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

TITLE OF INFORMATION COLLECTION: Cognitive Interviews for Risk and Benefit Perception Scale Development Study

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The U.S. Food and Drug Administration (FDA) requires that prescription drug advertisements be balanced in their presentation of risk and benefit information. The proliferation of consumer-directed prescription drug information in recent years has prompted FDA to enhance its efforts to ensure that risks and benefits are clearly and fairly presented. Patients receive information on drugs not only from their doctors and pharmacies, through patient labeling and FDA-mandated Medication Guides, but also via direct-to-consumer (DTC) advertising on television, in magazines, online, and on social networks. Moreover, research suggests that consumers struggle with the concepts of risk and efficacy and often overestimate drug efficacy. As a result, it is important for FDA to understand and accurately measure how consumers are making sense of this information and how it impacts decisions related to prescription drugs.

   FDA's Office of Prescription Drug Promotion (OPDP) has an active research program that investigates how DTC advertising influences consumer knowledge, perceptions, and behavior. Consequently, FDA needs a pool of reliable and valid measurement items to assess consumers' drug risk and benefit perceptions—as well as other elements of prescription drug decision making—consistently across studies. This project is designed to test measurement candidate items via cognitive interviewing to identify comprehension, response, recall, and terminology barriers. The results will be used to improve and narrow the measurement pool, which will be subsequently tested in an experimental study not included in this information collection.

2. **Intended use of information:**

   The information gathered in this project will be used to improve and narrow the measurement pool for a future quantitative study of risk and benefit perceptions of DTC advertising. The long-term objective is to improve the measurement validity and reliability of risk and benefit perceptions and to ensure effective communication of risk information in DTC television and print ads.

3. **Description of respondents:**

   For the study, 27 participants will be recruited by local recruitment firms in the Raleigh, NC and Washington, DC areas. Participants will be 18 or over; will have been diagnosed with hypertension or chronic pain; will not work in the health, pharmaceutical, or research fields; and will not have participated in an interview or focus group within the past year. Approximately 1/3 of participants will be newly diagnosed with hypertension or chronic pain, another 1/3 will be satisfied with their current treatment for hypertension or chronic pain, and another 1/3 will be dissatisfied with their current treatment for hypertension or chronic pain.

We will use recruitment firms for participant recruitment and a contractor, RTI, for survey administration and data collection. Once the recruitment firms have contacted individuals, the firms will assess their eligibility using a tailored telephone screener (**Appendix A**). If eligible, participants will be invited to participate in the interviews. Participants will be provided with a written copy of the informed consent form at the interview (**Appendix B**). The interviewer will review the informed consent form with each participant prior to the interview, answer any participant questions, ask participants to sign the form if they agree to participate, and provide a copy of the form to each participant. The interviews will take approximately 1 ½ hours. Participants will be offered $75 for their time.

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:**

   April 1, 2014 – December 1, 2014

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

   The study will be administered in person at an interview facility. For each session, a trained interviewer will lead the discussion using a structured interview guide (**Appendix C**). Participants will view a video or print ad for a fictitious prescription drug that treats either hypertension or chronic pain and then be asked to answer multiple candidate items about the advertised drug.

   We have developed a pool of candidate items, which we have organized into modules (**Appendix C**). To reduce participant burden, we will test a few items from each module in each interview. The same set of interview questions/probes will be used for all candidate items within a module. This approach will allow greater comparison of results across interviews while reducing the need for participants to answer similar/repetitive candidate items.

   During the interviews, one note taker will observe and document the major themes in each interview. With the consent of participants, we will audio record each interview. Interview notes will be stored in a locked filing cabinet in the RTI project director's office, and audio recordings will be stored on a password protected server that is accessible only to research team members.

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 (**Appendix B**). 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 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
Sample outgo	432	--	--	--	--
Number to complete the screener (25%)	108	1	108	.03	3.6
Number eligible	36	--	--	--	--

for survey (33%)					
Number to complete the survey	27	1	27	1.5	40.5
Total	603	1	**135**	--	**44.1**

REQUESTED APPROVAL DATE: April 1, 2014

NAME OF PRA ANALYST & PROGRAM CONTACT: Ila S. Mizrachi

FDA CENTER: Center for Drug Research and Evaluation