B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

Pretesting includes various methods and approaches. The methods 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 a baseline of data gathered over many years of pretesting materials on cancer and other negative tobacco-related health outcomes among professional, patient, and public audiences.

In general, pretesting relies on qualitative methods and is not intended to yield results that are statistically projectable. However, tobacco communication messages will be designed and marketed with specific audiences in mind (e.g., 13-17 year olds, 18-24 year olds, tobacco users who intend to quit, non-users, health care professionals, and tobacco retailers). 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, all respondents are 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 these particular audiences with statistical sampling procedures employed to identify potential survey respondents. Mail, telephone, and Internet surveys will seek a convenience sample that nonetheless has a reasonable degree of diversity in key demographic characteristics such as age, gender, education, and race/ethnicity. FDA does not intend to generate nationally representative results or precise estimates of population parameters using these surveys.. Telephone samples may be selected with random digit dialing (RDD) techniques, 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.

B.2. Procedures for the Collection of Information

Questions in all pretesting 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 pretesting submission will follow standard state-of-the-art approaches adapted from marketing and communications research. In this context, the

term pretesting 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 pretesting 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 it, 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, including 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 pretests using this method of data collection; in a standard pretest, 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 comprise the desired target audience. In an intercept interview, people are randomly asked to participate in a message or strategy pretest about health. This methodology is usually employed when pretest 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 someplace like a shopping mall, a smoking cessation clinic, or a smoking shelter of a large "smoke-free" building. 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). FDA's Center for Tobacco Products will have one or more 1-800 numbers to receive calls on tobacco-related topics. As an add-on to some of these calls, several brief questions about tobacco 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 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 pretest drafts of FDA concepts and materials. Surveys can either be mailed to respondents along with the draft being pretested, accessed on-line at a designated Internet location, or distributed to respondents gathered at a central location. FDA does not intend to generate nationally representative results or precise estimates of population parameters using these surveys.

Internet surveys can be administered to online panels and may use experimental designs to test hypotheses of 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 (for example, a smoking cessation clinic) 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.

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 pretesting process. Twenty-five to 50 gatekeepers are generally queried as part of a materials pretest. The information included in the questionnaire is complementary to that requested of target audience members.

Omnibus Survey. An omnibus survey is a telephone interview survey in which different organizations add questions to a single questionnaire, thereby sharing the cost. This technique uses random-digit-dialing (RDD) 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/ethnicity. FDA does not intend to generate nationally representative results or precise estimates of population parameters using these surveys.. Because these surveys are conducted on a weekly or bi-weekly basis, they are an efficient way to obtain pretest 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 to complete the interviews.

Because of the increase in the prevalence of adults with only wireless telephones, cell-phone survey methodology may be used to limit coverage biases that could potentially be introduced by landline-only telephone surveys. Results from the 2006 National Health Interview Survey suggest that one out of every eight American adults live in households with only wireless telephones. The percentage of wireless-only households is highest among younger adults (25% of 18 to 24 year olds, and 29% of 25 to 29 year olds). Furthermore, results indicate that wireless-only adults are more likely to be current smokers than adults living in households with a landline (30% vs. 19%).[1] Given the known differences in demographics and lifestyle preferences between wireless-only and landline adults, cell-phone surveys offer a way to reduce this potential problem of coverage bias.

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 evaluation purposes, or to make policy or regulatory decisions.

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 10 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 on-line 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.

B.3. <u>Methods to Maximize Response Rates and Deal with Non-response</u>

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:

[1]"Wireless Substitution: Early Release of Estimates Based on the National Health Interview Survey, July – December 2006. (PDF)" Blumberg, Stephen J., and Julian V. Luke. May 14, 2007a. Report by the U.S. Centers for Disease Control and Prevention.

- 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 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 on-line).

B.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.

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

Conrad Choiniere in FDA's Center for Tobacco Products, among others, including contractors who may be chosen to collect formative pretesting information, will be responsible for the design of statistical and sampling procedures undertaken as part of these data collection activities.

C. ATTACHMENTS

1. H.R. 1256, The Family Smoking Prevention and Tobacco Control Act
2. The Federal Food Drug and Cosmetic Act, Section 1003(d)(2)(D)
3. The Public Health Service Act, Section 301
4. 60-Day Federal Register Notice
5. Statement of Exemption from 45 CFR 46