

United States Food and Drug Administration

Focus Groups as Used by the Food and Drug Administration

OMB CONTROL NO. 0910-0497

SUPPORTING STATEMENT

**Part B. Statistical Methods**

1. Respondent Universe and Sampling Methods

Study participants will include members of the general public, health care professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic. To identify potential variation according to regional differences, each information collection will be conducted at multiple sites in the U.S.

The focus groups will generate qualitative data and the results from the focus groups will not be used to make statements representative of the universe of study, to produce statistical descriptions (careful, repeatable measurements), or to generalize the data beyond the scope of the sample.

Focus groups are a valuable tool for qualitative data collection; they allow for the efficient collection of information, in-depth exploration of major themes and perspectives, and help develop new insights. Some of these benefits are not available through traditional quantitative surveying. The accuracy, reliability, and applicability of the results of these focus groups will be adequate for this purpose and as such, the samples associated with this collection are not subjected to the same scrutiny as scientifically drawn samples where estimates are published or otherwise released to the public. The specific sample planned for each individual collection and the method for soliciting participation will be described fully in each collection request.

Data collection will consist of a focus group methodology. In a focus group, a small group of people (typically 8-12 individuals) engage in a discussion of selected topics of interest typically directed by a moderator who guides the discussion in order to obtain the group's opinions, particularly the why's and how's behind a behavior or attitude at question (Edmunds, 1999; Krueger & Casey, 2000). Focus groups capture the collective insight of a group while preserving individual preferences. In this setting, participants can describe their experiences and preferences without the limitations of preset response categories. Furthermore, focus groups produce rich data complete with nuances that often may be obscured in quantitative data collection techniques. Focus groups are used to produce qualitative data to help develop, design, and interpret quantitative results obtained from surveys or experiments.

Since focus group is a qualitative research methodology, statistical methods will not be employed to analyze focus group data, as it is not appropriate to report the percentage of focus group participants who expressed a particular view (Carey, 1995; Morgan, 1995; National

Cancer Institute, 2002; Webb & Kevern, 2001). Typically, not every participant in a group comments on every issue discussed (Carey, 1995), and the course of discussion will vary across groups, with some topics emerging in one group and not in another (Carey, 1995; Morgan, 1995). Instead, descriptors such as “many,” “several,” and “few” will be used to qualitatively describe the relative number of participants or groups who expressed a particular view.

## 2. Procedures for the Information Collection

The typical steps for an information collection is as follows.

a. Screen and recruit participants, using current and pertinent databases such as local telephone directories, American Medical Association Masterfile®. Prior to group discussion, consent forms will be signed by all participants.

b. Conduct focus group discussion, not to exceed two hours, under the direction of one or more professionally trained moderators. The discussion will generally follow OMB-approved guide Discussions are usually audio- and video-recorded to aid data analysis. When needed, discussions will also be streamed from a facility to other locations to allow remote observation. A verbatim transcript will be compiled for each group.

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

Since focus group is a qualitative research methodology, response rate is not a relevant issue. Participants will be recruited from sources which offer an abundant supply of the target audience. In the past, physician participants have been recruited from a sample of the American Medical Association (AMA) Masterfile®, which includes all licensed U.S. physicians, both AMA members and nonmembers. Lay participants are generally recruited from the database of the commercial research facilities where the groups are held.

To minimize the possibility of having too few appropriate focus group participants (thereby forcing group cancellation), as many as 25% more participants are invited to each group than are needed. In the event that too many participants report, excess participants will receive the honorarium and will be dismissed.

## 4. Tests of Procedures or Methods to be Undertaken

Pretesting of focus group protocols may be done with internal staff, a limited number of external colleagues, and/or customers who are familiar with the programs and products. If the number of pretest respondents exceeds nine members of the public, the Agency will submit the pretest focus group protocol for review under this generic clearance.

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

FDA staff will be responsible for developing the moderator guides with advice, if needed, from data collection contractors. FDA staff will analyze the data.