drugs suggests that specific risk disclosures may be more vivid communicators of risk than general descriptors (Morris, Mazis and Brinberg, 1989). Although one would likely assume that quantity and frequency descriptors would directly influence risk perceptions, it is unclear how such perceptions would work. For example, would increasing the number of drinks per day (from 2 to 3 to 4) decrease risk perceptions (under the assumption that consumers would interpret the message to mean that the more drinks the higher the threshold for risk) or would the more drinks listed serve as a cue to the consumer of a greater amount of risk? Morris, Swasy and Mazis (1994) found that pregnant women believed that they could control the risks associated with alcoholic beverage consumption by moderating the quantity and/or frequency of alcoholic beverage consumption. Therefore, quantity-frequency descriptions may not be an important influence of the absolute level of risk presented by a product if consumers believe that they can control their drinking and thereby moderate their risk exposure.

Stimuli: Several different versions of the alcohol warning will be created (see Appendix C for a listing of the study variables). Specificity of risk outcome will be varied at 2 levels: general and specific. The language for the specific health problems will be "internal bleeding" (to represent NSAIDs) or "liver damage" (to represent acetaminophen). Also, variations will be constructed to communicate the quantity of alcohol consumed (3 levels: 2 vs 3 vs 4 drinks per day), and frequency of consuming alcoholic beverages (3 levels: generally vs usually vs frequently). In addition, two versions of these warnings will be created; one version with the signal words "Alcohol Warning" present and one version without signal words. Participants will be assigned at random so that half will see warning versions with, and half without, the signal words. If we find no differences between the signal words present/absent conditions, we will combine these for the full analysis. In all, 36 variations will be created (2 (levels of risk specificity) X 3 (quantity of alcohol consumed) X 3 (frequency of alcohol consumption) X 2 (presence or absence of signal words). Each participant will view only 18 of the variations; presence or absence of signal words will be a between-subject factor while all other factors are

within-subject.

A mock-up of a single analgesic label will be created. The mock-up will contain a fictitious brand name and fictitious active ingredient. The product will be identified as a "pain reliever" as its statement of pharmacological activity. In the warning section of the back panel there will be an identified alcohol warning section; however, the information in the section of the label containing the alcohol warning will be blanked out (e.g., all X's).

Dependent Measures: The dependent measure of interest is the research participants' perceptions of the risk of taking the product. Because there is no a priori standard or outcome that is preferable, this study will assess the degree to which various risk communication phrasing differentially communicates risk perceptions (see Appendix D for a copy of the questionnaire).

Slovic et al. (1987; 1989) conceive of risk perception in terms of a number of factors. For the purpose of this study, we will examine how risk communication phrasing influences consumers' perceptions of the:

1. General perception of product danger,
2. Probability of a negative outcome,
3. Severity of the negative outcome if it occurs, and
4. Controllability (preventability) of a negative outcome.

In addition, consumers will be asked to rate the clarity or understandability of the warning message.

Procedure: Eligible research participants who agree to participate will be shown the single mocked-up label and told that this is the general information about this new product. They will be told that the purpose of the study is to examine how different ways of warning consumers about drinking alcoholic beverages while taking this product influences their perceptions about the product's risks. They will be shown the alcohol warning section with the information blanked-out.

They will then be asked to quickly view different ways of phrasing the warning message. They will be shown 18 variations of the warning message. Following each warning message, research participants will be asked to rate the warning on the five scale items (four risk perception items and one understandability item). The scales will range from 0 to 10. Participants will be asked to circle the number that best represents their rating of the warning message on that outcome measure. The order of the 18 variations will randomized. For each participant, the order will be systematically varied based on this initial randomization

Following the rating of the individual warning variations, participants will be asked to complete a single questionnaire that measures literacy ability, general views about the risks of consuming alcoholic beverages, and demographic characteristics (including measures of how many alcoholic beverages they consume during an average week).

Number of Research Participants: Approximately 288 research participants will be recruited for the study. By virtue of random assignment, half the participants will see a label with the specific risk stating that there is an increased risk of internal bleeding and half will see a risk stating that there is an increased risk liver damage. A separate analysis of these two risks will be undertaken. If there is no significant differences and the observed differences are judged to be of no interpretative significance, then the data will be analyzed together. Otherwise, two separate analyses will be undertaken.

A2. Uses of the Information

The information from these two studies will be used to help FDA make decisions about the placement of the AIs and the wording for the OTC alcohol warning for analgesics. This research is directly applicable to concerns about the label wording and design of OTC products.

A3. Use of Automated Information Technology

Automated information technology is not relevant to the collection of information for these studies. These studies collect data through face-to-face personal interviews. It is necessary to expose participants to mock-ups of OTC labels on prototypical packages. In addition, the interviewer will need to record participant responses and provide appropriate probes when needed. Automated technology will be used in data reduction and analysis. Burden will be minimized by recording data on a one-time basis for each respondent, and keeping interviews to less than 30 minutes.

A4. Efforts to Avoid Duplication

No similar information collection is currently available. We have conducted in-depth literature reviews and we have found no research that has focused on the specific topics investigated by these studies. In the Federal Register of August 16, 1995, the agency issued a notice calling for data on the extent to which OTC labeling influenced consumer knowledge, judgment and behavior. FDA also sought such feedback through hearings conducted in conjunction with this Federal Register announcement. No similar information was found or obtained in any of these efforts.

A5. Impact (if any) on Small Business and Methods Used to Minimize Burden

This data collection effort does not involve small business or similar entities. A contract is already in place with Chilton Research Services to collect these data in mall intercept studies. FDA will conduct the analyses and write the descriptive report.

A6. Consequences if the Information was not Collected or Collected Less Frequently

If this information was not collected FDA would not have empirical information about the

placement of AIs and the effect of the various alcohol warnings. FDA's decisions about these issues influences the entire population of the United States, given that virtually all citizens use common OTC drugs at some time in their lives. It is important for FDA to invest in data collection at this time so that labeling decisions can be based, in part, upon empirical information.

A7. Special Circumstances

a) Requiring respondents to report information to the agency more than quarterly. This is a one-time-only collection.

b) Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it. This is not applicable to the proposed information collection. This effort requires respondents to examine a prototype leaflet(s) and answer a series of questions. Immediate reactions will be solicited. No written responses will be solicited.

c) Requiring respondents to submit more than an original and two copies of any document. Respondents will not be asked to submit any documents.

d) Requiring respondents to retain records for more than three years. Respondents will not be asked to retain any records.

e) Data will be collected from a geographically diverse set of shopping malls. The malls will be in locations that serve sociodemographic diverse populations. We believe that this diversity will generally represent the population of OTC users. However, because this is not a probability sample we cannot project results to the US population. Because these studies use experimental designs for the majority of the issues investigated, the results will concentrate on discussing conclusions regarding variations in OTC label design.

f) Requiring the use of a statistical data classification that has not been reviewed and approved by OMB. This study will not use data collection that has not been approved by OMB. Standard categories for data classification will be used for demographic data.

g) Including pledged of confidentiality or data security procedures that unnecessarily impede sharing of data with other agencies. FDA will receive data from the contractor in a format that does not individually identify respondents with any personal information. There will be no problems with confidentiality or data security when sharing data.

h) Requiring respondents to submit proprietary trade secrets. There are no requirements for respondents to submit trade secrets. The respondents will be consumers in shopping malls asked to volunteer for participation.

A8. Agency's Federal Register Notice and Consultations

Following the procedures for review, the Agency has sent a notice forward to be published in the Federal Register. The notice was published on May 23, 1997. It describes these studies and solicits public review and comment. At the same time the FDA has placed copies of this supporting statement and the draft questionnaires on its website to permit associations/individuals who had previously commented at FDA hearings or who have had a long-standing interest in this matter to solicit their review of the studies.

A9. Payments or Gifts to Respondents

We propose to pay respondents $5 for participation in this study. Consultation with the contractor indicates that this small incentive is necessary to conduct the study. Subcontractors have stated that they refuse to conduct the study unless participants are paid. Concerns about the generality of the study results suggests that an expected increase in participation rate in this study will also serve to make the study data more applicable to the general population.

A10. Confidentiality

No personally identifiable information will be sent to the agency. All information that can identify individual respondents will be kept by the contractor in a form that is separate from the data provided to FDA. This information will be kept by the contractor in a secured fashion that will not permit unauthorized personnel to examine any of the collected information.

A11. Sensitive Questions

There are no sensitive questions that raise privacy concerns (e.g., sexual behavior, religious beliefs).

A12. Hour Burden

Respondents will be asked to review OTC drug labels (Study C) or to examine several different mock-ups and respond to certain terminology (Study D) and answer brief questionnaires. We estimate that the entire burden respondent time will be approximately 30 minutes. This is a one-time data collection effort. The respondent burden chart is listed below:

Study	No. of Respondents	Ann. Freq per Response	Tot. Ann. Responses	Ann. Hrs. per Response	Total Hours
C	216	1	216	.5	108
D	288	1	288	.5	144

A13. Costs to Respondents

There are no costs to respondents associated with this data collection effort.

A14. Costs to Government

Total data collection costs by contractor for 504 study respondents	$

A15. Changes in Burden

This is not a repeat of a previous data collection effort. Therefore, there are no changes or adjustments reported in A13 or A14.

A16. Tabulation, Publication Plans, Project Time Schedule

a) Tabulation and analysis. Results of the studies will be tabulated and analyzed to examine the influence of format variations. Analyses of variance and covariance will be used as the primary analytical technique for both studies. Conjoint analyses will also be used for Study D. In a conjoint analysis design, research participants react to the simultaneous influence of multiple variations in stimuli. This permits analysis of the influence of these multiple variables on consumer decisions. In addition, data tabulation showing confidence intervals will be used to examine basic findings.

b) Publication. It is anticipated that the findings from these studies will be presented in FDA reports and in publications in scientific journals.

c) Schedule. Data collection will begin as soon as logistically possible after OMB approval is obtained. Data analysis will take approximately 2-3 months and reports will follow in 2-3 months following data analysis.

A17. Approval To Not Display OMB Expiration Date.

We are not seeking approval to not display the OMB expiration date . The OMB control number and information collection expiration date will be displayed on the questionnaires.

A18. Exemptions to Certification Statement

We are not seeking any exemptions to the certification statement listed in Item 19, “Certification for Paperwork Reduction Act Submissions,” on OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

B1. Respondent Universe and Sample Selection

All respondents will be over 18 years of age and be able to read English. The research will be undertaken by FDA through an existing contract by FDA's Center for Food Safety and Nutrition with Chilton Research Services.

There will be approximately 504 interviews conducted, using central-location-intercept methodology. This constitutes approximately 63 interviews at each of 8 geographically disperse shopping malls in the U.S.. There will be an equal number of males and females interviewed at each location . Malls will be selected to assure that the respondent universe represents varying degrees of education and other socioeconomic and ethnic variables.

B2. Procedures for Collection of Information

The research design has been outlined previously. This information collection does not employ probability sampling of respondents. Study C is an experimental study. Random assignment of respondents to groups will permit inferences to be made about the effects of format variations in this study. However, we will not conclude that the results can be projected to the US population. Study D collects respondents' reactions to label variations and to specific language that could be used to convey critical labeling information. Here too, we will not conclude that the results can be projected to the US population.

B3. Procedures to Maximize Response Rates

Respondents will be recruited by interviewers at 8 shopping malls. Participants will be told the research will help the Food and Drug Administration design product labels for OTC products. It is hoped that this information will be sufficient to convince participants to participate in the study. In addition, a small incentive ($5) will be offered.

B4. Tests of Procedures

We have conducted focus groups to help design the stimulus material and to aid in questionnaire development. No further pre-testing will be conducted.

B5. Contacts

The general study design for this and for previous studies and for these types of measures has been reviewed with several faculty members of the American University, Department of Marketing (e.g., Drs. Mazis, Swasy and Hastak). We are in contact with the Nonprescription Drug Manufacturers' Association and other trade and consumer organizations regarding comments on these studies. We have also reviewed the study design and stimuli with a graphic/marketing design company (Greenfield/Belser, Ltd.).

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Appendix A

Sample Back Panel for Cough/Cold Drug

Active Ingredients (In Each Softgel) — **Purposes**

Acetaminophen 250mg ..... Pain Reliever
Chlorpheniramine Maleate 10mg ..... Antihistamine
Dextromethorphan 35mg ..... Cough Suppressant
Pseudoephedrine Hydrochloride 40mg ..... Nasal Decongestant

Uses: for the temporary relief of these cold symptoms: ! sneezing ! runny nose ! cough ! nasal congestion

Warnings

Do Not Use

- 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

Ask a Doctor Before Use If You Have

- heart disease
- excessive phlegm (mucous)
- glaucoma
- high blood pressure
- thyroid disease
- diabetes
- a cough that lasts from smoking, asthma or emphysema
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- cough with fever, rash or headache that lasts

If You Are

- taking any drugs for asthma
- taking sedatives or tranquilizers

When Using This Product

- 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

Stop Using This Product If

- cough is accompanied by fever, rash or headache that lasts
- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days
- stomach pain occurs

Ask a doctor. These may be signs of a serious condition.

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.

Directions

Do not use more than directed.

Adults and children 12 years and over	Take 2 softgels every 4 hours. Do not take more than 4 doses in a 24-hour period.
Children 6 to 12 years	Take 1 softgel every 4 hours. Do not take more than 4 doses in a 24-hour period.
Children under 6 years	Should not use this product

Store at controlled room temperature, between 20^{0}C and 25^{0}C (68^{0}F and 77^{0}F).

Description of Stimulus Sets to be Presented

	Number of Active Ingredients: 2	Number of Active Ingredients: 3	Number of Active Ingredients: 4
Product Claim A	Stimulus Set: 1	Stimulus Set: 2	Stimulus Set: 3
Product Claim B	Stimulus Set: 3	Stimulus Set: 1	Stimulus Set: 2
Product Claim C	Stimulus Set: 2	Stimulus Set: 3	Stimulus Set: 1

Appendix B

Questionnaire for Study C

Please Print

RESPONDENT'S NAME: _____

STREET ADDRESS: _____

CITY: _____ STATE: _____

PHONE: AREA CODE: _____ NUMBER: _____

INTERVIEWER: _____ DATE: _____

RESPONDENT GENDER: MALE ..... 1 FEMALE 2

QUESTIONNAIRE:
PINK (COUGH/COLD First) 1
BLUE (PAIN RELIEVER First) 2

APPROACH MALES AND FEMALES WHO APPEAR TO BE 18 YEARS OR OLDER

Hello, my name is _____ of (MENTION YOUR SERVICE). We're conducting a study and I'd like to ask you a few questions.

A. Which one of these letter groups includes your age? [show card]

Under 18 ..... 1 (END)
18-24 ..... 2 (CONTINUE)
25-34 ..... 3 (CONTINUE)
35-44 ..... 4 (CONTINUE)
45-54 ..... 5 (CONTINUE)
55-64 ..... 6 (CONTINUE)
65+ ..... 7 (CONTINUE)

B1. Do you usually wear glasses, contacts, or use any other aid for reading?

Yes ..... 1 ASK B2
No ..... 2 SKIP TO C

B2. Do you have them with you?

Yes ..... 1 CONTINUE
No ..... 2 END

C. We would like to invite you back to our facility to complete a survey that will take approximately 30 minutes. In appreciation for your time, you will receive $5. Would you be willing to participate?

Yes ..... 1 CONTINUE
No ..... 2 END

- ESCORT RESPONDENT TO INTERVIEW AREA.
- REFER TO QUOTA CONTROL SHEET TO DETERMINE WHICH MAIN QUESTIONNAIRE COLOR TO USE.
- ATTACH MAIN QUESTIONNAIRE TO SCREENER AND CONTINUE.

****

MAIN QUESTIONNAIRE
PINK: COUGH/COLD First 1

RESPONDENT'S NAME: _____ CITY: _____

We are interested in learning how people use the information that appears on the label of over-the-counter medications to help them make purchase decisions. I will be showing you a display with packages from several different over-the-counter medicines. Note that we have covered-up the brand names on the products. I will then read a description of a medical problem that might be treated by these medications. For each description, I will ask you to select a product from the display to treat the problem.

After you have made your selection, I will ask you some questions about how you went about making your selection. Do you have any questions about this procedure? We will then repeat this procedure for another class of products. (IF RESPONDENT HAS QUESTIONS, REVIEW PROCEDURE)

STIMULUS DISPLAY SET (circle one): 1 2 3

STIMULUS DISPLAY ORDER: ____ ____ ____

(RECORD CODE NUMBERS IN ORDER DISPLAYED ON SHELF, FROM LEFT TO RIGHT)

SCENARIO READ (circle one): 1 2 3

[Show respondent display with three products]

Scenario 1: You are not feeling very well. Your symptoms include runny nose,

sneezing, watery eyes, and you have nasal congestion.

Scenario 2: You are not feeling very well. Your symptoms include runny nose, sneezing, coughing, and you have nasal congestion.

Scenario 3: You are not feeling very well. Your symptoms include runny nose, coughing, achiness, and you have nasal congestion.

You know that you do not have any medication at home. You stop at a store on the way home and see these medicines on display. Which one would you choose? Pretend you are at the store. You are free to examine these products just as if you were making a selection at a store. When you have made your decision, please hand it to the interviewer.

TIME SPENT EXAMINING LABELS: _____(MIN/SECONDS)

RECORD (check all that apply):

	Product 1	Product 2	Product 3
Respondent picks up package	_____	_____	_____
Respondent turns package to view back of label	_____	_____	_____
Respondent asks question about product	_____	_____	_____
Product Selected	_____	_____	_____

Now I'd like to ask you some questions about how you went about selecting the product.

1. First, tell me why is it that you choose that specific product? Anything else?

_____
_____
_____
_____

1b. What information, if anything, on the label influenced your choice? [probe] Anything else?

_____
_____
_____
_____

2a. I'm going to ask you about the three different product labels. For each of these products,

please tell me that product is different from the other products displayed.

Product 1_____

Product 2_____

Product 3_____

2b. For each of these products, please tell me the major advantage or benefit to the consumer in using this product:

Product 1_____

Product 2_____

Product 3_____

3. For each of the following statements, tell me which of the three products (Product 1, 2, or 3) is best described by the statement:

RECORD RESPONSE (1, 2, or 3) or 4= don't know, 5=all the same/no difference

_____ a. This label on this product is easiest to understand
_____ b. This label is best at telling me what the drug does and does not do
_____ c. This product is the strongest of the products displayed
_____ d. This product's effects last the longest of the products displayed
_____ e. This product works fastest of the products displayed
_____ f. This product is the safest of all the products displayed.
_____ g. This label gives me the information that I want to know.
_____ h. This label has information that I have trouble understanding
_____ I. This label does not tell me what I want to know about the product
_____ j. This product's effects last the shortest of the products displayed.
_____ k. This product is the weakest of the products listed
_____ l. This product takes the longest to work of the products displayed
_____ m. This is the most dangerous of the products displayed
_____ n. People would be most interested in reading the back label on this product.
_____ o. This label would be most useful helping someone to decide whether or not to take the drug
_____ p. I really like the format or layout of the front of the box
_____ q. It is easy to find information about this product on the back of the box
_____ r. The information on the front of the box is confusing.

.....

This completes the first part of the study. Now, I would like to repeat this exercise using

a different class of drugs:

STIMULUS DISPLAY SET (circle one): 1 2 3

STIMULUS DISPLAY ORDER: ____ ____ ____

(RECORD CODE NUMBERS IN ORDER DISPLAYED ON SHELF, FROM LEFT TO RIGHT)

SCENARIO READ (circle one): 1 2 3

[Show respondent display with three products]

Scenario 1: You get a phone call from a female family member. She says that her symptoms include headache, backache, and minor arthritis pain. She does not want to take any medicine that will make her drowsy.

Scenario 2: You get a phone call from a female family member. She says that her symptoms include headache, upset stomach, and minor arthritis pain. She does not want to take any medicine that will make her drowsy.

Scenario 3: You get a phone call from a female family member. She says that her symptoms include headache, upset stomach, and is retaining water and feels bloated. She does not want to take any medicine that will make her drowsy.

She says that there are no appropriate medicines at home. She asks you to stop at a store on the way home to buy medicine for her. You make a stop at a store and see these medicines on display. Which one would you choose? Pretend you are at the store. You are free to examine these products just as if you were making a selection at a store. When you have made your decision, please hand it to the interviewer.

TIME SPENT EXAMINING LABELS: _____(MIN/SECONDS)

RECORD (check all that apply):

	Product 1	Product 2	Product 3
Respondent picks up package	_____	_____	_____
Respondent turns package to view back of label	_____	_____	_____
Respondent asks question about product	_____	_____	_____

Product Selected _____ _____ _____

Now I'd like to ask you some questions about how you went about selecting the product.

4a. First, tell me why is it that you choose that specific product? Anything else?

_____
_____
_____
_____

4b. What information, if anything, on the label influenced your choice? [probe] Anything else?

_____
_____
_____
_____

5a. I'm going to ask you about the three different product labels. For each of these products, please tell me that product is different from the other products displayed.

Product 1_____

Product 2_____

Product 3_____

5b. For each of these products, please tell me the major advantage or benefit to the consumer in using this product:

Product 1_____

Product 2_____

Product 3_____

6. For each of the following statements, tell me which of the three products (Product 1, 2, or 3) is best described by the statement:

RECORD RESPONSE (1, 2, or 3) or 4= don't know, 5=all the same/no difference

_____ a. This label on this product is easiest to understand
_____ b. This label is best at telling me what the drug does and does not do
_____ c. This product is the strongest of the products displayed
_____ d. This product's effects last the longest of the products displayed

_____ e. This product works fastest of the products displayed
_____ f. This product is the safest of all the products displayed.
_____ g. This label gives me the information that I want to know.
_____ h. This label has information that I have trouble understanding
_____ I. This label does not tell me what I want to know about the product
_____ j. This product's effects last the shortest of the products displayed.
_____ k. This product is the weakest of the products listed
_____ l. This product takes the longest to work of the products displayed
_____ m. This is the most dangerous of the products displayed
_____ n. People would be most interested in reading the back label on this product.
_____ o. This label would be most useful helping someone to decide whether or not to take the drug
_____ p. I really like the format or layout of the front of the box
_____ q. It is easy to find information about this product on the back of the box
_____ r. The information on the front of the box is confusing.

7. REALM

[Give the respondent a laminated copy of the REALM and score answers on an unlaminated copy that is attached to a clipboard. Hold the clipboard at an angle so the respondent is not distracted by the scoring procedure]

Now I'm going to ask you to say some words out loud. These are words that sometimes appear on over-the-counter medications. I want to hear you read as many words as you can from these lists. Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word. [Emphasize that these words are hard for a lot of people and it's ok if they can't pronounce all of them.]

[If the respondent takes more than five seconds on a word, say "blank" and point to the next word, if necessary, to move the respondent along. If the respondent begins to miss every word, have him/her pronounce only known words. Count as an error any word not attempted or mispronounced. Score by marking a check (✓) after each correct word, a minus (-) after each mispronounced word, and a zero (0) after words not attempted. Count as correct any self-corrected word.]

fat _____	ingredient _____
flu _____	temporary _____
pill _____	exceed _____
dose _____	inhale _____
eye _____	nausea _____
stress _____	excessive _____
smear _____	pharmacist _____
notify _____	relief _____
gallbladder_____	heartburn _____
calories _____	effectiveness _____
depression_____	drowsiness _____
miscarriage_____	prolonged _____
pregnancy_____	inhibit _____
arthritis _____	placebo _____
hepatitis _____	liquid _____
antibiotics_____	muscle _____
diagnosis _____	symptom _____
potassium _____	thalidomide _____
anemia _____	congestion _____
obesity _____	chronic _____
osteoporosis_____	sinusitis _____

DEMOGRAPHIC INFORMATION

Now I have just a few questions for classification purposes.

8. What is your marital status? Is it:
   a. Married
   b. Single
   c. Widowed
   d. Divorced
   e. Separated

9. Which one of these letter groups shows the last grade of school that you completed? [show card]
   a. Grade school or less
   b. Some high school
   c. Completed high school
   d. Some college
   e. Completed college
   f. Graduate school or more
   g. Other education beyond high school (business, technical, etc.)

10. Which one of these letter groups represents your profession? [show card] ____record letter

11. In general, would you say your health is:
   a. Excellent
   b. Very good
   c. Good
   d. Fair
   e. Poor

12. How often have you used an over-the-counter <u>cough/cold drug</u> in the past six months? Would you say:
   a. Zero times
   b. One or two times
   c. Three or four times
   d. Five or six times
   e. Seven or more times

13. How often have you used an over-the-counter <u>pain reliever drug</u> in the past six months? Would you say:
   a. Zero times
   b. One or two times
   c. Three or four times
   d. Five or six times
   e. Seven or more times

14. Are you being treated for any of the following medical conditions? List all that apply [show card]

a. Heart disease
b. High blood pressure
c. Asthma
d. Depression
e. High cholesterol
f. Stomach ulcers
g. Emphysema

15. Which one of these letter groups includes your total annual family income? [show card]

a. Under $25,000
b. $25,000 - $29,999
c. $30,000 - $34,999
d. $35,000 - $39,999
e. $40,000 - $49,999
f. $50,000 - $59,999
g. $60,000 - $74,999
h. $75,000 and over

16. Which one of these letter groups represents your ethnic group? [show card]

a. Black/Non-Hispanic
b. Hispanic
c. Asian/Pacific Islander
d. White/Non-Hispanic
e. Indian or Alaskan Native
f. Other

Thank respondent for participating.

MAIN QUESTIONNAIRE
BLUE: PAIN RELIEVER First.....2

RESPONDENT'S NAME: _____ CITY: _____

We are interested in learning how people use the information that appears on the label of over-the-counter medications to help them make purchase decisions. I will be showing you a display with packages from several different over-the-counter medicines. Note that we have covered-up the brand names on the products. I will then read a description of a medical problem that might be treated by these medications. For each description, I will ask you to select a product from the display to treat the problem.

After you have made your selection, I will ask you some questions about how you went about making your selection. Do you have any questions about this procedure? We will then repeat this procedure for another class of products. (IF RESPONDENT HAS QUESTIONS, REVIEW PROCEDURE)

STIMULUS DISPLAY SET (circle one): 1 2 3

STIMULUS DISPLAY ORDER: ____ ____ ____

(RECORD CODE NUMBERS IN ORDER DISPLAYED ON SHELF, FROM LEFT TO RIGHT)

SCENARIO READ (circle one): 1 2 3

[Show respondent display with three products]

Scenario 1: You get a phone call from a female family member. She says that her symptoms include headache, backache, and minor arthritis pain. She does not want to take any medicine that will make her drowsy.

Scenario 2: You get a phone call from a female family member. She says that her symptoms include headache, upset stomach, and minor arthritis pain. She does not want to take any medicine that will make her drowsy.

Scenario 3: You get a phone call from a female family member. She says that her symptoms include headache, upset stomach, and is retaining water and feels bloated. She does not want to take any medicine that will make her drowsy.

She says that there are no appropriate medicines at home. She asks you to stop at a store on the way home to buy medicine for her. You make a stop at a store and see these medicines on display. Which one would you choose? Pretend you are at the store. You are free to examine

these products just as if you were making a selection at a store. When you have made your decision, please hand it to the interviewer.

TIME SPENT EXAMINING LABELS: _____(MIN/SECONDS)

RECORD (check all that apply):

	Product 1	Product 2	Product 3
Respondent picks up package	_____	_____	_____
Respondent turns package to view back of label	_____	_____	_____
Respondent asks question about product	_____	_____	_____
Product Selected	_____	_____	_____

Now I'd like to ask you some questions about how you went about selecting the product.

1. First, tell me why is it that you choose that specific product? Anything else?

_____
_____
_____
_____

1b. What information, if anything, on the label influenced your choice? [probe] Anything else?

_____
_____
_____
_____

2a. I'm going to ask you about the three different product labels. For each of these products, please tell me that product is different from the other products displayed.

Product 1_____

Product 2_____

Product 3_____

2b. For each of these products, please tell me the major advantage or benefit to the consumer in using this product:

Product 1_____

Product 2_____

Product 3_____

3. For each of the following statements, tell me which of the three products (Product 1, 2, or 3) is best described by the statement:

RECORD RESPONSE (1, 2, or 3) or 4= don't know, 5=all the same/no difference

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_____ c. This product is the strongest of the products displayed
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_____ g. This label gives me the information that I want to know.
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_____ p. I really like the format or layout of the front of the box
_____ q. It is easy to find information about this product on the back of the box
_____ r. The information on the front of the box is confusing.

.....

This completes the first part of the study. Now, I would like to repeat this exercise using a different class of drugs:

STIMULUS DISPLAY SET (circle one): 1 2 3

STIMULUS DISPLAY ORDER: ____ ____ ____

(RECORD CODE NUMBERS IN ORDER DISPLAYED ON SHELF, FROM LEFT TO RIGHT)

SCENARIO READ (circle one): 1 2 3

[Show respondent display with three products]

Scenario 1: You are not feeling very well. Your symptoms include runny nose, sneezing, watery eyes, and you have nasal congestion.

Scenario 2: You are not feeling very well. Your symptoms include runny nose, sneezing, coughing, and you have nasal congestion.

Scenario 3: You are not feeling very well. Your symptoms include runny nose, coughing, achiness, and you have nasal congestion.

You know that you do not have any medication at home. You stop at a store on the way home and see these medicines on display. Which one would you choose? Pretend you are at the store. You are free to examine these products just as if you were making a selection at a store. When you have made your decision, please hand it to the interviewer.

TIME SPENT EXAMINING LABELS: _____(MIN/SECONDS)

RECORD (check all that apply):

	Product 1	Product 2	Product 3
Respondent picks up package	_____	_____	_____
Respondent turns package to view back of label	_____	_____	_____
Respondent asks question about product	_____	_____	_____
Product Selected	_____	_____	_____

Now I'd like to ask you some questions about how you went about selecting the product.

4a. First, tell me why is it that you choose that specific product? Anything else?

_____
_____
_____
_____

4b. What information, if anything, on the label influenced your choice? [probe] Anything else?

_____
_____
_____
_____

5a. I'm going to ask you about the three different product labels. For each of these products, please tell me that product is different from the other products displayed.

Product 1_____

Product 2_____

Product 3_____

5b. For each of these products, please tell me the major advantage or benefit to the consumer in using this product:

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Product 2_____

Product 3_____

6. For each of the following statements, tell me which of the three products (Product 1, 2, or 3) is best described by the statement:

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_____ m. This is the most dangerous of the products displayed
_____ n. People would be most interested in reading the back label on this product.
_____ o. This label would be most useful helping someone to decide whether or not to take the drug
_____ p. I really like the format or layout of the front of the box
_____ q. It is easy to find information about this product on the back of the box
_____ r. The information on the front of the box is confusing.

7. REALM

[Give the respondent a laminated copy of the REALM and score answers on an unlaminated copy that is attached to a clipboard. Hold the clipboard at an angle so the respondent is not distracted by the scoring procedure]

Now I'm going to ask you to say some words out loud. These are words that sometimes appear on over-the-counter medications. I want to hear you read as many words as you can from these lists. Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word. [Emphasize that these words are hard for a lot of people and it's ok if they can't pronounce all of them.]

[If the respondent takes more than five seconds on a word, say "blank" and point to the next word, if necessary, to move the respondent along. If the respondent begins to miss every word, have him/her pronounce only known words. Count as an error any word not attempted or mispronounced. Score by marking a check (✓) after each correct word, a minus (-) after each mispronounced word, and a zero (0) after words not attempted. Count as correct any self-corrected word.]

fat _____	ingredient _____
flu _____	temporary _____
pill _____	exceed _____
dose _____	inhale _____
eye _____	nausea _____
stress _____	excessive _____
smear _____	pharmacist _____
notify _____	relief _____
gallbladder_____	heartburn _____
calories _____	effectiveness _____
depression_____	drowsiness _____
miscarriage_____	prolonged _____
pregnancy_____	inhibit _____
arthritis _____	placebo _____
hepatitis _____	liquid _____
antibiotics_____	muscle _____
diagnosis _____	symptom _____
potassium _____	thalidomide _____
anemia _____	congestion _____
obesity _____	chronic _____
osteoporosis_____	sinusitis _____

DEMOGRAPHIC INFORMATION

Now I have just a few questions for classification purposes.

8. What is your marital status? Is it:
   a. Married
   b. Single
   c. Widowed
   d. Divorced
   e. Separated

9. Which one of these letter groups shows the last grade of school that you completed? [show card]
   a. Grade school or less
   b. Some high school
   c. Completed high school
   d. Some college
   e. Completed college
   f. Graduate school or more
   g. Other education beyond high school (business, technical, etc.)

10. Which one of these letter groups represents your profession? [show card] ____record letter

11. In general, would you say your health is:
   a. Excellent
   b. Very good
   c. Good
   d. Fair
   e. Poor

12. How often have you used an over-the-counter <u>cough/cold drug</u> in the past six months? Would you say:
   a. Zero times
   b. One or two times
   c. Three or four times
   d. Five or six times
   e. Seven or more times

13. How often have you used an over-the-counter <u>pain reliever drug</u> in the past six months? Would you say:
   a. Zero times
   b. One or two times
   c. Three or four times
   d. Five or six times
   e. Seven or more times

14. Are you being treated for any of the following medical conditions? List all that apply [show card]

a. Heart disease
b. High blood pressure
c. Asthma
d. Depression
e. High cholesterol
f. Stomach ulcers
g. Emphysema

15. Which one of these letter groups includes your total annual family income? [show card]

a. Under $25,000
b. $25,000 - $29,999
c. $30,000 - $34,999
d. $35,000 - $39,999
e. $40,000 - $49,999
f. $50,000 - $59,999
g. $60,000 - $74,999
h. $75,000 and over

16. Which one of these letter groups represents your ethnic group? [show card]

a. Black/Non-Hispanic
b. Hispanic
c. Asian/Pacific Islander
d. White/Non-Hispanic
e. Indian or Alaskan Native
f. Other

Thank respondent for participating.

Appendix C

Description of Study D Variables

		QUANTITY OF ALCOHOL CONSUMED								
		2 Drinks per Day			3 Drinks per Day			4 Drinks per Day		
		RATE OF CONSUMPTION								
		Generally	**Usually**	**Frequently**	**Generally**	**Usually**	**Frequently**	**Generally**	**Usually**	**Frequently**
SIGNAL WORD	**"Alcohol Warning"**	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk
		Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk
	None	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk	General Risk
		Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk	Specific Risk

Appendix D

Questionnaire for Study D

Please Print

RESPONDENT'S NAME: _____

STREET ADDRESS: _____

CITY: _____ STATE: _____

PHONE: AREA CODE: _____ NUMBER: _____

INTERVIEWER: _____ DATE: _____

RESPONDENT GENDER: MALE ..... 1 FEMALE 2

APPROACH MALES AND FEMALES WHO APPEAR TO BE 18 YEARS OR OLDER

Hello, my name is _____ of (MENTION YOUR SERVICE). We're conducting a study and I'd like to ask you a few questions.

A. Which one of these letter groups includes your age? [show card]

Under 18 ..... 1 (END)
18-24 ..... 2 (CONTINUE)
25-34 ..... 3 (CONTINUE)
35-44 ..... 4 (CONTINUE)
45-54 ..... 5 (CONTINUE)
55-64 ..... 6 (CONTINUE)
65+ ..... 7 (CONTINUE)

B1. Do you usually wear glasses, contacts, or use any other aid for reading?

Yes ..... 1 ASK B2
No ..... 2 SKIP TO C

B2. Do you have them with you?

Yes ..... 1 CONTINUE
No ..... 2 END

C. We would like to invite you back to our facility to complete a survey that will take approximately 30 minutes. In appreciation for your time, you will receive $5. Would you be willing to participate?

Yes ..... 1 CONTINUE
No ..... 2 END

- ESCORT RESPONDENT TO INTERVIEW AREA.
- ATTACH MAIN QUESTIONNAIRE TO SCREENER AND CONTINUE.

****

RESPONDENT'S NAME: _____ CITY: _____

We are interested in learning how to best communicate warning information about certain over-the-counter medicines. I will be showing you some information that could appear on the package of these medicines and ask you to rate the information.

Do you have any questions about this procedure? (IF RESPONDENT HAS QUESTIONS, REVIEW PROCEDURE)

Proceed: [Show respondent sample label]

This represents the back panel of an over-the-counter pain reliever. Notice that there is one section of this label with the information is "Xed" out. This section is intended to communicate the risk of using alcoholic beverages when using this product.

There are various ways of phrasing this information. I am going to show you a series of cards where this information is stated in different ways. After reading each of these statements, please rate the statement on each of these five scales (show card with scales). Just say the number that best represents your view of how that statement should be rated on each scale. Remember, your best guess is fine and that there are no right or wrong answers. We are just interested in your views. Any questions?

Show respondent first statement

Record:

1. Statement Code Letter : _____

Ask:

2. How likely is it that people's health would be damaged by this product?

0	1	2	3	4	5	6	7	8	9	10
Not at All Likely										Extremely Likely

3. If people have a negative outcome from using this drug, how serious would it be?

0	1	2	3	4	5	6	7	8	9	10
Not at All Serious										Extremely Serious

4. To what extent can people control or prevent the hazards from using this drug?

0	1	2	3	4	5	6	7	8	9	10
Not at All Controllable										Extremely Controllable

5. How difficult to understand is the information presented in this message?

0	1	2	3	4	5	6	7	8	9	10
Not at All Difficult										Extremely Difficult

[REPEAT FOR ALL 18 STIMULI]

This ends this task, now I'd like to ask a few more questions.

6. REALM

[Give the respondent a laminated copy of the REALM and score answers on an unlaminated copy that is attached to a clipboard. Hold the clipboard at an angle so the respondent is not distracted by the scoring procedure]

Now I'm going to ask you to say some words out loud. These are words that sometimes appear on over-the-counter medications. I want to hear you read as many words as you can from these lists. Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word.

[If the respondent takes more than five seconds on a word, say "blank" and point to the next word, if necessary, to move the respondent along. If the respondent begins to miss every word, have him/her pronounce only known words. Count as an error any word not attempted or mispronounced. Score by marking a check (T) after each correct word, a minus (-) after each mispronounced word, and a zero (0) after words not attempted. Count as correct any self-corrected word.]

fat _____	ingredient _____
flu _____	temporary _____
pill _____	exceed _____
dose _____	inhale _____
eye _____	nausea _____
stress _____	excessive _____
smear _____	pharmacist _____
notify _____	relief _____
gallbladder_____	heartburn _____
calories _____	effectiveness _____
depression_____	drowsiness _____
miscarriage_____	prolonged _____
pregnancy_____	inhibit _____
arthritis _____	placebo _____
hepatitis _____	liquid _____
antibiotics_____	muscle _____
diagnosis _____	symptom _____
potassium _____	thalidomide _____
anemia _____	congestion _____
obesity _____	chronic _____
osteoporosis_____	sinusitis _____

DEMOGRAPHIC INFORMATION

Now I have just a few questions for classification purposes.

8. What is your marital status? Is it:
   a. Married
   b. Single
   c. Widowed
   d. Divorced
   e. Separated

9. Which one of these letter groups shows the last grade of school that you completed? [show card]
   a. Grade school or less
   b. Some high school
   c. Completed high school
   d. Some college
   e. Completed college
   f. Graduate school or more
   g. Other education beyond high school (business, technical, etc.)

10. Which one of these letter groups represents your profession? [show card] _____ record

11. In general, would you say your health is:
   a. Excellent
   b. Very good
   c. Good
   d. Fair
   e. Poor

12. How often have you purchased an over-the-counter <u>pain reliever drug</u> in the past six months? Would you say:
   a. Zero times
   b. One or two times
   c. Three or four times
   d. Five or six times
   e. Seven or more times

13. Are you being treated for any of the following medical conditions? List all that apply. [show card]
   a. Heart disease
   b. High blood pressure
   c. Asthma
   d. Depression
   e. High cholesterol

f. Stomach ulcers
g. Emphysema

14. In general, how often would you say that you consume any alcoholic beverages, such as beer wine or liquor. Would you say you consume alcoholic beverages: (check one)

a. Every day _____
b. At least once a week _____
c. At least once a month _____
d. At least once every 2 months _____
e. Less than every 2 months _____
f. Don't Know/Can't Remember _____

15. In general, when you drink alcoholic beverages, about how many drinks do you consume. Think of a drink as a bottle or can of beer, a glass of wine or a shot of liquor. (check one)

a. About one drink _____
b. About two drinks _____
c. About three drinks _____
d About four drinks _____
e. More than four drinks _____
f. Don't Know/Can't Remember _____

16. Which one of these letter groups includes your total annual family income? [show card]

a. Under $25,000
b. $25,000 - $29,999
c. $30,000 - $34,999
d. $35,000 - $39,999
e. $40,000 - $49,999
f. $50,000 - $59,999
g. $60,000 - $74,999
h. $75,000 and over

17. Which one of these letter groups represents your ethnic group? [show card]

a. Black/Non-Hispanic
b. Hispanic
c. Asian/Pacific Islander
d. White/Non-Hispanic
e. Indian or Alaskan Native
f. Other

Thank respondent for participating.