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

TITLE OF INFORMATION COLLECTION: Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   By their very nature, medical and health decisions are comparative (e.g., treat versus not treat). For consumers, these decisions may include the use of prescription drug products versus over the counter products versus herbal supplements, as well as one prescription brand versus another prescription brand. Similarly, advertising is often comparative. In prescription drug advertising, sponsors are permitted to include truthful, non-misleading information about the price of their products in promotion. This may extend to price comparison information, wherein sponsors may include information about the price of a competing product in order to make advantageous claims. Currently, when price comparisons are made, the ad should also include context that the two drugs may not be comparable in terms of efficacy and safety and that the acquisition costs presented do not necessarily reflect the actual prices paid by consumers, pharmacies, or third party payers. Despite the inclusion of this additional information, there is concern that adding contextual information about efficacy or safety is not sufficient to correct the impression that the products are interchangeable and that price is the main factor to consider. The Office of Prescription Drug Promotion (OPDP) plans to investigate, through empirical research, the impact of price comparison information and additional contextual information on prescription drug product perceptions. This will be investigated in direct-to-consumer (DTC) and healthcare-directed professional advertising for prescription drugs.

   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.

2. **Intended use of information:**

   The information gathered in this project will be used to test stimuli and improve and narrow the measurement pool for a subsequent quantitative study of price comparison information and additional contextual information on prescription drug product perceptions.

3. **Description of respondents:**

   We will identify potential participants through a local research recruiting firm in the Raleigh, NC area. The firm will recruit consumer participants, screen them for eligibility in the study, and invite them to participate. The firms will use a screener (**Appendix A**) to contact and screen potential participants, confirm their interest, and schedule them for pre-determined timeslots. We are planning to recruit 9 adult individuals who self-report

as having been diagnosed with diabetes, and who do not work in the health, pharmaceutical, or marketing fields.

We will provide participants with a written copy of the informed consent. The interviewer will review the informed consent form (**Appendix A**) with each participant prior to the interview, answer any participant questions, ask the participant to sign the form if he/she agrees to participate, and provide a copy of the written form to the 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:**

   October 15, 2014 – December 1, 2014

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

   Participants will be asked to view a direct-to-consumer (DTC) ad for a product designed to treat diabetic peripheral neuropathy. 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 A**). Participants will view a print ad for a fictitious prescription drug that treats diabetic peripheral neuropathy and then be asked to answer questions about the advertised drug. The fictitious prescription drug is modeled on a real drug used to treat that condition and was created with the input of an expert reviewer in the Office of Prescription Drug Promotion at FDA. 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 study contractor'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 A**). 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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sample outgo	144	--	--	--	--
Number to complete the screener (25%)	36	1	36	.03 (2 minutes)	1.08
Number eligible for survey (33%)	12	--	--	--	--
Number to complete the survey	9	1	9	1.5	13.5
Total				--	

					14.58

REQUESTED APPROVAL DATE: October 1, 2014

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