DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date April 13, 2011

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Approval of FDA Focus Group "Investigating Online Drug Buying Knowledge and Attitudes"
OMB Control No. 0910-0676

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB

Through HHS Reports Clearance Officer

The Food and Drug Administration (FDA), Office of Planning, Office of the Commissioner, is seeking OMB approval under the generic clearance 0910-0676 to conduct a focus group study on "Investigating Online Drug Buying Knowledge and Attitudes." The purpose of the study is to gain insight into the knowledge of online buying safety and the reasons consumers choose to or not to buy prescription drugs online in order to inform a communications campaign to encourage the safe use of online pharmacies. FDA expects to draft communication messages based on the findings from this initial series of six (6) focus groups. The findings will be considered by the Center for Drug Evaluation and Research in its evaluation of draft messages and recommendations for improved communications with the public. FDA plans to seek future OMB approval to conduct additional focus groups to test these draft communication messages. The data will not be used for the purposes of making policy or regulatory decisions.

1. Purpose of focus groups

The Food and Drug Administration (FDA) proposes to conduct a series of six (6) focus groups. The groups will discuss people's knowledge of online buying safety and their reasons for choosing to purchase or not to purchase from an online pharmacy.

Consumers are increasingly turning to the Internet to purchase prescription drugs because of the convenience, cost, and privacy. Unfortunately, only 4 percent of websites reviewed by the National Association of Boards of Pharmacy appear to be in compliance with pharmacy laws and practice standards (as of July 2010). Recent studies indicate that the majority of people with some college education are unable to detect multiple untrustworthy features of illegal online pharmacies. The FDA has identified significant public health risks to consumers who buy drugs from these illegal websites as the products may be counterfeit or substandard and therefore dangerous if they have too much, too little, or contain the wrong active ingredient or harmful ingredients. In order to educate consumers on how to safely purchase drugs online, the FDA has enlisted Booz Allen Hamilton to develop and implement an integrated public outreach campaign. 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 drugs online.

In order to effectively develop materials for the communications campaign, the FDA must understand how the public thinks about purchasing prescription drugs online. They must understand people's perceptions of the safety of buying prescription drugs online, their attitudes toward buying prescription drugs online in general, and their motivations for buying prescription drugs online. To this end, the FDA is proposing to conduct a series of six (6) focus groups that will provide insight into these perceptions and attitudes. These focus groups will help to develop the initial communications to be used in the communications campaign. FDA plans to seek future OMB approval to conduct additional focus groups to test these draft communication messages.

Although much literature currently exists on the benefits and risks of purchasing from online pharmacies, little research has been conducted investigating the underlying motivations for purchasing prescription drugs online. Likewise, although some evidence suggests that people have little knowledge of the key indicators that a pharmacy is safe to use, little research exists regarding the way people learn about, search for, and select online pharmacies. The proposed focus groups will help to answer these questions.

The groups will focus on participants' experiences buying from online pharmacies and their reasons for doing so. The participants will respond to a series of questions posed to them by a trained moderator with experience in conducting in-person focus groups. The questions concern participants' thoughts about:

- how often and from where they buy prescription drugs online
- why they initially bought from (or would buy from) and continue to buy from online pharmacies
- the online pharmacies they have purchased (or would purchase) from
- the problems they have experienced (or can imagine) from buying prescription drugs online
- what to look for to ensure that an online pharmacy is not fraudulent

A trained facilitator will moderate the groups using the attached Moderator Guide to ensure that all relevant topic areas are addressed. The groups will be audio taped. An additional individual will be present to take notes throughout the focus group. These recordings and notes will be used by the moderator and note taker to prepare a final report.

2. Description of Statistical Methods

a. Respondent universe

The Contractor (Booz Allen Hamilton) will use existing lists of an opted-in universe of potential respondents obtained from local research facilities. They will contact potential respondents by telephone and screen them for eligibility (see attached Participant Screener draft). The Contractor will use existing lists of an opted-in universe of potential respondents obtained from local research facilities.

Respondents will be individuals who routinely fill or buy at least one prescription medicine. This will include those who buy for themselves as well as for those buying as a caretaker of another. All respondents also will be routine internet users. Only people who use prescription drugs and use the internet are likely to purchase from an online pharmacy. In addition, respondents in each focus group will be split 50% each between those who have purchased from an online pharmacy in the past and those who have not. Respondents will include sufficient representation from multiple demographic groups, including age, income, education, gender, and ethnicity/race. Respondents will be recruited in the Washington, DC area, the San Diego, CA area, and the rural areas outside Omaha, NE. Given the possible convenience of ordering drugs online in rural areas, FDA feels it is important to ensure that a rural area is sufficiently represented.

The participant screen will include demographic questions to ensure sufficient representation from each demographic segment. The participant screener will include items on race and ethnicity consistent with OMB standards:

Are you Hispanic or Latino?
- Yes
- No

What is your race? Please select one or more.
- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Pacific Islander

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.

b. Information collection procedures

The Contractor will use a participant screener to recruit participants and a moderator guide to facilitate guided discussion.

The Contractor will provide FDA with an independent analysis of the results, based on the tapes and notes taken during the groups. Two to three days before the date of a particular focus group, the Contractor will call or email participants a reminder (at the participant's preference), including the date, time and location of the focus group. This reminder will inform participants about how the groups will be recorded and reported, and the voluntary nature of their participation. At the beginning of each group, the moderator will provide participants with a copy of the release form and ask them to sign it to consent to participate and to have the session taped.

The Contractor will comply with additional safeguards for ensuring participant information is kept private to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to an individual.

Discussion will begin on or near the prearranged time. Per the Moderator Guide, after short introductions, the moderator will ease participants into a discussion of specific topics with more general "warm-up" questions. The moderator will not pose any questions of a sensitive or private nature. The moderator will continue to facilitate the discussion until all of the topics in the moderator guide have been addressed as time allows. 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. In addition, a specific time will be set aside for participants to ask questions of the moderator. Reliability and validity will be assessed iteratively within the discussions by revisiting participants' verbalizations and asking for clarification. This will be done both within the course of the individual sessions and between the separate sessions.

Using the notes and audio tapes, 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. Since focus

group research constitutes a qualitative methodology, quantitative results will not be reported.

c. Expected response rate

The Contractor will recruit approximately seventy-two (72) individuals, expecting to have eight (8) to ten (10) participants per group. No more than twelve (12) participants will participate in a group. Past experience has shown that this amount of over-recruitment generally ensures that enough participants will arrive for the groups.

As described in section 2b, the Contractor will contact potential respondents by telephone and screen them for eligibility. Participants will receive a $75 incentive for their participation. They will receive a reminder email/phone call 2-3 days prior to the scheduled session.

Rationale for Incentives: The Contractor (Booz Allen) has recommended that participants be offered $75. These estimates are based on the contractor's experience with past qualitative studies, and on our investigation of standard incentives across multiple metro regions. Incentives reflect the value that a focus group participant places on their free time. Our investigation revealed that standard rates varied from $65 to $100, with an average price of $79. Table 1 provides an overview of our findings.

Table 1. Focus Group Facilities Contacted and Quoted Incentive Prices

Focus Group Facility	Location	Incentive Price
Essman Research	Des Moines, IA	$75
Metro Research	Fairfax, VA and Alexandria, VA	$100
Opinions Unlimited	Dallas, TX	$75
Plaza Research	San Diego, CA	$75 - $100 depending on location within the San Diego Area
Shugoll Research	Bethesda, MD	$85
Taylor Research Group	San Diego, CA	$65

[a] All inquiries to focus group facilities were made on February 18, 2011. Locations notionally represent our proposed locations for conducting these focus groups

Booz Allen's experience in this area, and our investigations of customary incentives used industry-wide, indicate that offering an incentive that is below the accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following.

- Increased time and cost of recruitment
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group. This incurs additional costs and puts additional burden on the recruited participants who have to reschedule their participation in the focus group

3. Estimate of the burden:

The time required for screening and participation will be two hours per participant. We will include no more than thirteen (13) participants in each of the six (6) focus groups, producing a conservative total estimated respondent burden of one hundred fifty-six (156) hours.

Table 2. Estimated Annual Reporting Burden for Selected Respondents

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
78	1	78	2	156

[a] There are no capital costs or operating and maintenance costs associated with this collection of information.

Attachments: Participant Screener

Moderator Guide