

FDA Ad Exposure Frequency Study
06.04.15

[PROGRAMMER: Insert OMB control number on every screen page]

INTRODUCTION

Please make sure you are comfortable and can read the screen from where you sit. For the next 90 minutes, you will watch a television program with some commercials and then answer questions on this computer. Please watch the entire television program, including the commercials. After you have finished watching the television program, you will be instructed to answer some questions.

On the next few screens, you will be shown an informed consent form that describes the study and your rights as a study participant in more detail.

[PROGRAMMER: New screen with INFORMED CONSENT FORM]

First, we would like you to click on the following link to watch an hour-long television program. Then you will be directed to the survey.

Make sure you are comfortable and can read the screen from where you sit.

INSERT DIRECTIONS FOR INCREASING SIZE OF FONT ON COMPUTER

Because the survey will include some audio, we first want to be sure the sound on your computer is active and you can hear the advertisement.

Please put your headphones on now, if you have not already done so.

When you are ready, you can test the volume of your speakers by pressing the “Play” button on the file below. As a reminder, the “Play” button looks like this ►.

[INSERT AUDIO FILE]

To stop or pause the audio, press the “Pause” button (||). You may play this audio file as many times as needed.

To adjust the volume, please use the laptop keyboard. The yellow box in the image below shows the volume keys.

To adjust the volume “up,” use the + key. To adjust the volume “down,” use the – key.

If you have questions or technical difficulties, please raise your hand and someone will come and assist you.



[PROGRAMMER: Insert LINK TO VIDEO STIMULI. At completion of video, go to new screen to begin survey]

[PROGRAMMER: New screen]

SURVEY INSTRUCTIONS

You may remove your headphones at this time, as the survey will not include any additional audio.

Please answer the following questions. We estimate that the survey will take you about 20 minutes to complete.

1a. Were you able to view and hear the tv show and ads?

[Recall drug name]

1. One of the ads you saw was for a medication for seasonal allergies. Do you recall the name of that drug? Was it:
 - Rheutopia
 - [DRUG X]
 - Coravaz

[Counter arguing (# of negative thoughts)]

2. The name of the seasonal allergy drug you saw advertised was [DRUG X]. Please think of the [DRUG X] ad you watched. List all thoughts (including unrelated thoughts) that came to your mind as you watched it.

[INCLUDE 1 LARGE TEXT BOX WITH CHARACTER COUNTERS]

- 2b. Now that you have listed your thoughts, please rate each one as either positive (+), negative (-) or neutral (0):

[INCLUDE SMALL BOX NEXT TO EACH THOUGHT FOR RATING]

[RANDOMIZE ORDER OF QUESTION BLOCK 3-15 and QUESTION 16]

[RANDOMIZE ORDER OF Q3 and Q4]

[Recall-Risks (unaided)]

3. What are the side effects or risks of [DRUG X]? (Please list as many side effects or risks as you can remember.) **[open ended]**

[INCLUDE SAME NUMBER OF TEXT BOXES AS NUMBER OF RISKS IN AD-(12)]

[Recall-Benefits (unaided)]

4. What are the benefits of [DRUG X]? (Please list as many benefits as you can remember.)

[open ended] [INCLUDE SAME NUMBER OF TEXT BOXES AS NUMBER OF BENEFITS IN AD-(5)]

5. What else do you remember from the [DRUG X] ad? **[open-ended]**

[INCLUDE LARGE TEXT BOX WITH CHARACTER COUNTER]

[RANDOMIZE ORDER OF Q6 and Q7]

[Recognition-Risks]

6. Please check which of the following statements were mentioned in the ad as side effects or risks of taking [DRUG X]. Select “Mentioned in the Ad” if the side effects or risks are mentioned in the ad, even if the statement does not match word for word what you recall from the ad. Even if you think a statement is true, please select it only if it was mentioned in the ad. Check all that apply.

[RANDOMIZE ORDER]	Mentioned In Ad	Not Mentioned In Ad
a. The most common side effects of [DRUG X] include headache, viral infection, sore throat, coughing and nosebleeds.	X	
b. [DRUG X] can cause nausea in some people.		X
c. Some people may experience eye problems from [DRUG X] such as glaucoma or cataracts.	X	
d. [DRUG X] may cause slow wound healing.		X
e. In rare cases, [DRUG X] can cause severe allergic reactions.	X	
f. [DRUG X] can cause extreme dizziness in some people.	X	
g. Contact your doctor if you experience sudden changes in hearing.		X

[Recognition-Benefits]

7. Please check which of the following statements were mentioned in the ad as benefits of taking [DRUG X]. Select “Mentioned in the Ad” if the benefits are mentioned in the ad, even if the statement does not match word for word what you recall from the ad. Even if you think a statement is true, please select it only if it was mentioned in the ad. Check all that apply.

[RANDOMIZE ORDER]	Mentioned In Ad	Not Mentioned In Ad
a. [DRUG X] is taken once a day.	X	
b. [DRUG X] is non-drowsy.		X
c. [DRUG X] is available in pill form.		X
d. [DRUG X] can treat runny nose.	X	
e. [DRUG X] is non-habit forming.	X	
f. [DRUG X] can also be used to treat the common cold.		X
g. [DRUG X] can treat nasal congestion.	X	

[RANDOMIZE ORDER OF QUESTION BLOCK 9-10 and QUESTION BLOCK 12-13]

Most people don't know how a prescription drug will affect them until they've taken the drug. But we'd like you to make your **best guess** based on the [DRUG X] ad you just saw. Please answer the following questions based on **what you saw in the [DRUG X] ad**.

[Perceived Risk (Likelihood)]

9. In your opinion, if you were to take [DRUG X], how likely would you be to have side effects or risks?

- Not at all likely
- Slightly likely
- Moderately likely
- Very likely
- Extremely likely

[Perceived Risk (magnitude)]

10. If you did have side effects or risks, how serious do you expect they would be?

- Not at all serious
- Somewhat serious
- Moderately serious
- Very serious

- Extremely Serious

[Perceived Efficacy (Likelihood)]

RANDOMIZE ORDER

12. In your opinion, if you were to take [DRUG X], how likely is it that the drug would work for you?

- Not at all likely
- Slightly likely
- Moderately likely
- Very likely
- Extremely likely

[Perceived Efficacy (Magnitude)]

13. In your opinion, how effective would [DRUG X] be in helping your seasonal allergies?

- Not at all effective
- Slightly effective
- Moderately effective
- Very effective
- Extremely effective

[Risk/benefit balance]

14. Think about the risks and benefits of [DRUG X]. How would you rate the drug overall?

- Risks completely outweigh benefits
- Risks mostly outweigh benefits
- Risks slightly outweigh benefits
- Risks and benefits are equal
- Benefits slightly outweigh risks
- Benefits mostly outweigh risks
- Benefits completely outweigh risks

[Behavioral Intentions]

15. Based on the ad, how likely are you to do each of the following behaviors?

	Not at all likely	Slightly likely	Moderately likely	Very likely	Extremely likely
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[ASK 19 ONLY OF RESPONDENTS WHO VIEWED THE AD MORE THAN ONCE]

19. How much attention did you pay to the last ad you saw about [DRUG X]?
- None
 - Very little
 - Some
 - Quite a bit
 - A great deal

[Perceptions of FDA approval of ads and ad claims]

20. Would you say the following statements are true or false?

		True	False
a.	a. The FDA only approves prescription drugs that have been found to be extremely effective.		
b.	b. The FDA only approves prescription drugs that do not have serious side effects.		
	c. Only prescription drugs that have been found to be extremely effective can be advertised to consumers.		
	d. Prescription drugs that have serious side effects cannot be advertised to consumers.		
	e. The U.S. Food and Drug Administration (FDA) approves all prescription drug TV ads before they can be shown to the public.		
	f. All of the information in prescription drug ads is true and accurate.		
	g. I believe in all of the information provided in prescription drug TV ads		
	h. Only the safest prescription drugs are allowed to be advertised to the public in TV ads.		

[Perceptions of ad truthfulness]

- 21a. In your opinion, how misleading was the [DRUG X] ad you saw?
- Not at all misleading
 - Slightly misleading
 - Moderately misleading

- Very misleading
- Extremely misleading

[RANDOMIZE ORDER OF QUESTION 23 and QUESTION 24]

[Attitudes toward amount of risk information in ad]

22. How do you feel about the amount of risk information presented in the [DRUG X] ad?

- The ad did not have enough risk information
- The ad had just the right amount of risk information
- The ad had too much risk information

[Attitudes toward amount of benefit information in ad]

23. How do you feel about the amount of benefit information presented in the [DRUG X] ad?

- The ad did not have enough benefit information
- The ad had just the right amount of benefit information
- The ad had too much benefit information

[Perceived ease of understanding]

[RANDOMIZE ORDER OF QUESTIONS 24 and 25]

24. Based on the ad you just saw, how easy or difficult to understand were the benefits of using [DRUG X]?

- Difficult to understand
- Somewhat difficult to understand
- Neither easy nor difficult to understand
- Somewhat easy to understand
- Easy to understand

25. Based on the ad you just saw, how easy or difficult to understand were the risks of using [DRUG X]?

- Difficult to understand
- Somewhat difficult to understand
- Neither easy nor difficult to understand
- Somewhat easy to understand
- Easy to understand

[Biased processing/inattention]

26. I would prefer not to think about seasonal allergy treatment at the moment

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

[Perceived worry about side effects/drug therapy concerns]

27. If you took [DRUG X], how concerned would you be about the side effects?

- Not at all concerned
- Slightly concerned
- Moderately concerned
- Very concerned
- Extremely concerned

Thank you for answering those questions about the [DRUG X] ad. Now, we would like to ask for your personal opinion about a few other topics.

[Next screen]

[Need for cognition]

28. How much do you agree or disagree with the following statements?

	1				5
[RANDOMIZE ORDER]	Disagree a lot	Disagree	Uncertain	Agree	Agree a lot

- a. I like to have the responsibility of handling a situation that requires a lot of thinking.
- b. I prefer complex to simple problems
- c. I try to anticipate and avoid situations where there is a likely chance I will have to think in depth about something.

[Health Literacy]

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

- Not at all confident
- Slightly confident

- Moderately confident
- Very confident
- Extremely confident

[TV/Media Use]

30. In the past 7 days, on how many days did you . . .
- Read a newspaper or magazine _____
 - Watch television_____
 - Listen to the radio (including in the car, at home or at work)_____
 - Use the Internet for email _____
 - Use the Internet, other than for e-mail_____

[Current Prescription Drug Use]

31. Are you currently taking, or have you ever taken, any prescription drugs for seasonal allergies?
- Currently taking
 - Have taken in the past but not currently taking
 - Have never taken, and not considering taking
 - Have never taken, but considering taking

[ASK ONLY OF THOSE WHO ANSWER “CURRENTLY TAKING” TO 31].

[Medication necessity]

32. We would like to ask you about your personal views about seasonal allergy medications prescribed for you. Below are statements other people have made about their medications. Please indicate how much you agree or disagree with them by checking the appropriate box. There are no right or wrong answers. We are interested in your personal views.

[RANDOMIZE ORDER]	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree
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- a. My health, at present, depends on my seasonal allergy medications
- b. My life would be impossible without my seasonal allergy medications
- c. Without my seasonal allergy medications I would be very ill
- d. My health in the future will depend on my seasonal allergy

medications

e. My seasonal allergy
medications protect me from
becoming worse

**[ASK ONLY OF THOSE WHO ANSWER THAT THEY ARE CURRENTLY TAKING A
DRUG IN QUESTION 31.]**

[Satisfaction with current treatment]

33. How satisfied are you with your current seasonal allergy treatment?
- Not at all satisfied
 - Slightly satisfied
 - Moderately satisfied
 - Very satisfied
 - Completely satisfied

[Satisfaction with AVAILABLE treatments]

34. Think about drugs for seasonal allergies that are currently available. How satisfied are you with their ability to control your allergies?
- Not at all satisfied
 - Slightly satisfied
 - Moderately satisfied
 - Very satisfied
 - Completely satisfied

[History of Side Effects]

[Programmer: Please place 35 and 36 on the same screen]

35. Have you ever had a serious side effect from a prescription drug?
- Yes
 - No
 - Don't Know
36. Have you ever had a serious side effect from a prescription **allergy** drug?
- Yes
 - No
 - Don't Know

[Illness Duration]

37. When did a healthcare professional first tell you that you had seasonal allergies?

- Six months ago or less
- More than six months ago but less than a year ago
- More than a year ago but less than 5 years ago
- Five years ago or longer

[Illness severity]

38. In general, how severe are your seasonal allergies? Would you describe them as:
- Very mild
 - Mild
 - Moderate
 - Serious
 - Severe

[Illness knowledge]

39. In general, how much would you say you know about seasonal allergies? Would you say you know:

- Nothing at all
 - Only a slight amount
 - Some
 - More than some but not a lot
 - A lot
40. Which of the following is a common symptom of seasonal allergies?
- Sneezing
 - Chronic pain in the ears and eyes
 - Excessive thirst
 - Vomiting
 - Don't know
41. Which of the following is another name for seasonal allergies?
- Histamine
 - Halitosis
 - Hay fever
 - Heat rash
 - Don't know
42. Seasonal allergies are often caused by your body's allergic response to:
- Parasites
 - Petals

- Pollen
- Seeds
- Don't know

43. What typically causes seasonal allergies in the fall?

- Orchard grass
- Bluegrass
- Pollinating trees
- Ragweed
- Don't know

[Age]

44. Please tell us your age

[open ended] (VALID AGE RANGE SHOULD BE 18-100)

[Gender]

45. What is your sex?

- Male
- Female

[Education]

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

- Less than high school
- High school graduate (high school diploma or GED)
- Some college, but no degree
- Associate's degree (2-year)
- Bachelor's degree (4-year) (example: BA, BS)
- Advanced or postgraduate degree (example: MA, MD, DDS, JD, PhD, EdD)

[Race]

47. What is your race? (Select all that apply)

- American Indian or Alaska Native
- Asian
- Black or African-American
- Native Hawaiian or Other Pacific Islander
- White
- Some Other Race

[Ethnicity]

48. Are you:

- Hispanic or Latino
- Not Hispanic or Latino

Closing

This concludes the survey. Our goal was to gather patient reactions to important information about prescription drugs. To get your true reaction to this information, we used a fake brand of drug in this project.

[DRUG X] is not a real drug and it is not available for use or sale. Please contact your healthcare provider for any questions about seasonal allergies.

Thank you very much for your time.

Now that you are finished, please raise your hand, and an administrator will escort you out of the survey room quietly so as not to disturb other survey takers.