

Appendix C

Multiple Indications Study Questionnaire

DHHS research authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)). Confidentiality protected by 5 U.S.C. 552(a) and (b) and 21 CFR part 20.

OMB Control #xxxxx Expires xxxxx

[PROGRAMMER: Question piping is in green font]

AUDIO AND VIDEO CHECK INSTRUCTIONS

Before beginning the survey, please complete a brief **audio and video test**. Make sure your computer is on with the volume turned up, then click the Continue button to start the audio and video test.

[PROGRAMMER: NEXT SCREEN - AUDIO CHECK]

[Audio Check]

Please identify the animal you just heard.

- 1 Dog [Terminate]
- 2 Cat [Terminate]
- 3 Elephant [Terminate]
- 4 Frog [CORRECT]
- 5 Ape [Terminate]
- 6 Horse [Terminate]
- 7 Bird [Terminate]
- 8 I could not hear an animal [Terminate]

[PROGRAMMER: NEXT SCREEN - VIDEO CHECK]

[Video Check]

What animal can you see in the video above?

- 1 Dog [Terminate]
- 2 Cat [Terminate]
- 3 Elephant [CORRECT]
- 4 Frog [Terminate]
- 5 Ape [Terminate]
- 6 Horse [Terminate]
- 7 Bird [Terminate]
- 8 I could not see an animal [Terminate]

[PROGRAMMER: NEXT SCREEN]

ADVERTISEMENT INSTRUCTIONS

On the next screen, you will see a television advertisement for a new product. The ad may take 15-30 seconds to start playing.

Make sure you are comfortable and can read the screen from where you sit. Do your best to remember details about the ad.

Once you finish viewing the ad, please click the Continue button.

[DISPLAY ASSIGNED AD] [SUPPRESS "CONTINUE" BUTTON UNTIL AD FINISHES PLAYING]

[PROGRAMMER: NEXT SCREEN]

We would like you to watch the ad a second time. Please click the Continue button to view the ad again.

[DISPLAY ASSIGNED AD AGAIN] [SUPPRESS "CONTINUE" BUTTON UNTIL AD FINISHES PLAYING]

[PROGRAMMER: NEXT SCREEN]

Q1. Were you able to see and hear the ad from start to finish both times?

- Yes
 No [Terminate]
 Not sure [Terminate]

[PROGRAMMER: For remaining questions, if respondent does not provide response, prompt with, "Are you sure you don't want to provide a response?" before allowing to continue.]

Now, please answer the following questions based on the ad you saw. If you don't know or aren't sure of the answer to a question, just take your best guess.

[PROGRAMMER: NEXT SCREEN]

[BENEFIT RECALL]

Q2. What are the benefits of [DRUG X/DRUG Y]? Please be as detailed and specific as possible when entering your answer in the space provided. List as many benefits as you can remember from the ad.

[Open Field]

[Study 1 codes: diabetic neuropathy/diabetes pain/diabetes nerve pain, nerve pain, burning pain/sensation, pins and needles, shooting pain, widespread pain, pain, overactive nerves, chronic pain, fibromyalgia, anxiety; don't know/not sure; diabetic health; other]

[Study 2 codes: rheumatoid arthritis/RA, psoriatic arthritis/PA, osteoarthritis, arthritis, joint pain, pain and/or swelling and/or inflammation, helps stop progression of joint damage, clearer skin, ulcerative colitis, stomach/bowel/abdominal pain/problems, diarrhea, don't know/not sure, other]

[PROGRAMMER: NEXT SCREEN]

[INDICATION RECOGNITION]

Q3. Consider the following list of health conditions which may or may not have been mentioned in the ad you watched.

Please read each statement and select whether you think the statement is true or false **based strictly on the information you remember seeing in the ad.**

[PROGRAMMER: SHOW FOR STUDY 1]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

[DRUG X] is for adults with...	True	False
a. Diabetes-related nerve pain		
b. Fibromyalgia		
c. Generalized anxiety disorder		
d. Chronic pain		
e. Depression		
f. Asthma		
g. High cholesterol		

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

[DRUG Y] is for adults with...	True	False
a. Rheumatoid arthritis		
b. Psoriatic arthritis		
c. Ulcerative colitis		
d. Joint pain		
e. Lymphoma		
f. Acne		
g. High cholesterol		

[PROGRAMMER: NEXT SCREEN]

[RISK RECOGNITION]

Q4. Consider the following list of risks or side effects. Some of these were mentioned in the ad you saw as risks or side effects of taking [DRUG X/DRUG Y]. Please answer the question below **based on the information you remember seeing in the ad.**

If you remember a risk or side effect being mentioned, check “Mentioned in the ad”. If not, check “Not mentioned in the ad”.

[PROGRAMMER: SHOW FOR STUDY 1]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

[DRUG X] can cause...	Mentioned in the ad	Not Mentioned in the ad
a. thoughts of suicide		
b. trouble breathing		
c. a life-threatening interaction with another drug called monoamine oxidase inhibitor (MAOI)		
d. paralysis		
e. hallucinations		

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

[DRUG Y] can cause...	Mentioned in the ad	Not Mentioned in the ad
a. nervous system problems		
b. serious infections		
c. perforations (tears) in the stomach or intestines		
d. trouble falling or staying asleep		
e. heart failure		

[PROGRAMMER: NEXT SCREEN]

[GENERAL INDICATION COMPREHENSION]

Q5. Based on the information in the ad, in addition to treating [diabetes-related nerve pain/rheumatoid arthritis], [DRUG X/DRUG Y] can treat other health conditions.

- True
- False

[PROGRAMMER: NEXT SCREEN]

Q6. [DRUG X/DRUG Y] can treat **any type** of [chronic pain/joint pain] not just [diabetes-related nerve pain].

1

2

3

4

5

Definitely false

Definitely
true

[PROGRAMMER: NEXT SCREEN]

[PROGRAMMER: NEW SCREEN FOR EACH QUESTION Q7D-Q10D]

[PROGRAMMER: SHOW Q7D-Q10D FOR STUDY 1]

[PROGRAMMER: RANDOMIZE Q7D-Q10D]

For the next set of questions, answer whether you think each person would be a good candidate for taking [DRUG X] based on the information you saw in the ad.

[PROGRAMMER: NEXT SCREEN]

[INDICATION OVERGENERALIZATION]

Q7D. Ryan has chronic back pain and needs a prescription drug to manage his symptoms. Based on the information in the ad, is he a good candidate for [DRUG X]?

- Yes
- No

[FIRST INDICATION COMPREHENSION]

Q8D. Mark has pain in his feet. His doctor says the pain is caused by nerve damage related to his diabetes. Based on the information in the ad, is he a good candidate for [DRUG X]?

- Yes
- No

[SECOND INDICATION COMPREHENSION]

Q9D. Michelle experiences widespread pain and fatigue. Her doctor recently told her she has fibromyalgia. Based on the information in the ad, is she a good candidate for [DRUG X]?

- Yes
- No

Q10D. Kate is experiencing persistent worry and anxiety. Her doctor diagnosed her with generalized anxiety disorder. Based on the information in the ad, is she a good candidate for [DRUG X]?

- Yes
- No

[PROGRAMMER: NEXT SCREEN]

[PROGRAMMER: NEW SCREEN FOR EACH QUESTION Q7RA-Q10RA]

[PROGRAMMER: SHOW Q7RA-Q10RA FOR STUDY 2]

[PROGRAMMER: RANDOMIZE Q7RA-Q10RA]

For the next set of questions, answer whether you think each person would be a good candidate for taking [DRUG Y] based on the information you saw in the ad.

[PROGRAMMER: NEXT SCREEN]

[INDICATION OVERGENERALIZATION]

Q7RA. Ryan is experiencing joint pain. His doctor told him the pain is caused by torn cartilage. Based on the information in the ad, is he a good candidate for [DRUG Y]?

- Yes
- No

[FIRST INDICATION COMPREHENSION]

Q8RA. Mark is experiencing joint redness and swelling. His doctor says this is caused by his rheumatoid arthritis. Based on the information in the ad, is he a good candidate for [DRUG Y]?

- Yes
- No

[SECOND INDICATION COMPREHENSION]

Q9RA. Michelle experiences swollen fingers and toes. Her doctor recently told her she has psoriatic arthritis. Based on the information in the ad, is she a good candidate for [DRUG Y]?

- Yes
- No

Q10RA. Kate was recently diagnosed with ulcerative colitis. She experiences abdominal pain and diarrhea. Based on the information in the ad, is she a good candidate for [DRUG Y]?

- Yes
- No

[PROGRAMMER: NEXT SCREEN]**[MISCONCEPTION ABOUT INDICATION INFORMATION]****[PROGRAMMER: SHOW Q11D FOR STUDY 1]**

[PROGRAMMER: Notes for Q11D. Study 1:

- Condition 1 - Main indication condition: randomize the combination of indications shown to respondents: diabetes-related nerve pain and fibromyalgia OR diabetes-related nerve pain and generalized anxiety disorder,
- Condition 2 - Main indication + similar indication condition show diabetes-related nerve pain and fibromyalgia,
- Condition 3 - Main indication + dissimilar indication condition show diabetes-related nerve pain and generalized anxiety disorder.

Q11D. Based on your understanding of the ad you watched, please answer the following question.

People who have been diagnosed with diabetes-related nerve pain can take **DRUG X** only if they have **also** been diagnosed with [Condition 1 and 2: fibromyalgia / Condition 1 and 3: generalized anxiety disorder].

- True
- False

[PROGRAMMER: SHOW FOR STUDY 2]

[PROGRAMMER: Notes for Q10RA. Study 2

- Condition 1 - Main indication condition: randomize the combination of indications shown to respondents: rheumatoid arthritis and psoriatic arthritis OR rheumatoid arthritis and ulcerative colitis,
- Condition 2 - Main indication + similar indication condition show rheumatoid arthritis and psoriatic arthritis,
- Condition 3 - Main indication + dissimilar indication condition show rheumatoid arthritis and ulcerative colitis.]

Q11RA. Based on your understanding of the ad you watched, please answer the following question.

People who have been diagnosed with rheumatoid arthritis can take **DRUG Y** only if they have also been diagnosed with [Condition 1 and 2: psoriatic arthritis / Condition 1 and 3: ulcerative colitis].

- True
- False

[PROGRAMMER: NEXT SCREEN]

[PERCEIVED RISK OF OTHER CONDITIONS]

[PROGRAMMER: SHOW Q12D-Q13D FOR STUDY 1]

[PROGRAMMER: RANDOMIZE ORDER OF Q12D-Q13D]

[PROGRAMMER - Keep this text on screen for Q12D and Q13D: “Based on your understanding of the ad you watched, please answer the following question.”]

Q12D. People with diabetes-related nerve pain are at greater risk for developing fibromyalgia.

1	2	3	4	5
Definitely false				Definitely true
				true

[PROGRAMMER: NEXT SCREEN]

Q13D. People with diabetes-related nerve pain are at greater risk for developing generalized anxiety disorder.

1	2	3	4	5
Definitely false				Definitely true
				true

[PROGRAMMER: SHOW Q12RA-Q13RA FOR STUDY 2]

[PROGRAMMER: RANDOMIZE ORDER OF Q12RA-Q13RA]

[PROGRAMMER - Keep this text on screen for Q12RA and Q13RA: “Based on your understanding of the ad you watched, please answer the following question.”]

Q12RA. People with rheumatoid arthritis are at greater risk for developing psoriatic arthritis.

1	2	3	4	5
Definitely false				Definitely true

[PROGRAMMER: NEXT SCREEN]

Q13RA. People with rheumatoid arthritis are at greater risk for developing ulcerative colitis.

1	2	3	4	5
Definitely false				Definitely true

[PROGRAMMER: NEXT SCREEN]

[AD-PROMPTED ACTIONS]

[PROGRAMMER: Keep this text on screen for Q14-Q22 “Based on the ad you saw...”]

Q14. How likely are you to look for more information about [DRUG X/DRUG Y]?

1	2	3	4	5	6
Not at all likely					Extremely likely

Q15. How likely are you to ask your doctor for more information about [DRUG X/DRUG Y]?

1	2	3	4	5	6
Not at all likely					Extremely likely

[PROGRAMMER: NEXT SCREEN]

[PERCEIVED BENEFIT - MAGNITUDE]

Q16. How much would [DRUG X/DRUG Y] improve [diabetes-related nerve pain/rheumatoid arthritis] symptoms?

1	2	3	4	5	6
No improvement					Substantial improvement

[PERCEIVED BENEFIT - LIKELIHOOD]

Q17. How likely is it that [DRUG X/DRUG Y] would [reduce diabetes-related nerve pain/relieve rheumatoid arthritis] symptoms?

1	2	3	4	5	6
Not at all likely					Extremely likely

[PROGRAMMER: NEXT SCREEN]

[PERCEIVED RISK - MAGNITUDE]

Q18. How serious are [DRUG X/DRUG Y]'s side effects?

1	2	3	4	5	6
Not at all serious					Extremely serious

[PERCEIVED RISK - LIKELIHOOD]

Q19. How likely is it that you would experience at least one side effect if you took [DRUG X/DRUG Y]?

1	2	3	4	5	6
Not at all likely					Extremely likely

[PROGRAMMER: NEXT SCREEN]

[PERCEIVED RISK AND EFFICACY - COMPARATIVE]

Q20. [DRUG X/DRUG Y] is more effective than other prescription drugs that treat [diabetes-related nerve pain/rheumatoid arthritis].

1	2	3	4	5	6
Strongly disagree					Strongly agree

Q21. [DRUG X/DRUG Y] is safer than other prescription drugs that treat [diabetes-related nerve pain/rheumatoid arthritis].

1	2	3	4	5	6
Strongly disagree					Strongly agree

[PROGRAMMER: NEXT SCREEN]

[BENEFIT/RISK TRADEOFF]

[PROGRAMMER: RANDOMIZE ORDER OF ITEMS]

	1	2	3	4	5	6	
a. A bad option	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A good option
b. Harmful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Helpful
c. Useless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Useful

[PROGRAMMER: NEXT SCREEN]

[HEALTH LITERACY]

Q26. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

[PROGRAMMER: NEXT SCREEN]

[PAST EXPERIENCE WITH DISEASE TREATMENT]

[PROGRAMMER: SHOW Q27D FOR STUDY 1]

Q27D. How familiar are you with prescription drugs for...

	1	2	3	4	5	6
	Very unfamiliar					Very familiar
[randomize order of items]						
diabetes-related						
nerve pain						
fibromyalgia						
generalized						
anxiety disorder						

[PROGRAMMER: SHOW Q27RA FOR STUDY 2]

Q27RA. How familiar are you with prescription drugs for...

	1	2	3	4	5	6
	Very unfamiliar					Very familiar
[randomize order of items]						
rheumatoid						

arthritis
psoriatic
arthritis
ulcerative colitis

[PROGRAMMER: NEXT SCREEN]

[PROGRAMMER: SHOW Q28D-Q30D FOR STUDY 1]

Q28D. Have you ever experienced diabetes-related nerve pain?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q29D. Have you ever been diagnosed with diabetes-related nerve pain?

- Yes
- No [PROGRAMMER NOTE: GO TO Q31]
- Don't know [PROGRAMMER NOTE: GO TO Q31]

[PROGRAMMER: NEXT SCREEN]

Q30D. Have you ever taken a prescription drug for diabetes-related nerve pain?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

[PROGRAMMER: SHOW FOR STUDY 2]

Q30RA. Have you ever taken a prescription drug for rheumatoid arthritis?

- Yes
- No
- Don't know

[PROGRAMMER: NEXT SCREEN]

Q31. Have you ever heard of [DRUG X/DRUG Y] before today?

- Yes
- No

[PROGRAMMER: NEXT SCREEN]

[DEBRIEF]

The purpose of this study is to learn about reactions to prescription drug information. To get a real-life reaction, we used a pretend product in this study. While [DRUG X/DRUG Y] is not a real product and is not available for sale, your participation in this important study helps us better understand how to communicate the benefits and risks of prescription drugs to consumers clearly and usefully. Your responses will help make prescription drug information clearer. Please see your health care provider for questions about [diabetes-related nerve-pain/rheumatoid arthritis].

You have been very helpful. Thank you very much for your participation!