B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

For each proposed study, FDA will provide a description of the sample frame used to select the participants, the screening questionnaire/protocol, and moderator guide/script. Below we provide a general description of our data collection methods.

1. Respondent Universe and Sampling Methods

Focus group studies are directed group discussions that enable skilled observers to infer the underlying views and assumptions of the group members that are expressed in the discussion. Focus group research relies on qualitative methods and is not intended to yield results that can be generalized to the overall population. Results of this research will not be used to make statements representative of the universe of study, to produce statistical descriptions (careful, repeatable measurements), or to generalize the information beyond the scope of the sample.

For these focus group studies, we may use quota sampling to select a convenience sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience. Response rate is not applicable to quota sampling because this type of sampling results in a nonprobability sample which is not representative of the population. In these studies, we will usually initially contact respondents by telephone or through the mail; over-recruiting is done to compensate for not following up with non-respondents. In certain cases, cluster sampling may be used to form focus groups for specific purposes in which a population grouped by household or by residence may be desired.

2. Procedures for the Collection of Information

Focus groups, or group interviews, are used to obtain insights into target audience perceptions, beliefs, and attitudes in the early stages of the communication process (i.e., in concept, strategy, and materials development.) Focus groups are usually composed of 8 - 10 people who have characteristics similar to the target audience or to subgroups of the target audience. The groups are conducted by a professional moderator who keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion outline, which allows him/her to change direction as the discussion unfolds and new topics emerge. .

Focus groups will generally be held in locations that participants travel to by car or short-range public transportation. When a specialized population of participants is necessary, such as physicians with expertise in a particular specialty, focus groups may be held at scientific or academic meetings. Some geographic diversity may be built in where such diversity is deemed appropriate by conducting focus groups in different regions across the 48 contiguous United States. Sometimes, however, when there is a particular need for rapidly gathering information from people who are located across the United States, focus groups may be held by telephone and may use Web technology to decrease burden and increase efficiency.

All data collection and analysis will be performed in compliance with OMB standards and guidance, Privacy Act, and Protection of Human Subjects requirements.

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

To reduce the number of no-shows, scheduled focus group participants will be sent a reminder letter and/or telephone call giving the time of the interview and directions to the location. As described in Part A of the supporting statement, participants will receive a stipend. As previously noted, the information collected under this generic clearance will be qualitative; these methods to deal with non-response are adequate for this purpose.

4. Test of Procedures or Methods to be Undertaken

Before each information collection is implemented, we will pilot test the moderator guide and study protocol. Lessons from the pilot test will be identified, and changes as necessary will be incorporated into the moderator guide and study protocol. All pilot tests will involve internal staff or no more than nine members of the public. If we require more than nine pretest respondents from the public, we will submit the pretest protocol for review and approval under this generic clearance.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Focus group studies are qualitative in nature and do not require statistical consultation.

In general, FDA plans to use a contractor to for recruiting and conducting focus group discussions. They will also provide an analysis of the information and provide a summary report. FDA has a contract for this purpose currently with Harvrey Marketing Inc., which is expiring 30 September 2011.