B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

For the entire study, 6,650 (1,650 for the pretests, 5,000 for the main studies) participants will be recruited (see Table 1 for a breakdown). Individuals in the main study will include 1,000 prescreened individuals with asthma (Phase 1) and 4,000 prescreened individuals who self-identify as having a weight problem, defined as a BMI of 25 or greater (Phase 2). Study invitations will be sent to individuals with these medical conditions in the existing KnowledgePanel® (see Appendix 4 for the study invitation and reminder emails).

GfK will take the following sampling steps:

1. Identify individuals with the two medical conditions at the rate of no more than one per household;
2. Randomly assign the panel into replicates and then release as many replicates as they think will be necessary under the most optimistic scenario;
3. After a short time in the field (somewhere between a few days and a week), re-evaluate the cooperation rate and then release additional replicates as needed to achieve the required number of completed interviews.

2. Procedures for the Collection of Information

Design Overview

Phase 1 will vary the **exposure** to the messages (*original ad alone* vs. *original + corrective* vs. *corrective ad* alone). The goal of Phase 1 is to examine how exposure to a combination of original and corrective DTC ads affects message recall, message comprehension, perceived drug efficacy, perceived drug risk, and intentions to ask about or use the drug. Specifically, we will compare consumers who see both the original and corrective ad with those

who see only the original ad, only the corrective ad, and neither ad. Participants in the Control condition will see a reminder ad for the product to control for brand name exposure.

Table 5: Design of Phase 1: Original Exposure by Corrective Exposure

	Exposure to Corrective Ad	
Exposure to Original Ad	Yes	No
Yes		
No		Control (Reminder ad)

Phase 2 will examine the **similarity** of the corrective ad's theme and visual elements to those of the original ad (*same ad elements* vs. *some similar ad elements* vs. *different ad elements*) and the **exposure delay** (time) between viewing the original ad and the corrective ad (*no delay* vs. *1 week delay* vs. *1 month delay vs 6 month delay*). The purpose of Phase 2 is to examine whether a corrective ad's ability to correct misinformation is related to (a) corrective ad similarity to the original ad and (b) time delay between original ad and corrective ad exposure.

We will systematically vary these two characteristics to create a study with a 4 (similarity to original ad) x 4 (exposure delay) design (see Table 6).

Table 6: Design of Phase 2: Corrective Ad Similarity by Exposure Time Delay

		Time between Original and Corrective			
Corrective Ad Similarity	Multiple exposure pod (2 viewings per sitting, for a total of 6 exposures*)	None	1 Week	1 Month	6 Months
Same ad elements as original					
Some similar elements as original					
Different ad elements than					

original					
Control (Do not see corrective)*					

*The control condition will be used to examine the impact of time delay on perceptions and intentions.

Prior to conducting the main study, we will pretest the stimuli, questionnaires, and data collection process. The first set of pretests will focus on the stimuli to (a) ensure participants perceive the stimuli as realistic, and (b) ensure participants notice and comprehend the original and corrective messages in the ads. The second pretest will focus on the questionnaires and data collection process. Its purpose will be to (a) ensure that survey questions solicit responses that meet the study's analytic goals and (b) ensure data are captured and stored accurately for each question. The pretests are not intended to affect the study design, sample or burden.

Procedure

All parts of this study will be administered over the internet. A total of 6,650 interviews will be completed. Participants will be randomly assigned to view one version of a DTC prescription drug television ad. Following their perusal of this ad, they will answer questions about their recall and understanding of the benefit and risk information, their perceptions of the benefits and risks of the drug, and their intent to ask a doctor about the medication.

Demographic and numeracy information will be collected. In addition, participants will answer questions about their familiarity with their medical condition. The entire procedure is expected to last approximately 25 minutes in Phase 1 and 1 hour in Phase 2. This will be a one-time (rather than annual) information collection.

Participants

Data will be collected using an Internet protocol. Approximately 1,000 consumers who have asthma will be recruited for Phase 1 of the study. Approximately 4,000 consumers who have self-identified as having a weight problem will be recruited for Phase 2 of the study. Because the task presumes basic reading abilities, all selected participants must speak and read English fluently. Participants must be 18 years or older.

Hypotheses

Phase 1

1. Individuals who see the original ad followed by the corrective ad will have more accurate perceptions of the product's risks and benefits, lower intention to use, less intention to seek information, and less positive perceptions of the ad compared to individuals who see only the original ad.
2. Individuals who see only the original ad will have less accurate perceptions of the product's risks and benefits, higher intention to use, greater intention to seek information, and more positive perceptions of the ad compared to individuals who see only the corrective ad.
3. We will explore the effects tested in the hypotheses to see if they are modified by individual differences and demographic variables. All other analyses are exploratory.

Phase 2

1. Individuals who see the original ad followed by the corrective ad will have less positive perceptions of the product's risks and benefits, lower intention to use, less intention to seek information, and less positive perceptions of the ad compared to individuals who see only the original ad.

    a. This effect will be strongest when the corrective ad is similar to the original ad.

b. This effect will be strongest when the corrective ad is shown close in time to the original ad.

3. We will explore the effects tested in the hypotheses to see if they are modified by individual differences and demographic variables. All other analyses are exploratory.

Analysis Plan

We will conduct ANOVAs (for continuous variables) and chi-squares and logistic regressions (for categorical variables) to test the hypotheses outline above. We will conduct these analyses both with and without covariates (e.g., demographic and health characteristics) included in the model. If a main effect is significant, we will conduct pairwise-comparisons to determine which conditions are significantly different from one another, with Bonferroni-adjusted *p*-values.

Power

The following assumptions were made in deriving the sample size for the study and the pretests: 1) 0.90 power, 2) 0.05 alpha or 0.0125 alpha (Bonferroni-adjusted for four comparisons) and 3) an effect size between small and medium. The table below shows the sample size required to detect differences with effect sizes ranging from conventionally "small" (f = 0.10) to "medium" (f = 0.25) for the comparison between the named group and unnamed group. Because our strictest analysis in both phases involves one degree of freedom and two groups, the following table applies to both phases and both pretests.

Table 7. Power Analysis Calculation.

A priori power analysis to determine sample size needed in F tests (ANOVA: fixed effects, main effects, and interactions) to achieve power of 0.90 (Faul et al., 2007).[1]

[1] Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A, (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods, 39*, 175-191.

		Effect size f*			Effect size f*		
Input							
		0.10	0.15	0.25	0.10	0.15	0.25
	α error probability	0.05	0.05	0.05	.0125	.0125	.0125
	Power (1 – β error probability)	0.90	0.90	0.90	0.90	0.90	0.90
	Numerator df	1	1	1	1	1	1
	Number of groups	2	2	2	2	2	2
Output							
	Critical F	3.85	3.86	3.89	6.25	6.27	6.34
	Denominator df	1,050	466	168	1,429	635	229
	Sample size per cell	**527**	**235**	**86**	**716**	**319**	**116**

*An effect size of 0.10 is traditionally considered small, whereas an effect size of 0.25 is considered medium (Cohen, 1988).[2] Here we have shown three different effect sizes centering around small to medium effects.

The proposed sample size for each arm is 250 for all four tests: Phase 1 main study, Phase 2 main study, stimuli pretesting, and questionnaire pretesting. For Phase 1, we will have 250 participants per cell, with a total of 1,000 participants in the 4 cells represented in the table (a 2 x 2 design). With this sample size, we will be able to detect small to medium effects with an unadjusted *p*-value of .05 and medium effects with a Bonferroni-adjusted *p*-value of .0125.

For Phase 2, we will have 250 participants per cell, with a total of 4,000 participants in the 16 cells represented in the table (a 4 x 4 design). With this sample size, we will be able to detect small to medium effects with an unadjusted *p*-value of .05 and medium effects with a Bonferroni-adjusted *p*-value of .0125.

Stimuli and questionnaire pretesting will be conducted prior to each study phase. As with the main study, the sample size in the stimuli pretesting (n=1,450) is sufficient to detect small differences between the original ad and corrective ad arms and small differences between the three ad similarity manipulations. The sample size in the questionnaire pretesting (n = 200) is sufficient to detect small to medium effects.

[2] Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd Ed). Hillsdale, NJ: Lawrence Erlbaum & Associates, Inc.

3. Methods to Maximize Response Rates and to Deal with Issues of Non-Response

This experimental study will use an existing Internet panel to draw a sample. The panel comprises individuals who share their opinions via the Internet regularly. The participation rate for similar studies is 65-70% percent without additional efforts to convert non-respondents. To help ensure that the participation rate is as high as possible, FDA and the contractor will:

- Design an experimental protocol that minimizes burden (short in length, clearly written, and with appealing graphics);
- Administer the experiment over the Internet, allowing respondents to answer questions at a time and location of their choosing;
- Email a reminder to the respondents who do not complete the protocol four days after the original invitation to participate is sent;
- Provide a toll-free hotline for respondents who may have questions or technical difficulty as they complete the experiment.

4. Test Procedures

Two types of pretesting will be employed as a test of procedures and stimuli. Cognitive testing with nine participants will be used to assess blatant glitches in questionnaire wording, programming, and execution of the study. Following cognitive testing, we will conduct two pretests with a total of 1,650 consumers to ensure that the stimuli are operationalized as planned and questionnaire wording is clear. Finally, we will run the main studies as described elsewhere in this document.

5. Individuals Involved in Statistical Consultation and Information Collection

The contractor, RTI International, will collect the information on behalf of FDA as a task order under a Quick-Turn-Around Research Services contract. Data analysis will be conducted by RTI and by the Research Team, Office of Prescription Drug Promotion (OPDP), Office of Medical Policy (OMP), CDER, FDA. The study team members are: Kathryn J. Aikin, Ph.D., 301-796-0569 (OPDP Project Director), Amie C. O'Donoghue, Ph.D., 301-796-0574 (OPDP Project Co-Director), and Brian Southwell, Ph.D., 919-541-8037 (RTI Project Director).