"Risk and Benefit Perception Scale Development"
(OMB Control Number 0910-0784)

Change Request (83-C)

October 15, 2015

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C). The purpose of this project is to develop and validate risk and benefit perception scales and to explore various methods for measuring perceptions, attitudes and intentions that can be used for OPDP research moving forward. The long-term objective is to improve the validity and reliability of risk and benefit perception measures to help ensure effective communication of product information in DTC ads. We are requesting an amendment to adjust the number of participants in Pretest 2 of this project. We are not seeking to change the study procedure.

The estimated annual hourly burden, formerly estimated as 6,310 hours has increased by 563 hours to a total estimated annual hourly burden of 6,873 hours. The increase to pretest hours is due to a programming error on the part of the contractor that resulted in a failure to properly randomize participants in Pretest 2. Lack of random assignment to condition means it is not possible to determine if potential differences between conditions are due to our independent variables or the characteristics of the participants in each condition. Thus, we will not be able to use the data from Pretest 2 to determine which items adequately discriminate between levels of the independent variable, drug risk and efficacy. A total of 543 participants completed Pretest 2 before the programming error was found. This was close to the original burden estimate for Pretest 2, so we are requesting to re-run Pretest 2 again with 500 additional participants in order to have usable data. In addition, based on the pretest numbers, we estimate that we may see more overage in the main study than originally estimated. As a result, we have increased the hours for the main study in order to account for this overage. A revised burden table is presented below.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response[1]	Total Hours
Pretest screener	23,000	1	3,000	0.033 (2 minutes)	99
Main study screener	20,000	1	20,000	0.03 (2 minutes)	600
Pretest	[1]1,648	1	1,648	.5 (30 minutes)	824

Main Study	10,700	1	10,700	.5 (30 minutes)	5,350
Total	35,348	1	35,348	--	6,873

[1]With online surveys, several participants may be completing the survey at the time that the total target sample is reached. Those participants are allowed to complete the survey, which can result in the number of completes going slightly over the target number. Based on two waves of pretesting, we estimate this amount at approximately 7% for the main study waves. Thus, if our target is 10,000, we have rounded up by an additional 700 to allow for some overage in each of four waves of testing.

Table 2.—Adjustments to Total Hours

Activity	Adjustment to Total Hours	Notes
Pretest screener	39 additional hours	Change described above
Main study screener	0	No Change
Pretest	274 additional hours	Change described above
Main Study	250 additional hours	Change described above
Total	563 additional hours	