

Attachment D
LABEL COMPREHENSION STUDY
GROUP 4 SCREENER

TELEPHONE RECRUITMENT SCRIPT

Hello, my name is _____ and I'm from [NAME OF RECRUITMENT FIRM]. I'm calling on behalf of RTI International and Concentrics Research about a study that is being sponsored by the U.S. Food and Drug Administration (FDA). We are looking for people to take part in a research study to review a label for a medicine that may be available over-the-counter soon, meaning without a prescription. We are not selling or promoting any medicine.

The study involves being in a one-time individual, in-person interview lasting no more than 45 minutes. The session will include looking at a list of medical terms and answering some questions about instructions for the medicine. The interview will be audio recorded, and project team members may observe the interview either in-person or by live streaming. You will be given \$50 [FORM TBD BY RECRUITMENT FIRM; CASH/CHECK ARE TYPICAL] at the end of the interview to reimburse you for your time and travel expenses.

To see if you qualify for this study, I need to ask you some questions that will take a few minutes of your time. The risk of others knowing your answers to the questions is minimal. To keep your information private, we will store your answers and contact information in separate, locked filing cabinets. This information will be destroyed at the end of the study. May I proceed with my questions?

Yes → CONTINUE [Thank respondent and proceed to Q1.]

No → [Thank respondent and end call.]

1. How old were you on your last birthday?

_____	<p>Over Age 18 → CONTINUE</p> <p>Under Age 18 → TERMINATE (Closing Script and Contact Information Sheet)</p> <p>Don't know/refused → TERMINATE (Closing Script and</p>
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Contact Information Sheet)
<p>SCREEN FOR A MIX OF AGES</p> <ul style="list-style-type: none"> • 18 - 29 years old • 30 - 49 years old • 50 - 64 years old • 65+ years old

2. Are you currently employed by [INSERT OPTIONS 1-6 BELOW]? (Check all that apply)

A marketing or research company	→ TERMINATE (Closing Script and Contact Information Sheet)
An advertising agency or public relations firm	→ TERMINATE (Closing Script and Contact Information Sheet)
A pharmacy or pharmaceutical company	→ TERMINATE (Closing Script and Contact Information Sheet)
A manufacturer of medicines	→ TERMINATE (Closing Script and Contact Information Sheet)
A managed care or health insurance company	→ TERMINATE (Closing Script and Contact Information Sheet)
A healthcare practice	→ TERMINATE (Closing Script and Contact Information Sheet)
A hospital emergency room	→ TERMINATE (Closing Script and Contact Information Sheet)
None of the above	→ CONTINUE
Refused	→ TERMINATE (Closing Script and Contact Information Sheet)

3. Have you ever worked for [INSERT OPTIONS 1-4 BELOW]? (Check all that apply)

Department of Health and Human Services		→ TERMINATE (Closing Script and Contact Information Sheet)
U.S. Food and Drug Administration		→ TERMINATE (Closing Script and Contact Information Sheet)
RTI International		→ TERMINATE (Closing Script and Contact Information Sheet)
Concentrics Research		→ TERMINATE (Closing Script and Contact Information Sheet)
None of the above		→ CONTINUE
Refused		→ TERMINATE (Closing Script and Contact Information Sheet)

4. Have you ever been trained or worked as a healthcare professional?

Yes		→ TERMINATE (Closing Script and Contact Information Sheet)
No		→ CONTINUE
Refused		→ TERMINATE (Closing Script and Contact Information Sheet)

5. Have you been in any market research study, product label study, or clinical trial in the past 12 months?

Yes		→ TERMINATE (Closing Script and Contact Information Sheet)
No		→ CONTINUE
Don't know		→ TERMINATE (Closing Script and Contact Information Sheet)
Refused		→ TERMINATE (Closing Script and Contact Information Sheet)

6. What is your gender? [Do not read response categories.]

Male		➔ GO TO Q4
Female		➔ CONTINUE
Other		➔ GO TO Q4
Refused		➔ CONTINUE
SCREEN FOR MIX OF MALE/FEMALE		

7. [IF FEMALE] Are you currently pregnant?

Yes		➔ CONTINUE
No		➔ CONTINUE
AIM FOR 1-2		

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

_____ Degree

[DO NOT READ LIST - ASSIGN RESPONSE TO EDUCATION LEVEL BELOW]

Less than high school		➔ CONTINUE
High school graduate (HS diploma or GED)		➔ CONTINUE
Some college (no degree)		➔ CONTINUE
College (2-year) degree (Associate degree)		➔ CONTINUE
College (4-year) degree (e.g., BA, BS, AB)		➔ CONTINUE
Some post-college		➔ CONTINUE
Advanced or post-graduate degree (e.g., Masters, MD, PhD)		➔ CONTINUE
Refused		➔ CONTINUE

9. How confident are you in filling out medical forms by yourself?

Extremely		➔ CONTINUE
Quite a bit		➔ CONTINUE
Somewhat		➔ CONTINUE
A little bit		➔ CONTINUE

Not at all		➔ CONTINUE
Don't know		➔ TERMINATE (Closing Script and Contact Information Sheet)
Refused		➔ TERMINATE (Closing Script and Contact Information Sheet)

10. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

Never		➔ CONTINUE
Rarely		➔ CONTINUE
Sometimes		➔ CONTINUE
Often		➔ CONTINUE
Always		➔ CONTINUE
Don't know		➔ CONTINUE
Refuse		➔ CONTINUE

11. Can you read, speak and understand English?

Yes		➔ CONTINUE
No		➔ TERMINATE (Closing Script and Contact Information Sheet)
Refused		➔ TERMINATE (Closing Script and Contact Information Sheet)

12. Do you normally wear corrective lenses, contacts, or glasses to read?

Yes		➔ CONTINUE
No		➔ CONTINUE
Refused		➔ TERMINATE (Closing Script and Contact Information Sheet)

13. Do you have any other problems with your eyes that would prevent you from being able to read?

Yes		→ TERMINATE (Closing Script and Contact Information Sheet)
No		→ CONTINUE
Refused		→ TERMINATE (Closing Script and Contact Information Sheet)

DEMOGRAPHIC QUESTIONS

14. Please answer the next two questions about your ethnicity and race.

Are you Hispanic or Latino?

Yes		→ CONTINUE
No		→ CONTINUE
Refused		→ CONTINUE

15. What is your race? (Please select one or more from the following):

[READ LIST IF NECESSARY- ASSIGN RESPONSE TO ONE OR MORE GROUPS BELOW]

American Indian / Alaska Native		→ CONTINUE
Asian		→ CONTINUE
Black or African American		→ CONTINUE
Native Hawaiian / other Pacific Islander		→ CONTINUE
White		→ CONTINUE
Some other race		→ DOCUMENT:
Refused		→ CONTINUE
SCREEN FOR MIX		

16. Was your total household income in 2016...?

Less than \$20,000		→ CONTINUE
\$20,000 - \$34,999		→ CONTINUE
\$35,000 - \$49,999		→ CONTINUE
\$50,000 - \$74,999		→ CONTINUE

\$75,000 - \$99,999		➔ CONTINUE
\$100,000 - \$149,999		➔ CONTINUE
\$150,000 or more		➔ CONTINUE
Refused		➔ CONTINUE

NOTE: USE THE CLOSING SCRIPT AND CONTACT INFORMATION SHEET TO SCHEDULE AN INTERVIEW.