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

TITLE OF INFORMATION COLLECTION: Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements (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, "Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements."

   Prescription drug advertising regulations (21 CFR 202.1) require that broadcast (TV or radio) advertisements present the product's major risks in either audio or audio and visual parts of the advertisement; this is often called the "major statement." There is concern that as currently implemented in (DTC) ads, the major statement is often too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic non-compliance due to fear of side effects. At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information. These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are serious and actionable, and include a disclosure to alert consumers that there are other product risks not included in the ad. For example, the disclosure could be, "This is not a full list of risks and side effects. Talk to your doctor and read the patient labeling for more information." The Office of Prescription Drug Promotion (OPDP) plans to investigate the effectiveness of this "limited risks plus disclosure" strategy 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 insomnia, high cholesterol, or depression (6 people for each condition), and who do not work in the health, pharmaceutical, or marketing fields.

Participants will be offered $75 for a 60-minute 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:**

July-August, 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.

Cognitive interviews will be divided into two rounds. Nine individuals will participate in each round. Participants will be asked to view an advertisement for a real drug on a laptop computer (participants will view the ad for the health condition that they were recruited for). The drugs in the ads are real, but the narration and superimposed text

regarding drug risks and side effects has been manipulated. After viewing the ad, participants will complete a survey on the laptop.

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	1	18
Total	**--**	**--**	**498**	**--**	**32.4**

REQUESTED APPROVAL DATE: July 6, 2015

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