Data To Support Drug Product Communications as Used by the Food and Drug Administration

(0910-0695)

SUPPORTING STATEMENT

B. Statistical Methods

1. Respondent Universe and Sampling Methods

Testing includes various methods and approaches. The method(s) chosen for use depend on the nature of the message or materials tested, as well as their intended audience. Recommended methodologies and sample sizes are based on a review of the relevant literature, consultation with experts in the field, and previous studies, regardless of source.
In general, testing relies on qualitative methods and is not intended to yield projectable results. However, communication messages will be designed and marketed with specific audiences in mind. In qualitative studies, quota sampling is often used 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 qualitative studies, respondents are usually initially contacted by telephone or through the mail; over-recruiting is done to compensate for not following up with non-respondents.

Where quantitative methods are used, information collection activities will target the particular audiences with statistical sampling procedures employed to identify potential respondents. Mail, telephone and Internet surveys typically will seek a convenience sample that nonetheless has a reasonable diversity in key demographic characteristics such as age, gender, education, and race/ethnicity. Telephone samples may be selected with random digit dialing

(RDD) techniques, lists, or with stratified sampling of telephone exchanges. For these samples, each sampling unit (e.g., telephone household or respondent within a household) has a known non-zero probability of selection.

2. Procedures for the Collection of Information

Questions in all testing methodologies include the following:

- Standard measures of communications that are designed to assess to what degree the message was successful in communicating information. These questions include measures of main idea recall, comprehension, believability, personal relevance, and likes and dislikes.
- Questions tailored for the communication message to address any special concerns the producer of the message may have (e.g., the effect and /or appropriateness of graphic depictions of negative health outcomes).

The methodologies planned for use in this submission will follow standard state-of-the-art approaches adapted from marketing and communications research. In this context, the term "testing" refers to testing messages, strategies, and communication materials, and should not be confused with "pretesting of questionnaires" prior to their full-scale use. The following methodologies will be used:

Individual In-depth Interviews. Individual in-depth interviews are used to elicit attitudes and perceptions that offer insight into better understanding critical influences on people's mental models (i.e., belief structures), or for testing message concepts, draft materials, and communication strategies. Individual in-depth interviews are ideal when the information in question requires in-depth probing or when individual rather than group responses are considered more appropriate. This methodology is appropriate for determining target audience attitudes, beliefs, and feelings, particularly those addressing potentially sensitive or emotional topics. In-

depth interviews are also cost-effective in eliciting comments on print materials. Individual in-depth interviews can either be conducted on-line at a designated Internet location, conducted in-person, or conducted over the telephone. In some cases, respondents can be sent material in advance, asked to read them, and told that someone will call to get their opinion.

Respondents for in-depth interviews are recruited from members of the target audience for the particular message or print material being tested. They are also recruited based on meeting other appropriate screening criteria, which may include their willingness to be interviewed. Specific written instructions in the form of a screening questionnaire are used during the recruitment process. The interviews themselves are conducted by skilled interviewers who follow a prescribed discussion outline. A minimum of 20-25 respondents are queried in tests using this method of data collection; in a standard test, 50 interviews are conducted. In-depth interviews are generally 30 to 45 minutes in length.

Intercept Interviews. Intercept interviews involve positioning interviewers at a central point or location commonly used by individuals who make up the desired target audience. In an intercept interview, people are randomly asked to participate in a message or strategy survey about health. This methodology is usually employed when reactions are desired on a non-sensitive topic over a fairly short period of time. Intercept interviews may be done in person or by telephone:

(a) *Central Location Intercepts*. In the case of central location intercepts, the point of interception could be some place such as a shopping mall or health clinic. After several initial screening questions, participants are asked a series of questions, often in relation to draft material they have been shown. This is followed by an interview of up to 20 minutes in length, depending on the nature and complexity of the topic and material presented.

(b) *Telephone Intercept Interviews*. With telephone intercepts, the intercept point is usually the terminus of a call-in number (e.g., a 1-800 number). The pertinent FDA Center will have one or more 1-800 numbers to receive calls on drug-product-related topics. As an add-on to some of these calls, several brief questions about communication messages can be asked, providing valuable input on whether FDA messages are understood and accepted. These telephone intercept interviews, conducted on a simple random sample basis, may range in length from less than a minute to several minutes.

Focus Groups. 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 are valuable in exploring consumer reactions to message concepts before additional resources are put into their development.

Self-Administered Surveys. Self-administered surveys can be used to validate belief structures derived from mental models research results, or to test drafts of FDA concepts and materials. Surveys can either be mailed to respondents along with the draft being tested, accessed on-line at a designated Internet location, or distributed to respondents gathered at a central location. Internet surveys can be administered to online panels and may use experimental designs to test hypotheses about the relative efficacy of communication messages. Willing participants recruited from the target audience are randomly assigned to treatment or control conditions.

After being exposed to the communication, participants are asked to provide information about their recall, emotional and cognitive reactions, beliefs, and behavioral intentions. When this method of pretesting is used, having at least 100 respondents per condition is desirable. In some cases, a follow-up survey may be conducted within a reasonable timeframe (e.g., one week) with those who complete the baseline survey.

When central location surveys are employed, people frequenting an expected location of the target audience are randomly stopped and screened to determine whether they meet the pre-determined selection criteria. When this method of pretesting is used, at least 50 respondents are included; using approximately 100 respondents is desirable.

When projects require in-depth responses on a few questions, self-administered surveys may be enhanced through remote oversight by an interviewer with the capability of adding pop-ups onscreen to probe answers by respondents.

FDA does not intend to generate nationally representative results or precise estimates of population parameters using these surveys.

Gatekeeper Review. When public education materials are distributed to their intended audiences through health professionals or intermediary organizations, the input of these groups to the concepts and materials is critical to a program's success. As a result, these intermediaries, or gatekeepers, are often queried through self-administered questionnaires as part of the testing process. Twenty-five to 50 gatekeepers are generally interviewed as part of a materials test. The questionnaire information is complementary to that requested of target audience members.

Omnibus Survey. An omnibus survey is a telephone or mail-back interview survey in which different organizations add questions to a single questionnaire, thereby sharing the cost. This technique uses random selection from an address list to speak to approximately 1,000

respondents with the intent of having a reasonable degree of diversity in key demographic characteristics such as age, gender, education and race or ethnicity. FDA does not intend to generate nationally representative results or precise population parameters using these surveys. Because these surveys are conducted on a weekly or bi-weekly basis, they are an efficient way to obtain test data from a larger number of consumers in a short period of time. To get such a quick and cost-effective turnaround, however, the vendor can make up to only four callbacks, resulting in a lower response rate than for custom surveys, where additional callbacks are made. Generally, for the most cost-effective approach, computer-assisted telephone interviewing (CATI) is used.

Because of the increase in the prevalence of adults who principally use wireless telephones, random selection from an address-based list, which increases access to wireless users, shall be used as appropriate to limit coverage biases that could potentially be introduced by landline-only telephone surveys. Results from the July-December data collection of the 2009 National Health Interview Survey suggest that one out of every six (16.3%) American adults live in mostly wireless households.[1] Moreover, ethnic differences have been diminishing. The percentage of adults living in mostly-wireless households in late 2009 varied between 16.2% for non-Hispanic black adults to 19.6% for non-Hispanic Asian adults.

FDA recognizes that, for the purposes of this generic clearance, omnibus surveys should only be used for internal purposes (e.g., to better understand consumer perceptions before going public with marketing campaigns). Omnibus survey results will not be used for program evaluation purposes, or to make policy or regulatory decisions.

[1] http://www.cdc.gov/nchs/data/nihs/earlyrelease/wireless201005.htm#wireless

For all methodologies, professionally recognized procedures will be followed in each information collection activity to ensure high quality data. Examples of these procedures include the following:

- A minimum of ten percent of telephone interviews will be monitored by supervisory staff;
- Data from mail or paper-and-pencil surveys will be computerized through scannable forms or checked through double-key entry;
- Observers will monitor focus groups, and focus group proceedings will be recorded; and
- Data submitted through online surveys will be subjected to statistical validation techniques (such as disallowing out-of-range values).

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

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

In the case of data collection activities that involve interviews or telephone, mail, and in-person surveys, several procedures proven effective in previous studies will be used to maximize response rates:

- Potential respondents will be informed about the importance of these studies and encouraged to participate through a variety of methods, including letters of support from key individuals.
- Experienced, highly-trained staff will moderate all focus groups and conduct all interviews and surveys.
- Interviewers will participate in thorough training sessions. Training topics will include study objectives, question-by-question reviews of data collection instruments, strategies for engaging respondents, role playing, and techniques for fostering respondent cooperation and survey completion.

- Well-defined conversion procedures will be established. If a respondent for a survey declines to be interviewed, a member of the contractor's conversion staff will contact the respondent to explain the importance of their participation. Conversion staff members are highly experienced telephone interviewers whose style and persuasive abilities have demonstrated success in eliciting cooperation. They receive a pay differential to acknowledge these skills, which also serves as an incentive to the interviewer pool, whose completion rates are carefully monitored to assess their qualifications to serve as conversion staff.
- For telephone interviews, outgoing calls that result in a disposition of "no answer," a busy signal, or an answering machine will be automatically rescheduled for subsequent attempts. Up to 20 outgoing calls to a given number with dispositions of the sort listed will be made before declaring it a non-response.
- Should a respondent interrupt an interview for any reason, such as needing to attend to a personal matter, the interviewer will reschedule or, in the case of telephone surveys, a predictive dialer will automatically reschedule the interview for completion at a later time.
- Fielding for telephone and mail surveys will occur over at least a six-week period. Based on past experience, this time frame will allow the contractor to reach individuals who are on vacation, out of the home during irregular periods, have a temporarily disconnected telephone, or who are not answering the phone for some other reason.
- Interview staff will be able to provide respondents with the name and telephone number of an official at FDA. This official will confirm with respondents the importance of their participation.
- A dedicated toll-free number will be established at FDA or a contractor's office to allow potential respondents to hear a pre-recorded message to confirm a study's legitimacy.

For mail surveys, a number of techniques will augment response rates:

- A self-addressed, stamped return envelope will be enclosed with each survey.
- Surveys will be mailed to respondents using stamps instead of metered postage labels.
- Creative and attractive graphics will be used to attract the attention of respondents (e.g., different colored paper for successive survey iterations).
- Hand-signed cover letters will be sent with each survey.
- Follow-up mail (up to 7 mailings) or phone contacts (up to 20 call-backs) will be made to encourage participation; participant objectivity will be encouraged by reminding participants about the importance of providing both negative and positive feedback.
- Respondents will be allowed the option of faxing back completed surveys (and possibly offered the option of completing the survey online).

4. Test of Procedures or Methods to be Undertaken

Before each information collection is implemented, a contractor will pilot test the instrument(s) and method of data collection. Lessons from the pilot test will be identified, and changes as necessary will be incorporated into the instrument and method. All pilot tests will involve no more than nine individuals unless OMB clearance is sought for more than nine.

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

We held discussions on the specifications for FDA generic clearances for communications testing of tobacco products and medical devices (OMB 0910-0674 and OMB 0910-0678, respectively) that have specifications that are identical to those in this generic clearance.