United States Food and Drug Administration

Generic Clearance for Qualitative Data to Support
Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

OMB Control No. 0910-0891

SUPPORTING STATEMENT

Part B. Statistical Methods

Data collection will consist of individual interviews, small group discussions, focus groups, and observations, i.e., qualitative methods. In interview style qualitative studies, an individual or small group of people (typically 2-12 individuals) engage in a discussion on selected topics of interest typically directed by a moderator/interviewer who guides the discussion in order to obtain the person or group's opinions, particularly the "whys" and "hows" behind a behavior or attitude at question (Edmunds, 1999; Krueger & Casey, 2000). Interviews and focus groups capture the insights of an individual, or the collective insight of a group while preserving individual preferences; participants can describe their experiences and preferences without the limitations of preset response categories. Observational studies can provide information on the "real world" behavior and practices of individuals. Qualitative methods often produce rich data complete with nuances that often may be obscured in quantitative data collection techniques. Qualitative methods can also be used to help develop, design, and interpret quantitative results obtained from surveys or experiments.

Since individual interviews, focus groups, and observations are qualitative research methodologies, statistical methods will not be employed to develop samples or to analyze the data (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.

1. <u>Respondent Universe and Sampling Methods</u>

   Study participants will include members of the general public and stakeholders with an interest in food and cosmetic products, dietary supplements, and animal food and feed. Inclusion and exclusion criteria will vary depending on the research topic. To identify potential variation according to regional differences, information collections may be conducted at multiple sites in the United States when appropriate.

The interviews, focus groups, and observations will generate qualitative data, and the results will not be used to make statements representative of the universe of study or to produce statistical descriptions.

The specific sample planned for each individual collection and the method for soliciting participation will be described fully in each collection request.

2. Procedures for the Collection of Information

The typical steps for qualitative information collections are as follows:

1. Screen and recruit participants using current and pertinent databases such as local telephone directories and lists maintained by recruitment facilities. Prior to group discussion, informed-consent forms will be reviewed by all participants as appropriate.

2. Conduct the interview or group discussion, not to exceed 2 hours, under the direction of one or more professionally trained interviewers or moderators. The discussion will follow OMB-approved guidelines. 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 interview or group.

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

These are qualitative research methodologies. Participants will be recruited from sources which offer an abundant supply of the target audience. In the past, participants have been recruited from commercial databases or through advertisements placed in a newspaper or online. Since results are not statistically generalizable, participation rates will be flexible based on the target audience and research question(s).

To minimize the possibility of having too few participants, as many as 25 percent more participants are invited than are needed. In the event that too many participants report, excess participants will be dismissed.

4. Test of Procedures or Methods to be Undertaken

Pretesting the instruments to be used in these qualitative studies may be done with internal staff or a limited number of external colleagues. If the number of pretest participants exceeds nine members of the public, the Agency will submit the pretest 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 and screening criteria with advice, if needed, from data collection contractors. Sometimes, contractors compile top line findings in the final report if necessary.