- When does FDA expect that data from phase I will be available?

Data collection for Study 1 has been placed on hold by FDA's contracting office because the contractor for this study failed to collect data on nine of the study variables. We are currently pursuing action against the contractor, which may include refielding of Study 1. If the study is refielded, data collection for Study 1 will occur concurrent to or after Studies 2 and 3, to be completed by September, 2008. Despite this unfortunate situation, we have learned a great deal from the pretesting and fielding of study 1 which will inform the data collection for studies 2 and 3.

- Please provide a brief description of "methods to maximize response rates and to deal with issues of non-response" (e.g., refusal conversion techniques, more on recruitment, etc.) The current written discussion in the supporting statement is a little sparse. Also, what is FDA's estimated RR for this collection? Does FDA have plans to analyze nonresponse bias?

Respondents will be recruited by professional market research firms located within shopping malls across the country. Trained interviewers will approach shoppers who look somewhat overweight in various locations in common areas of the malls (Note that screening questions are designed to obscure the purpose of the study, thus minimizing potential respondent discomfort). They will ask a series of screening questions to determine eligibility for the study and then ask if respondents would like to participate in the study.

Unlike telephone surveys, wherein phone numbers can be called repeatedly to increase response rate, it is not feasible for interviewers to stalk nonresponders around the mall to achieve compliance. Thus, responses will be obtained by approaching additional people rather than harassing existing refusers. Given the mode of administration, interviewers are unable to analyze nonresponse bias.

It should be noted that these studies are experimental manipulations and participants will be randomly assigned to one of several experimental conditions. Thus, factors related to projection from a sample to a population are non-issues. A mall-intercept methodology is a long-accepted practice for such experimental research on consumer information processing of marketing communications.

- In the questionnaire, item c "You are overweight and need to lose more than 15 pounds?" Please remind me whether this needs to be based on diagnosis from a doctor (consistent with a and b) or whether FDA will accept "self-diagnosis" by the respondent of the need to lose weight?

We will ask participants if they have ever been told by a doctor or other healthcare professional that they are overweight or need to lose more than 15 pounds.