DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date July 13, 2009

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

Subject Request for Approval of FDA Focus Group "Establishing a Baseline for Consumer Knowledge about Medical Product Benefits and Risks"
OMB Control No. 0910-0497

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 0910-0497 to conduct a focus group study on "Establishing a Baseline for Consumer Knowledge about Medical Product Benefits and Risks." The purpose of the study is to better inform the process by which FDA plans more effective risk communications about specific products, as well to guide formulation of the basic objectives of a campaign to provide consumers with the context they need to better understand new, and often uncertain, risk information. 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 twelve (12) focus groups. The groups will discuss consumers' perceptions of the risks and benefits of medical products.

Stories about newly discovered risks of some prescription drugs (e.g., Avandia, Vioxx, some antidepressants) and certain medical devices (e.g., coronary stents) have made headlines in major newspapers and broadcast media. FDA has been told by many concerned healthcare providers that their patients are learning about relevant product problems, and often taking inappropriate action (e.g., stopping critical medicines) even before their providers know about the issue and can institute their own communications with their patients. For FDA to plan informed programmatic communication activities, it needs better empirical data about how people might interpret the dissemination of emerging information on both the risks and benefits of medical products.

In the face of product sponsor focus on benefits, FDA has focused on product risks. However, the relative credibility of FDA versus product sponsors as information sources may make this focus problematic for consumers. Recent studies demonstrate how little consumers know about either statistics or the factors that enter into regulatory decision-making. Consequently, when consumers

hear about a newly identified risk associated with a medical product they use, they will not likely process this risk within the context of either the benefits of continuing use of the product, or the risks of stopping use of the product. Thus, even though FDA believes it has objectively informed consumers, their lack of an appropriate cognitive model in which to place this information means that it is likely they have not been effectively informed.

To effectively inform consumers about newly identified risks of medical products, FDA must understand how consumers think about both the risks and benefits of medical products. To this end, FDA is proposing to conduct a series of 12 focus groups. In these focus groups, FDA would explore consumers' cognitive models about medical product benefits and risks. The focus group feedback will help FDA to start formulating the basic objectives of a campaign to provide consumers with the better context they need in which to place new risk information more completely. The focus group data should better inform the process by which FDA plans more effective risk communications about specific products. FDA expects to draft communication messages based on the findings from this initial series of 12 focus groups. FDA plans to seek future OMB approval to conduct additional focus groups to test these draft communication messages.

Finally, the results of these focus groups will help inform the FDA's newly established Risk Communication Advisory Committee and would constitute a further effort to respond to the Institute of Medicine's recommendation in its September 2006 report "The Future of Drug Safety" that FDA improve its communications with the public.

The groups will focus on participants' personal beliefs and opinions about the risks and benefits of prescription medicines. 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:

- prescription medications, in general (including their likes and dislikes)
- the benefits of prescription medications, positive experiences, and limitations to benefits
- the risks, side effects, and adverse reactions of prescription medications
- what the word "safe" means in relation to risks
- deciding whether or not to take prescription medications
- newly emerging risks of existing medicines and understanding of the regulatory process

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 and video taped. Written and electronic transcripts of the focus groups will be prepared from these tapes, with all personally identifying information removed. These transcripts will be used by the moderator to prepare a final report.

2. Description of Statistical Methods

a. Respondent universe

FDA contracted with Olchak Market Research (OMR) to conduct these in-person focus groups. The Contractor will use a telephone screening facility to contact potential respondents by telephone and screen them for eligibility (see attached Participant Screener draft). The screening facility will use lists of an opted-in universe of potential respondents.

Participants will be recruited from the Washington, DC metropolitan area and the Sacramento, CA area. Participants will be recruited according to the criteria in the attached respondent screener. The focus groups will be a mix of men and women and will be diverse in race/ethnicity. The groups will also be internally homogenous with respect to education and recent experience with prescription medicines to avoid interference to the dynamics of the groups that could result from vastly different experiences. At each of the two locations, the focus groups will be broken down by education: Lower Education (no college credit) and Higher Education (at least some college credit). The education groups will be further segmented by medication use in the last six months: Chronic Users (taking at

least one prescription medication on a monthly basis), Intermittent Users (taking a prescription medication occasionally or on an "as needed" basis), and Caregivers (caring for a child less than 16 years old who takes at least one prescription medication on a monthly basis). Although it is possible for participants to be eligible for multiple medication use groups, each participant will be assigned to a single group consisting of a specific medication use segment. This breakdown (2 locations X 2 education levels X 3 medication use groups) will result in a total of 12 groups. These internally homogenous groups are intended to limit anomalous findings from interfering with group dynamics. FDA recognizes that the data collected are qualitative in nature and not statistically representative of population segments characterized by the groups.

b. Information collection procedures

The Contractor will use a participant screener and moderator guide to recruit participants and facilitate a guided discussion. The Contractor will provide FDA with an independent analysis of the results, based on the tapes and transcripts of the groups. Between 4-7 days before the date of a particular focus group, the Contractor will mail a confirmation letter to recruited participants. This 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 confirm that the participants read the consent form and orally consent to participate and to have the session taped. The consent will be taped as well.

The Contractor will comply with additional safeguards for ensuring participant confidentiality. 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 begins on or near the prearranged time. After short introductions, the moderator eases the participants into a discussion of specific topics with a more general "warm-up" question. The moderator does not pose any questions of a sensitive or private nature. The moderator continues to facilitate the discussion until all of the topics in the moderator guide have been addressed. Time is allowed to address ideas and questions spontaneously generated from the discussion. Reliability and validity are assessed iteratively within the discussions by revisiting participants' verbalizations and asking for clarification. This is done both within the course of the individual sessions and between the separate sessions.

Using the transcripts and audio and video tapes, the moderator will prepare final interpretive reports for the twelve (12) 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 are not reported.

c. Expected response rate

The Contractor will recruit approximately one hundred and forty-four (144) 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 show up 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 confirmation letter 4-7 days prior to the scheduled session and will be contacted with a reminder phone call the day prior to the scheduled session.

Rationale for Incentives: The Contractor (Olchak) has recommended that participants be offered $75. These estimates are based on Olchak's experience with past qualitative studies. Incentives reflect the value that a focus group participant places on their free time.

Olchak's long experience in this area indicates 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. There will be a total of no more than twelve (12) participants in twelve (12) groups, producing a conservative total estimated respondent burden of two hundred and eighty-eight (288) hours.

Table 1. Estimated Annual Reporting Burden for Selected Respondents[a]

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
144	1	144	2	288

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

Attachments: Draft Participant Screener
Draft Moderator Guide
Draft Confirmation Letter