

APPENDIX D

Pretest and Main Study Questionnaires

Pretest 1 Questionnaire

Format Study Questionnaire: PRETEST 1

Interview Protocol.

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

Instruction A. Thank you for agreeing to participate in this study today. Make sure you are comfortable and can read the screen from where you sit. Your answers are confidential and will not be connected to your name. Your input is extremely valuable.

[PROGRAMMER: Randomize such that the program flows in two orders, either (1) Instruction B, Instruction C, Q 1-10, Instruction D, Instruction E, Q11-22 OR (2) Instruction B, Instruction E, Q11-22, Instruction D, Instruction C, Q1-10. Record order.]

[PROGRAMMER: New screen]

Instruction B. When researchers want to know if a drug works, they conduct a clinical trial. In clinical trials, some people are given the real drug and others are given a fake drug (a placebo). No one knows who got what.

[PROGRAMMER: New screen]

Instruction C. Researchers look to see if people who got the real drug do better than people who did not get the real drug. Sometimes a drug is very effective and people who got the real drug do much better than people who got the placebo. Sometimes a drug is not effective and people who got the real drug do not do any better than people who got the placebo.

[PROGRAMMER: New screen]

[DRUG NAME] is a prescription drug you can take once a day to help prevent the return of heartburn symptoms. [PROGRAMMER: keep on screen for questions 1-10]

Imagine that a study was conducted to test the effectiveness of [DRUG NAME]. 100 people got a placebo (fake drug) and 100 people got [DRUG NAME]. Imagine that of the

100 people who got the placebo, 18 people had heartburn relief. [PROGRAMMER: keep on screen for questions 1-10]

[PROGRAMMER: Present questions 1 - 5 on the same screen]

[PROGRAMMER: randomize such that program flows in two orders, either 1-5 or 5-1]

Please read the following sentences and fill in the blanks.

1. If the drug [DRUG NAME] was EXTREMELY EFFECTIVE, how many people who got [DRUG NAME] would have heartburn relief?

- ____ out of 100 people who got the drug [DRUG NAME] had heartburn relief.
- __18__ out of 100 people who got the placebo had heartburn relief.

2. If the drug [DRUG NAME] was VERY EFFECTIVE, how many people who got [DRUG NAME] would have heartburn relief?

- ____ out of 100 people who got the drug [DRUG NAME] had heartburn relief.
- __18__ out of 100 people who got the placebo had heartburn relief.

3. If the drug [DRUG NAME] was MODERATELY EFFECTIVE, how many people who got [DRUG NAME] would have heartburn relief?

- ____ out of 100 people who got the drug [DRUG NAME] had heartburn relief.
- __18__ out of 100 people who got the placebo had heartburn relief.

4. If the drug [DRUG NAME] was A LITTLE EFFECTIVE, how many people who got [DRUG NAME] would have heartburn relief?

- ____ out of 100 people who got the drug [DRUG NAME] had heartburn relief.
- __18__ out of 100 people who got the placebo had heartburn relief.

5. If the drug [DRUG NAME] was NOT AT ALL EFFECTIVE, how many people who got [DRUG NAME] would have heartburn relief?

- ____ out of 100 people who got the drug [DRUG NAME] had heartburn relief.
- __18__ out of 100 people who got the placebo had heartburn relief.

[PROGRAMMER: new screen]

[PROGRAMMER: randomize such that program flows in two orders, either 6-10 or 10-6]

6. Imagine that **19 out of 100** people who got [DRUG NAME] had heartburn relief. How effective do you think [DRUG NAME] is?

1	2	3	4	5
Not at all effective	A little effective	Moderately effective	Very effective	Extremely effective

7. Imagine that **39 out of 100** people who got [DRUG NAME] had heartburn relief. How effective do you think [DRUG NAME] is?

1	2	3	4	5
Not at all effective	A little effective	Moderately effective	Very effective	Extremely effective

8. Imagine that **59 out of 100** people who got [DRUG NAME] had heartburn relief. How effective do you think [DRUG NAME] is?

1	2	3	4	5
Not at all effective	A little effective	Moderately effective	Very effective	Extremely effective

9. Imagine that **79 out of 100** people who got [DRUG NAME] had heartburn relief. How effective do you think [DRUG NAME] is?

1	2	3	4	5
Not at all effective	A little effective	Moderately effective	Very effective	Extremely effective

10. Imagine that **99 out of 100** people who got [DRUG NAME] had heartburn relief. How effective do you think [DRUG NAME] is?

1	2	3	4	5
Not at all effective	A little effective	Moderately effective	Very effective	Extremely effective

[\[PROGRAMMER: New screen\]](#)

Instruction D. As described earlier, when researchers want to know if a drug works, they conduct a clinical trial. In clinical trials, some people are given the real drug and others are given a fake drug (a placebo). No one knows who got what.

[\[PROGRAMMER: New screen\]](#)

Instruction E. Researchers look to see if people who got the real drug have more side effects than people who did not get the real drug. Sometimes a drug is very risky and people who got the real drug are much more likely to get a side effect than people who

got the placebo. Sometimes the drug is not at all risky and people who got the real drug are not any more likely to get a side effect than people who got the placebo.

[PROGRAMMER: New screen]

[DRUG NAME] is a prescription drug you can take once a day to help prevent the return of heartburn symptoms. One of its side effects is bone loss. [PROGRAMMER: Keep on screen for questions 11-22]

Imagine that a study was conducted to test the safety of [DRUG NAME]. 100 people got a placebo (fake drug) and 100 people got [DRUG NAME]. Imagine that of the 100 people who got the placebo, 2 people had bone loss. [PROGRAMMER: Keep on screen for questions 11-22]

[PROGRAMMER: Present questions 11 - 15 on the same screen]

[PROGRAMMER: randomize such that program flows in two orders, either 11-15 or 15-11]

Please read the following sentences and fill in the blanks.

11. If the drug [DRUG NAME] was EXTREMELY RISKY, how many people who got [DRUG NAME] would have to have bone loss?

- ____ out of 100 people who got the drug [DRUG NAME] had bone loss.
- 2 out of 100 people who got the placebo had bone loss.

12. If the drug [DRUG NAME] was VERY RISKY, how many people who got [DRUG NAME] would have to have bone loss?

- ____ out of 100 people who got the drug [DRUG NAME] had bone loss.
- 2 out of 100 people who got the placebo had bone loss.

13. If the drug [DRUG NAME] was MODERATELY RISKY, how many people who got [DRUG NAME] would have to have bone loss?

- ____ out of 100 people who got the drug [DRUG NAME] had bone loss.
- 2 out of 100 people who got the placebo had bone loss.

14. If the drug [DRUG NAME] was A LITTLE RISKY, how many people who got [DRUG NAME] would have to have bone loss?

- ____ out of 100 people who got the drug [DRUG NAME] had bone loss.
- 2 out of 100 people who got the placebo had bone loss.

15. If the drug [DRUG NAME] was NOT AT ALL RISKY, how many people who got [DRUG NAME] would have to have bone loss?

- ____ out of 100 people who got the drug [DRUG NAME] had bone loss.
- 2 out of 100 people who got the placebo had bone loss.

[PROGRAMMER: new screen]

[PROGRAMMER: randomize such that program flows in two orders, either 16-22 or 22-16]

16. Imagine that **83 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

17. Imagine that **63 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

18. Imagine that **43 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

19. Imagine that **23 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

20. Imagine that **13 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

21. Imagine that **8 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

22. Imagine that **3 out of 100** people who got [DRUG NAME] had bone loss. How risky do you think [DRUG NAME] is?

1	2	3	4	5
Not at all risky	A little risky	Moderately risky	Very risky	Extremely risky

23. Please describe what “bone loss” means to you. [\[open-ended\]](#)

24. Do you have heartburn or acid reflux disease?

Yes
No
Don't know or uncertain

25. Are you currently taking a prescription medicine for heartburn or acid reflux disease?

Yes
No
Don't know or uncertain

26. In general, how much do you feel you know about heartburn? Would you say you know:

1	2	3	4	5	6	7
Nothing at all						A lot

27. In general, how much do you feel you know about treatments for heartburn? Would you say you know:

1	2	3	4	5	6	7
Nothing at all						A lot

[\[PROGRAMMER: New screen\]](#)

The purpose of this research is to understand how people think about prescription drug information. In order to get an unbiased reaction to this information, we created a brand for this study. [DRUG NAME] is not a real product and it is not available for sale. Please see your healthcare professional for questions about heartburn or acid reflux disease.

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

Pretest 2 Questionnaire

[NOTE: In this pretest, participants will be randomly assigned to either answer questions about drug benefits or answer questions about drug risks]

[PROGRAMMER: Randomly assign participants to view the questions in one of the following orders: (1) Instruction A, Q1-Q5, Q11-Q16; (2) Instruction A, Q5 – Q1, Q11-Q16; (3) Instruction B, Q6-Q10, Q11-Q16; or (4) Instruction B, Q10-Q6, Q11-Q16. Record order.]

[PROGRAMMER: We need to record time in milliseconds spent on each screen (including questions) throughout protocol. Participants should not be able to return to questions after they have answered them.]

Interview Protocol.

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

(Instruction A) 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 prescription drugs. We will show you information about a prescription medication for heartburn five different times: each time the information about **how well the drug works** will change. After each time you see the information we will ask you some questions about it. Your answers are confidential and will not be connected to your name. Your input is extremely valuable.

(Instruction B) 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 prescription drugs. We will show you information about a prescription medication for heartburn five different times: each time the information about **the drug’s side effects** will change. After each time you see the information we will ask you some questions about it. Your answers are confidential and will not be connected to your name. Your input is extremely valuable.

[PROGRAMMER: New screen]

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)

What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here's what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 1 from pretest 1]% (X in 1,000)
Did [DRUG NAME] have side effects?		
<i>Serious side effects</i>		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 3 from pretest 1]% (X in 1,000)
<i>Symptom side effects</i>		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
	3% (30 in 1,000)	4% (50 in 1,000)

More people had diarrhea
(1 percentage point more)

2% (20 in 1,000)

3% (50 in 1,000)

More people had headaches
(1 percentage point more)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q1a. **(Gist Benefit Comprehension)** Based on the information in the Drug Facts Box, does [DRUG NAME] work better than a placebo?

- Yes
- No
- Not Sure

(Perceived Benefit)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q1b. If you took [DRUG NAME], how likely or unlikely do you think it is that [DRUG NAME] would help your heartburn?

- 1 2 3 4 5 6
- 7
- Very Very
- Unlikely
- Likely

Q1c. If [DRUG NAME] did help your heartburn, how effective do you think [DRUG NAME] would be?

- 1 2 3 4 5 6
- 7
- Would eliminate Would
- eliminate
- very little of my heartburn all of my
- heartburn

(Benefit Accuracy)

1 2 3 4 5 6 7
 Not at all Extremely
 Likely Likely

Q1g. How skeptical are you about the drug **benefits** presented in the Drug Facts Box?

1 2 3 4 5 6 7
 Not at all Extremely
 Skeptical Skeptical

[PROGRAMMER: New screen]

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)

What is this drug for? [DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it? Men and women bothered by heartburn or acid reflux disease
Who should NOT take it? Women who are pregnant or breastfeeding
What tests do patients need to take? none
Other things to consider doing: Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don’t smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here’s what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 2 from pretest 1]% (X in 1,000)

Did [DRUG NAME] have side effects?

Serious side effects

More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 3 from pretest 1]% (X in 1,000)
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Symptom side effects

More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
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More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)
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More people had headaches (1 percentage point more)	2% (20 in 1,000)	3% (50 in 1,000)
--	------------------	------------------

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q2a. **(Gist Benefit Comprehension)** Based on the information in the Drug Facts Box, does [DRUG NAME] work better than a placebo?

- Yes
- No
- Not Sure

(Perceived Benefit)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q2b. If you took [DRUG NAME], how likely or unlikely do you think it is that [DRUG NAME] would help your heartburn?

1 2 3 4 5 6

Very
Unlikely
Likely

Q2c. If [DRUG NAME] did help your heartburn, how effective do you think [DRUG NAME] would be?

1	2	3	4	5	6
	7				
Would eliminate eliminate very little of my heartburn					Would all of my

(Benefit Accuracy)

Q2d. According to the Drug Facts Box, does [DRUG NAME] increase, decrease, or have no effect on the chance of **heartburn relief**?

- a. Increases the chance of heartburn relief [\[go to Q2d1 and skip Q2d2\]](#)
- b. Decreases the chance of heartburn relief [\[go to Q2d2 and skip Q2d1\]](#)
- c. Has no effect on heartburn relief [\[skip Q2d2 and Q2d2\]](#)

Q2d1. In your opinion, how much does [DRUG NAME] increase the chance of heartburn relief?

1	2	3	4	5	6	7
Not at all						A lot

Q2d2. In your opinion, how much does [DRUG NAME] decrease the chance of heartburn relief?

1	2	3	4	5	6	7
Not at all						A lot

Q2e. According to the information in the Drug Facts Box, which statement is correct about how much [DRUG NAME] affects heartburn? Please select one answer.

[\[PROGRAMMER: randomize responses as either a-f or f-a\]](#)

[\[Note. Numbers in brackets are subject to change depending on pretest 1 results. Do not display brackets.\]](#)

Compared to taking a placebo, [DRUG NAME] increased the chance of **heartburn relief** by

- a. [1] percentage point
- b. [21] percentage points
- c. [41] percentage points
- d. [61] percentage points
- e. [81] percentage points
- f. [DRUG NAME] did not affect the chance of heartburn relief.

(Skepticism)

[PROGRAMMER: Randomize order of Qsf-g.]

Q2f. How likely is it that the drug **benefits** presented in the Drug Facts Box are true?

1	2	3	4	5	6	7
Not at all						Extremely
Likely						Likely

Q2g. How skeptical are you about the drug **benefits** presented in the Drug Facts Box?

1	2	3	4	5	6	7
Not at all						Extremely
Skeptical						Skeptical

[PROGRAMMER: New screen]

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)

What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none

Other things to consider doing:

Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here's what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 3 from pretest 1]% (X in 1,000)
Did [DRUG NAME] have side effects?		
Serious side effects		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 3 from pretest 1]% (X in 1,000)
Symptom side effects		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)
More people had headaches (1 percentage point more)	2% (20 in 1,000)	3% (50 in 1,000)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click "View Drug Facts Box." When you are done viewing the Drug Facts Box, please click "Back to Questions."

Q3a. **(Gist Benefit Comprehension)** Based on the information in the Drug Facts Box, does [DRUG NAME] work better than a placebo?

- Yes
- No
- Not Sure

(Perceived Benefit)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q3b. If you took [DRUG NAME], how likely or unlikely do you think it is that [DRUG NAME] would help your heartburn?

- | | | | | | |
|----------|------|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Very | | | | | |
| | Very | | | | |
| Unlikely | | | | | |
| Likely | | | | | |

Q3c. If [DRUG NAME] did help your heartburn, how effective do you think [DRUG NAME] would be?

- | | | | | | |
|-----------------------------|---|---|---|---|-----------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Would eliminate | | | | | Would |
| eliminate | | | | | |
| very little of my heartburn | | | | | all of my |
| heartburn | | | | | |

(Benefit Accuracy)

Q3d. According to the Drug Facts Box, does [DRUG NAME] increase, decrease, or have no effect on the chance of **heartburn relief**?

- a. Increases the chance of heartburn relief [\[go to Q3d1 and skip Q3d2\]](#)
- b. Decreases the chance of heartburn relief [\[go to Q3d2 and skip Q3d1\]](#)
- c. Has no effect on heartburn relief [\[skip Q3d1 and Q3d2\]](#)

Q3d1. In your opinion, how much does [DRUG NAME] increase the chance of heartburn relief?

1	2	3	4	5	6	7
Not at all						A lot

Q3d2. In your opinion, how much does [DRUG NAME] decrease the chance of heartburn relief?

1	2	3	4	5	6	7
Not at all						A lot

Q3e. According to the information in the Drug Facts Box, which statement is correct about how much [DRUG NAME] affects heartburn? Please select one answer.

[PROGRAMMER: randomize responses as either a-f or f-a]

[Note. Numbers in brackets are subject to change depending on pretest 1 results. Do not display brackets.]

Compared to taking a placebo, [DRUG NAME] increased the chance of **heartburn relief** by

- a. [1] percentage point
- b. [21] percentage points
- c. [41] percentage points
- d. [61] percentage points
- e. [81] percentage points
- f. [DRUG NAME] did not affect the chance of heartburn relief.

(Skepticism)

[PROGRAMMER: Randomize order of Qsf-g.]

Q3f. How likely is it that the drug **benefits** presented in the Drug Facts Box are true?

1	2	3	4	5	6	7
Not at all						Extremely
Likely						Likely

Q3g. How skeptical are you about the drug **benefits** presented in the Drug Facts Box?

1	2	3	4	5	6	7
Not at all						Extremely
Skeptical						Skeptical

[PROGRAMMER: New screen]

Only two more!

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)	
What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here's what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 4 from pretest 1]% (X in 1,000)
Did [DRUG NAME] have side effects?		
Serious side effects		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 3 from pretest 1]% (X in 1,000)
Symptom side effects		

(Skepticism)

[PROGRAMMER: Randomize order of Qsf-g.]

Q4f. How likely is it that the drug **benefits** presented in the Drug Facts Box are true?

1	2	3	4	5	6	7
Not at all						Extremely
Likely						Likely

Q4g. How skeptical are you about the drug **benefits** presented in the Drug Facts Box?

1	2	3	4	5	6	7
Not at all						Extremely
Skeptical						Skeptical

[PROGRAMMER: New screen]

Last one!

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)		
What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).	
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease	
Who should NOT take it?	Women who are pregnant or breastfeeding	
What tests do patients need to take?	none	
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don’t smoke.	
[DRUG NAME] Study Findings		
500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here’s what happened:		
<u>What difference did [DRUG</u>	People given a placebo	People given [DRUG

NAME] make?	(no drug)	NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 5 from pretest 1]% (X in 1,000)
Did [DRUG NAME] have side effects?		
<i>Serious side effects</i>		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 3 from pretest 1]% (X in 1,000)
<i>Symptom side effects</i>		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)
More people had headaches (1 percentage point more)	2% (20 in 1,000)	3% (50 in 1,000)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q5a. **(Gist Benefit Comprehension)** Based on the information in the Drug Facts Box, does [DRUG NAME] work better than a placebo?

- Yes
- No
- Not Sure

(Perceived Benefit)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q5b. If you took [DRUG NAME], how likely or unlikely do you think it is that [DRUG NAME] would help your heartburn?

1	2	3	4	5	6
	7				
Very	Very				
Unlikely					
Likely					

Q5c. If [DRUG NAME] did help your heartburn, how effective do you think [DRUG NAME] would be?

1	2	3	4	5	6
	7				
Would eliminate					Would
eliminate					
very little of my heartburn					all of my
heartburn					

(Benefit Accuracy)

Q5d. According to the Drug Facts Box, does [DRUG NAME] increase, decrease, or have no effect on the chance of **heartburn relief**?

- a. Increases the chance of heartburn relief [[go to Q5d1 and skip Q5d2](#)]
- b. Decreases the chance of heartburn relief [[go to Q5d2 and skip Q5d1](#)]
- c. Has no effect on heartburn relief [[skip Q5d1 and Q5d2](#)]

Q5d1. In your opinion, how much does [DRUG NAME] increase the chance of heartburn relief?

1	2	3	4	5	6	7
Not at all						A lot

Q5d2. In your opinion, how much does [DRUG NAME] decrease the chance of heartburn relief?

1	2	3	4	5	6	7
Not at all						A lot

Q5e. According to the information in the Drug Facts Box, which statement is correct about how much [DRUG NAME] affects heartburn? Please select one answer.

[PROGRAMMER: randomize responses as either a-f or f-a]

[Note. Numbers in brackets are subject to change depending on pretest 1 results. Do not display brackets.]

Compared to taking a placebo, [DRUG NAME] increased the chance of **heartburn relief** by

- a. [1] percentage point
- b. [21] percentage points
- c. [41] percentage points
- d. [61] percentage points
- e. [81] percentage points
- f. [DRUG NAME] did not affect the chance of heartburn relief.

(Skepticism)

[PROGRAMMER: Randomize order of Qsf-g.]

Q5f. How likely is it that the drug **benefits** presented in the Drug Facts Box are true?

1	2	3	4	5	6	7
Not at all						Extremely
Likely						Likely

Q5g. How skeptical are you about the drug **benefits** presented in the Drug Facts Box?

1	2	3	4	5	6	7
Not at all						Extremely
Skeptical						Skeptical

[PROGRAMMER: New screen]

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)

What is this drug for?

[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is

Who might consider taking it?	also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment). Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here's what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		X[level 3 from pretest 1] (X in 1,000)
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 3 from pretest 1] (X in 1,000)
Did [DRUG NAME] have side effects?		
<i>Serious side effects</i>		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 1 from pretest 1] (X in 1,000)
<i>Symptom side effects</i>		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)
More people had headaches (1 percentage point more)	2% (20 in 1,000)	3% (50 in 1,000)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q6a. **(Gist Risk Comprehension)** Based on the information in the Drug Facts Box, is [DRUG NAME] riskier than a placebo?

- Yes
- No
- Not Sure

(Perceived Risk)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q6b. If you took [DRUG NAME], how likely do you think it is that you would have any side effects or negative outcomes?

- | | | | | | |
|----------|--------|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Very | | | | | |
| | Very | | | | |
| Unlikely | | | | | |
| | Likely | | | | |

Q6c. If [DRUG NAME] did cause you to have side effects or negative outcomes, how serious would they be?

- | | | | | | |
|------------|---------|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Not at all | | | | | |
| | Very | | | | |
| serious | | | | | |
| | serious | | | | |

(Risk Accuracy)

Q6d. According to Page 2 of the ad, does [DRUG NAME] increase, decrease, or have no effect on the chance of **heartburn relief**?

- a. Increases the chance of heartburn relief [[go to Q6d1 and skip Q6d2](#)]
- b. Decreases the chance of heartburn relief [[go to Q6d2 and skip Q6d1](#)]
- c. Has no effect on heartburn relief [[skip Q6d1 and Q6d2](#)]

[PROGRAMMER: New screen]

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)

What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here's what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 3 from pretest 1]%(X in 1,000)
Did [DRUG NAME] have side effects?		
<i>Serious side effects</i>		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 2 from pretest 1]%(X in 1,000)
<i>Symptom side effects</i>		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
	3% (30 in 1,000)	4% (50 in 1,000)

More people had diarrhea
(1 percentage point more)

2% (20 in 1,000)

3% (50 in 1,000)

More people had headaches
(1 percentage point more)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q7a. **(Gist Risk Comprehension)** Based on the information in the Drug Facts Box, is [DRUG NAME] riskier than a placebo?

- Yes
- No
- Not Sure

(Perceived Risk)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q7b. If you took [DRUG NAME], how likely do you think it is that you would have any side effects or negative outcomes?

- 1 2 3 4 5 6
- 7
- Very
Unlikely Very
Likely

Q7c. If [DRUG NAME] did cause you to have side effects or negative outcomes, how serious would they be?

- 1 2 3 4 5 6
- 7
- Not at all
serious Very
serious

(Risk Accuracy)

Q7d. According to Page 2 of the ad, does [DRUG NAME] increase, decrease, or have no effect on the chance of **heartburn relief**?

Did [DRUG NAME] have side effects?

Serious side effects

More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 3 from pretest 1]%(X in 1,000)
---	------------------	---

Symptom side effects

More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
--	------------------	------------------

More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)
---	------------------	------------------

More people had headaches (1 percentage point more)	2% (20 in 1,000)	3% (50 in 1,000)
--	------------------	------------------

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q8a. **(Gist Risk Comprehension)** Based on the information in the Drug Facts Box, is [DRUG NAME] riskier than a placebo?

- Yes
- No
- Not Sure

(Perceived Risk)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q8b. If you took [DRUG NAME], how likely do you think it is that you would have any side effects or negative outcomes?

- | | | | | | |
|----------|--------|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Very | | | | | |
| | Very | | | | |
| Unlikely | | | | | |
| | Likely | | | | |

- b. [21] percentage points
- c. [41] percentage points
- d. [61] percentage points
- e. [81] percentage points
- f. [DRUG NAME] did not affect the chance of bone loss.

(Skepticism)

[PROGRAMMER: Randomize order of Qsf-g.]

Q8f. How likely is it that the drug **side effects** presented in the Drug Facts Box are true?

1	2	3	4	5	6	7
Not at all						Extremely
Likely						Likely

Q8g. How skeptical are you about the drug **side effects** presented in the Drug Facts Box?

1	2	3	4	5	6	7
Not at all						Extremely
Skeptical						Skeptical

[PROGRAMMER: New screen]

Only two more!

Please read the Drug Facts Box below. When you have read the information, please click “continue” to answer questions about this Drug Facts Box.

Prescription Drug Facts: [DRUG NAME] (fentomeprozole)	
What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here’s what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 3 from pretest 1] (X in 1,000)
Did [DRUG NAME] have side effects?		
<i>Serious side effects</i>		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 4 from pretest 1] (X in 1,000)
<i>Symptom side effects</i>		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)
More people had headaches (1 percentage point more)	2% (20 in 1,000)	3% (50 in 1,000)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q9a. (Gist Risk Comprehension) Based on the information in the Drug Facts Box, is [DRUG NAME] riskier than a placebo?

- Yes
- No
- Not Sure

What is this drug for?	[DRUG NAME] is used (for up to 8 weeks) to heal acid-related damage to the lining of the esophagus and to help continue this healing. [DRUG NAME] is also used to treat the symptoms of acid reflux disease (persistent heartburn on two or more days per week, despite diet changes and treatment).
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease
Who should NOT take it?	Women who are pregnant or breastfeeding
What tests do patients need to take?	none
Other things to consider doing:	Eat frequent small meals. Avoid fatty food, excessive alcohol, and eating close to bedtime. Don't smoke.

[DRUG NAME] Study Findings

500 adults with bothersome heartburn were given [DRUG NAME] or a placebo (no drug) for 2 weeks. Here's what happened:

What difference did [DRUG NAME] make?	People given a placebo (no drug)	People given [DRUG NAME]
Number of people	247	253
Did [DRUG NAME] Help?		
More people had heartburn relief (X percentage points more)	18% (180 in 1,000)	X[level 3 from pretest 1]%(X in 1,000)
Did [DRUG NAME] have side effects?		
<i>Serious side effects</i>		
More people had bone loss (X percentage points more)	2% (20 in 1,000)	X[level 5 from pretest 1]%(X in 1,000)
<i>Symptom side effects</i>		
More people had abdominal pain (2 percentage points more)	3% (30 in 1,000)	5% (50 in 1,000)
More people had diarrhea (1 percentage point more)	3% (30 in 1,000)	4% (50 in 1,000)

More people had headaches
(1 percentage point more)

2% (20 in 1,000)

3% (50 in 1,000)

Now please answer the following questions based on the Drug Facts Box you saw. You can look back at the Drug Facts Box as you answer questions. If you would like to see it again, please click “View Drug Facts Box.” When you are done viewing the Drug Facts Box, please click ‘Back to Questions.’

Q10a. **(Gist Risk Comprehension)** Based on the information in the Drug Facts Box, is [DRUG NAME] riskier than a placebo?

- Yes
- No
- Not Sure

(Perceived Risk)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q10b. If you took [DRUG NAME], how likely do you think it is that you would have any side effects or negative outcomes?

- 1 2 3 4 5 6
- 7
- Very Very
- Unlikely Likely

Q10c. If [DRUG NAME] did cause you to have side effects or negative outcomes, how serious would they be?

- 1 2 3 4 5 6
- 7
- Not at all Very
- serious serious

(Risk Accuracy)

Q10d. According to Page 2 of the ad, does [DRUG NAME] increase, decrease, or have no effect on the chance of **heartburn relief**?

a. Increases the chance of heartburn relief [\[go to Q10d1 and skip Q10d2\]](#)

Laptop computer / Netbook computer
Desktop computer
Handheld phone (iPhone, Blackberry, Droid)
Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
Other: _____

[End time: _____]

(Debriefing)

The purpose of this research is to understand how people think about prescription drug information. In order to get an unbiased reaction to this information, we created a brand for this study. [DRUG NAME] is not a real product and it is not available for sale. Please see your healthcare professional for questions about heartburn or acid reflux disease.

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

Pretest 3 Questionnaire

[NOTE: This pretest is conducted only in the risk design. It has two variables. First, participants will be randomly assigned to see a Drug Facts Box with the smallest risk level or the largest risk level. Second, participants will be randomly assigned to either have access to the ad while answering questions or not. The questions are the same in all conditions but the programming and instructions for viewing the ad differ for the second variable]

[PROGRAMMER: We need to record time in milliseconds spent on each screen (including questions) throughout protocol. We need to record the number of times participants go back and look at the ad in Condition 2.]

Interview Protocol.

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

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 confidential, and no one will ever connect your name with your answers. Your input is extremely valuable.

[PROGRAMMER: New screen]

Even though it is on a computer screen, please read this ad as if it were in a magazine. Imagine that this ad is for a product that you might be interested in for yourself. You can take as much time as you want to review it. We will ask you some questions about the ad later in the study.

The ad has two pages. You can enlarge and flip between the pages by clicking on the "Next" and "Back" buttons at the bottom of each page. Once you finish viewing the ad, please click "Start Next Part of Study" to move to the next part of the study.

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

Q1. Were you able to view the ad for [DRUG NAME]?

Yes

No (terminate)

Not sure (terminate)

[If participants are allowed to view the ad throughout the survey, do not show "View Ad" links on this page]

[PROGRAMMER: Randomly assign participants to one of the following sets of instructions. For participants in the second set, add “View Ad Page 1” and “View Ad Page 2” buttons on all screens that will take participants back to the ad. The “Back” and “Next” buttons should allow access to both pages of the ad. A “Back to Questions” button should bring participants back to the questionnaire, at the same point in the questionnaire where they left]

[PROGRAMMER: New screen]

(Condition 1 Instructions) Now please answer the following questions based on the ad you saw.

(Condition 2 Instructions) Now please answer the following questions based on the ad you saw. You can look back at the ad as you answer questions. If you would like to see the ad again, please click “View Ad Page 1” or “View Ad Page 2.” When you are done viewing the ad, please click ‘Back to Questions.’
Now please answer the following questions based on the ad you saw.

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

Over the counter drug
Prescription drug
Herbal supplement
Lens cleaner
Don't know

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

High blood pressure
Heartburn
Migraine headaches
Seasonal allergies
Don't know

Q4. **(Recall of Risks, Open-ended 1)** What are the side effects of [DRUG NAME]?

Q5. **(Gist Risk Comprehension)** Based on the information on Page 2 of the ad, is [DRUG NAME] riskier than a placebo?

Yes
No
Not Sure

(Perceived Risk)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q6. If you took [DRUG NAME], how likely do you think it is that you would have any side effects or negative outcomes?

1 2 3 4 5 6

7

Very Very
Unlikely Likely

Q7. If [DRUG NAME] did cause you to have side effects or negative outcomes, how serious would they be?

1 2 3 4 5 6

7

Not at all Very
serious serious

Q8. **(Recall of Risks)** Please check which of the following were mentioned on Page 2 of the ad as side effects of taking [DRUG NAME]. Even if you think a statement is true, please select it only if it was mentioned on Page 2 of the ad.

[PROGRAMMER: *randomize Q8a-h*]

	Mentioned on Page 2 of the ad	NOT mentioned on Page 2 of the ad
a. [DRUG NAME] may cause abdominal pain.	x	
b. A serious side effect of [DRUG NAME] is bone loss.	x	
c. Women who are pregnant should not take [DRUG NAME].	x	
d. [DRUG NAME] may cause headaches.	x	
e. [DRUG NAME] may cause nausea.		x

Q12. According to Page 2 of the ad, which statement is correct about how much [DRUG NAME] affects bone loss? Please select one answer.

[PROGRAMMER: randomize responses as either a-f or f-a]

[Note. Numbers in brackets are subject to change depending on pretest results. Do not display brackets.]

Compared to taking a placebo, [DRUG NAME] increased the chance of **bone loss** by

- a. [1] percentage point
- b. [21] percentage points
- c. [41] percentage points
- d. [61] percentage points
- e. [81] percentage points
- f. [DRUG NAME] did not affect the chance of bone loss.

Q13. What percentage (%) of people who took [DRUG NAME] had **abdominal pain** at the end of the 2 week study?

___% (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100; if response is not numeric, use explanation, “please use only numbers”)

Q14. What percentage (%) of people who took [DRUG NAME] had **diarrhea** at the end of the 2 week study?

___% (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100; if response is not numeric, use explanation, “please use only numbers”)

Q15. What percentage (%) of people who took [DRUG NAME] had **headaches** at the end of the 2 week study?

___% (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100; if response is not numeric, use explanation, “please use only numbers”)

Q16. (Recall of Benefits, Open-ended 2) What are the benefits of [DRUG NAME]?

Q17. (Gist Benefit Comprehension) Based on the information on Page 2 of the ad, does [DRUG NAME] work better than a placebo?

- Yes
- No
- Not Sure

(Perceived Benefit)

For the next two questions, think about your experience with heartburn or imagine that you have had experience with heartburn.

Q18. If you took [DRUG NAME], how likely or unlikely do you think it is that [DRUG NAME] would help your heartburn?

1 2 3 4 5 6
7
Very Very
Unlikely
Likely

Q19. If [DRUG NAME] did help your heartburn, how effective do you think [DRUG NAME] would be?

1 2 3 4 5 6
7
Would eliminate Would
eliminate all of my
very little of my heartburn heartburn

Q20. (Recall of Benefits) Please check which of the following were mentioned on Page 2 of the ad as benefits of taking [DRUG NAME]. Even if you think a statement is true, please select it only if it was mentioned on Page 2 of the ad.

[PROGRAMMER: randomize Q20a-f]

	Mentioned on Page 2 of the ad	NOT mentioned on Page 2 of the ad
a. [DRUG NAME] treats heartburn.	x	
b. [DRUG NAME] can reduce symptoms of acid reflux disease.	x	
c. There are not tests patients need to take while on [DRUG NAME].	x	
d. [DRUG NAME] can reduce the risk of diabetes.		x
e. [DRUG NAME] is the #1 prescribed		x

[PROGRAMMER: randomize responses as either a-f or f-a]

[Note. Numbers in brackets are subject to change depending on pretest results. Do not display brackets.]

Compared to taking a placebo, [DRUG NAME] increased the chance of **heartburn relief** by

- a. [1] percentage point
- b. [21] percentage points
- c. [41] percentage points
- d. [61] percentage points
- e. [81] percentage points
- f. [DRUG NAME] did not affect the chance of heartburn relief.

[PROGRAMMER: randomize Q25a-c]

Q25. (**Behavioral Intention**) Please rate how likely or unlikely you are to do each of the following behaviors. Select one response for each row.

	Not at all likely	Somewhat likely	Very likely	Extremely likely
a. Talk to your doctor about [DRUG NAME]				
b. Look for more information about [DRUG NAME]				
c. Take [DRUG NAME] if prescribed				

Q26. (**Attitude toward Drug**) Thinking overall about the risks and benefits, would you say [DRUG NAME] has:

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

Q27. Please rate your agreement or disagreement with the following statement.

Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
-------------------	-------------------	----------------------------------	----------------------	----------------------

The possible benefits of [DRUG NAME] are worth the possible side effects for people with heartburn.

[PROGRAMMER: Randomize order of Q28a-b]

Q28. (Attitude toward the drug facts box) Please rate your agreement or disagreement with each of the following statements.

Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
-------------------	-------------------	----------------------------------	----------------------	----------------------

Page 2 of the ad clearly communicated the *benefits* of [DRUG NAME].

Page 2 of the ad clearly communicated the *risks* of [DRUG NAME].

Q29. Please think about how the risks and benefits of [DRUG NAME] were presented on Page 2 of the ad. Did Page 2 of the ad place more emphasis on risks or more emphasis on benefits?

1	2	3	4	5	6	7
More emphasis on risks						More
emphasis						on
						benefits

(Skepticism)

[PROGRAMMER: Randomize order of Qs 30-31, and Qs 32-33.]

Q30. How likely is it that the drug **benefits** presented on Page 2 of the ad are true?

1	2	3	4	5	6	7
Not at all						Extremely

Q37. Are you currently taking a prescription medicine for heartburn or acid reflux disease?

- Yes
- No
- Don't know or uncertain

Q38. In general, how much do you feel you know about heartburn? Would you say you know:

- | | | | | | | |
|----------------|---|---|---|---|---|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Nothing at all | | | | | | A lot |

Q39. In general, how much do you feel you know about treatments for heartburn? Would you say you know:

- | | | | | | | |
|----------------|---|---|---|---|---|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Nothing at all | | | | | | A lot |

Q40. Have you ever seen any advertising for [DRUG NAME] before today?

- Yes
- No
- Not sure

Q41. (Objective Numeracy) Now here are some questions that require you to use numbers to solve the problem. Some are easy and others are more difficult. No calculators please- 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!

[PROGRAMMER: DO NOT randomize Q41a-c]

a. 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 [fill in the blank. PROGRAMMER: set acceptable range from 0 to 1,000]

b. 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 [fill in the blank. PROGRAMMER: set acceptable range from 0 to 1,000]

c. 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 [fill in the blank. PROGRAMMER: set acceptable range from 0 to 100, including decimals; if response is not numeric, use explanation, “please use only numbers”]

Q42. Did you receive any help on the questions that had math 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

Q43. What are you using 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: _____

[End time: _____]

(Debriefing)

The purpose of this research is to understand how people think about prescription drug information. In order to get an unbiased reaction to this information, we created a brand for this study. [DRUG NAME] is not a real product and it is not available for sale. Please see your healthcare professional for questions about heartburn or acid reflux disease.

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

Main Study Questionnaire

[PROGRAMMER: We need to record time in milliseconds spent on each screen (including questions) throughout protocol. Participants should not be able to return to questions after they have answered them.]

Interview Protocol.

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

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 confidential and will not be connected to your name. Your input is extremely valuable.

[PROGRAMMER: New screen]

Even though it is on a computer screen, please read this ad as if it were in a magazine. Imagine that this ad is for a product that you might be interested in for yourself. You can take as much time as you want to review it. We will ask you some questions about the ad later in the study.

The ad has two pages. You can enlarge and flip between the pages by clicking on the "Next" and "Back" buttons at the bottom of each page. Once you finish viewing the ad, please click "Start Next Part of Study" to move to the next part of the study.

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

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

Q1. Were you able to view the ad for [DRUG NAME]?

Yes

No (terminate)

Not sure (terminate)

[If participants are allowed to view the ad throughout the survey, do not show "View Ad" links on this page]

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

Over the counter drug

Prescription drug

Q8. **(Recall of Risks)** Please check which of the following were mentioned on Page 2 of the ad as side effects of taking [DRUG NAME]. Even if you think a statement is true, please select it only if it was mentioned on Page 2 of the ad.

[PROGRAMMER: *randomize Q8a-h*]

	Mentioned on Page 2 of the ad	NOT mentioned on Page 2 of the ad
a. [DRUG NAME] may cause abdominal pain.	x	
b. A serious side effect of [DRUG NAME] is bone loss.	x	
c. Women who are pregnant should not take [DRUG NAME].	x	
d. [DRUG NAME] may cause headaches.	x	
e. [DRUG NAME] may cause nausea.		x
f. [DRUG NAME] may cause dizziness.		x
g. People with kidney problems should not take [DRUG NAME].		x
h. A serious side effect of [DRUG NAME] is joint pain.		x

(Risk Accuracy)

Q9. According to Page 2 of the ad, does [DRUG NAME] increase, decrease, or have no effect on the chance of **bone loss**?

- a. Increases the chance of bone loss [\[go to Q9a and skip Q9b\]](#)
- b. Decreases the chance of bone loss [\[go to Q9b and skip Q9a\]](#)
- c. Has no effect on bone loss [\[skip Q9a and Q9b\]](#)

Q9a. In your opinion, how much does [DRUG NAME] increase the chance of bone loss?

Q14. What percentage (%) of people who took [DRUG NAME] had **diarrhea** at the end of the 2 week study?

___% (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100; if response is not numeric, use explanation, "please use only numbers")

Q15. What percentage (%) of people who took [DRUG NAME] had **headaches** at the end of the 2 week study?

___% (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100; if response is not numeric, use explanation, "please use only numbers")

Q16. (Recall of Benefits, Open-ended 2) What are the benefits of [DRUG NAME]?

Q17. (Gist Benefit Comprehension) Based on the information on Page 2 of the ad, does [DRUG NAME] work better than a placebo?

- Yes
- No
- Not Sure

(Perceived Benefit)

Q18. If you took [DRUG NAME], how likely or unlikely do you think it is that [DRUG NAME] would help your heartburn?

- | | | | | | |
|----------|------|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Very | | | | | |
| Unlikely | Very | | | | |
| Likely | | | | | |

Q19. If [DRUG NAME] did help your heartburn, how effective do you think [DRUG NAME] would be?

- | | | | | | |
|-----------------------------|---|---|---|---|-----------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | 7 | | | | |
| Would eliminate | | | | | Would |
| eliminate | | | | | |
| very little of my heartburn | | | | | all of my |
| heartburn | | | | | |

about [DRUG
NAME]
c. Take [DRUG
NAME] if
prescribed

Q26. (Attitude toward Drug) Thinking overall about the risks and benefits, would you say [DRUG NAME] has:

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

Q27. Please rate your agreement or disagreement with the following statement.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
The possible benefits of [DRUG NAME] are worth the possible side effects for people with heartburn.					

[PROGRAMMER: Randomize order of Q28a-b]

Q28. (Attitude toward the drug facts box) Please rate your agreement or disagreement with each of the following statements.

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
Page 2 of the ad clearly communicated the <i>benefits</i> of [DRUG NAME].					
Page 2 of the ad clearly communicated the <i>risks</i> of [DRUG NAME].					

No
Not sure

Q41. (Objective Numeracy) Now here are some questions that require you to use numbers to solve the problem. Some are easy and others are more difficult. No calculators please- 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!

[PROGRAMMER: DO NOT randomize Q41a-c]

a. 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 [fill in the blank. PROGRAMMER: set acceptable range from 0 to 1,000; if response is not numeric, use explanation, "please use only numbers"]

b. 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?

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(e.g., calculator, other person, website)? It's okay if you did—we just want an honest answer.

Yes (write source _____)
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Q43. What are you using to complete today's survey?

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Other: _____

[End time: _____]

(Debriefing)

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