FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "TESTING COMMUNICATIONS ON DRUGS PRODUCTS" (0910-0695)

.

TITLE OF INFORMATION COLLECTION: Testing FDA's Drug Safety Communications with Consumers to Improve Consumer Knowledge about How FDA Communicates Risks and Benefits of Prescription Medicines

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The study was commissioned by the Food and Drug Administration (FDA) to help understand how possible changes to information in drug safety communications (DSCs) could improve the understanding and behavioral outcomes for consumers and patients who view them.

2. **Intended use of information:**
   The FDA plans to use lessons learned from this study to enhance future Drug Safety Communications and other communications.

   The study aim to address the following research questions:

   1. How do changes in the formatting of DSCs influence consumers' (A) ability to understand information, (B) perceptions of the risk of the drug being addressed, and (C) behavioral intentions?
   2. How are perceptions of risk and behavioral intentions affected by the inclusion of additional contextual information in the discussion of adverse events?
   3. What is the effect of using different approaches to communicating numeric information on consumers' understanding and risk perception?
   4. How does the use of different terms to describe the FDAs actions affect consumers' perceptions of risk?
   5. What are consumers' preferences for the presentation/format of risk ratings scales?
   6. How do various types of risk rating scales affect risk perception and behavioral intention?
   7. How do manipulations of the DSC title (inclusion of the drug name; title length; readability) affect attentiveness and likelihood to read the full DSC?

3. **Description of respondents:**
   Respondents will be drawn from the general population and screened for one of two medical conditions: diabetes (n=1300) or constipation (n=1300).

4. **Date(s) to be Conducted:**
   As soon as possible (expected to start in September 2015)

5. **How the Information is being collected:**
   The sampling frame for this study is adult participants screened for one of our two target medical conditions from i-Say, an online consumer panels maintained by Ipsos, the

Agency's contractor for this study. For Ipsos' panel, U.S. consumers who are 18 or older are invited to join the panel primarily through an affiliate marketing program. Select web sites, portals, and Internet service providers partner with Ipsos to promote panel membership through targeted email campaigns as well as placement of banner and pop-up advertisements. Consumers may also join the panel through referrals from existing panel members and re-enlistment of former members. Currently, the panel has approximately 400,000 participants.

The target sample size for the experimental study is 2,600 respondents (1,300 with diabetes and 1,300 with constipation). For the constipation population, the sample frame will be the complete i-Say panel, and a demographic profile will be developed prior to the study so that the overall sample of panelists who are screened to participate in the study will be balanced to American Community Survey (ACS) statistics in terms of gender, age, education, and census region. For the diabetes sample, the sample frame will consist of individuals on the i-Say panel who have already been pre-identified as having diabetes, and a demographic profile (in terms of gender, age, and education,) will be established using National Health Interview Survey (NHIS) statistics for the U.S. adult diabetes population.

The Agency does not intend to generate nationally representative results or precise estimates of population parameters from this study. The study will use a convenience sample rather than a probability sample. Despite the attempt to match the study's sample with probability sample-based benchmarks, matching is used solely to produce a sample with a reasonable degree of diversity in key demographic characteristics. Rather than its representativity, the strength of the proposed experimental study lies in its internal validity, on which meaningful estimates of differences within conditions can be produced and generalized.

Individuals in the sample will be emailed an invitation to the survey. Once they click a URL embedded in the invitation, they will be routed to the consent form for the questionnaire. Upon consent, basic screeners will be asked to ensure they qualify for the survey. If a participant does not qualify, they will be thanked and exited out of the survey. If a participant does qualify for one of the two conditions, they will be routed to that condition. For the survey, we have five different segments. In each segment, respondents will randomly receive one of the possible stimuli (either a control drawn from existing Drug Safety Communications, or a manipulated version), and then asked a series of questions regarding the text they were just shown.

6. **Confidentiality of Respondents:**
All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that their responses will be kept confidential. No personally identifiable information will be included in the data files delivered by contractors to the Agency. Information will be kept private to the extent permitted by law.

Confidentiality will be assured by using an independent contractor, Ipsos, to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The contractor will only share data and/or information with the Agency in an aggregated form

or format, which does not permit it to identify individual respondents. Details of the Ipsos privacy policy can be found at http://www.ipsos-na.com/privacy/.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in accordance with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

7. **Amount and justification for any proposed incentive**
Study respondents will be recruited from members of the contractor's consumer panel. Members have voluntarily agreed to join the panel and to participate in regular online surveys. As described below, no direct cash incentives are offered for panel participation.

The use of incentives is a standard practice in data collection in general (see the American Association of Public Opinion Research Best Practices Guidelines at http://www.aapor.org/Best_Practices1.htm#best9) to ensure adequate participation, high-quality data, and that participants are reasonably diverse in age, gender, and education.

Ipsos's i-Say panelists participate in two main incentive programs: sweepstakes drawings and a per-survey point system. For the sweepstakes component, drawings are held several times a year among panelists who have participated in surveys, with various prizes offered. Panelists are entered for each survey in which they participate. Points can be redeemed for electronic gift cards, prepaid cards, PayPal payments and charitable donations.

8. **Questions of a Sensitive Nature**
There are no questions of a sensitive nature.

9. **Description of Statistical Methods**
Data will be analyzed in aggregate. We will use basic cross tabs and frequencies to identify trends and patterns in the data. We will test research hypotheses with ANOVAs, linear regression, chi-square tests, and correlations, as appropriate for the type of data (discrete, continuous, binary) and the research question. Analyses will include covariates including demographic variables and health status. We will conduct post-hoc tests on significant results to identify individual groups that differ from one another, if there are more than two groups in the analysis. Planned comparisons will be used to identify experimental conditions to the control condition.

We conducted a power analysis to determine an appropriate sample size for the most complex survey module, which will require the most power to analyze. The most complex analysis will consist of a 2x2x2x2 ANCOVA with the following factors: medical condition (diabetes, constipation), bullet presence (present, not present), presence of bold text (present, not present), and presence of headings (present, not present). The analysis assumes one degree of freedom in the numerator, 16 groups, three covariates (to be determined), an α-level of .05, and a small effect size (Cohen's $d = .1$). To achieve 95% power, a sample size of 1300 is required. Therefore, we will collect 2600 completed surveys with the assumption that about half of the respondents will complete any give module.

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

FDA will ensure that the final instrument will take no more than 25 minutes as noted in the burden table below and will work to reduce the length to 20 minutes.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Survey Questionnaire for Diabetes respondents:	1,300	25	541.67
Survey Questionnaire for Constipation Participants	1,300	25	541.67
Total	2600		1083.34

REQUESTED APPROVAL DATE: As soon as possible or Oct. 1, 2015

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