TITLE OF INFORMATION COLLECTION: Pretests for a Study on Quantitative Information in Direct-to-Consumer Television Advertisements

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   A previous FDA study found that simple quantitative information could be conveyed in direct-to-consumer (DTC) television ads in ways that increased consumer's knowledge about the drug.[1] However, this research only tested simple information (e.g., one clinical trial, comparison to placebo). Drug information can be much more complicated (e.g., complicated endpoints). Can consumers take more complicated information into account when assessing prescription drug information in television DTC ads? We plan to conduct two studies that will build on previous research by (1) examining more complicated quantitative information, (2) examining quantitative information for both benefits and risks, and (3) examining how visuals designed to represent efficacy interact with the inclusion of quantitative information. This specific information collection is designed to pretest the questionnaires and stimuli to be used in these future experimental studies. Specifically, the pretests will allow us to create stimuli (television ads) that vary in the amount, complexity, and visualizations of quantitative information. In addition, the pretests will allow us to pilot aspects of the measurement instruments, stimuli, and/or procedures.

2. **Intended use of information:**

   The information gathered in this project will be used to create questionnaires and stimuli for two future quantitative studies of DTC television ads (not included in this information collection). The long-term objective is to ensure effective communication of prescription drug benefit and risk information in DTC television ads.

3. **Description of respondents:**

   For the study, 1,010 participants (200 in Pretest 1, 270 in Pretest 2, 270 in Pretest 3 and 270 in Pretest 4) will be recruited from Research Now's opt-in online e-Rewards® Opinion panel. Sample sizes are based on a priori power calculations (power = .80, alpha = .10, f = .15-.20). The target population is the adult noninstitutionalized population in the US with access to the Internet and who are 60 years of age or older. Each panel member will complete a prescreening questionnaire and we will recruit participants who indicate that they are 60 years of age or older who do not work for a pharmaceutical company, an advertising agency, or a market research company (see Appendix A for the recruitment and reminder emails and Appendix B for the screener). The screener includes

[1] O'Donoghue, A.C., Sullivan, H.W., Aikin, K.J., Chowdhury, D., Moultrie, R.R., & Rupert, D.J. (2014). Presenting efficacy information in direct-to-consumer prescription drug advertisements. *Patient Education and Counseling, 95*(2), 271-280.

quotas for gender, race, and education to ensure demographic diversity. The advertisement used in the study will be for a fictitious prescription drug indicated to treat cataracts. We selected a sample of participants 60 years and older to increase the likelihood that participants will be interested in the drug and therefore motivated to pay attention to the ad during the study. Because the sample is not nationally representative, we do not plan to use these data to make generalizable conclusions, such as estimating population parameters.

4. **Date(s) to be Conducted:**

   November 1, 2015 – December 1, 2016

5. **How the Information is being collected:**

   All parts of this study will be administered over the internet. Four pretests will be conducted.

   In Pretest 1, we will ask participants questions about drug efficacy to define the quantitative information to be used as the manipulation of the quantitative efficacy claim in Study 1 (see Appendix C for the questionnaire). In Pretest 2-4 we will pilot aspects of the measurement instruments, stimuli, and/or procedures for two future experimental studies. In Pretest 2, participants will be randomly assigned to view one of nine versions of a DTC television ad (Table 1). In Pretests 3 and 4, participants will be randomly assigned to view one of six versions of a DTC television ad (Tables 2 and 3). After viewing the ad, participants will answer a series of questions, including questions about their recall, understanding, and perceptions of the information in the ad (see Appendices C-E for the questionnaires). The entire procedure for all four pretests is expected to last approximately 20 minutes.

   Based on the results of Pretest 1, we will create the stimuli for Pretest 2 and conduct the second pretest. Next, we will conduct Pretests 3 and 4, making any needed changes to the stimuli, procedure, or questionnaires between Pretests 3 and 4.

Table 1. Pretest 2 Design.

		Quantitative Risk Claim		
		No	Yes: General Statement (e.g., seen in less than 10% of patients)	Yes: Specific Statement (e.g., seen in less than 10%, 5%, and 1%)
Quantitative Efficacy Claim	No			
	Yes: simple (e.g., improved vision by 40%)			
	Yes: complex (e.g., improved vision by 40% in 83% of patients)			

Table 2. Pretests 3 Design.

		Images of Improvement

		None	Small or accurate difference conveyed in images	Large or overstated difference conveyed in images
Quantitative Benefit Claim	No			
	Yes			

Table 3. Pretests 4 Design.				
		Images of Improvement		
		None	Small or accurate difference conveyed in images	Large or overstated difference conveyed in images
Quantitative Benefit Claim	No			
	Yes			

6. **Confidentiality of Respondents:**

Panel members who are eligible and who are interested in taking the survey will click on a link that takes them to an online informed consent page (Appendix F). Participants will be presented with a screen explaining that their participation is voluntary and that survey findings will be de-identified. Participants will also be provided with telephone number for the Office of Research Protection for the contractor, RTI International, as well as the direct telephone number for the RTI International project director should they have any questions or concerns about the study or their participation. Participants will mark their consent by checking a box on the screen that indicates they understand the study and agree to participate. If participants do not acknowledge their consent, they will be unable to proceed with the survey.

Participants will access the survey questionnaires by using a unique, secure Web URL that is e-mailed to them. Individuals then access the survey by entering an appropriate e-mail address and password. Panel members' passwords are stored in a secured state within Research Now's panel management database software. Throughout the survey, questionnaire data are copied to a secured, centralized database for data processing. All data transfers of survey responses from participants' personal computers to the main servers pass through redundant firewalls. Research Now provides strong encryption methods for transmitting and receiving data and uses secret-key and public-key cryptography combinations to protect sensitive information. Additionally, information that is stored on servers is encrypted during backed-ups and the information is stored in a secured offsite location. The privacy of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). These methods will all be approved by RTI's Institutional Review Board prior to collecting any information as well as FDA's Research Involving Human Subjects Committee.

No personally identifiable information will be sent to FDA. All information that can

identify individual participants will be maintained by the independent contractor in a form that is separate from the data provided to FDA. For all data, alpha numeric codes will be used instead of names as identifiers. These identification codes (rather than names) are used on any documents or files that contain study data or participant responses.

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

7. Amount and Justification for any Proposed Incentive

For completing a survey, participants will receive approximately $5.00 in e-Rewards currency which can be exchanged in the Research Now marketplace for a variety of items (airline miles, hotel points, magazines, movie tickets, etc.).

Following OMB's "Guidance on Agency and Statistical Information Collections," we offer the following justification for our use of these incentives.

Data quality: Because providing a market-rate incentive should increase response rates, it should also significantly improve validity and reliability to an extent beyond that possible through other means. Previous research suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research (such as those with lower education, e.g., Guyll, Spoth, & Redmond, 2003). Furthermore, there is some evidence that using incentives can reduce nonresponse bias in some situations by bringing in a more representative set of respondents (Castiglioni & Pforr, 2007; Singer, 2002; Singer, 2006). This may be particularly effective in reducing nonresponse bias due to topic saliency (Groves et al., 2006).

Past experience: Research Now, the contractor for this study, has conducted hundreds of health-related surveys in the past year. Research Now offers incentives to its panel members for completing surveys, with the amount of incentive for consumer surveys determined by the length of the survey. Their experience indicates that the requested amount is reasonable for a 20 minute survey.

Reduced survey costs: Recruiting with market-rate incentives is cost-effective. Lower participation rates will likely impact the project timeline because participant recruitment will take longer and, therefore, data collection will be slower and more costly.

Castiglioni, L., & Pforr, K. (2007). The effect of incentives in reducing non-response bias in a multi-actor survey. *Presented at the 2nd annual European Survey Research Association Conference*, Prague, Czech Republic, June, 2007.

Groves, R., Couper, M., Presser, S., Singer, E., Tourangeau, R., Acosta, G., & Nelson, L. (2006). Experiments in producing nonresponse bias. *Public Opinion Quarterly,* 70(5), 720-736.

Guyll, M., Spoth, R., & Redmond, C. (2003). The effects of incentives and research requirements on participation rates for a community-based preventive intervention research study. *Journal of Primary Prevention*, *24*(1), 25-41.

Singer, E. (2002). The Use of Incentives to Reduce Nonresponse in Household Surveys. (R. M. Groves, D. A. Dillman, J. L. Eltinge, & R. J. A. Little, Eds.)*Survey nonresponse*, (051), 163-178. University of Michigan Institute for Social Research. Retrieved from http://www.isr.umich.edu/src/smp/Electronic.

Singer, E. (2006). Nonresponse bias in household surveys. *Public Opinion Quarterly*, 70(5), 637-645.

8. **Questions of a Sensitive Nature**

   This data collection will not include sensitive questions.

9. **Description of Statistical Methods**

   We will report descriptive statistics for all variables (for instance, frequencies and percents). We will conduct logistic regressions to test for differences among conditions on categorical variables. We will conduct analysis of variance (ANOVAs) to test for difference among conditions on continuous variables.

BURDEN HOUR COMPUTATION:

Table 4.--Estimated Annual Reporting Burden[1] –Pretest 1

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sample outgo	3,360				
Number to complete the screeners (10%)	336	1	336	.05 (3 min.)	17
Number eligible for survey (70%)	235	--	--	--	--
Number to complete the survey (85%)	200	1	200	.33 (20 min.)	66
Total			536		83

Table 5.--Estimated Annual Reporting Burden[1] –Pretest 2

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
Sample outgo	4,540	--	--	--	--
Number to complete the screener (10%)	454	1	454	.05 (3 min.)	23
Number eligible for survey (70%)	318	--	--	--	--
Number to complete the survey (85%)	270	1	270	.33 (20 min.)	89
Total			724		112

Table 6.--Estimated Annual Reporting Burden[1] –Pretest 3					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
Sample outgo	4,540				--
Number to complete the screener (10%)	454	1	454	.05 (3 min.)	23
Number eligible for survey (70%)	318	--	--	--	
Number to complete the survey (85%)	270	1	270	.33 (20 min.)	89
Total			724		112

Table 7.--Estimated Annual Reporting Burden[1] Pretest 4					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
Sample outgo	4540				--
Number to complete the screener (10%)	454	1	454	.05 (3 min.)	23
Number eligible for survey (70%)	318	--	--	--	
Number to complete the survey (85%)	270	1	270	.33 (20 min.)	89
Total			724		112

REQUESTED APPROVAL DATE: November 1, 2015

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FDA CENTER: Center for Drug Research and Evaluation