FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CONCEPT TESTING FOR Online Pharmacy Communications Campaign (0910-0677)

TITLE OF INFORMATION COLLECTION: Concept Testing for Online Pharmacy Communications Campaign

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   Consumer research is needed to test creative concepts and key messages for an FDA public outreach campaign to educate consumers on how to safely purchase prescription medicine online. In order to effectively develop materials for the campaign, FDA must test these concepts and messages to ensure that consumers find them relevant, understandable, and appealing. To this end, the FDA proposes conducting up to six (6) focus groups that will provide insight into consumers' reactions to these creative concepts and messages. These focus groups will help to refine the core concepts and messages of the communications campaign.

   FDA is authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 393) to ensure the safety of foods and veterinary medicine. FDA's Center for Drug Evaluation and Research (CDER) has identified significant public health risks to consumers who buy medicine from illegal websites because the products could have too much, too little, or contain the wrong active ingredient or dangerous ingredients. FDA, along with the Drug Enforcement Agency and multiple other state, national, and international organizations, regulates online pharmacies based on applicable laws. Although these organizations have helped make the U.S. pharmaceutical distribution system one of the safest in the world, the proliferation of online pharmacies has contributed to a rise in counterfeit or otherwise substandard medicine on the global market. To protect American consumers from the increasing threat of rogue online pharmacies, FDA is developing an integrated public outreach campaign to educate consumers on how to safely purchase prescription medicine online. This campaign will inform the public of the risks of buying from illegal online pharmacies, educate consumers on the indicators of a legal or illegal online pharmacy, and teach consumers how to safely purchase prescription medicine online.

2. **Intended use of information:**

   The purpose of the study is to test creative concepts and key messages developed for a communications campaign to encourage the safe use of online pharmacies among consumers.

   FDA has drafted communication messages based on the findings from formative research which included a review of literature, an environmental scan, in-depth interviews with stake holders, and six focus groups with Internet users. The findings were used to help develop draft messages and recommendations for improved communications with the public. FDA now seeks further OMB approval to conduct six (6) additional focus groups

to test these draft communication messages. The data will not be used for the purposes of making policy or regulatory decisions.

3. **Description of respondents:**

The focus group participants will be adults residing in the U.S. who use Internet services to obtain prescription medicine for themselves or in a caregiver role. The participants will be recruited from existing lists of an opted-in universe of potential respondents obtained from recruitment facilities.

Of the six groups, three will be held in-person in which 12 people will be recruited to seat 8-10 in each group. The other three groups will be held online using video conferencing technology in which 10 people will be recruited to seat 6-8. The total number of participants is 66. The groups will have the following characteristics:

- 40 percent will have purchased prescription medicine through Internet services associated with health insurance or "brick-and-mortar" national chain stores.
- 60 percent will have purchased prescription medicine through independent online pharmacies. Examples of independent online pharmacies include Drugstore.com, and sites advertising discounts on medicines from Canada or another foreign country. By definition, these independent pharmacies will not be associated with U.S. health insurance or "brick-and-mortar" national chain stores.
- Mix of gender, household income, race/ethnic origin, age

4. **Date(s) to be Conducted:**

September 19, 2011 – September 23, 2011

5. **How the Information is being collected:**

Participants will be recruited from existing lists of an opted-in universe of candidates obtained from professional research facilities. They will be screened for eligibility using an FDA-approved script (see attached Participant Screener draft). Those successfully completing the requirements of the screening will be invited to join the focus group, and will be informed of their rights as a study participant as described in section 6 below. The Contractor will call or email participants two days before the event to remind them of the date, time, and location of the focus group. Participants will sign a release form describing the limited use of audio and video recordings of the sessions.

The sessions will take place in meeting facilities (courtesy of contractor Booz Allen Hamilton) or virtually via video conferencing. Per the Moderator Guide (see attached draft), after short introductions, the moderator will ease participants into a discussion of specific topics with more general "warm-up" questions. The moderator will continue to facilitate the discussion around the concepts and messages to be tested. Should time begin to run short, the moderator will highlight some key questions (starred in the Moderator Guide). Time will be allowed to address ideas and questions spontaneously generated from the discussion. At the conclusion of the sessions, participants will be thanked and

directed to the FDA web site and toll-free number should they have questions on the topic. Participants will receive a check for $75 as a token of appreciation for their time.

A note taker will also be present during the sessions. All sessions will be audiotaped and transcribed.

Using the notes and transcripts, the moderator and note taker will prepare final interpretive reports for the six (6) groups. The raw data for these reports will be the words, phrases, sentences, and non-verbal responses of the participants. The final report will be based on the discursive data gathered from each group. The report will detail the characteristics of each group and will highlight variations and commonalities between the groups. Based on the findings, the report will provide recommendations for refining the messages. Since focus group research constitutes a qualitative methodology, quantitative results will not be reported.

6. **Confidentiality of Respondents:**

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to Interviewees by means of scripts read prior to telephone interviews. Interviewees also will be advised of: the nature of the activity; the purpose and use of the data collected; FDA sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, Interviewees will be assured that there are no penalties for deciding not to respond, either to the information collection as a whole or to any particular questions.

All participants will be provided with a release form, informing them of the purpose of the survey and guaranteeing that everything they say will remain private to the extent permitted by law. Likewise, FDA will receive no personally identifying information about participants, including their full names. Additionally, it will inform the participant that the focus group will be recorded for accuracy purposes.

Only personnel from a contractor conducting the information collection will have access to individual-level interview data. All contracted project staff conducting the information collection must take required measures to ensure the privacy and anonymity of data. Personally identifiable data shall be limited to information that may be required in the process of enrollment. Personally identifiable information will be accessible to only those contractors who need them and will not be linked to interview data. All personally identifiable data will be destroyed following interview data collection. Neither FDA employees nor any employee of any other Agency will have access to this information.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of communication messages. Raw data from data collections that include sensitive information will not be retained once the data have been extracted and aggregated. The

information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

7. **Questions of a Sensitive Nature**

   Questions about illegal purchases of pharmaceutical medicine may be sensitive. During the sessions, interviewees will be asked if they had ever knowingly bought prescriptions over the Internet, or if they may consider doing so in the future. Interviewees will be assured that the information is voluntary and will be treated as private and anonymous, and that they don't have to answer this question.

8. **Description of Statistical Methods**

   This research will use qualitative methods. Thematic analysis will be used to assess observations from the focus groups. Counts of participants will be reported and organized by location and purchasing characteristics (i.e. buying from independent online pharmacy sites, or from services connected to health insurance/national chain store).

BURDEN HOUR COMPUTATION:

Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Consumers of online pharmacy sites	66	120	132

REQUESTED APPROVAL DATE: September 16, 2011

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