

**DRUG LABELING STUDY A
MAIN QUESTIONNAIRE
PINK**

OFFICE USE ONLY

ID

SITE INTERVIEW NUMBER:

Start time : am pm

(CHOOSE LABEL ACCORDING TO RANDOMIZATION SHEET.)

(RECORD LABEL VERSION:)

15-17

The US Food and Drug Administration is interested in how people read and understand the labels that appear on foods and over-the-counter medications. I'm going to be showing you the labels from two products. The first is for raisin bran. I'd like you to read the label as if you were considering purchasing the product. Then I'm going to show you a label from a cough/cold drug. I'd also like you to read the label as if you were considering purchasing the product. Then I'm going to ask you some questions about the information on these labels. Do you have any questions about this procedure? **(IF YES, REVIEW PROCEDURE WITH RESPONDENT.)**

**(HAND RESPONDENT FOOD LABEL AND ALLOW RESPONDENT TO READ. TIME
RESPONDENT TO NEAREST SECOND.)**

Take as much time as you need to read the label and hand it back to me when you are finished.

(TIME SPENT READING FOOD LABEL: SECONDS)

(REMOVE LABEL FROM VIEW.)

18-20

**(HAND RESPONDENT DRUG LABEL AND ALLOW RESPONDENT TO READ. TIME
RESPONDENT TO NEAREST SECOND.)**

Here is the next label. Take as much time as you need to read the label and hand it back to me when you are finished.

(TIME SPENT READING DRUG LABEL: SECONDS)

(REMOVE LABEL FROM VIEW.)

21-23

(MAKE SURE LABELS ARE NOT IN VIEW)

Now I'd like to ask you some questions. When answering, think only about the drug label.

1a. First, tell me all the information you can remember from the drug label.

1b. What else can you remember about the drug that was stated on the label? Tell me everything that you can remember, including anything about the warnings and directions. **(PROBE: "What else?")**

2. Now I'm going to ask you some questions about the label. For each of the following statements, tell me if you think the statement is true or false, or if you don't know the answer, according to the information on the label.

(RANDOM START)

	True	False	DK	REF	
___ a. You should stop using this product if stomach pain occurs.	1	2	8	9	32-
___ b. A person using this drug should take no more than 10 softgels in a 24-hour period.	1	2	8	9	33-
___ c. This product relieves nasal congestion due to the common cold.	1	2	8	9	34-
___ d. This product relieves persistent cough from smoking.	1	2	8	9	35-
___ e. People with heart disease should ask a doctor before taking this product.	1	2	8	9	36-
___ f. This product can be taken with drugs used to treat depression.	1	2	8	9	37-
___ g. This product can be given to children 8 years of age.	1	2	8	9	38-

	True	False	DK	REF	
___ h. A person taking a drug for asthma should ask a doctor before use.	1	2	8	9	39-
___ i. You may continue to use this product if cough is accompanied by fever or a persistent headache.	1	2	8	9	40-
___ j. This product can be given to children under age 6.	1	2	8	9	41-
___ k. You should stop using this product if you get a rash.	1	2	8	9	42-
___ l. A person using this drug should not exceed 4 doses in 24 hours.	1	2	8	9	43-
___ m. If stomach pain occurs while taking this product, you can continue to use this product as soon as the pain improves.	1	2	8	9	44-
___ n. Women should not take this product during the <u>last</u> 5 months of pregnancy.	1	2	8	9	45-
___ o. People with liver disease should not take this product unless directed by a physician.	1	2	8	9	46-
___ p. People using a prescription medication to treat a mental condition should not take this product.	1	2	8	9	47-
___ q. A person with a persistent cough from smoking should ask a doctor before use.	1	2	8	9	48-
___ r. Women should avoid taking this product during the <u>first</u> 4 months of pregnancy.	1	2	8	9	49-
___ s. A person with a cough that lasts from emphysema cannot use this product.	1	2	8	9	50-
___ t. A person taking a drug for the treatment of asthma cannot use this product.	1	2	8	9	51-

(RETURN DRUG LABEL TO RESPONDENT)

3. Now I'd like you to think about personally using this drug. Answer each of these questions based on the label.

(RECORD TIME BETWEEN READING OF THE QUESTION AND RESPONDENT'S ANSWER)

- a. At what temperature should this drug be stored?

_____ degrees (_____ SECONDS)

52-54

55-56

Next, I'm going to ask you about some situations in which you or another person has to decide whether or not to use this drug.

- b. Imagine you've got a cough and are running a fever of 99 degrees. What is the maximum number of days you can take this drug?

_____ days

57-59

(RECORD TIME BETWEEN READING OF THE QUESTION AND RESPONDENT'S ANSWER)

- c. Now think about another person who is taking this drug and has stomach pain. Should this person:

(READ LIST)

60-

Keep taking the drug 1

Talk to a doctor 2

Stop taking the drug 3

(_____ SECONDS)

61-62

(DO NOT READ)

Don't Know 8

Refused 9

- d. If you took a dose of the drug at 9:00 am, according to the label, when would you take your next dose?

_____ am pm
63-66 67-

OR

_____ hours later
68-69

(RECORD TIME BETWEEN READING OF THE QUESTION AND RESPONDENT'S ANSWER)

- e. Now think about another person who is considering taking this drug but has breathing problems. Should this person:

(READ LIST) 70-
Keep taking the drug 1
Talk to a doctor 2 (_____ SECONDS)
Stop taking the drug 3 71-72

(DO NOT READ)
Don't Know 8
Refused 9

- f. Imagine you have a child, age 13. How many softgels can you give the child in one dose?
_____ # of softgels
73-

- g. What about a person who has just learned she is pregnant and is considering taking this product? Should she:

(READ LIST) 74-
Keep taking the drug 1
Talk to a doctor 2
Stop taking the drug 3

(DO NOT READ)
Don't Know 8
Refused 9

(RECORD TIME BETWEEN READING OF THE QUESTION AND RESPONDENT'S ANSWER)

- h. What about a person who is considering taking this product but is having nervousness and difficulty sleeping? Should this person:

(READ LIST) 75-
Keep taking the drug 1
Talk to a doctor 2 (_____ SECONDS)
Stop taking the drug 3 76-77

(DO NOT READ)
Don't Know 8
Refused 9

SPACE 78-79
80-2 DUP 1-5

(HAND RESPONDENT CARD 2)

4. Next, I'm going to ask you some questions about the drug label. I'd like you to rate the drug label on a scale from 0 to 10, where 0 means "not at all" and 10 means "very".

(RANDOM START)

___ a. How willing would someone be to read the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

6-7

___ b. How useful is the label in helping someone decide whether or not to use the drug?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

8-9

___ c. How much do you like the format or layout of the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

10-11

___ d. How easy is it to find information in the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

12-13

___ e. How difficult is it to see each of the words printed on the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

14-15

___ f. How difficult was it to read the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

16-17

___ g. How important would it be for someone to read all the information in the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

18-19

___ h. How confusing is the format or layout of the label?

0	1	2	3	4	5	6	7	8	9	10		98	99
not at all										very		DK	REF

20-21

___ i.	How well organized is the format or layout of the label?															22-23
	0	1	2	3	4	5	6	7	8	9	10		98	99		
	not at all										very		DK	REF		
___ j.	How easy to understand is the information in the label?															24-25
	0	1	2	3	4	5	6	7	8	9	10		98	99		
	not at all										very		DK	REF		
___ k.	How easy would it be for someone with poor eyesight to read the words printed on the label?															26-27
	0	1	2	3	4	5	6	7	8	9	10		98	99		
	not at all										very		DK	REF		

(HAND RESPONDENT CARD 2)

5. Please rate the label on the back of the box on the following items on a scale from 0 to 10, where 0 means “not at all” and 10 means “very”.

(RANDOM START)

___ a.	Important													28-29	
	0	1	2	3	4	5	6	7	8	9	10		98	99	
	not at all										very		DK	REF	
___ b.	Relevant													30-31	
	0	1	2	3	4	5	6	7	8	9	10		98	99	
	not at all										very		DK	REF	
___ c.	Means a lot to me													32-33	
	0	1	2	3	4	5	6	7	8	9	10		98	99	
	not at all										very		DK	REF	
___ d.	Valuable													34-35	
	0	1	2	3	4	5	6	7	8	9	10		98	99	
	not at all										very		DK	REF	
___ e.	Exciting													36-37	
	0	1	2	3	4	5	6	7	8	9	10		98	99	
	not at all										very		DK	REF	

___ c.	Know which drugs interact with this one.													52-53
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ d.	Remember the warnings.													54-55
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ e.	Know when to stop taking the drug.													56-57
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ f.	Know what conditions are treated by this drug.													58-59
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ g.	Identify the correct dosage for a child.													60-61
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ h.	Tell the difference between a minor side effect and a major reaction.													62-63
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ i.	Identify who should not take this drug.													64-65
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF
___ j.	Know when you should ask a doctor or health professional if side effects occur.													66-67
	0	1	2	3	4	5	6	7	8	9	10		98	99
	no confidence at all										totally confident		DK	REF

Now I'd like to ask some general questions about the drug and the label. When answering, use the 1 to 5 scale on the card. **(IF NECESSARY SAY: You can use any number on the scale between 1 and 5.)**

(RANDOM START)

(HAND RESPONDENT CARD 4)

___ 7a. Overall, how safe would you say this drug is?

1	2	3	4	5
not at all				very
safe				safe

68-

(HAND RESPONDENT CARD 5)

___ 7b. Overall, how effective would you say this drug is?

1	2	3	4	5
not at all				very
effective				effective

69-

(HAND RESPONDENT CARD 6)

___ 7c. Using a scale from 1 to 5, where 1 means a small amount and 5 means a large amount, how would you rate the amount of information in the drug label?

1	2	3	4	5
a small				a large
amount				amount

70-

(HAND RESPONDENT CARD 7)

___ 7d. Using a scale from 1 to 5, where 1 means not at all and 5 means a lot, how would you say the important information in the drug label stood out?

1	2	3	4	5
not at all				a lot

71-

(HAND RESPONDENT CARD 7)

___ 7e. When you first read the label, would you say your attention was focused just on the drug information label:

1	2	3	4	5
not at all				a lot

72-

— 7f. Think about the way the information was presented in the label. Overall, how useful was the presentation?

1	2	3	4	5
not at all				very
useful				useful

__ 7g. Using a scale from 1 to 5, where 1 means hard to read and 5 means easy to read, how would you rate the label?

1	2	3	4	5
hard to				easy to
read			read	

— 7h. Using a scale from 1 to 5, where 1 means very hard and 5 means very easy, how easy was it to find the important information on the label?

1	2	3	4	5
very hard				very easy

__ 7i. Overall, how much did you trust the information in the label?

1 2 3 4 5
not at all a lot

7j. Overall, how believable was the information in the label?

1	2	3	4	5
not at all				very
believable				believable

8. Now I'm going to ask you to say some words out loud. I want to hear you read as many words as you can from these lists. **(HAND RESPONDENT CARD 12. HOLD QUESTIONNAIRE AT AN ANGLE SO THE RESPONDENT IS NOT DISTRACTED BY THE SCORING PROCEDURE.)** Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word.

10

	Correct	Incorrect	Not Attempted			Correct	Incorrect	Not Attempted		
fat <FAHT>	1	2	3	6-		ingredient <INN-GREE- DEE -ENT>	1	2	3	22-
flu 23- <FLOO>	1	2	3		7-	temporary <TEM-PUH-RARE-REE>		1	2	3
pill <PIL>	1	2	3	8-		exceed 1 <ECK- SEED >	2	3		24-
dose <DOS>	1	2	3	9-		inhale <INN-HAY-UL>	1	2	3	25-
eye <I>	1	2	3	10-		nausea <NAW-ZEE-UH>	1	2	3	26-
stress <STRES>	1	2	3	11-		excessive <ECK- SESS -SIV>	1	2	3	27-
smear <SM-EAR>	1	2	3	12-		pharmacist < FARM -UH-SIST>	1	2	3	28-
notify <NO-TIF-FY>	1	2	3	13-		relief <REE- LEEF >	1	2	3	29-
gallbladder <GAL-BLAH-DERR>	1	2	3	14-		heartburn <HART- BERN >	1	2	3	30-
calories <COW- LUH -REEZ>	1	2	3	15-		effectiveness <EFF- FEKK -TIV-NESS>	1	2	3	31-
depression <DEE- PRESS -SHUN>	1	2	3	16-		drowsiness <DROW-ZEE-NESS>	1	2	3	32-
miscarriage <MISS- KAH -RIDGE>	1	2	3	17-		prolonged <PRO-LAWNGD>	1	2	3	33-
pregnancy < PREG -NEN-SEE>	1	2	3	18-		inhibit <INN- HIB -IT>	1	2	3	34-
arthritis <AR- THRY -TISS>	1	2	3	19-		placebo <PLUH- SEE -BO>	1	2	3	35-
hepatitis <HEP-UH- TY -TISS>	1	2	3	20-		liquid < LICK -WID>	1	2	3	36-
antibiotics <AN-TY-BY-AHH-TIKS>	1	2	3	21-		muscle 1 <MUH- SULL >	2	3		37-

	Correct	Incorrect	Not Attempted	
diagnosis <DY-IGG-NO-SIS>	1	2	3	38-
potassium <PO-TAS-SEE-UM>	1	2	3	39-
anemia <UH-NEE-MEE-UH>	1	2	3	40-
obesity <OH-BEE-SEH-TEE>	1	2	3	41-
osteoporosis <OS-TEE-OH-POUR-ROW-SIS>	1	2	3	42-

	Correct	Incorrect	Not Attempted	
symptom <SIM-TUM>	1	2	3	43-
thalidomide <THA-LID-DOH-MIDE>	1	2	3	44-
congestion <CON-JEST-SHUN>	1	2	3	45-
chronic <KRAH-NIK>	1	2	3	46-
sinusitis <SIE-NUH-SY-TISS>	1	2	3	47-

9. I'm going to give you a card with six words printed on it. **(HAND RESPONDENT CARD 13)** I'm going to read each one to you. After I read the word, I'd like you to define it as if you saw it in a dictionary. If you're not sure about the definition, your best guess is fine. **(RECORD STATEMENTS VERBATIM. PROBE ONCE "Anything else?" AFTER RESPONSE.)**

(RANDOM START)

__a. placebo

_____	48-
_____	49-
_____	50-
_____	51-

__b. thalidomide

_____	52-
_____	53-
_____	54-
_____	55-

__c. effectiveness

_____	56-
_____	57-
_____	58-
_____	59-

__d. temporary

_____	60-
_____	61-
_____	62-
_____	63-

__e. symptoms

_____	64-
_____	65-
_____	66-
_____	67-

__f. health professional

_____	68-
_____	69-
_____	70-
_____	71-

SPACE 72-79
80-4 DUP 1-5

Now I have just a few questions for classification purposes.

10. What is your marital status? Are you:

6-

(READ LIST)

Married 1
Separated 2
Divorced 3
Widowed 4
Never Married 5

(DO NOT READ)

Don't Know 8
Refused 9

(HAND RESPONDENT CARD 14)

11. Which one of these letter groups shows the last grade of school that you completed?

7-

a. Grade school or less 1
b. Some high school 2
c. Completed high school 3
d. Some college 4
e. Completed college 5
f. Graduate school or more 6
g. Other education beyond high school
(business, technical, etc.) 7

Don't Know 8
Refused 9

(HAND RESPONDENT CARD 15)

12. Which of these letter groups represents your profession?

8-9

a. Professional/Technical	1
b. Manager/administrator	2
c. Sales Worker	3
d. Clerical	4
e. Craft	5
f. Operatives (Except Transportation)	6
g. Transport Operatives	7
h. Laborer	8
I. Service Worker	9
j. Farmer and Farm Manager	10
k. Farm Laborer	11
l. Retired	12
m. Housewife	13
n. Student	14
o. Unemployed	15
p. Military	16
Don't Know	98
Refused	99

13. In general, would you say your health is:

10-

(READ LIST)

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

(DO NOT READ)

Don't Know	8
Refused	9

14. How often have you purchased an over-the-counter cough/cold drug in the past six months?
Would you say:

11-

(READ LIST)

Zero times 1
One or two times 2
Three or four times 3
Five or six times 4
Seven or more times 5

(DO NOT READ)

Don't Know 8
Refused 9

15. How often have you purchased an over-the-counter pain reliever drug in the past six months?
Would you say:

12-

(READ LIST)

Zero times 1
One or two times 2
Three or four times 3
Five or six times 4
Seven or more times 5

(DO NOT READ)

Don't Know 8
Refused 9

16. How often have you purchased an over-the-counter sunscreen in the past six months?
Would you say:

13-

(READ LIST)

Zero times 1
One or two times 2
Three or four times 3
Five or six times 4
Seven or more times 5

(DO NOT READ)

Don't Know 8
Refused 9

(HAND RESPONDENT CARD 16)

17. Are you being treated for any of these medical conditions? Please tell me the letters of all that apply.

14-

(CIRCLE ALL THAT APPLY)

- a. Heart disease 1
- b. High blood pressure . . . 2
- c. Asthma 3
- d. Depression 4
- e. High cholesterol 5
- f. Stomach ulcers 6
- g. Emphysema 7
- h. None 0

Don't Know 8

Refused 9

(HAND RESPONDENT CARD 17)

18. Which one of these letter groups includes your total annual family income?

15-

- a. Under \$25,000 0
- b. \$25,000 - \$29,999 1
- c. \$30,000 - \$34,999 2
- d. \$35,000 - \$39,999 3
- e. \$40,000 - \$49,999 4
- f. \$50,000 - \$59,999 5
- g. \$60,000 - \$74,999 6
- h. \$75,000 and over 7

Don't Know 8

Refused 9

(HAND RESPONDENT CARD 18)

19. Which one of these letter groups represents your ethnic group?

16-

- a. Black/Non-Hispanic 1
- b. Hispanic 2
- c. Asian/Pacific Islander 3
- d. White/Non-Hispanic 4
- e. Indian or Alaskan Native 5
- f. Other 6

Don't Know 8

Refused 9

For validation purposes, may I have your first name, address and telephone number?

Respondent's Name: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Area Code: _____ Telephone Number: _____

END TIME ____ : ____ AM PM

17-20

21-

DATE: _____

**THANK RESPONDENT FOR PARTICIPATING.
GIVE RESPONDENT INCENTIVE.**

INTERVIEWER NAME: _____

SPACE 22-79
80-5

OMB NO.: 0910-0343
EXPIRATION DATE: 11/30/97