Study #5814A September, 1997

DRUG LABELING STUDY A MAIN QUESTIONNAIRE WHITE

OFFICE USE ONLY

	ID
SITE INTERVIEW	1-5 NUMBER:
	6 - 9
Start tim	$me _ _ : _ am pm_{14}$

(CHOOSE LABEL ACCORDING TO RANDOMIZATION SHEET.) (RECORD LABEL VERSION: _____)

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 of two products. The first is for raisin bran. I'd like you to read the label as if you were considering purchasing the product. This is just to give you a chance to practice reading labels. Then I'm going to show you a label from a pain reliever 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 the drug label. 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.

(RECORD 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.

24 -
 25 -
26 -
27 -

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?"**)

 	28 -
	29 -
	30 -
	31 -

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, <u>according to the information</u> <u>on the label</u>.

•	DOM START)	True	False	DK	REF	
a.	You should stop using this product if stomach pain occurs.	1	2	8	9	32-
b. 33-	A person using this drug should not exceed 10 tablets in a 24-hour period.	1	2	8	9	
c.	This product does not reduce fever.	1	2	8	9	34-
d.	This product treats minor aches and pains associated with headache.	1	2	8	9	35-
e.	People taking medications for high blood pressure should ask a doctor before taking this product.	1	2	8	9	36-
f.	People allergic to other pain relievers can take this product.	1	2	8	9	37-
g.	This product can be given to children 14 years of age.	1	2	8	9	38-

		True	False	DK	REF	
h.	People who consume more than 3 alcohol-containing drinks per day should ask a doctor for advice before use.	1	2	8	9	39 -
i.	You should consult a physician before using this product if the area that hurts is red and swollen.	1	2	8	9	40 -
<u> </u>	This product can be given to children over age 16.	1	2	8	9	41 -
k.	You can take up to 4 tablets in 6 hours if the pain is severe.	1	2	8	9	42 -
1.	A person using this drug should not take more than 6 tablets 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.	People with stomach ulcers can use this product.	1	2	8	9	45 -
0.	People with liver disease should not take this product unless directed by a physician.	1	2	8	9	46 -
p.	A person who is allergic to aspirin should not use this product.	1	2	8	9	47 -
q.	This product may cause swelling and redness in the painful area.	1	2	8	9	48 -
r.	This product may make ulcers worse.	1	2	8	9	49 -
S.	You should not take this product within 24 hours of consuming alcohol.	1	2	8	9	50 -
t.	A person using this product should take 2 tablets every 6 hours while symptoms persist.	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)

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're taking this drug to relieve sore muscles. 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	(_SECONDS)
Stop taking the drug	3	61 - 62	

(DO NOT READ)

Don't Know	•	•		•		•	•	•	•	•		8
Refused	•	•	•	•	•	•	•	•	•	•	•	9

d. Imagine you have a child, age 15. How many tablets can you give the child in one dose? ______tablets

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

e. Now think about another person who is considering taking this drug but is allergic to aspirin. Should this person:

(READ LIST)	64	-
Keep taking the drug	1	
Talk to a doctor	2	(SECONDS)
Stop taking the drug	3	65 - 66
(DO NOT READ)		
Don't Know	8	
Refused	9	

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

. <u>.</u>	_ am	pm
67 - 70		71 -
OR		

_____ hours later

g. What about a person who has an ulcer and is considering taking this product? Should this person:

(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 under a doctor's care for high blood pressure? 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)			

(DO HOT KEAD)	
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)

`	How will		ould so	omeon	e be to	o read	the lat	oel?					6 - 7
no	0 1 ot at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	0-7
b.	How use	ful is t	he lab	el in h	elping	some	one de	cide v	wheth	ner or not to use t	he drugʻ	?	8 - 9
no	0 1 ot at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	0-9
c.	How muc	ch do y	you lik	the the	format	t or lay	out of	the la	abel?				10 - 11
no	0 1 ot at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	10 - 11
d.	How easy	y is it t	o find	inform	nation	in the	label?	,					10 10
no	0 1 ot at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	12 - 13
e.	How diff	icult is	s it to s	see ead	ch of t	he wo	rds pri	nted o	on the	e label?			14 15
no	0 1 ot at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	14 - 15

f. How difficult was it to read the label?									16 17				
not	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	16 - 17
g.	How imp	ortant	would	l it be	for so	meone	to rea	ad all	the in	formation in the l	abel?		
not	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	18 - 19
h.	How con	fusing	is the	forma	at or la	yout o	f the l	abel?					
not	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	20 - 21
i.	How wel	l orgai	nized i	s the f	format	or lay	out of	the la	bel?				
not	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	22 - 23
j.	How easy	y to un	Idersta	nd is t	the info	ormati	on in t	the lat	oel?				
not	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	24 - 25
k.	How easy	y woul	ld it be	e for s	omeon	e with	n poor	eyesig	ght to	read the words p	rinted o	on the label?	
not	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	26 - 27

(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

0	1	2	3	4	5	6	7	8	9	10	98	99	
not at al	11									very	DK	REF	

b.	Relevant												
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	30 - 31
C.	Means a l	lot to r	ne										
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	32 - 33
d.	Valuable												
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	34 - 35
e.	Exciting												a.c. a=
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	36 - 37
f.	Appealing												28 20
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	38 - 39
g.	Fascinatir	ng											
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	40 - 41
h.	Involving												
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	42 - 43
i.	Interestin	g											
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	44 - 45
j.	Needed												
no	0 1 t at all	2	3	4	5	6	7	8	9	10 very	98 DK	99 REF	46 - 47

(HAND RESPONDENT CARD 3)

Based on your reading of the label, please tell me how confident you are that you could do the following 6. tasks using a scale from 0 to 10 where 0 means "no confidence at all" and 10 means "totally confident":

48 - 49

50 - 51

52 - 53

54 - 55

56 - 57

58 - 59

	DOM ST Recogniz			e (bac	l) react	tions.						
no confi at all		2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF
b.	Follow th	e dire	ctions	for ta	king th	e corr	ect do	se				
no confi at all		2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF
c.	Know wh	ich dr	ugs in	teract	with th	nis one	e.					
no confi at all		2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF
d.	Remembe	er the	warnin	igs.								
no confi at all		2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF
e.	Know wł	en to	stop ta	aking	the dru	lg.						
no conf at all		2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF
f.	Know wh	at cor	dition	s are t	reated	by thi	s drug	.				

no cor at a			2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF	56 57
g.	Ide	entify	the co	orrect	dosage	e for a	child.							60 - 61
	0	1	2	3	4	5	6	7	8	9	10	98	99	00 - 01
no cor at a		nce									totally confident	DK	REF	

h. Tell the	e differe	ence be	etween	a mii	nor sid	le effe	ct and	a ma	jor reaction.			
0 1 no confidence at all	2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF	62 - 63
i. Identify	y who s	hould	not tal	ke this	s drug.							64 - 65
0 1 no confidence at all	2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF	04 - 03
j. Know	when yo	ou sho	uld asl	k a do	ctor of	r healt	h prof	essio	nal if side effe	cts occur.		66 - 67
0 1 no confidence at all	2	3	4	5	6	7	8	9	10 totally confident	98 DK	99 REF	00 - 07

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 6)

____7a. Would you say the amount of information contained in the drug label was:

1	2	3	4	5
a small				a large
amount				amount

(HAND RESPONDENT CARD 7)

_____7b. Would you say the important information in the drug label stood out:

1	2	3	4	5
not at all				a lot

(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

69-

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

(HAND RESPONDENT CARD 7)

_____7e. When you first read the labels, would you say your attention was focused just on the drug information label:

1 2 3 4 5 not at all a lot

(HAND RESPONDENT CARD 8)

____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

(HAND RESPONDENT CARD 9)

____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	

(HAND RESPONDENT CARD 10)

_____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

(HAND RESPONDENT CARD 7)

____7i. Overall, how much did you trust the information on the label?

1 2 3 4 5 not at all a lot

75-

76-

72-

71-

73-

(HAND RESPONDENT CARD 11)

____7j. Overall, how believable was the information on the label?

2 1 3 4 5 not at all very believable believable

SPACE 78 - 79 80-3 DUP 1-5

Now I'm going to ask you to say some words out loud. I want to hear you read as many words as you 8. 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.

(IF THE RESPONDENT TAKES MORE THAN FIVE SECONDS ON A WORD, SAY "BLANK" AND POINT TO THE NEXT WORD, IF NECESSARY, TO MOVE THE **RESPONDENT ALONG. IF THE RESPONDENT BEGINS TO MISS EVERY WORD, HAVE** HIM/HER PRONOUNCE ONLY KNOWN WORDS. COUNT AS CORRECT ANY SELF-**CORRECTED WORD.**)

	Correct Inc	correct A	Not ttempted		Correct In	correct Att	Not empted	
fat < F AHT>	1	2	3	б-	ingredient 1 <inn-gree-DEE-ENT></inn-gree-	2	3	22-
flu <floo></floo>	1	2	3	7-	temporary 1 <tem-puh-rare-ree< td=""><td>> 2</td><td>3</td><td>23-</td></tem-puh-rare-ree<>	> 2	3	23-
pill < P IL>	1	2	3	8-	exceed 1 2 <eck-seed></eck-seed>	3	24-	
dose <dOS></d	1	2	3	9-	inhale 1 <inn-hay-ul></inn-hay-ul>	2	3	25-
eye <i></i>	1	2	3	10-	nausea 1 <naw-zee-uh></naw-zee-uh>	2	3	26-
stress < STR ES>	1	2	3	11-	excessive 1 <eck-SESS-SIV></eck-	2	3	27-
smear < SM -EAR>	1	2	3	12-	pharmacist 1 < FARM -UH-SIST>	2	3	28-
notify <no-tif-FY></no-tif-	1	2	3	13-	relief 1 <ree-leef></ree-leef>	2	3	29-
gallbladder < GAL -BLAH-	1 •DERR>	2	3	14-	heartburn 1 <hart-BERN></hart-	2	3	30-
calories <cow-LUH-I</cow-	1 REEZ>	2	3	15-	effectiveness 1 <eff-FEKK-TIV-NESS</eff-	> 2	3	31-
depression <dee-PRESS</dee-	1 -SHUN>	2	3	16-	drowsiness 1 <drow-zee-ness></drow-zee-ness>	2	3	32-
miscarriage <miss-KAH-</miss-		2	3	17-	prolonged 1 <pro-lawngd></pro-lawngd>	2	3	33-
pregnancy < PREG -NEN-	1 -SEE>	2	3	18-	inhibit 1 <inn-HIB-IT></inn-	2	3	34-
arthritis <ar-THRY-T</ar-	1 TISS>	2	3	19-	placebo 1 <pluh-SEE-BO></pluh-	2	3	35-
hepatitis <hep-uh-TY</hep-uh-	1 -TISS>	2	3	20-	liquid 1 < LICK -WID>	2	3	36-
antibiotics <an-ty-by-4< td=""><td>1 AHH-TIKS</td><td>2</td><td>3</td><td>21-</td><td>muscle 1 2 <muh-SULL></muh-</td><td>3</td><td>37-</td><td></td></an-ty-by-4<>	1 AHH-TIKS	2	3	21-	muscle 1 2 <muh-SULL></muh-	3	37-	

		Not
Correct	Incorrect	Attempted

diagnosis <dy-igg-no-s< th=""><th>1 IS></th><th>2</th><th>3</th><th>38-</th><th>symptom <sim-tum></sim-tum></th><th>1</th><th>2</th><th>3</th><th>43-</th></dy-igg-no-s<>	1 IS>	2	3	38-	symptom <sim-tum></sim-tum>	1	2	3	43-
potassium <po-TAS-SEE-U</po-	1 UM>	2	3	39-	thalidomide <tha-LID-DOI</tha-	1 H- MIDE >	2	3	44-
anemia <uh-NEE-MEE</uh-	1 -UH>	2	3	40-	congestion <con-JEST-SH</con-	1 IUN>	2	3	45-
obesity <oh-BEE-SEH-</oh-	1 TEE>	2	3	41-	chronic < KRAH -NIK>	1	2	3	46-
osteoporosis <os-tee-oh-po< td=""><td></td><td></td><td>3</td><td>42-</td><td>sinusitis <SIE-NUH-SY-'</td><td>1 TISS></td><td>2</td><td>3</td><td>47-</td></os-tee-oh-po<>			3	42-	sinusitis < SIE -NUH-SY-'	1 TISS>	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)

	4
	4
	5
	5
b. thalidomide	
	5
	5
	5
	5
c. effectiveness	
	5
	5
	5
	5
_d. temporary	
	6
	6
	6
	6
e. symptoms	
	6
	6
	6
	6
f. health professional	
	6
	6
	7
	7

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:

(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?

a. Grade school or less 1
b. Some high school
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

6-

(HAND RESPONDENT CARD 15)

12. Which of these letter groups represents your profession?

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

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

(READ LIST)

Excellent	1
Very good	2
Good	
Fair	4
Poor	5

(DO NOT READ)

Don't Know	•	•	•	•	•	•	•	•	•	•	•	8
Refused						•		•				9

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

(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 <u>pain reliever drug</u> in the past six months? Would you say:

(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 <u>sunscreen</u> in the past six months? Would you say:

(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

11-

13-

(HAND RESPONDENT CARD 16)

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

(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?
 - 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?

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

15-

-								
THANK RESPONDENT FOR PARTICIPATING. GIVE RESPONDENT INCENTIVE.								

INTERVIEWER NAME: _____

SPACE 22 - 79 80 - 5

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