

UNITED STATES FOOD & DRUG ADMINISTRATION

Data Collections to Support Drug Product Communications

OMB Control No. 0910-0695 – Generic Clearance - EXTENSION

**SUPPORTING STATEMENT – Part B: Statistical Methods**

1. Respondent Universe and Sampling Methods

Communication studies include various methods and approaches. The method(s) chosen depends on the nature of the topic, messages or materials; research questions to be answered and intended audience(s). Recommended methodologies and sample sizes are determined by FDA social scientists/communication experts based on a review of the relevant literature, consultation with external experts, and previous studies, regardless of source.

Communication studies often rely on qualitative methods that are not intended to yield generalizable 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 through requests sent to online panels, where over-recruiting is done to compensate for non-responsive participants.

Where quantitative methods are used, information collection activities will be conducted with members of the target audience with statistical sampling procedures employed to ensure representation from members of the target audience. Mail, telephone, and internet surveys typically will seek a convenience sample that has reasonable diversity in key demographic characteristics such as age, gender, education, race/ethnicity, and geographic location. For any method used, each sampling unit will have a known non-zero probability of selection.

For both qualitative and quantitative methods, online panel providers may be used to recruit participants. Online panels will be composed of individuals who have been pre-screened for their willingness to participate in online surveys who will then be invited to respond to the survey opportunity. The online panel provider may use other methods (e.g., social media) to recruit additional participants as needed to supplement their existing panels for a particular study. Telephone sampling may also be employed using random digit dialing (RDD) techniques lists, or with stratified sampling of telephone exchanges.

2. Procedures for the Collection of Information

The methodologies planned for use in this submission will follow standard approaches adapted from marketing and communications research. The following methodologies will be used:

*Individual In-depth Interviews:* Individual in-depth interviews are used to elicit attitudes and perceptions, experiences, and behaviors that offer insight into better understanding critical influences on people's mental models (i.e., belief structures); or for study message concepts, draft materials, and communication strategies. Individual in-depth interviews are ideal when the information in question requires in-depth probing, to follow up on focus group findings that may need clarification or more detailed or specific information, or when individual rather than group responses is 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 online through platforms such as Zoom, in person at a facility, or 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. A screening questionnaire is used during the recruitment process to ensure potential participants meet the target audience requirements. The interviews themselves are conducted by skilled interviewers who follow a discussion guide. In-depth interviews are generally 45 to 60 minutes in length.

*Intercept recruitment:* Intercept recruitment involve positioning recruiters at a central point or location commonly used by individuals who make up the desired target audience. In intercept recruitment, people are asked to participate in a study about a topic of interest. This methodology is usually employed when reactions are desired on a topic over a fairly short period of time. Intercept interviews may be done in person:

- **Central Location Intercepts.** In the case of central location intercepts, the point of interception could be a place such as a shopping mall or health clinic. After initial screening questions, participants can be asked to respond to a series of questions in relation to material(s) they have been shown, asked to participate in an in-person interview on a topic of interest, or asked to participate in a study at a later time.

*Focus Groups:* Focus groups, or group interviews, are typically used to obtain insights into target audience perceptions, beliefs, attitudes, knowledge, behaviors, etc., especially in the early stages of the communication process. Focus groups are usually composed of 8 to 10 people who have characteristics of the target audience or to subgroups of the target audience. The groups are conducted by a professional moderator who facilitates the discussion and keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion guide, which allows him/her to change direction as the discussion unfolds and new topics emerge. Focus groups are valuable for their interactivity, allowing participants build on and/or disagree with others' ideas, thus providing a more complete understanding of consumer reactions to topics and concepts.

*Self-Administered Surveys:* Self-administered surveys are used to gain representative findings and can be used to validate belief structures derived from mental models research

results, or to study drafts of FDA concepts and materials. Surveys can be administered to respondents online, which is most common, gathered at a central location, or mailed. Surveys may ask questions about a topic or materials of interest or use experimental designs to study the efficacy of communication messages or strategies. For example, participants can be randomly assigned to treatment or control conditions and after being exposed to a communication material, are asked to provide information about their knowledge, recall, emotional and cognitive reactions, beliefs, and behavioral intentions. 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.

*Gatekeeper Review:* The input of health professional, patient advocacy or other organizations' memberships may be sought about relevant drug topics or public education materials. As a result, these intermediaries, or gatekeepers, are often queried as part of the study process.

*Omnibus Survey:* An omnibus survey is a telephone or mail-back interview survey in which different organizations add questions to a single questionnaire, thereby decreasing the burden to participants and allowing the costs to be shared by the organizations. This technique uses selection from an address list to speak to respondents with the intent of having diversity in key demographic characteristics such as age, gender, education and race or ethnicity.

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 2022 National Health Interview Survey suggest that seven in 10 (71.7%) American adults live in wireless-mostly households.<sup>1</sup> The percentage of adults living in wireless-mostly households in late 2022 varied between 69.5% for non-Hispanic black adults to 73% for non-Hispanic Asian adults.

For all methodologies, professionally recognized procedures will be followed in each information collection activity to ensure high-quality data. Examples of these procedures may 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 monitoring focus groups and/or interviews, either in real-time and/or through audio/video recordings,
- In-depth interviews and focus group proceedings will be recorded and transcribed.
- Data submitted through online surveys will be subjected to statistical validation techniques (such as disallowing out-of-range values).

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<sup>1</sup> <https://www.cdc.gov/nchs/data/nhis/earlyrelease/wireless202305.pdf>

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.

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, which may include notes of support from key individuals.
- Potential participants will be notified the study is being conducted on behalf of the U.S. FDA.
- Experienced, highly trained staff will moderate all focus groups and conduct all interviews and surveys.
- Should a participant not be able to attend a scheduled interview, the recruiter will attempt to reschedule.
- Participant recruiting will be conducted for as long as needed to fill the pre-identified sample size and target audience criteria.
- Fielding for self-administered surveys will be conducted for as long as needed to fill the pre-identified sample size and target audience criteria.
- For participants with questions or those who wish to verify a study's legitimacy, they will be provided with the name, telephone number, and email address of the study principal investigator or an official at FDA.

For mail surveys, a number of techniques may be used to augment response rates:

- A self-addressed, stamped return envelope or a link provided for electronic responses.
- Stamps instead of metered postage labels.
- Creative and attractive graphics to help attract attention.
- Hand-signed cover letters.
- Follow-up mail (up to 7 mailings) or phone contacts (up to 20 call-backs) to encourage participation.
- Reminders of the importance of both negative and positive feedback.

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

Before each quantitative information collection is implemented, the instrument(s) and method of data collection will be pilot tested. Findings and lessons from the pilot will be incorporated into the instrument and/or method. Pilot tests will involve no more than nine individuals unless OMB clearance is sought for more than nine.

Before each qualitative information collection is implemented, the contractor will conduct a moderator training and role-playing session to go over the study objectives, question-by-question reviews of data collection instrument(s), strategies for engaging respondents, and

techniques or fostering respondent cooperation and completion. Lessons from the training will be identified, and relevant changes will be incorporated into the guide and method.

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

Individual collection requests are reviewed by lead scientists in our Center for Drug Evaluation and Research (CDER).