

Appendix 1

Consumer Perceptions of Warnings for Medications That May Cause Sedation Respondent Screener

Recruiting Goals

- Two groups in each location: Washington DC, Southern U.S., Northern U.S.
- The groups will be segmented by level of education (3-HS ed. or less and 3-post HS).
- All groups will have a mix of races and ethnicities
- All groups will be mixed gender, with an attempt to have an equal number of males and females.
- Ages 18 and over, with a range of ages in each group.
- All participants must have valid drivers license and drive most days of the week (3-heavy drivers (drive for living e.g., truck, bus, train, plane or if employment involves driving, other than commuting, e.g., delivery services, patrol officers), 3-light drivers 30 minutes a day most days of the week, e.g., commuters, kids carpool)
- All participants must be able to read, understand and speak English.
- All participants who normally wear corrective lenses, contacts, or glass to read must have them with them during the focus group.
- All participants must have taken an OTC medication and/or a prescription medication within the past 6 months.
- Participants cannot have participated in a focus group or a similar study in the past 6 months. Participation in phone surveys is allowable.
- 12 recruits per group in order to get 8-12 to participate.
- Participants will receive \$75 incentives.
- Each focus group will last approximately 120 minutes.
- Groups will be audio- and video-taped. Obtain participant's consent.
- The identity of the participants will remain confidential.
- Groups at the Washington DC site will be observed by staff from the Food and Drug Administration (FDA). FDA will travel to other sites if funding permits.
- Participants do not have to answer any questions that they do not want to, but are encouraged to participate.

Hello Mr. /Ms. _____, my name is _____ and I'm calling about a market research study in your area. We are recruiting for an upcoming focus group in which participants will be asked to share their thoughts and feelings about warning information in OTC and Prescription labels. Would you mind answering a few questions?

Screening Questions

- Q1. Before I start, are you at least 18 years old?
1. YES
 2. NO → Can I speak with someone at least 18 years old? If no, when would be a good time to call back and speak with someone at least 18 years old? Or, is there no one over 18 in the household? SET UP CALL BACK TIME or TERMINATE IF NO ONE OVER 18.

Q2. Are you trained or employed as a health care professional?

- Yes → eliminate [thank respondent politely]
- No → continue

Q3. Have you participated in a focus group within the past 6 months?

- Yes → eliminate [thank respondent politely]
- No → continue

Q4. Do you have a valid driver's license?

- Yes → continue
- No → eliminate [thank respondent politely]

Q5. Do you drive most days of the week?

- Yes → continue
- No → eliminate [thank respondent politely]

Q6. How many hours a day do you drive? _____

- 30 minutes or greater → continue
- Less than 30 minutes a day → eliminate [thank respondent politely]

Q7. What are you driving activities?

- Commuting to work
- Driving kids to various activities
- Running errands
- Drive for employment (Taxi driver, truck driver, bus driver etc...)
- Employment requires driving (Delivery, patrol officer etc...)
- Other _____

Q8. Have you taken an Over-The-Counter (OTC) medication and/or a prescription medication within the last 6 months?

- Yes → continue
- No → eliminate [thank respondent politely]

Demographic Questions

Q1. Determine gender

- Male
- Female

Q2a. What is your age?"

- [Specify]

Q2b. If the person refuses to report age, then say "I understand you don't want to tell me your age. Which of the following category of age are you in?"

- 18-29 → continue
- 30-39 → continue
- 40-49 → continue
- 50-59 → continue
- 60-69 → continue
- 70 and over → continue

Q3. What is the highest level of education that you have completed?

- Less than high school → lower education group
 - High school graduate or GED → lower education group
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- Technical/vocational school → lower education group
 - Community college → higher education group
 - Some college (1-3 years towards Bachelor's degree) → higher education group
 - College (Bachelor's degree) → higher education group
 - Advanced degree (post graduate degree) → higher education group

Q4. Are you of Hispanic or Latino origin?

- Yes → Hispanic groups (and other groups)
- No → continue

Q5. What is your race? I am going to read several categories of race. You may choose one or more categories as they apply. Are you?

- White → continue
- Black or African American → continue
- Asian → continue
- Native Hawaiian or other Pacific Islander → continue
- American Indian or Alaskan Native → continue
- Other → continue

We would like to invite you to participate in a focus group to discuss issues relating warning information on OTC and Prescription labels with about 10 other participants. The discussion will last approximately two hours and will be video- and audio-taped and observed by the focus group staff. Your participation and everything you say during the discussion will remain confidential. You will receive a \$75. Additionally, we will serve you snacks and beverages before the group discussion starts. Are you interested in participating in this focus group?

- Yes -> continue
 - No -> [Thank the person for his/her time]
- I'm glad that you will be able to join us! The focus group will take place on (Day), (Date), at [6:00 or 8:00 p.m.] at [site location]. If you normally wear corrective lenses, contacts, or glass to read please remember to have them with you during the focus group.

Will you be available to participate at this time?

- Yes
- No -> **[Thank the person for his/her time]**

I would like to send you a confirmation letter and directions to the facility. In order to do so, could you please tell me your mailing address (or fax number, e-mail address) and a phone number where you can be reached:

Name: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Phone: _____
 Email: _____
 Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call [recruiter] at [telephone number] if this should happen. We look forward to seeing you on [date] at [time]. If you use reading glasses, please bring them with you to the focus group.