TITLE OF INFORMATION COLLECTION: Animation in Direct-to-Consumer Promotion: Cognitive Interviews

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

These cognitive interviews are part of a larger research project to examine whether animation in prescription drug promotion inflates efficacy perceptions, minimizes risk, or otherwise hinders comprehension of drug risks and benefits. To investigate these issues, we will conduct two experiments to examine how (1) type of animation and (2) non-human personification in prescription drug promotion influence consumer comprehension, processing, and perception of risk and benefit information. Understanding how issues of animation and personification affect perceptions of both risks and benefits can help the FDA to better understand how prescription drug risk and benefit information is processed and consider potential policy implications.

The purpose of the cognitive interviews is to test potential items to identify comprehension, response, recall, and terminology barriers. We will test the response scale/options of each candidate item to ensure they are clear, meaningful, and easy to answer.

2. Intended use of information:

We will use the cognitive interviews proposed here to strengthen the measurement of variables in quantitative studies that are planned to follow these interviews. We intend to clarify questionnaire items based on these interviews to ensure that we are utilizing participants wisely in the larger quantitative studies.

3. Description of respondents:

We propose two waves of cognitive interviews (one wave per experiment) before conducting the pretests. Each wave of interviews will include nine participants (n=18 total) and will take place in Bethesda, MD. In each cognitive interview wave, we will test questionnaire items in 60-minute individual interviews with adult consumers who have been diagnosed with at least one of the study's two medical conditions (chronic dry eyes and psoriasis) to ensure the questions are clear, meaningful, and easy to answer (e.g., number of points on scale, number and placement of response anchors, anchor wording).

4. Date(s) to be conducted and location(s):

We plan to conduct the interviews between April 1, 2016 and June 1, 2016 at the Shugoll Research facility in Bethesda, MD.

5. How the Information is being collected:

Recruitment Procedures and Method

We will identify potential participants through a local recruitment firm, who will contact individuals and screen them for eligibility using a 9-item questionnaire (***Attachment A***). During the interview, participants will view a promotional video for a fictitious prescription drug twice and respond to multiple questions about the promoted drug. A trained interviewer will conduct each interview using a structured interview guide (***Attachment B***).

To ensure adequate participation and high data quality, we propose a participant incentive of $100. This amount is aligned with the standard market rate of $100 for a 60-minute interview, is based on the current cost of gas and other travel expenses, and ensures that participants are reasonably diverse in age, income, and education.

We will audio record all interview sessions. The cognitive interviews are anticipated to last one hour.

6. Confidentiality of Respondents:

All data will be collected with an assurance that participants' identity, along with their personal demographic information, will be held confidential and not used for reasons outside the scope of the research described unless with their consent. The consent form will contain a statement emphasizing that a participant's identity or personal information will not be linked to his/her responses. Additionally, moderators will not ask participants to provide identifying information as part of their responses; however, in order to establish a rapport with the participant, moderators will address participants by their first name. All analyses will be done in the aggregate and respondent information will not be appended to the data file used. Further, no identifying information will be included in the data files delivered to FDA.

With participant's permission, sessions will be audio recorded to create transcriptions of the interview for reporting purposes. The consent forms will contain language that notifies participants of the audio recording. Before each interview begins, the participant will sign the informed consent form and will be given a copy of the form for their records (see ***Attachment C***).

Only FDA personnel and other study team members directly involved in the research will view the interviews. All equipment will be operated and maintained according to industry standard practices, and all software validated using industry standard quality assurance practices.

Contractors will not share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court orders, or other legal processes. Further, if a participant makes a direct threat of harm to his/herself or others, RTI reserves the right to take action out of concern for him or her and for others.

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). All identifying information, including information collected during screening and audio recording, will be kept on a separate password-protected computer and/or in locked cabinets for a period of 3 years only accessible by RTI, after which they will be destroyed by securely shredding documents or permanently deleting electronic information. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

7. Amount and justification for any proposed incentive:

Participants will receive an incentive as a token of appreciation for participating in the interviews.

As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[1] The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research, we are asking participants to provide thought-intensive, open-ended feedback on concepts that require a high level of engagement.

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[2] as well as provide enough motivation for them to participate in the study rather than another activity.

If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with moderator and observer time.[3] Additionally, low participation can cause a difficult and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs.

To ensure adequate participation and high data quality, we propose a participant incentive of $100. This amount is aligned with the standard market rate of $100 for a 60-minute interview, and is based on the current cost of gas and other travel expenses, and ensures that participants are reasonably diverse in age, income, and education.

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1 Halpen, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(*7*), 801-803.

2 Russell, M.L., Moralejo, D.G., & Burgess, E.D. (2000). Participants' perspectives. *Journal of Medical Ethics, 26*(*2*), 126-130.

3 Morgan, D.L. & Scannell, A.U. (1998). *Planning Focus Groups*. Thousand Oaks, CA: Sage.

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (i.e. Sample Size & Method of Selection):

No statistical methods will be used.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Table 1 shows the estimated annual reporting burden.

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[a]	Total Hours
Number to complete the screener (assumes 5% eligible)	480	1	480	.08 (5 minutes)	39
Number eligible for interview	24	--	--	--	--
Number of completes	18	1	18	1 (60 minutes)	18
Total					**57**

[a]Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

NAME OF PRA ANALYST & PROGRAM CONTACT: April, 2016 (would like to commence information collection data as soon as practicable).

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FDA CENTER: Center for Drug Evaluation and Research, Office of Prescription Drug Promotion