Supporting Statement
Docket No. 2005N-0016

Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Study 1
OMB Control Number 0910-0591
Docket Number 2005N-0016
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A. Justification

A1. Necessity for the Information Collection

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug is misbranded if it's labeling or advertising is false or misleading. In addition, Section 502(n) of the Act specifies that advertisements for prescription drugs and biological products must provide a true statement of information "in brief summary" about the advertised product's "side effects, contraindications and effectiveness." Generally, the display text of an advertisement discloses the product's indication and benefits and major risks (fair that the information about risks must include *each specific side effect and contraindication* from the advertised drug's approved labeling. The regulation also specifies that the phrase *side effect and contraindication* refers to all of the categories of risk information required in the approved product labeling written for health professionals, including the Warnings, Precautions, and Adverse Reactions sections. Thus, every risk in an advertised drug's approved labeling must be addressed to meet these regulations and this is usually accomplished with an accompanying page of information, commonly referred to as the "brief summary." The Food and Drug Administration (FDA) is responsible for enforcing the Act and implementing regulations.

In recent years, FDA has become concerned about the adequacy of the brief summary in consumer-directed print advertisements. Because the regulations do not specify how to address each risk, sponsors can use discretion in fulfilling the brief summary requirement under 202.1(e)(3)(iii). Frequently, sponsors print their adjacent page of information in small type, repeating verbatim the risk-related sections of the approved product labeling (also called the package insert, professional labeling, prescribing information, and direction circular). This labeling is written for health professionals, using medical terminology. Consequently, the brief summary often consists of medical jargon and technical language presented in small font with little white space. Although FDA believes that this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, FDA recognizes that it is not the ideal way to communicate risk information to consumers. Research has shown that many consumers attempt to read the brief summary in prescription drug print advertisements if they are especially interested in the drug, but as a general rule they typically read little or none of the brief summary information (Aikin, Swasy and Braman, 2004). 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, which includes prime users of prescription and OTC products, increases in size yearly. However, because of decreasing vision, this group may have greater difficulty reading the label on certain consumer products, including the small font words in the brief summary.

In February, 2004, FDA issued a draft guidance encouraging the use of consumer-friendly language in the brief summary in print DTC prescription drug advertisements (see Appendix A for a copy of the draft guidance). The goal of the guidance was to improve the communication of important risk information to consumers by making the information easier to understand. The agency provided a number of format and content suggestions for revising the brief summary, including use of the risk-related sections of the approved patient labeling, use of the highlights section from professional labeling, and use of a consumer-friendly version of the highlights section from professional labeling. The agency also requested research and comment on these and other possible variations.

Research on reading behavior and document simplification suggests that the use of less complex terminology, presented in shorter sentences, with a more organized or *chunked* structure should improve consumer processing for at least three reasons. First, it should decrease the *cognitive load* produced by the current physician-directed format. Cognitive load is an index of the memory demands necessary to process information. When the cognitive load is higher, a greater amount of mental resources must be devoted to solve the problem. Therefore, a brief summary format with a lower cognitive load should be more fully processed than one with a higher load (Chandler & Sweller, 1991). Second, a brief summary format that is more structured and organized should provide readers with less imposing processing demands, increasing consumers' willingness and self-perceived ability to read and understand the presented material. Research suggests that consumers are more likely to engage in behavior that they believe they can successfully complete (Bandura, 1986; Wood & Bandura, 1989). Third, a brief summary that provides readers with clear signals regarding the most important information should help readers prioritize the importance of the presented information, increasing the probability that the set of information identified as important is subjected to more complete mental processing, and thereby improving the communication of that information (Lorch, et al., 1993, 1995, 1996).

A2. Uses of the Information

The information from this study will be used to help FDA make decisions about possible alternative consumer-friendly formats for prescription drug brief summaries. The research can also support industry construction of and FDA review decisions about DTC prescription drug advertising.

A3. Use of Automated Information Technology

Automated information technology will be used in the collection of information for this study. The contracted research firm will collect data through face-to-face personal

interviews involving computer administration in some portions. The interviewer will use the computer to record participant responses and provide appropriate probes when needed. In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each respondent, and by keeping interviews to less than 30 minutes.

A4. Efforts to Avoid Duplication

FDA is aware of two industry-sponsored studies on the topic of the brief summary. We have reviewed the design and results of these studies and adapted our methodology appropriately so as to avoid duplication. In addition, we solicited comment on our proposed design and questionnaire from the authors of these two studies.

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 through the Center for Food Safety and Nutrition (CFSAN) is already in place with Synovate, Inc. 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 usefulness of consumer-friendly brief summary formats, or the impact of consumer-friendly brief summary formats on comprehension and understanding of important prescription drug risk information. It is important for FDA to invest in data collection at this time so that regulatory activities 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. The proposed study requires respondents to examine a prototype print DTC prescription drug advertisement 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) *Conducting a survey that is not designed to be generalizable to the universe of study*.

Data will be collected from a geographically diverse set of shopping malls. The malls will be in locations that serve diverse social and demographic populations. We believe that this diversity will generally represent the population of the United States. Because this is not a probability sample, however, we cannot project results to the US population. This study uses experimental designs for the majority of the issues investigated, and therefore the results will focus on variations in consumer-friendly brief summary formats.

f) *Requiring the use of a statistical data classification that has not been reviewed and approved by OMB.* This study will only use data collection methods that have been approved by OMB. OMB-approved data classification categories will be used to obtain demographic data.

g) *Including pledge 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 identifiers. 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 individuals who are approached in shopping malls around the country who are asked to volunteer to participate.

A8. Agency's Federal Register Notice and Consultations

FDA submitted a design of the currently proposed study, the first of three, to the Federal Register in February 2005. The 60-day public comment period closed April 11, 2005. We received two comments, both from industry members. The following summary describes the suggestions and comments of these parties and our reaction to these comments. Additionally, the Appendix contains our responses to specific comments regarding specific questionnaire items.

Both comments included statements of support for the research itself. Specifically, one commenter described the proposed study as "a necessary first step" and agreed that it would be shortsighted to examine issues of content and format (our to-be-proposed second and third studies) without first investigating the uses of the brief summary. The other commenter stated that it supports "FDA's action to conduct research to determine how to optimize the content and format of risk information in print advertisements." Moreover, this commenter strongly encouraged FDA to ensure that all three of the proposed studies be conducted to ensure benefit in assessing regulatory practices.

FDA also sent copies of this supporting statement and the draft questionnaires to several associations and 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.

Comments to be Adopted

We appreciate the comments of the two parties who spent time and energy thinking about our study and agree that several suggestions will improve the research. We will adopt these comments with little modification.

In the original proposal, our stimulus ad displayed a prescription drug that was available in a new patch form. We proposed this administration mechanism because we required a legitimate advertising draw that was not safety or efficacy based and thought a new administration form would solve these issues. Commenter B expressed concern that because the patch is a less common mode of administration than the typical pill, such a novel product might alter individuals' normal information search behavior and skew our results. The commenter suggested that we present a drug with the standard administration form, a pill. With consideration, we have decided to drop the patch delivery mechanism and instead feature a "once-weekly" dosing regimen as a differentiation point in the advertisement. We feel this dosing claim will be realistic, interesting, not confounded with safety or efficacy, and should avoid potential problems related to less common administration mechanisms.

In our notice, we had proposed examining education level by blocking respondents by those who have attended some college or less and those who have attended some college or more. Commenter A suggested that we segment education level further than proposed, and that we specifically add more "high school or less" individuals. We agree that education is an important variable that may influence key responses, and will measure finer segments of education. Additionally, we will ensure that a minimum of 30% of our sample has a high school degree or lower.

Commenter A also noted that we should ensure a mix of currently treating respondents and not yet treating respondents within the diagnosed population to reflect reality. Although we do not have the resources to screen and solicit subjects and control on this variable, we plan to inquire as to participants' prescription and non-prescription drug usage and aim for a blend of treaters and not-yet-treating individuals.

We concur with the reviewers' concern that participants be recruited in a manner that does not bias their responses. We plan to use blinded recruitment so that respondents do not know exactly why they were chosen for the study, the nature of the interview, or the purpose of the research, as suggested by Commenter A.

Commenter B suggested that the main body of our stimulus ad fulfill all of the regulatory requirements for a truthful, fair and balanced ad. The final stimulus ad has been evaluated by reviewers in the Division of Drug Marketing, Advertising and Communications for compliance with all applicable regulations.

Comments to be Adopted with Modifications

The proposed mock brief summary contained a wide variety of topics culled from a review of existing brief summaries and from the input of focus groups. Commenter B suggested that we remove all sections in our mock brief summary not currently required

by regulation. We considered this suggestion and agree that some sections may be removed at this stage in the research. For example, a section on "Lab Test Abnormalities" may not be useful to consumers during initial exposure to a brand in a magazine read-through, as simulated in our study.

The main purpose of our first study, however, is to determine how people use the brief summary and *what sections people find more or less useful*. In order to fully assess this question, we feel that we must include sections that are not currently required. It may be reasonable to assume that people use the brief summary to decide whether to talk to their doctors about the advertised drug, however, people may also use the brief summary to verify claims on the main page, to compare the advertised drug to another, or to keep on hand as a reference. Until we know how people use the brief summary, we cannot assume that certain sections are irrelevant. Moreover, we cannot assume that the sections currently required by regulation are the only valuable sections without testing this assumption. Those sections currently required by law (e.g., warnings, precautions, contraindications, adverse events) are also those that consumers are likely to find most useful and will always be placed in the first column in our mock brief summaries. Nevertheless, we find it impossible to fully address our research question without including other sections.

In balancing the tradeoff between the realism of the magazine-reading situation and the need for experimenter control, our original proposal had left the issue of mode of presentation open. Both commenters suggested that it would be valuable to measure the amount of time each participant spends reading the main page and the brief summary page of the display ads. After much discussion we have decided to initially present the stimulus ad on a computer screen. Participants will be presented with a page or two of instructions and their reading speed will be tracked when they click the option to move to the next page. Then they will be presented with the test ad as well as two other filler ads, at least one of which will have two pages, a "front" and a "back." These ads will enable us to determine basic reading speeds as well as comparative speeds between the main page and brief summary page and between the test ad and other ads. Given the importance of the reading time variable, we have chosen to exercise more experimental control to assess reading times and page-switching (via computer-based recording of times and switching) rather than present the test ad in a magazine mock-up which would not permit a reliable assessment of these reading behaviors.

Another comment discussed sample size issues, limited resources, and tradeoffs. Commenter A suggested that we have a minimum of 75 respondents per cell rather than 30 per cell. Commenter B described a plan that would have doubled our sample size from approximately 400 to approximately 800, but expressed understanding that resource limitations may prohibit this approach. Therefore, this commenter suggested reducing the number of medical conditions studied from four to two, maintaining asthma and high cholesterol. Additionally, the commenter suggested that disease severity *within* condition may be an important variable that affects consumer use of the brief summary.

Our modifications have taken these related comments into account. Our original plan

was a 4 x 2 design, with four medical conditions (asthma, high cholesterol, allergies, and obesity) and two levels of drug risk severity (high and low) included. We proposed this design for several reasons. First, to ensure generalizability, we suggested four medical conditions that would vary in symptom presentation, severity, and chronicity. Second, we manipulated drug risk severity to address the idea that information search on the brief summary page might differ given the risk information included on the main page.

On the basis of all comments, we have revised this design. We now propose a 3 x 2 design, with three medical conditions (asthma, high cholesterol, and obesity) and two levels of disease severity (high and low). Dropping the allergy category, which already includes a number of OTC options, still leaves us with a range of conditions. We will maintain the obesity category due to its public health implications and current public interest. We were persuaded by the argument that severity within disease may be an important driver of information search and will include this variable as a covariate.

Comments Considered and Not Adopted

Commenter A suggested that we conduct qualitative research before embarking on a quantitative project. Specifically, she suggested that qualitative one-on-one interviews may better address the questions we plan to ask. We have already conducted focus groups that have guided the development of the questions we plan to ask in the proposed study and the two to follow it. These groups also provided initial ideas about how people use the brief summary and what they prefer in terms of content and format.

Commenter A also requested that we ask more qualitative questions at the beginning of the study before delving into quantitative questions. We are limited, however, to approximately 20 minutes with each respondent, and can therefore ask only a limited number of questions. Recognizing this restriction, we have included as many open-ended questions as we can, but at this time we feel we cannot add substantially more questions to the interview.

Commenter A also suggested that we use an existing, known prescription product in our stimulus materials instead of a new-to-market, novel one. Given the research goal, we feel it is essential to control for likely confounds that might arise from prior experience with existing, known product. Therefore, we will continue to use a new-to-market drug as a stimulus.

Commenter B recommended that we avoid randomly selecting people face-to-face inside a mall, but instead use a random-digit dialing procedure to recruit participants. In discussions with the contractor, we had discussed using a prescreened panel. However, given resource constraints, the contractor felt that recruitment would be more effective if the traditional mall-intercept procedure was employed. As noted earlier, prior to the study these respondents will not be sensitized to the specific task or the purpose of the research; participants will be informed of these issues at the end of the study.

We will not be using a mock-up of a magazine, as suggested by Commenter B, for

reasons discussed earlier. Our main interest is in participants' viewing of the brief summary when they have viewed it rather than whether it is compelling enough to stop to look at. We instead plan to use computer technology to measure the amount of time spent reading the main page and the brief summary page. Based in part on Commenter B's suggestions, we will include at least two other advertisements to obtain comparative reading times, and to diffuse the pressure on the reading of the stimulus ad.

For a detailed analysis of questionnaire comments and responses, please see Appendix C.

A9. Payments or Gifts to Respondents

We are proposing to offer respondents $5 for their participation.

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. All 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

FDA estimates that 800 individuals will need to be screened to obtain a respondent sample of 400. The screeners are expected to take 2 minutes, for a total screener burden of 24 hours. The 400 respondents will then be asked to respond to a series of questions about the brief summary. We estimate the response burden for the consumer part of the survey to be 20 minutes, for a burden of 132 hours. The estimated total burden for this data collection effort is 156 hours. This is a one-time data collection effort. The respondent burden chart is listed below:

Estimated Annual Reporting Burden				
No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800 (screener)	1	800	.03	24
400 (questionnaire)	1	400	.33	132
Total		1,200	.36	156

There are no capital costs or operating and maintenance costs associated with this collection.

A13. Costs to Respondents

There are no costs to respondents associated with this data collection effort outside of the burden reflected in A12.

A14. Costs to Government

These surveys will be conducted under an existing contract. Total data collection costs by contractor will be $84,000.

A15. Changes in Burden

This is a new collection of information. 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 way people use the brief summary and the topics they find most useful. We expect main effects and/or interactions of two main independent variables (risk level and risk severity) depending on the dependent variable. Each question in the questionnaire represents a potential dependent variable, plus two other measures, time spent on each page in total and number of times each page is viewed. Analyses of variance and covariance will be used as the primary analytical technique, with reading speed, age and participant gender as potential covariates. Our analysis plan includes descriptive statistics such as frequencies and correlations used to determine associations and nonparametric measures such as chi-square used when dealing with proportions. We plan to analyze the results within disease condition.

b) *Publication.* A final report of the study procedures and results will be issued at the end of the data collection period, as specified in the contract. The results will be reported to the FDA Commissioner, and it is anticipated that the findings from these studies will be presented in FDA reports and in publications in scientific journals. The results will also be available on the Division of Drug Marketing, Advertising and Communications (DDMAC) website.

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 Not to Display OMB Expiration Date

We are not seeking approval to not display the OMB expiration date. The OMB approval

number and 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," of OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

B1. Respondent Universe and Sample Selection

Eligible participants will be recruited for participation in eight geographically dispersed malls serving a variety of socioeconomic classes. Recruited subjects will be screened for: ability to read English, presence of a pre-existing medical condition or caregiver status, ability to visually process the label (have reading glasses available if necessary) and age (18 years of age or older) and education level. They will be asked to participate in a study of consumer product advertising that lasts no more than 20 minutes. The majority of participants are expected to be recruited in the mall setting. Additional participants may be recruited from existing internet panels if necessary.

Research has shown that motivated participants tend to engage in more effortful information processing (e.g., Lord et al., 1984; Neuberg, 1989; Tetlock & Kim, 1987). Individuals who suffer from one of the two conditions are expected to be more motivated to read the advertisement and the brief summary than individuals who do not suffer from these conditions. One half of the respondents in each condition will be sufferers and the other half will provide care to someone who has the condition. Participants will be randomly assigned to the risk condition. Each participant will see only one experimental advertisement/brief summary.

The questionnaire seeks to measure the thoughts and goals people have when reading the brief summary and the topics they find most useful. Dependent variables include time spent reading page one and page two of the ad, ratings of usefulness of topics, and measures of goals and risk perceptions.

The specific dependent variables for this study are outlined below (see Appendix D for a copy of the questionnaire).

Question #s	Variable Measured
Recorded time	Time spent reading ad and brief summary, to serve as a covariate or as an index of reading skill
1-2	Awareness of stimuli
3	Thoroughness of general reading

4	Depth of processing of page 2
5	Processing goals
6a-b	Topics of interest
6c	Perceived missing topics
7	Perceived usefulness of each topic
8a-c	Understanding of risks and benefits
8d, g	Motivation to take action from ad
8e,f	Believability of stimuli and claims
8h-i	Interplay between page one and page two
8.1	Personal relevance (check for involvement)
9a-b	Behavioral intention
9c	Perceived risk-benefit tradeoff
10	Caregiver demographics
11	Diagnosed demographics
12-14	General demographics

All respondents will be over 18 years of age and be primary English speakers. A Spanish-language questionnaire will not be developed for this study as virtually all DTC advertising for the three selected conditions is in English. The research will be undertaken by FDA through an existing contract by FDA's Center for Food Safety and Nutrition with Synovate, Inc. Approximately 400 interviews will be conducted. This constitutes approximately 100 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. The sample size is based on our experience with studies of prescription drug label variations. Prior experience with a RAND corporation study conducted by the FDA in the mid 1980's indicated that the effects of label variations are likely to be quite subtle. A cell size of between 50 and 100 participants is necessary to have sufficient power to detect differences. Since we do not have estimates of effect sizes, we cannot do a power calculation. Therefore we chose a cell size of 66 as reasonable figure. Our design for this study is a 3 x 2 (6 cells). At 66 participants per cell, this equals approximately 400 participants.

B2. Procedures for Collection of Information

Ads for three types of drugs will be used in this study: treatments for high cholesterol, asthma, and obesity. In all instances drugs will be fictional in terms of their name and the precise information presented. However, they will be based upon typical members of the drug class to provide realistic stimuli (see Appendix B for stimuli). Mock-ups of prototypical DTC print advertisements will be used to present the brief summary information to further assure the use of realistic stimuli. Each participant will be asked to read one advertisement/brief summary as they would if they came across the ad in a magazine. Time spent reading the main body copy of the ad and the brief summary will be recorded separately. After the participant has finished reading the ad and brief summary, he or she will be asked questions about information in the main ad and the brief summary. Finally, demographic and health care utilization information will be collected.

This information collection does not employ probability sampling of respondents. 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.

B3. Procedures to Maximize Response Rates

Respondents will be recruited from an existing internet panel maintained by the contractor and interviewed at 8 shopping malls. Participants will be told they will be evaluating a new product concept. This procedure has been reviewed and approved by FDA's human subject protection committee (RIHSC).

B4. Tests of Procedures

We have conducted focus groups to help narrow down the topics for investigation and to aid in questionnaire development. The contractor has also reviewed the questionnaire. Nine completed interviews will be used as a test of procedures.

B5. Contacts

The contact individuals are Kathryn J. Aikin, Ph.D., (Project Officer), FDA Division of Drug Marketing, Advertising, and Communications, WO BLDG 22, RM 1438, (301) 796-1200, and Leigh Seaver, Ph.D., Synovate, Inc., 703-790-9099.

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