



**December 16, 2009**

**SUBJECT: MEMO TO THE PAPERWORK REDUCTION ACT FILE**

Questions between FDA and OMB:

December 7, 2009

1. The sample size proposed for the pretesting and main study seems very excessive. Pretesting is a good idea, but it is not clear why they need 700 people in each of two rounds for a pretest. It is not clear why 50 or so per round would not give adequate information.

We'd like to be able to draw conclusions from the pretests regarding the success or failure of our manipulations. This will give us the opportunity to tweak the manipulations prior to fielding the study with a large sample. We'd also like to get an estimate of the standard error in each cell. We need an adequate sample size to do this. A sample size of 50 is approximately 3 participants per cell, which is not sufficient to draw conclusions. We plan to have 675 participants per sample (15 conditions \* 45 participants per cell), a number that we think is necessary to draw appropriate conclusions from the pretests.

2. For the main study, the power analysis shows they wanted about 250 cases per group and it is not clear how this translates into the 6000 they plan to have. Furthermore, B.1 refers to only 1500 people in the study.

B.1 is a typo. The number here and in the burden chart should read 5,250 (15 conditions \* 100 participants per cell for the high blood pressure sample + 15 conditions \* 250 participants per cell for the general population sample). We will add the following statement to the power analysis

section, "A per group sample size of 100 should provide adequate power to detect medium effect sizes across our designs, and smallish effect sizes in some of our designs."

3. On the questionnaire, it seems that items Q3 and Q5 are asking for the same thing, as are Q13 and Q14.

That is correct. Two questions is the minimum necessary to estimate reliability.

4. Q20-24 are likely coming from KN, but Q23 should not refer to "ethnic group;" these are races.

We will replace the word "ethnic group" with the word "race."