United States Food and Drug Administration

Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

OMB Control No. or 0910-0876

SUPPORTING STATEMENT

Part B.: Statistical Methods :

1. Respondent Universe and Sampling Methods

The participant universe for the quantitative testing may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participants for the surveys, focus groups, and in-depth interviews will be selected from a web-based panel or other appropriate and relevant lists. All selected participants will receive an email inviting them to participate in the study. Individuals who choose to participate will complete a screener and, if eligible, receive a questionnaire or be invited to be interviewed. Sample selections will be monitored to ensure they are diverse in terms of age, gender, education, and ethnicity/race. Other sampling sources may also be employed.

Studies under this collection will rely on both quantitative methods and qualitative methods and use convenience sampling rather than probability sampling. Therefore, the studies are not intended to yield results that are statistically projectable, nationally representative or precise estimates of population parameters. When probability samples are employed (such as through an online panel), representative estimates to the national population will not be made.

2. Procedures for the Collection of Information

For most studies submitted under this generic clearance, FDA will use an online panel or market research vendor. When participants are recruited through online panels or other lists, the vendor will send email invitations to the target audience. Each invitation will contain the OMB expiration date, the study title, and the estimated amount of time for participation. For the surveys, once a participant enters the secure web site, they will see a brief introduction informing them of the confidential and voluntary nature of the survey. Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL.

Individuals contacted to participate in focus groups or in-depth interviews will be invited to complete a screener to determine study eligibility. During the screening process, potential participants will be asked for personal information, including demographics and behaviors surrounding FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Like the process of selecting survey participants, eligible focus group and in-depth interview participants

will be told the title of the study, the estimated amount of time for participation, and, if applicable, amount of incentive provided Once a participant agrees and begins the study, a brief introduction will be presented informing the participant of the OMB Control Number, OMB Expiration date, PRA Statement, and the study's secure and voluntary nature. The information gathered in these studies will be kept secure to the extent provided by law.

Questionnaires will be designed to measure awareness and understanding of FDA messaging on the issue requiring communication urgency. Demographic and other behavioral information may also be collected from the participants. In some cases, participants may be asked to view messaging before responding to questions.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are expected, but if they are necessary, they will be described in the individual submissions.

Use of Periodic Data Collection Cycles to Reduce Burden

Each submission will be a one-time data collection effort.

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

Experience with online studies suggests that about 15 percent of those who are sent survey invitations will complete a study. Despite, this low baseline value, FDA will implement several procedures to increase participation wherever possible. We will conduct cognitive interviews and pretests to help improve understandability of the questionnaire to reduce participant burden and to enhance interview administration. We will keep the questionnaire at a reasonable length to minimize breakoffs. Tested recruitment and data collection procedures will be used to maximize cooperation and to achieve the desired response rates.

4. Test of Procedures or Methods to be Undertaken

FDA plans to conduct cognitive interviews and focus groups to evaluate and refine the draft survey questionnaire and in-depth interview and focus group moderator guides. Cognitive interviews and focus groups help identify areas where the materials are ambiguous, burdensome, or confusing for participants. Study materials will be revised accordingly.

Additionally, FDA will conduct pretests to thoroughly test the programmed surveys and stimuli. Study materials will be revised based on the pretest findings.

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

In general, FDA plans to use a contractor for recruiting, survey programming, and study administration. If needed, the contractor will also provide an analysis of the data and provide a summary report.