DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service
Food and Drug Administration

Memorandum

Date October 30, 2009

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

Subject Request for Approval of FDA Focus Group, "Warning Labels and Consumer Understanding"; 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), Center for Drug Evaluation and Research (CDER) is seeking OMB approval under the generic clearance 0910-0497 to conduct a set of six focus groups entitled, "Warning Labels and Consumer Understanding Focus Groups." The purpose of the focus groups is to understand consumers' perception of the current warning labels for medications that may interfere with an individual's ability to operate a vehicle or machinery and to identify alternative language and/or pictograms that consumers believe may help enhance this understanding.

The focus groups will explore how the current warnings that describe a product that may interfere with an individual's ability to operate a vehicle or machinery are interpreted. The focus groups will also explore alternative ways to convey the warning (words, pictogram or combination) and where the warning should be located. Finally, the focus group will also discuss other label elements that may affect consumer comprehension.

A respondent screener and moderator's guide (see Appendices I and II) prepared by CDER, will be used by the Contractor (OMR, Inc.) to recruit participants and facilitate the guided discussion.

A total of six focus groups will be conducted at three different locations: Washington, DC, Atlanta, GA and Chicago, IL. Individuals participating in the groups must be adults, at least 18 years old and must meet the criteria listed in the respondent screener. Of note, participants must have valid drivers license and drive most days of the week with a mix of driving activities. All participants must have purchased or used OTC medications, and/ or been prescribed prescription drugs within the past 6 months.

The Contractor will recruit 12 individuals for each focus group discussion, expecting to have 8 to 12 participants per group, with a minimum of 8 participants. No more than 12 individuals will participate in a group. The Contractor will contact potential respondents by telephone and screen them for eligibility. To maximize response rate, recruiters will contact each sample unit at least five times to screen for eligibility and recruit for participation. Additionally, respondents will receive a reminder call and confirmation letter before the groups convene and a $75.00 incentive for their participation.

For focus groups employing similar respondent selection criteria, the incidence of a successful completed telephone screening is between 30-40%. The recruiter will require approximately five minutes to complete the screening interview for a selected participant, and will require less time to disqualify a potential respondent.

The time required for screening and participation will be 2 hours per participant. There will be a total of no more than 72 participants in four groups, producing a total estimated respondent burden of 144 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
72	1	72	2	144

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

CDER would like to begin the focus group study in December, 2009.

The data from these focus groups will be used to obtain insight on consumers understanding of the current warnings and ways to improve comprehension.

If you have any questions, please contact Capt. Laura Shay on 301.796.0994.

Attachments