FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Risk and Benefit Perception Scale Development Focus Groups

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The focus groups are part of a larger research project to develop a pool of reliable and valid measurement items for assessing consumer perceptions of prescription drug benefits and risks. As OPDP's research program has matured, risk and benefit perception measurements have evolved over time. This has resulted in perception measures that, while internally valid, tend to vary by study. FDA will be able to use the validated measurements consistently across multiple studies, thus streamlining survey development and ensuring generalizability of study findings.

The purpose of the focus groups is to identify the relevant constructs prior to testing candidate measurement items.

2. Intended use of information:

The groups will help FDA to (a) understand how consumers judge a prescription drug's risks and benefits prior to taking it, (b) determine how important perceived risk and perceived benefit are in one's decision to take a prescription drug, and (c) identify additional factors that influence prescription drug decision making and, therefore, should be measured in subsequent parts of this study.

3. Description of respondents:

Half of the groups will be comprised of consumers who recently began taking a prescription drug for the first time (New Users). The other half of the groups will consist of consumers who recently switched prescription drugs (Switching Users) or began taking additional prescription drugs for the same illness (Adding Users).

4. Date(s) to be conducted and location(s):

We propose ten focus groups with consumers (n=9 per group; n=90 total) at market research facilities in Washington, D.C.; Raleigh, NC; Denver, CO; and Portland, OR. The groups will be conducted during FY2013. Table 1 shows the number of focus groups in each location and with each consumer population.

Table 1. Number of Focus Groups by Location and Population.

Location	New Users	Switching / Adding Users	Total Number of Groups
Washington, DC	3	2	5
Raleigh, NC	--	1	1

Denver, CO	1	1	2
Portland, OR	1	1	2
Total	**5**	**5**	**10**

5. How the Information is being collected:
We will identify potential participants through local recruitment firms, who will contact individuals, screen them for eligibility, and invite them to participate (***Appendix A***). A trained moderator will conduct each focus group using a semi-structured guide (***Appendix B***). The consent form can be found in ***Appendix C***. Each group will last two hours.

6. Number of focus groups:
We will conduct ten groups.

7. Amount and justification for any proposed incentive:
To ensure adequate participation and high data quality, we propose a participant incentive of $75. According to Karen Sollod of OMR Market Research and Focus Groups based in Washington, D.C., most facilities offer incentives of $100 for two-hour focus groups. This amount is based on the current cost of gas and other travel expenses, and it ensures that participants are reasonably diverse in age, income, and education. Consequently, we propose an incentive of $75 to ensure a reasonable cross-section of participants.

8. Questions of a Sensitive Nature:
There are no questions of a sensitive nature. However, it is possible that certain medical conditions carry stigma that might make it uncomfortable for participants to disclose their medical conditions or discuss their experiences. We have included language in the screener that makes it clear that (1) participation in the focus groups will entail talking about the respondent's own medical condition and medication experiences and (2) the groups will comprise people with a wide variety of medical conditions.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):
Participants will be screened for prescription drug use (see ***Appendix A***). Participants will be further screened for timing of prescription drug use (within the last 6 months, within the last year) and type of prescription (new drug, prescription switch, additional prescription). We estimate that 270 respondents will be screened in order to recruit 90 focus group participants (see Table 2).

Table 2: BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Number of respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
270 (screener)	1	270	0.333	9
90 (focus groups)	1	90	2	180
Total				**189**

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