FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF COMMUNICATION TESTING FOR DRUG PRODUCTS (0910-0695)

TITLE OF INFORMATION COLLECTION: Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC Prescription Drug Ads (Cognitive Interviews)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) is seeking OMB approval under the generic clearance 0910-0695 to conduct cognitive interviews for the project, "Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC Prescription Drug Ads."

In a typical promotional campaign, consumers may be exposed to a direct-to-consumer (DTC) prescription drug ad any number of times. Perceptual and cognitive effects of increased ad exposure frequency have been studied extensively from a marketing perspective.[1] For instance, one study demonstrated that a commercial message repeated twice generates better recall than a message broadcast only once.[2] Another study demonstrated that increased ad exposures improve product attitudes and recall for product attributes, particularly when the substance of the repeat messages is varied.[3] Generally, it has been argued that first exposure to an ad results in attention, second exposure affects learning of the advertised message, and third and subsequent exposures reinforce the learning effects of the second exposure.[4] To our knowledge, the literature concerning ad exposure frequency has not been extended to include specific attention to prescription drug ads. Similar effects to those observed for other ads may occur. However, prescription drug ads are unique in that they are required to provide a balanced presentation of benefit and risk information[5] whereas other ad types tend to include only benefit information. The number of instances in which consumers are exposed to a prescription drug ad may have important effects on their perception and mental processing of risk and benefit information presented. If benefit information in drug ads is presented in a more appealing format than risk information, then benefit information may dominate consumer attention and memory upon first ad exposure. Risk information may not be processed and remembered until after several ad exposures. These questions have potential public health implications.

[1] Jeong, Y., Sanders, M., & Zhao, X. (2011). Bridging the gap between time and space: Examining the impact of commercial length and frequency on advertising effectiveness. *Journal of Marketing Communications, 17,* 263-279.
[2] Singh, S.N., Linville, D., & Sukhdial, A. (1995). Enhancing the efficacy of split thirty-second television commercials: An encoding variability application. *Journal of Advertising, 24,* 13-23.
[3] Haugtvedt, C.P., Schumann, D.W., Schneier, W.L., & Warren, W.L. (1994). Advertising repetition and variation strategies: Implications for understanding attitude strength. *Journal of Consumer Research, 21,* 176-189.
[4] Naples, M.J. (1997). Effective frequency: Then and now. *Journal of Advertising Research, 37,* 7-12.
[5] See 21 CFR 202.1 (e)(5)(ii).

The Office of Prescription Drug Promotion (OPDP) plans to examine the effects of variation in ad exposure frequency on perception and mental processing of risk and benefit information in DTC prescription drug ads through empirical research.

2. **Intended use of information:**

The project described in this request is designed to test stimuli and measurement candidate items via cognitive interviewing to identify comprehension, response, recall, and terminology barriers. The results will be used to improve the stimuli and narrow the question pool. The stimuli and resulting questionnaires will be subsequently used in an experimental study not included in this information collection.

3. **Description of respondents:**

We will identify potential participants through local research recruiting firms in the Washington, DC and Raleigh, NC areas. We are planning to recruit two waves of cognitive interviews with adult consumers (N=18) who self-report as having been diagnosed with asthma, and who do not work in the health, pharmaceutical, or marketing fields.

Participants will be offered $125 for a two-hour interview. This amount is the standard market rate for the interview length, is based on the current cost of gas and other travel expenses, and ensures that participants are reasonably diverse in age, income, and education.

Because the sample is not nationally representative, we do not plan to use these data to make generalizable conclusions, such as estimating population parameters.

Table 1. Number of Interviews by Location and Guide.

Location	Total Number of Interviews
Washington, DC	9
Raleigh, NC	9
Total	**18**

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

February, 2015

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

Recruitment Information

Staff from the cognitive interview facilities will conduct subject recruitment using the participant screeners (attached) to contact and screen potential participants, confirm their interest, and schedule them for pre-determined timeslots. The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper

location on the agreed upon date and time. Facilities will intentionally over-recruit to ensure the minimum number of participants needed come to their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Cognitive Interviews

RTI staff members will serve as moderators for all focus groups and interviews. OPDP staff members will observe most, if not all, of the sessions from the observation rooms at the focus group facilities or remotely using streaming technology.

A trained interviewer will conduct each interview using a structured interview guide (attached). The focus group facilities will make audio recordings to ensure a verbatim record of the proceedings is captured.

The two rounds of interviews will have distinct purposes. In the first round, we will test the stimuli for the main study. In order to test ad exposure frequency in a realistic setting, we will ask respondents to view a one-hour television program in which 6 advertising reels have been embedded. Participants will be randomized to view our DTC ad one, three, or six times, and then will answer survey questions. Because a cognitive interview designed to test both the one-hour stimulus and the 20 minute survey would be too long and burdensome, we propose testing the stimuli and just a handful of main outcome measures in the first round of interviews and then testing just the 90-second DTC ad and the remaining survey items in the second round of cognitive interviews.

6. **Confidentiality of Respondents:**

No personally identifiable information will be sent to FDA. At the beginning of each interview, we will ensure participants understand that their participation is voluntary and that they can skip questions or stop participating at any time. We will protect participants' confidentiality by not using names in notes and by storing all notes and recordings in a locked filing cabinet in the RTI project director's office (hardcopy) or on a password protected project server (electronic). We also will assure participants that research findings and reports will not contain any personal information.

The recruitment firms will store screening information in locked file cabinets (hardcopy) or on a password protected computer (electronic) in order to invite respondents and send them reminder letters / calls. Only the recruitment firms will have access to this information; RTI will be provided de-identified screening data for participants (i.e., first names only, no other contact info). Names of participants will be used solely to facilitate contact. After the study is completed, the recruitment firms will destroy the screening information and will be permitted to keep only participant demographic information on file (i.e., age, sex, race, education).

RTI and FDA will not have the full names or any contact information for any of the participants. Therefore, there will be no link between the data collected and the participants' identities.

A consent form will be provided to participants before they begin the survey (attached). The consent form states that participation and responses to individual questions is voluntary and that their responses and information will be kept private to the extent allowable by law.

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).

Confidentiality 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 20.63). These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC) prior to collecting any information.

7. **Questions of a Sensitive Nature**

   This data collection will not include sensitive questions.

8. **Description of Statistical Methods**

   We will report descriptive statistics for all variables (for instance, frequencies and percents).

BURDEN HOUR COMPUTATION:

Table 2. Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)	Total Hours
Sample outgoing	1,200	--	--	--	--
Number to complete the screener (40%)	480	1	480	.03 (2 minutes)	14.4
Number eligible for survey 5%)	24	--	--	--	--
Number of completes	18	1	18	2	36
Total	**--**	**--**	**498**	**--**	**50.4**

REQUESTED APPROVAL DATE: January 2, 2015

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff
Ila.Mizrachi@fda.hhs.gov
(301)796-7726

Kevin R. Betts, Ph.D.
Psychologist
U.S. Food and Drug Administration
Office of Prescription Drug Promotion
10903 New Hampshire Avenue
Building 51, Room 3220
Silver Spring, MD 20993
Phone: 240.402.5090

Kevin.Betts@fda.hhs.gov

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