

***DATA TO SUPPORT COMMUNICATIONS TO EDUCATE CONSUMERS ON HOW TO
SAFELY PURCHASE DRUGS ONLINE***

SUPPORTING STATEMENT B

Food and Drug Administration
Center for Drug Evaluation and Research

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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The Respondent Universe for this study is American adults, eighteen years or older, who use the Internet. Individuals who do not use the Internet are not anticipated targets for communications efforts around the safe use of online pharmacies.

The FDA is proposing to use an online panel which conducts surveys via the Internet using an all-volunteer panel of respondents. When an interactive survey is initiated, a random sample of those who agreed to participate in the pre-established panel is drawn from this pool of potential respondents, and all members of the sample are sent an email invitation to participate in the survey, which includes a link that will take them to the survey on a secure server. Respondents never know when they are going to receive an invitation to take part in a survey, and they never know what subject matter is included in the survey until they click on the invitation link in their email.

The email link inside the interactive poll invitation expires after one use as a security measure to guarantee the veracity of the polling methodology. The survey is active until such time as it is deemed that the proper number of respondents has completed the survey to fulfill the requirements of that particular project. This is typically three to five days.

Under 5 CFR 1320.5 (D)(2)(v), there is a requirement that a statistical survey should be designed to produce valid and reliable results that can be generalized to the universe of study. In general, the use of online panels are not thought to be representative of the American public, unlike the more traditional randomized telephone and postal mail methodologies. However, using an online panel for this study is preferable to a representative sample of the general public because our target population is American adults who use the Internet. The sample pulled from the online panel should be sufficiently relevant and diverse for the purposes of this study.

Using an online panel of sufficient size and diversity panel has some unique advantages compared to traditional telephone polling, particularly since this is a study intended only to interview Americans who use the Internet. Studies of the subject show the Internet access penetration in the United States today is over 80%, and that percentage continues to increase. This, combined with the fact that an increasing number of younger respondents do not own landline telephones, suggests that the Internet is becoming a more and more viable means of reaching some key demographic groups. From an operational point of view, online surveys are attractive for another reason – their lower cost to the government. In addition, larger sample sizes obtainable from this methodology allow for more powerful cluster analyses and prompt recognition of emerging groups and patterns.

Another significant benefit of this methodology is that a survey can be fielded in a very short amount of time. It has been the case on many occasions that within the typical six week collection period for a traditional mail survey or some telephone surveys, something happens which is reported in the media and may affect the variables of interest, making early survey responses systematically different from later responses. This electronic survey is expected to take less than one week to complete, decreasing the likelihood that an event may occur to systematically change later responses.

B.2. Procedures for the Collection of Information

Questions shall include the following:

Question Type	Example Information to Collect	Question Numbers in Survey
Demographic & socio-economic	<p>Parental status, marital status, educational attainment, region of residence (urban, rural, or suburban place), and income.</p> <p>Note that gender, race, and age will be populated from existing information voluntarily provided by participants when they opted into the panel.</p>	21-25
Self-reported health	General sense of the respondent's health status and number of prescription medicines regularly used	17,18
Favored methods of obtaining information about purchasing prescription drugs online	What sources of information do respondents use when seeking this information, such as online searches, medical providers, pharmacists, insurers, news sources, etc.; most trusted sources	13,14
Attitudes toward ordering prescription drugs online	How strongly Internet users agree (on Likert scales) with propositions about online purchasing of prescription medicines: e.g., costs will be reduced, better access to medical records, increased risk of fraud	9-11
General attitudes and behaviors toward shopping online	How strongly Internet users agree (on Likert scales) with propositions about online shopping in general: e.g., online shopping is convenient, dislike giving credit card or personal information out online, the Internet is the best place to find bargains, online shopping saves time.	2
Use and access to technology	E.g. whether they have broadband at home, use a cell phone only (and thus do not have a landline phone at home), and whether they ever use the Internet someplace other than home or work	19,20
Whether the respondent has purchased prescription drugs online, or intends to do so in the future	This is the key dependent variable	3-8
Self-efficacy in purchasing online medicines safely	How strongly Internet users agree (on Likert scale) that they know how to purchase medications online safely?	12

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Screen shots of these questions are provided in Attachment 5.

We recognize and acknowledge the risks for collecting this data, including but not limited to accuracy of the data, unwillingness to answer questions seen as too personal, non-response bias, incomplete or out-of-range data, and duplicate responses. For each of these risks, professionally recognized procedures will be followed in each information collection activity to ensure high quality data. Examples of these procedures include the following:

- Data submitted through on-line surveys will be subjected to statistical validation techniques (such as disallowing out-of-range values).
- Links to the survey will expire after use to avoid contamination of the sample.

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

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

There are several procedures proven to be effective in previous studies and will be used to maximize response rates:

- Potential respondents will be informed about the importance of these studies and encouraged to participate.
- Experienced, highly-trained staff will oversee the survey to ensure that the servers and network connections are functioning properly
- The survey will provide respondents with the name, telephone number, and email address of an official at FDA. When asked, 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.
- Non-respondents will receive a second request to complete the survey.

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

To pilot the survey, nine individuals participated in cognitive testing in which they were asked to read the questions and discuss them with the evaluator. Participants were told to tell the evaluator any thoughts they had about the questions and answer choices, whether they found something confusing, did not understand something, or if were uncertain about how to answer and why they were uncertain. Participants also pointed out typos and made some word change recommendations to make items clearer. The evaluator made notes of any comments from participants. The table below shows a breakdown of participants by demographic information.

Ethnicity	White: 6 Non-White: 3
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Education Level	High School Equivalency or Less: 3 College Degree: 4 Advanced Degree: 2
Gender	Male: 3 Female: 6
Age	25-40: 6 40+: 3

Participants were able to complete the survey in an average of 12 minutes. Words or phrases that were confusing were identified, and the questions were revised as needed. In some cases, stimuli were necessary to respondents to answer the questions as intended. For example, “ordering prescriptions online” raised questions on whether prescription medicines included contacts, since a prescription is needed to obtain contacts; also, this phrase prompted questions on whether pet medicines were prescriptions. Questions 9-11 provide information on attitudes towards online prescription purchases. Those who do not currently purchase prescriptions online were unsure how to answer these questions without prompting, and it is important to obtain their responses for information to predict who is likely to be our future target audience and enable us to do comparisons to look for group differences. For this reason we added this statement to question 9: “Regardless of whether you have purchased prescription medicines online or not, please indicate the extent to which you agree or disagree with each of the following statements based on your impressions and experiences with online shopping.”

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

Felicia Stewart, M.A. and Miriam Campbell, Ph.D. in FDA and contractors Alison Ottenbreit, Ph.D. and Elyse Levine, Ph.D. will be responsible for the design of statistical and sampling procedures undertaken as part of these data collection activities. Elyse Levine and Alison Ottenbreit will also be responsible for the analysis of the resulting data.