

Attachment A

OMB Control No: 0910-0497
Expiration Date: 12/31/2026

Focus Groups Examining Consumer Reporting of Adverse Events
Screeners

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The time required to complete this Screener is estimated to average 6 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRStaff@fda.hhs.gov.

This study is being conducted on behalf of the U.S. Food and Drug Administration.

Recruiting Goals for Online Focus Groups:

- o Recruit 8 participants for 4 to 6 participants to show.
- o Groups will also be segmented by education level (high, low) and participant self-identified ethnicity and race (Hispanic; non-Hispanic Asian; non-Hispanic Black; non-Hispanic American Indian/Alaska Native; non-Hispanic Native Hawaiian/Pacific Islander; non-Hispanic White).
- o Participants will represent a mix of ages and genders.
- o Participants will be recruited from geographic regions across the United States.
- o The moderator expects that each person will have tested their connection, which could take up to 10 minutes, and will log in 15 minutes before the start time of the group.

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Sample Focus Group Schedule

| Group | Group Demographic Characteristics | Education |
|----------|---|------------------|
| Group 1 | Hispanic | Higher Education |
| Group 2 | | Lower Education |
| Group 3 | Non-Hispanic Black | Higher Education |
| Group 4 | | Lower Education |
| Group 5 | Non-Hispanic Asian | Higher Education |
| Group 6 | | Lower Education |
| Group 7 | Non-Hispanic American Indian/Alaska Native | Higher Education |
| Group 8 | | Lower Education |
| Group 9 | Non-Hispanic Native Hawaiian/Pacific Islander | Higher Education |
| Group 10 | | Lower Education |
| Group 11 | Non-Hispanic White | Higher Education |
| Group 12 | | Lower Education |

Introduction:

My name is () and I'm calling about a research study we are conducting on behalf of the U.S. Food and Drug Administration, also known as the FDA. We are recruiting for an upcoming focus group about consumers' experiences with prescription drugs and drugs that you can purchase without a prescription, such as Tylenol or cold medicines. The group will last about one hour and you will be provided with \$75 as a token of our appreciation for your time and effort in participating in this study.

*IF NEEDED: A focus group is when a small group of individuals come together to talk about a certain topic.

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1. Would you be interested in seeing if you qualify to participate in the focus group?

- Yes
- No -> eliminate [thank respondent politely]

2. Would now be a good time to ask you a few questions to see if you're eligible to be in one of the groups?

- Yes
- No -> ask for a better time to screen the participant [DATE/TIME/CONTACT NUMBER]

3. I am going to read some age categories --- please tell me which category your age falls in. [RECRUIT A MIX OF AGE SEGMENTS]

- Under 18 years old -> eliminate [thank respondent politely]
- 18 - 30
- 30-50
- 50-65
- 65+

4. Do you work for any of the following?

- A Market Research Firm -> eliminate
- A Health Organization (e.g., doctor's office, hospital) -> eliminate
- U.S. Food and Drug Administration -> eliminate
- Pharmaceutical [Drug] Company -> eliminate

5. Are you or have you ever taken a prescription medication for any of the following conditions?

- Diabetes
- Gout
- Blood clots anywhere in your body
- Irregular heartbeat
- Other
- None of the above or not taking prescription medication

6. Are you of Hispanic, Latino, or of Spanish origin?

- Yes-> [potentially eligible for **Hispanic** groups]
- No -> [potentially eligible for **non-Hispanic** groups]

7. I am going to read several categories of race. Please select the category or categories that you feel best describes you.

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- Black or African American
 - Asian
 - American Indian or Alaska Native
 - Native Hawaiian or Other Pacific Islander
 - White
 - Prefer not to answer [IF YES TO HISPANIC, CONTINUE; if NO TO HISPANIC, READ: I'm sorry, but we are interested in hearing from people from different racial backgrounds. If you would like to answer, then I could see if you qualify for one of our groups. If not, [-> eliminate] I understand and thank you so much for your time today.]
8. What sex were you assigned at birth, on your original birth certificate?
- Female
 - Male [RECRUIT NO MORE THAN 3 MALES FOR EACH GROUP]
 - Refused
 - Don't know
9. Do you currently describe yourself as male, female or transgender?
- Female
 - Male
 - Transgender
 - None of these
10. **What is the highest level of education that you have completed?**
- Less than high school graduate -> lower education
 - High school graduate or GED -> lower education
 - Attended/graduated technical/vocational school-> lower education
 - Some community college ->lower education
 - Community college degree (e.g., Associate's) ->lower education
 - Some college (toward bachelor's degree) ->higher education
 - College graduate (bachelor's degree) -> higher education
 - Attended or graduated with advanced degree ->higher education [SOFT QUOTA: Seat no more than 2 advanced degree participants per group]
11. **Have you participated in a focus group within the past six months?**
[Interviewer: participation in telephone or internet surveys is allowed]
- Yes ->eliminate
 - No
12. **The focus group conversation will be held online. Do you have access to any of the following for the purposes of the focus group? [ONLY recruit those who answer "yes" to all]**

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- A computer (desktop, laptop), a smartphone, iPad or other tablet (Record which one they have. LIMIT 2 SMARTPHONE PARTICIPANTS PER GROUP)
- High speed internet access
- A webcam
- A quiet space at home/or other private space from which you can participate

13. Are you comfortable with using a video platform such as Zoom on your device for the interview?

- Yes
- No -> eliminate

You qualify for our study. The discussion group will be held on [DATE] at [TIME] and will last about 60 minutes. For your time and opinions, you will receive \$75 at the end of the session.

14. Would you like to participate in the group discussion at [TIME] on [DATE]?

- Yes -> continue
- No -> eliminate

Great! May I please have your phone number or e-mail address to send you a confirmation letter with instructions? [Verify email address and phone number. SEE NEXT PAGE TO COMPLETE ALL CONTACT INFORMATION]

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****NOTE** THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND FOCUS GROUP DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUP.**

We are asking for your contact information only for sending you a reminder letter and giving you a call to remind you of the discussion group. We will destroy all contact information at the end of the groups.

NAME: _____

ADDRESS: _____

CITY: _____

ZIP CODE: _____

E-MAIL: _____

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: _____

BEST PHONE NUMBER: _____

Is there another time and number we can try if we miss you?

ALTERNATE TIME:

ALTERNATE PHONE NUMBER:

Thank you. Those are all the questions I have today. Before the focus group, you will receive a copy of a form that describes your rights as a participant. Please take a moment to read through that before you join the group. In addition, you will receive a link to join using Zoom, a video conferencing service. Please join about 15 minutes before the start of the focus group to ensure you have time to sign in. If you have any questions or find that you are unable to attend, please call [PRC's phone number] as soon as possible.

Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].