DRAFT Questionnaire: MAIN STUDIES

Programming instructions are indicated in blue font.
Questions specific to STUDY 1 are in GREEN.
Questions specific to STUDY 2 are in RED.

[PROGRAMMER:

• The viewing time of each page of the ad must be timed separately in milliseconds.
• Program progresses to the questioning in a "one-way" manner
• Record time in milliseconds spent on each screen (including questions) throughout protocol.]

Interview Protocol

(Present Informed Consent Form. Participants will be blind to FDA's sponsorship.)

[PROGRAMMER: Screen 1. TIME SPENT ON SCREEN IN MILLISECONDS]

Thank you for agreeing to participate in this study today.

Make sure you are comfortable and can read the screen from where you sit. This study is about advertising for a new product. We will show you an ad for a new product then ask you some questions about it. Your answers are private and will not be connected with your name. Your input is extremely valuable.

[PROGRAMMER: Screen 2. TIME SPENT ON SCREEN IN MILLISECONDS]

Some ads have two pages, others have only one. We will ask you some questions about the ad after you have finished reading it.

[PROGRAMMER: Screen 3. TIME SPENT ON SCREEN IN MILLISECONDS]

If you want to see a bigger image of the page, you can enlarge the page by clicking on it, and for two page ads you can flip between the pages by clicking the "Next" and "Back" buttons at the bottom of the screen. Once you finish reading the ad, please click "Start Next Part of Study" to move to the next part of the study. You may begin when you are ready.

 [PROGRAMMER: Record time in milliseconds spent on each page of each print ad.]

Now please answer the following questions based on the ads you saw.

Q1.   Were you able to view the ad for DRUG X?
       Yes
       No ➔ [Terminate]
       Not sure ➔ [Terminate]

Q1b.   Please list the thoughts that were going through your mind as you viewed the ad for DRUG X and list them below. Use one line for each thought.

[PROGRAMMER: Five separate text boxes]

Q2. What type of product is DRUG X? [PROGRAMMER: randomize responses]

Over the counter drug
Prescription drug
Herbal supplement
Lens cleaner
Not sure

Q3. What condition does DRUG X treat? [PROGRAMMER: randomize responses]

High blood pressure
Insomnia
Migraine headaches
Seasonal allergies
Diabetes
Acid Reflux/GERD
Not sure/Don't know

Q4. In your own words, what are the benefits of DRUG X? Use as many lines as you need.
[PROGRAMMER: Four separate text boxes]

[PROGRAMMER: Randomize order of Q5-Q6]

(Perceived Benefit)

Q5.   Based on the information in the ad, how effective would DRUG X be for you?

1	2	3	4	5	6	7
Not at all effective			Moderately effective			Very effective

Q6.   Based on the information in the ad, how well would DRUG X work for you?

1	2	3	4	5	6	7
Not at all well			Moderately well			Very well

[PROGRAMMER: randomize order of Q7a-h. Record time spent on series]

(Recall of Benefits)
[STUDY 1 ONLY]
Q7.   Based on the information in the ad, please check which of the following are

benefits of taking DRUG X.

	Yes	No	Don't Know
a. DRUG X is taken twice a day.		x	
b. DRUG X can be used for up to 3 months.	x		
c. DRUG X can help you stay asleep for up to 8 hours.	x		
d. DRUG X is safe for people with kidney problems.	x		
e. DRUG X treats insomnia in adults and children ages 10 and up.		x	
f. DRUG X is the #1 prescribed medication for insomnia.		x	
g. DRUG X combines two ingredients.	x		
h. DRUG X can be habit-forming.		x	
i. DRUG X leaves your system within 4 hours.		x	

[STUDY 2 ONLY]
Q7.   Based on the information in the ad, please check which of the following are benefits of taking DRUG X.

	Yes	No	Don't Know
a. You take DRUG X once a day.	x		
b. DRUG X can be taken with other blood pressure medications.	x		
c. You take DRUG X once a month.		x	
d. DRUG X can reduce your bad cholesterol levels.		x	
e. DRUG X can reduce your risk of having a stroke.	x		
f. DRUG X is approved to treat children under age 18.		x	
g. DRUG X can help prevent heart attacks.	x		
i. DRUG X is the #1 prescribed high blood pressure medication.		x	

Q8.   In your own words, what are the side effects and negative outcomes of DRUG X?
Use as many lines as you need.

(Perceived Risk)

Q9.   Based on the information in the ad, how safe would DRUG X be for you?

1	2	3	4	5	6	7
Not at all Safe			Moderately safe			Very safe

Q10.   Based on the information in the ad, how risky would DRUG X be for you?

1	2	3	4	5	6	7
Not at all risky			Moderately risky			Very risky

Q11.   Based on the information in this ad, how likely is it that you would have a side effect from DRUG X?

1	2	3	4	5	6	7
Not at all likely			Moderately likely			Very likely

[PROGRAMMER: Randomize order of Q12a-i. Record time spent on series.]
(Recall of Risks)
[STUDY 1 ONLY]
Q12.   Based on the information in the ad, please check which of the following are risks of taking DRUG X.

	Yes	No	Don't Know
a. TTP is a risk when you take DRUG X		x	
b. You need blood tests when taking DRUG X.		x	
c. People with liver problems should not take DRUG X.	x		
d. A common side effect of DRUG X is ringing in the ears.	x		
e. A common side effect of DRUG X is blurred vision.	x		
f. People with a history of depression should not take DRUG X.	x		
g. A common side effect of DRUG X is dizziness.	x		
h. People with kidney problems should not take DRUG X.		x	
i. A common side effect of DRUG X is joint pain.		x	
j. DRUG X may cause hallucinations.	x		

[STUDY 2 ONLY]
Q12.   Based on the information in the ad, please check which of the following are risks of taking DRUG X.

	Yes	No	Don't Know
a. Taking some kinds of over-the-counter cough medicines at the same time as taking DRUG X increases your risk of having a heart attack.		x	
b. DRUG X may cause excitability.		x	
c. DRUG X may cause an allergic reaction called angiodema.	x		
d. You should not stop taking DRUG X suddenly.	x		

e. A common side effect of DRUG X is skin rash.	x		
f. Antibiotics may not work as well if you use DRUG X at the same time.		x	
g. A common side effect of DRUG X is dry cough.	x		
h. A common side effect of DRUG X nausea.		x	

[PROGRAMMER: Rotate order of Q13-Q14]

(Perceived Comparative Benefit and Risk)

Q13. Compared to other treatments you could take for insomnia, how well do you think DRUG X works?

> Much better
> Somewhat better
> About the same
> Somewhat worse
> Much worse

Q14. Compared to other treatments you could take for insomnia, how safe or risky do you think DRUG X is?

> Much safer
> Somewhat safer
> About the same
> Somewhat riskier
> Much riskier

[PROGRAMMER: If Q13 = much better (1) or Q13 = somewhat better (2), ask Q15]

Q15. You said DRUG X works better than other treatments for insomnia. What in the ad made you say DRUG X works better?
[PROGRAMMER: Four separate text boxes]

Codes to be determined through pretesting

[PROGRAMMER: If Q14 = somewhat riskier (4) or Q14 = much riskier (5), ask Q16]

Q16. You said DRUG X was more risky than other treatments for insomnia. What in the ad made you say DRUG X was more risky?
[PROGRAMMER: Four separate text boxes]

Codes to be determined through pretesting

Q17. Thinking overall about the risks and benefits of DRUG X, would you say it has:

1	2	3	4	5	6	7
More risks benefits than benefits risks			Equal risks and benefits			More than

[PROGRAMMER: Randomize order of Q18a-d. Record time spent on series.]

(Risk/Benefit Tradeoff)

Q18. Please rate your agreement or disagreement with each of the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. The ad clearly communicated the *benefits* of DRUG X.					
b. The ad clearly communicated the *risks* of DRUG X.					
c. The ad evenly balanced the *risks and*					

benefits of DRUG X.					

(Behavioral Intention)

Q19a. How likely or not likely are you to look for more information about DRUG X?

       Not at all likely
       Somewhat likely
       Very likely
       Extremely likely

Q19b. How likely or not likely are you to switch to DRUG X?

       Not at all likely
       Somewhat likely
       Very likely
       Extremely likely

(Perceived Quality)
Q20.   How would you rate the quality of DRUG X?

   1 ------- 2------- 3 ------- 4 ------- 5 -------- 6 -------- 7
 Poor quality   Good quality

[PROGRAMMER: Randomize order of Q21a-c]
(Attitude toward Ad. From Bhutada et al., 2009, Shen & Chen, 2007, and MacKenzie & Lutz, 1989)

Q21.   In your opinion, was the ad for DRUG X: Please select one response for each row.

a.   1   2   3   4   5   6
       7
  Good
    Bad

b.   1   2   3   4   5   6
       7
  Pleasant
Unpleasant

c.   1   2   3   4   5   6
       7
  Favorable

Unfavorable

Q22a. Do you remember seeing a **coupon or other type of offer** in the ad for DRUG X?

Yes
No
Not sure

[If OFFER=NONE, skip to Q25a]
[PROGRAMMER: IF QUOTA GROUPS 4-24, SHOW THE FOLLOWING INTRODUCTION: Now we will show you the ad again. This ad had information about a coupon or offer for TRALSOM. When answering the next few questions, please think <u>only</u> about the coupon or offer mentioned in the ad. IF QUOTA GROUPS 1-3, SHOW THE FOLLOWING INTODUCTION: Now we will show you the ad again.]

 [PROGRAMMER: SHOW AD AGAIN]

This ad had information about a **coupon or offer** for DRUG X. When answering the next few questions, please think <u>only</u> about the **coupon or offer** mentioned in the ad.

Q22b. What did the coupon or offer say? Please choose one. [PROGRAMMER: Randomize response choices]

"Money-Back Guarantee"
"Free 7-day Trial"
"Free 30-day Trial"
"$20 off cost of your prescription"
"#1 prescribed"
"Buy one, get one free"
"Buy two, get one free"
"$20 off the cost of your co-pay"
Don't know or uncertain

[Programmer: If OFFER=NONE, skip Q23 and Q24]
[PROGRAMMER: SHOW AD AGAIN]

 (Inferences about Offer)
Q23a. In your own words, list all your thoughts, reactions and ideas that went through your mind while you were looking at the **coupon or offer** in the ad for DRUG X. Please use a separate line for each thought.
[PROGRAMMER: Five separate text boxes]

| |
| |
| |
| |
| |

Q23b. For each of the thoughts, reactions and ideas you listed, indicate whether the thought was positive, negative or neutral.
[PROGRAMMER: Display responses from Q23a. For each response, include a drop-down choice box or other appropriate choice box with the choices POSITIVE, NEGATIVE, NEUTRAL]

You said…	Is it…
[insert each response from Q24a above in a separate box]	POSITIVE NEGATIVE NEUTRAL

(Peripheral Cue)

Q24a. To what extent do you agree or disagree that the **coupon or offer** was:

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. Noticeable					
b. Believable					
c. Distracting					

Q24b. How likely would you be to use this coupon or offer for DRUG X?

      1   2   3   4   5   6   7

Definitely use   Definitely not
the offer   use the offer

[PROGRAMMER: Randomize order of Q25a-d]
(Skepticism)

Q25a. How likely is it that the benefits of the drug presented in this ad are true?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

Not at all
Likely

Extremely
Likely

Q25b. How skeptical are you about the truth of the benefits of the drug presented in this ad?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

Not at all
Skeptical

Extremely
Skeptical

Q25c. How likely is it that the risks of the drug presented in this ad are true?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

Not at all
Likely

Extremely
Likely

Q25d. How skeptical are you about the truth of the risks of the drug presented in this ad?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

Not at all
Skeptical

Extremely
Skeptical

[Q26 BLANK]

[PROGRAMMER: randomize order of Q27a-i. Record time spent on series.]
(Coupon Proneness and Quality-Price Relationship)

Q27.   These next few questions are about coupons.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
a. Redeeming coupons makes me feel good.					
b. I enjoy clipping coupons out of newspapers.					
c. When I use coupons, I feel that I am getting a good deal.					

d. I enjoy using coupons, regardless of the amount I save by doing so.					
e. Beyond the money I save, redeeming coupons gives me a sense of joy.					
f. Generally speaking, the higher the price of a product, the higher the quality.					
g. The old saying "you get what you pay for" is generally true.					
h. The price of the product is a good indicator of its quality.					
i. You always have to pay a bit more for the best.					

(Subjective Health Literacy)

Q28. 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
Rarely
Sometimes
Often
Always

(Objective numeracy)

Q29. Now here are some questions that require you to use numbers to solve the problem. Some are easy, and others are more difficult. Please don't use a calculator: We'd like you to answer on your own. Remember, almost everyone will have trouble with these questions, so don't be upset if some are difficult—just do your best!

a. What is the correct answer:

17 – 8 + 4 = ?

   a. 11
   b. 13
   c. 21
   d. 23
   e. 29
   f. Don't know

b. What is the correct answer:

100 x 15 x 20 = ?

   a. 1,500
   b. 15,000
   c. 30,000
   d. 150,000
   e. 300,000
   f. Don't know

c. Imagine that you flip a fair coin 1,000 times. What is your best guess about how many times the coin would come up heads in 1,000 flips?

___ times out of 1,000 [PROGRAMMER: set acceptable range from 0 to 1,000]

d. In the BIG BUCKS LOTTERY, the chance of winning a $10 prize is 1%. What is your best guess about how many people would win a $10 prize if 1,000 people each buy a single ticket to BIG BUCKS LOTTERY?

_____ people [PROGRAMMER: set acceptable range from 0 to 1,000]

e. In ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME PUBLISHING SWEEPSTAKES will win a car?

___ percent [PROGRAMMER: set acceptable range from .001 to 100]

(Subjective Numeracy 1st part)
Q30. For each of the following questions, please check the box that best reflects how good you are at doing the following things:

a. How good are you at working with fractions?

$\square_1$ $\square_2$ $\square_3$ $\square_4$ $\square_5$ $\square_6$

Not at all   Extremely
good   good

b. How good are you at working with percentages?

$\square_1$ $\square_2$ $\square_3$ $\square_4$ $\square_5$ $\square_6$

Not at all   Extremely
good   good

c. How good are you at calculating a 15% tip?

$\square_1$ $\square_2$ $\square_3$ $\square_4$ $\square_5$ $\square_6$

Not at all   Extremely
good   good

d. How good are you at figuring out how much a shirt will cost if it is 25% off?

$\square_1$ $\square_2$ $\square_3$ $\square_4$ $\square_5$ $\square_6$

Not at all   Extremely
good   good

(Subjective Numeracy 2nd part)
Q31. For each of the following questions, please check the box that best reflects your answer:

a. When reading the newspaper, how helpful do you find tables and graphs that are part of a story?

$\square_1$ $\square_2$ $\square_3$ $\square_4$ $\square_5$ $\square_6$

Not at all   Extremely
helpful   helpful

b. When people tell you the chance of something happening, do you prefer that they use words ("it rarely happens") or numbers ("there is a 1% chance)?

$\square_1$ $\square_2$ $\square_3$ $\square_4$ $\square_5$ $\square_6$

Always Prefer   Always Prefer
Words   Numbers

c. When you hear a weather forecast, do you prefer predictions using percentages ("there will be a 20% chance of rain") or predictions using only words ("there is a small chance of rain today")?

☐₁   ☐₂   ☐₃   ☐₄   ☐₅   ☐₆

Always Prefer Percentages   **Always Prefer Words**

d. How often do you find numerical information to be useful?

☐₁   ☐₂   ☐₃   ☐₄   ☐₅   ☐₆

Never   **Very Often**

Now a few questions to help us describe our sample of participants.

[STUDY 1 ONLY]

Q32. Do you have sleep problems, such as trouble falling asleep, staying asleep, or insomnia?

       Yes
       No
       Don't know or uncertain

Q33. In general, how much do you feel you know about sleep problems?

       A lot
       A good bit
       Some
       Only a slight amount
       Nothing at all

Q34. In general, how much do you feel you know about **treatments** for sleep problems?

       A lot
       A good bit
       Some
       Only a slight amount
       Nothing at all

Q35. What type of product are you using to treat your sleep problems? You may select more than one.
       Prescription drug
       Over the counter drug
       Herbal supplement
       Something other product
       Behavior changes
       Nothing/I am not treating my sleep problems {skip to Q37}

Q36.   How satisfied or dissatisfied are you with the treatment for your sleep problems that you are using now?

        Very satisfied
        Somewhat satisfied
        Somewhat dissatisfied
        Very dissatisfied

[STUDY 2 ONLY]

Q32.   Do you have high blood pressure?
        Yes
        No
        Don't know or uncertain

Q33. In general, how much do you feel you know about high blood pressure?

        A lot
        A good bit
        Some
        Only a slight amount
        Nothing at all

Q34.   In general, how much do you feel you know about **treatments** for high blood pressure?

        A lot
        A good bit
        Some
        Only a slight amount
        Nothing at all

Q35.   What type of product are you using to treat your high blood pressure? You may select more than one.
        Prescription drug
        Over the counter drug
        Herbal supplement
        Something other product
        Behavior changes
        Nothing/I am not treating my high blood pressure {skip to Q37}

Q36.   How satisfied or dissatisfied are you with the treatment for your high blood pressure that you are using now?

        Very satisfied

Somewhat satisfied
Somewhat dissatisfied
Very dissatisfied

(Likelihood of Switching)
Q37. Based on what you read in the ad for DRUG X, how likely are you to switch from your current treatment to DRUG X?

1	2	3	4	5	6

  7
Not at all   Moderately
Very
likely   likely
likely

[Q38 BLANK]

Q39a. In your opinion, how risky are prescription drugs compared to over-the-counter drugs? Prescription drugs are…

1	2	3	4	5	6	7

Much less risky   About   Much more risky
                     the same

Q39b. In your opinion, how effective are prescription drugs compared to over-the-counter drugs? Prescription drugs are…

1	2	3	4	5	6	7

Much less   About   Much more
effective   the same   effective

Q40. What did you use to complete today's survey?
       Laptop computer / Netbook computer
       Desktop computer
       Handheld phone (iPhone, Blackberry, Droid)
       Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
       Other: _____

Q41. Did you receive any help on the questions that had numbers in them from anything or anyone (e.g., calculator, other person, website)? It's okay if you did—we just want an honest answer.
       Yes (write source_____)
       No

Q42.   Are you now covered by any form of health insurance or health plan? This includes any private insurance plan through your employer or a plan that you purchased yourself, as well as a government program like Medicare or Medicaid.

Yes

No   (skip Q43)

Don't Know

Q43.   Does your current insurance plan help pay for prescription drugs?

Yes

No

Don't Know

QP1.   Did you read the instructions at the beginning of the study?

Yes

No

[End time: _____]

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

[Closing and debriefing, Study 1]
The purpose of this research is to learn about consumer reactions to medical advertising. In order to get a real-life reaction to this information, we created a brand to use in this study. DRUG X is not a real product and it is not available for sale. Please see your healthcare professional for questions about insomnia.

[Closing and debriefing, Study 2]
The purpose of this research is to learn about consumer reactions to medical advertising. In order to get a real-life reaction to this information, we created a brand to use in this study. DRUG X is not a real product and it is not available for sale. Please see your healthcare professional for questions about high blood pressure.

END