FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

TITLE OF INFORMATION COLLECTION: Pilot Study Regarding Framing of Risks in DTC Prescription Drug TV Ads

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   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 direct-to-consumer (DTC) ads, the major statement is often too long, resulting in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic non-compliance due to fear of side effects.[1] At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information.[2, 3] These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are severe, serious and actionable, and include both a framing statement describing the level of risk and a disclosure to alert consumers that there are other product risks not included in the ad. The Food and Drug Administration (FDA) has previously investigated the effectiveness of this "limited risks plus disclosure" strategy through empirical research.[4] This pilot project will investigate the impact of framing statements describing the level of risk for prescription drug products promoted in the context of a DTC television ad.

2. **Intended use of information:**

   We will use the survey proposed here to examine consumers' understanding of the framing statement used to describe the level of risk in a DTC prescription drug TV ad. The intended use of the information is to provide background information for FDA on consumer interpretation of the framing statements. FDA is also separately seeking public comment on a "limited risks plus disclosure" approach, the proposed categories of risk, and how to identify the risks that should be included in the major statement.[5]

---

1 Delbaere, M., & Smith, M. (2006). Health care knowledge and consumer learning: the case of direct-to-consumer drug advertising. *Health Mark Quarterly, 23*(3), 9.

2 Friedman, M., & Gould, J. (2007). Consumer attitudes and behaviors associated with direct-to-consumer prescription drug marketing. *Journal of Consumer Marketing, 24*(2), 100-109.

3 Frosch, D. L., Krueger, P. M., Hornik, R. C., Cronholm, P. F., & Barg, F. K. (2007). Creating demand for prescription drugs: a content analysis of television direct-to-consumer advertising. *The Annals of Family Medicine, 5*(1), 6-13.

4 Betts, K. R., Boudewyns, V., Aikin, K. J., Squire, C., Dolina, S., Hayes, J. J., & Southwell, B. G. (2017). Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. *Research in Social and Administrative Pharmacy*.

5 Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments. (2017). Docket 2017-N-2936, 82 FR 39598.

3. **Description of respondents:**

We intend to recruit a convenience sample of consumers representative of the general population in terms of gender, age, ethnicity, and education, with at least 20% of the sample having a high school education or less. Within medical condition, participants will be randomly assigned to view one of three possible versions of a TV ad, as depicted in Table 1. The major statement of important risk information in each ad will be modified to include only severe, serious and actionable risks. Preceding the major statement will be one of three opening statements designed to frame the seriousness of the risks. Following exposure to the ad, participants will respond to several dependent measures designed to assess perceptions of the product.

Table 1: Design

Type of Framing Statement	Medical Condition 1	Medical Condition 2	Medical Condition 3
Statement 1 ("severe, life-threatening reactions")			
Statement 2 ("serious reactions")			
Statement 3 ("reactions")			

Framing Statement Manipulation

We intend to create the stimuli using existing DTC television ads for the three medical conditions. Stimuli variations for three versions will be achieved by replacing the audio track of the original ad with the revised risk and framing statements. Variations of the framing statement are:

Framing statements:

A. *[Drug] can cause severe, life threatening reactions. These include…"*
B. *[Drug] can cause serious reactions. These include…"*
C. *[Drug] can cause reactions. These include…"*

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

We plan to conduct field the survey between July, 2018 and February, 2019.

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

Recruitment Procedures and Method

Consumer panel members eligible to participate in the current survey will be contacted through an e-mail invitation from the panel managers which will include a secure, non-identifiable link to the web-based survey**.** In each survey invite, panelists are informed about the survey topic in a topline, non-leading way before participation. Recruitment will continue until the target sample size for completed surveys is reached.

The survey sample will be drawn from eligible members based on pre-specified criteria. A pre-profiled sample is used to minimize screen-outs and provide a better quality panelist experience. Once a sample has been selected, email invites are automatically randomized so as not to induce bias. The online opt-in panel provider places a limit on both the number of invites available to all members (normally two or fewer surveys per month) and on the number of qualified completes to avoid excessive survey participation which would otherwise create survey fatigue and potential bias.

Each participant will be randomly assigned to view a television ad for a prescription drug for either rheumatoid arthritis, cancer, or diabetes and will be asked to complete an online survey assessing their benefit/risk perceptions, intentions, and attitudes toward the drug.

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 and that participants can withdraw from the study at any time. All analyses will be done in the aggregate and respondent information will not be appended to the data file used.

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.

No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. Respondent identity and information will remain private to the extent permitted by law. The privacy 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).

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).

7. **Amount and justification for any proposed incentive:**

Participants will receive an incentive as a token of appreciation for participating in the interviews. Panelists are rewarded for taking part in surveys with a structured incentive scheme, reflecting the length of survey and nature of the sample. The incentive amount for the pilot study is $7.50 in e-Rewards currency (estimated to be the equivalent of $1.40) per respondent based on survey length and incidence.

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.[6] The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate.

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[7] 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.[8] 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.

8. **Questions of a Sensitive Nature:**

None.

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

In order to obtain our sample of U.S. adults for the consumer study, we will use a nonprobability panel provided by GfK. GfK will obtain panelists from online panel vendors that use an opt-in process for recruitment. The panel is demographically balanced, including racial and ethnic minorities, a wide range of different age groups, and individuals with relatively less educational attainment. Using the screening questionnaire approved by FDA, 1,953 individuals will be recruited. Participants in the study will be volunteers, and will not be randomly or systematically selected by GfK. FDA does not intend to generate nationally or locally representative results or precise estimates of

---

6 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.

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

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

population parameters from this study. Therefore, the sample used is a convenience sample rather than a probability sample.

The focus of this survey is to assess the impact of the framing statement on consumer assessments of product risks and benefits using experimental methods rather than making population-based inferences. Therefore, a nonprobability panel is a reasonable choice. Nevertheless, we will ensure a demographically diverse sample with respect to gender, age, race/ethnicity, and education. Further, GfK will create population-representative survey weights for nonprobability samples using an approach that draws on exclusive access to their probability-based KnowledgePanel. Specifically, profile information that GfK has on file for a demographically similar set of KnowledgePanel members will be used to provide benchmarks for calibrating the opt-in sample to the probability-based KnowledgePanel. This will ensure the sample has a reasonable degree of diversity in key demographic characteristics.

Table 2 provides a summary of the soft quotas that will help guide recruitment of participants in this study. Soft quotas will not be used to strictly enforce a quota or limit for any category and will not necessarily reflect population-representative sampling. Instead, they will help to guide recruiting a diverse sample during the course of the study. Soft quotas will be assessed at the study level; throughout the recruitment process, the respondent pool will be evaluated to adjust for any demographic over or under sampling. These requirements will be communicated to recruiters who will then make the adjustments to reach the required target populations.

Table 2: Summary of Screening Soft Quotas for Study[a]

Category	Classification	Soft Quotas
Gender	Male	49%
	Female	51%
Race/Ethnicity	White, Non-Hispanic	64%
	Black, Non-Hispanic	12%
	Asian, Non-Hispanic	6%
	Other/Two or more races, Non-Hispanic	2%
	Hispanic	16%
Age[b]	18–24	12%
	25–44	34%
	45–64	34%
	65 or Older	20%
Education	High school graduate or less	20%
	No college/some college	33%
	College graduate	47%

a U.S. Census. (2016). *American Fact Finder.* Retrieved from http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml

b Note: Adjusted age to total 100%

Eligible consumer participants for the pilot study will be adults who speak English. We will exclude individuals who work in the health care, marketing, advertising, or pharmaceutical industries from the sample.

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

Table 3: Estimated Annual Reporting Burden.

Activity	No. of Respondents			Participation Time (minutes)	Burden (hours)
Number to complete the screener	4,008			.033 (2 minutes)	134
Number eligible for interview	3,006				
Number of completes	1,953			.33 (20 minutes)	651
Total					**785**

REQUESTED APPROVAL DATE: June 30, 2018

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff
ila.mizrachi@fda.hhs.gov
(301)796-7726

Kathryn Aikin, Ph.D.
Social Science Analyst
Kathryn.aikin@fda.hhs.gov
301-796-0569

FDA CENTER: Center for Drug Evaluation and Research (FDA/CDER)