

MK-0803 MEVACOR™ OTC Pivotal Label Comprehension Study #90-NG

Attachment C1

BRUNO and RIDGWAY Research Associates, Inc.
Lawrenceville, NJ 08648 Tel (609) 895-9889 Fax (609) 895-6669

6712
6/13/03
Final

LABEL COMPREHENSION STUDY
Screening Questionnaire
Representative Sample

RESPONDENT'S NAME: _____

SAMPLE
1(X) Representative

ADDRESS: _____

RACE (Q. C):
1() White/Caucasian/Other/Ref.
2() Non-Caucasian

CITY: _____ STATE: _____ ZIP: _____

PHONE #:(AREA CODE) _____(NUMBER) _____

WORDS INCORRECT
1() 0-5
2() 6 or more

DATE OF INTERVIEW: _____

TIME START: _____ TIME END: _____ TOTAL LENGTH: _____

GENDER
1() Male
2() Female

INTERVIEWER'S NAME: _____

RESCHEDULE DATE: _____ TIME: _____

RESPONDENT TYPE:
1() CONCEPT REJECTER (ENDED INTERVIEW AT Q. J)
2() COMPLETED INTERVIEW

AGE GROUP (Q. A/B)
1() 18-34
2() 35-44
3() 45-54
4() 55+

CITY:

- | | | | |
|----------------------------|-----------------------|------------------------|-----------------------|
| 01() Atlanta, GA | 08() Dallas, TX | 15() Hicksville, NY | 22() San Diego, CA |
| 02() Boston, MA | 09() Fresno, CA | 16() Orlando, FL | 23() Springfield, MO |
| 03() Bridgeport, CT | 10() Greensboro, NC | 17() Peoria, IL | 24() Tampa, FL |
| 04() Buffalo, NY | 11() Houston, TX | 18() Philadelphia, PA | 25() Washington, DC |
| 05() Chicago, IL | 12() Livingston, NJ | 19() Phoenix, AZ | |
| 06() Cleveland, OH | 13() Los Angeles, CA | 20() Portland, OR | |
| 07() Colorado Springs, CO | 14() Nashville, TN | 21() San Antonio, TX | |

(APPROACH MEN AND WOMEN WHO APPEAR TO BE 18 YEARS OF AGE AND OLDER.)

INTRODUCTION:

Hello, I'm _____ from Bruno and Ridgway Research Associates in Princeton, NJ. We are conducting a nationwide survey among people aged 18 and older regarding healthcare products. Are you in this age group or not?

- () Yes - (CONTINUE)
() No - (TERMINATE AND TALLY) 1 2 3 4 5 6 7 8 9 0 X Y

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A. What is your year of birth? _____
Y() Refused

(INTERVIEWER: CHECK BIRTH YEAR GRID TO FIND RESPONDENT'S AGE GROUP.
RECORD AGE GROUP ON FRONT OF SCREENER.)

(IF UNDER 18 OR OVER QUOTA, TERMINATE AND TALLY.)
1 2 3 4 5 6 7 8 9 0 X Y

(IF REFUSED BIRTH YEAR, CONTINUE. OTHERWISE SKIP TO Q. C.)

B. (HAND RESPONDENT CARD A) Please tell me which of these age groups you are in. (RECORD BELOW AND ON FRONT OF SCREENER.)

- 1() 18-34
- 2() 35-44
- 3() 45-54
- 4() 55-64
- 5() 65+ - (RECORD AS 55+ ON FRONT OF SCREENER)

(IF UNDER 18 OR REFUSED AGE RANGE OR OVER QUOTA, TERMINATE AND TALLY.)
1 2 3 4 5 6 7 8 9 0 X Y

(TAKE BACK CARD A AND HAND CARD B)

C. To ensure we represent the opinions of all different types of people, we need to interview people in all races. This information is very important for the analysis of this study and is kept completely confidential. Which one or more of the following best describes your race? (MARK ALL THAT APPLY)

- 1() White/Caucasian
- 2() African-American
- 3() American Indian or Alaskan Native
- 4() Asian or Pacific Islander
- 5() Hispanic
- X() Other (SPECIFY:) _____
- Y() REFUSED

IF ANY BOXED ANSWER IS MARKED, RECORD ON FRONT OF SCREENER AS "NON-CAUCASIAN"

(TAKE BACK CARD B)

D. Have you participated in a market research survey in this mall within the past 3 months?

- () Yes - (TERMINATE & TALLY) 1 2 3 4 5 6 7 8 9 0 X Y
- () No - (CONTINUE)

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E. Sometimes the type of work people do affects the products they buy. Are you, yourself, or is any member of your family or any close friend, employed . . . (READ LIST)?

	<u>YES</u>	<u>NO</u>
By an advertising agency	()	()
By a market research company	()	()
By a company that processes or manufactures pharmaceutical, medical or healthcare products	()	()
As a <u>manager</u> of a drugstore, supermarket or mass merchandising store.....	()	()
As a physician, nurse or pharmacist	()	()

(IF "YES" TO ANY OF THE ABOVE, TERMINATE & TALLY.) 1 2 3 4 5 6 7 8 9 0 X Y

(HAND CARD C)

F. I am going to read you a list of some specific health issues. After I read each one, please tell me the statement on this card that best describes how concerned you are about that issue for yourself. The first health issue is . . . ? (READ FIRST ITEM BELOW)

	<u>Extremely Concerned</u>	<u>Very Concerned</u>	<u>Somewhat Concerned</u>	<u>Not At All Concerned</u>
Your blood pressure level.....	1 ()	2 ()	3 ()	4 ()
Amount of fiber in your diet	1 ()	2 ()	3 ()	4 ()
Amount of fat in your diet	1 ()	2 ()	3 ()	4 ()
Your cholesterol level.....	1 ()	2 ()	()	()

IF BOXED ANSWER MARKED, TERMINATE AND TALLY
1 2 3 4 5 6 7 8 9 0 X Y

(TAKE BACK CARD C.)

G. Do you usually wear glasses when you read?

- () Yes - (CONTINUE)
- () No - (SKIP TO BOXED INSTRUCTIONS BEFORE Q. I)

H. Do you have your reading glasses with you today?

- () Yes - (CONTINUE)
- () No - (TERMINATE & TALLY) 1 2 3 4 5 6 7 8 9 0 X Y

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<p>INTERVIEWER: RESPONDENT HAS QUALIFIED FOR "QUOTA COUNT." BE SURE TO RECORD RESPONDENT'S NAME UNDER APPROPRIATE GENDER & AGE.</p>

(HAND RESPONDENT PRODUCT DESCRIPTION)

- I. Here is a description of a new healthcare product that may soon be available in stores that sell nonprescription medicines. Carefully read the description, taking as much time as you need. Please tell me when you are finished. (CONTINUE WHEN RESPONDENT FINISHES)

(HAND CARD D)

- J. Which statement on this card best describes how likely you would be to consider using MEVACOR™ OTC?

<p>1 () Definitely would consider 2 () Probably would consider 3 () Might or might not consider</p>	➔	CONTINUE
<p>4 () Probably would not consider 5 () Definitely would not consider</p>	➔	THANK AND END INTERVIEW SAVE QUESTIONNAIRE

(TAKE BACK PRODUCT DESCRIPTION AND CARD D)

- K. The reason for my questions is that I would like to get your opinion about MEVACOR™ OTC. The survey takes about 45 minutes, and I think you will find it interesting. We will pay you \$20 for your time. Would you be willing to help us?

() Yes - (SKIP TO Q. M) () No - (CONTINUE)

- L. We would really like your opinions, so if you can come back another day this week, we will pay you an additional \$5, that's \$25 total for your time. Would you be willing to come back and help us at another time?

() Yes – (SCHEDULE INTERVIEW ON FRONT OF SCREENER)
() No - (REMOVE NAME FROM QUOTA COUNT SHEET. TERMINATE & TALLY.
YOU DO NOT NEED TO SAVE THIS SCREENER.)

1 2 3 4 5 6 7 8 9 0 X Y

(CONTINUE AT INTERVIEWING FACILITY. REMIND RESPONDENT TO WEAR READING GLASSES IF NEEDED)

- M. We're going to begin with a word list of medical-related terms. These words are sometimes found on packages of medicines. I'd like you to read the words to me. We want to make sure that the people who write the labels and instructions for medicines use words people are familiar with. (HAND RESPONDENT WORD LIST.) I want to hear you read as many words as you can from

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this list. Begin with the first word and read each word aloud. If you come to a word you cannot read, do the best you can or say “pass” and go on to the next word. (AFTER WORD LIST IS COMPLETED, REMOVE LIST.)

INTERVIEWER:

- Follow along on the word list below.
- After each word is read, **circle any word that is mispronounced or not attempted.** If a word is self-corrected, it counts as correct.
- If respondent takes more than 5 seconds on a word, say “pass” and point to the next word, if necessary, to move along. If respondent begins to miss every word, instruct to pronounce only known words.

NUMBER OF WORDS CIRCLED BELOW:

- 1() 0 - 5 words – (RECORD ON FRONT OF SCREENER)
2() 6 or more words – (RECORD ON FRONT OF SCREENER)

LIST 1

fat
flu
pill
dose
eye
stress
smear
nerves
germs
meals
disease
cancer
caffeine
attack
kidney
hormones
herpes
seizure
bowel
asthma
rectal
incest

LIST 2

fatigue
pelvic
jaundice
infection
exercise
behavior
prescription
notify
gallbladder
calories
depression
miscarriage
pregnancy
arthritis
nutrition
menopause
appendix
abnormal
syphilis
hemorrhoids
nausea
directed

LIST 3

allergic
menstrual
testicle
colitis
emergency
medication
occupation
sexually
alcoholism
irritation
constipation
gonorrhea
inflammatory
diabetes
hepatitis
antibiotics
diagnosis
potassium
anemia
obesity
osteoporosis
impetigo

CONTINUE WITH MAIN QUESTIONNAIRE

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Attachment C2

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6712
6/13/03
Final

LABEL COMPREHENSION STUDY
Screening Questionnaire
Literacy Augment Sample

RESPONDENT'S NAME: _____

<u>SAMPLE</u> 2(X) Literacy Augment
--

ADDRESS: _____

<u>RACE (Q. C):</u> 1() White/Caucasian/Other/Ref. 2() Non-Caucasian
--

CITY: _____ STATE: _____ ZIP: _____

PHONE #: (AREA CODE) _____ (NUMBER) _____

<u># WORDS INCORRECT</u> 1() 0-5 2(X) 6 or more
--

DATE OF INTERVIEW: _____

TIME START: _____ TIME END: _____ TOTAL LENGTH: _____

<u>GENDER</u> 1() Male 2() Female

INTERVIEWER'S NAME: _____

RESCHEDULE DATE: _____ TIME: _____

<u>RESPONDENT TYPE:</u> 2(X) COMPLETED INTERVIEW

<u>AGE GROUP (Q. A/B)</u> 1() 18-34 2() 35-44 3() 45-54 4() 55+

CITY:

- | | | | |
|----------------------------|-----------------------|------------------------|-----------------------|
| 01() Atlanta, GA | 08() Dallas, TX | 15() Hicksville, NY | 22() San Diego, CA |
| 02() Boston, MA | 09() Fresno, CA | 16() Orlando, FL | 23() Springfield, MO |
| 03() Bridgeport, CT | 10() Greensboro, NC | 17() Peoria, IL | 24() Tampa, FL |
| 04() Buffalo, NY | 11() Houston, TX | 18() Philadelphia, PA | 25() Washington, DC |
| 05() Chicago, IL | 12() Livingston, NJ | 19() Phoenix, AZ | |
| 06() Cleveland, OH | 13() Los Angeles, CA | 20() Portland, OR | |
| 07() Colorado Springs, CO | 14() Nashville, TN | 21() San Antonio, TX | |

(APPROACH MEN AND WOMEN WHO APPEAR TO BE 18 YEARS OF AGE AND OLDER.)

INTRODUCTION:

Hello, I'm _____ from Bruno and Ridgway Research Associates in Princeton, NJ. We are conducting a nationwide survey among people aged 18 and older regarding healthcare products. Are you in this age group or not?

- () Yes - (CONTINUE)
 () No - (TERMINATE AND TALLY) 1 2 3 4 5 6 7 8 9 0 X Y

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A. What is your year of birth? _____
Y() Refused

(INTERVIEWER: CHECK BIRTH YEAR GRID TO FIND RESPONDENT'S AGE GROUP.
RECORD AGE GROUP ON FRONT OF SCREENER.)

(IF UNDER 18 OR OVER QUOTA, TERMINATE AND TALLY.)
1 2 3 4 5 6 7 8 9 0 X Y

(IF REFUSED BIRTH YEAR, CONTINUE. OTHERWISE SKIP TO Q. C.)

B. (HAND RESPONDENT CARD A) Please tell me which of these age groups you are in. (RECORD BELOW AND ON FRONT OF SCREENER.)

- 1() 18-34
- 2() 35-44
- 3() 45-54
- 4() 55-64 - (RECORD AS 55+ ON FRONT OF SCREENER)
- 5() 65+

(IF UNDER 18 OR REFUSED AGE RANGE OR OVER QUOTA, TERMINATE AND TALLY.)

1 2 3 4 5 6 7 8 9 0 X Y

(TAKE BACK CARD A AND HAND CARD B)

C. To ensure we represent the opinions of all different types of people, we need to interview people in all races. This information is very important for the analysis of this study and is kept completely confidential. Which one or more of the following best describes your race? (MARK ALL THAT APPLY)

- 1() White/Caucasian
- 2() African-American
- 3() American Indian or Alaskan Native
- 4() Asian or Pacific Islander
- 5() Hispanic

X() Other (SPECIFY:) _____
Y() REFUSED

IF ANY BOXED ANSWER IS MARKED, RECORD ON FRONT OF SCREENER AS "NON-CAUCASIAN"

(TAKE BACK CARD B)

D. Have you participated in a market research survey in this mall within the past 3 months?

- () Yes - (TERMINATE & TALLY) 1 2 3 4 5 6 7 8 9 0 X Y
- () No - (CONTINUE)

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E. Sometimes the type of work people do affects the products they buy. Are you, yourself, or is any member of your family or any close friend, employed . . . (READ LIST)?

	<u>YES</u>	<u>NO</u>
By an advertising agency	()	()
By a market research company	()	()
By a company that processes or manufactures pharmaceutical, medical or healthcare products	()	()
As a <u>manager</u> of a drugstore, supermarket or mass merchandising store.....	()	()
As a physician, nurse or pharmacist	()	()

(IF "YES" TO ANY OF THE ABOVE, TERMINATE & TALLY.) 1 2 3 4 5 6 7 8 9 0 X Y

(HAND CARD C)

F. I am going to read you a list of some specific health issues. After I read each one, please tell me the statement on this card that best describes how concerned you are about that issue *for yourself*. The first health issue is . . . ? (READ FIRST ITEM BELOW)

	<u>Extremely Concerned</u>	<u>Very Concerned</u>	<u>Somewhat Concerned</u>	<u>Not At All Concerned</u>
Your blood pressure level.....	1 ()	2 ()	3 ()	4 ()
Amount of fiber in your diet	1 ()	2 ()	3 ()	4 ()
Amount of fat in your diet	1 ()	2 ()	3 ()	4 ()
Your cholesterol level.....	1 ()	2 ()	() ()	

IF BOXED ANSWER MARKED, TERMINATE AND TALLY
1 2 3 4 5 6 7 8 9 0 X Y

(TAKE BACK CARD C.)

G. Do you usually wear glasses when you read?

- () Yes - (CONTINUE)
- () No - (SKIP TO Q. I)

H. Do you have your reading glasses with you today?

- () Yes - (CONTINUE)
- () No - (TERMINATE & TALLY) 1 2 3 4 5 6 7 8 9 0 X Y

MK-0803 MEVACOR™ OTC Pivotal Label Comprehension Study #90-NG

6712 - Page 4 (Scr – Literacy Augment)

(HAND RESPONDENT PRODUCT DESCRIPTION)

- I. Here is a description of a new healthcare product that may soon be available in stores that sell nonprescription medicines. Carefully read the description, taking as much time as you need. Please tell me when you are finished. (CONTINUE WHEN RESPONDENT FINISHES)

(HAND CARD D)

- J. Which statement on this card best describes how likely you would be to consider using MEVACOR™ OTC?

1() Definitely would consider 2() Probably would consider 3() Might or might not consider	➔	CONTINUE
() Probably would not consider () Definitely would not consider	➔	TERMINATE & TALLY 1 2 3 4 5 6 7 8 9 0 X Y

(TAKE BACK PRODUCT DESCRIPTION AND CARD D.)

- K. The reason for my questions is that I would like to get your opinion about a healthcare product. The survey takes less than 5 minutes, and I think you will find it interesting. Would you be willing to help us out?

- () Yes - (CONTINUE)
() No - (TERMINATE & TALLY) 1 2 3 4 5 6 7 8 9 0 X Y

INTERVIEWER: TAKE RESPONDENT TO INTERVIEWING ROOM.

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(CONTINUE AT INTERVIEWING FACILITY. REMIND RESPONDENT TO WEAR READING GLASSES IF NEEDED)

- L. We're going to begin with a word list of medical-related terms. These words are sometimes found on packages of medicines. I'd like you to read the words to me. We want to make sure that the people who write the labels and instructions for medicines use words people are familiar with. (HAND RESPONDENT WORD LIST.) I want to hear you read as many words as you can from this list. Begin with the first word and read each word aloud. If you come to a word you cannot read, do the best you can or say "pass" and go on to the next word. (AFTER WORD LIST IS COMPLETED, REMOVE LIST.)

INTERVIEWER:

- Follow along on the word list below.
- After each word is read, **circle any word that is mispronounced or not attempted.** If a word is self-corrected, it counts as correct.
- If respondent takes more than 5 seconds on a word, say "pass" and point to the next word, if necessary, to move along. If respondent begins to miss every word, instruct to pronounce only known words.

NUMBER OF WORDS CIRCLED BELOW:

- 1 () 0 - 5 words – (TERMINATE & TALLY) 1 2 3 4 5 6 7 8 9 0 X Y
 2 () 6 or more words – (CONTINUE)

LIST 1

fat
 flu
 pill
 dose
 eye
 stress
 smear
 nerves
 germs
 meals
 disease
 cancer
 caffeine
 attack
 kidney
 hormones
 herpes
 seizure
 bowel
 asthma
 rectal
 incest

LIST 2

fatigue
 pelvic
 jaundice
 infection
 exercise
 behavior
 prescription
 notify
 gallbladder
 calories
 depression
 miscarriage
 pregnancy
 arthritis
 nutrition
 menopause
 appendix
 abnormal
 syphilis
 hemorrhoids
 nausea
 directed

LIST 3

allergic
 menstrual
 testicle
 colitis
 emergency
 medication
 occupation
 sexually
 alcoholism
 irritation
 constipation
 gonorrhea
 inflammatory
 diabetes
 hepatitis
 antibiotics
 diagnosis
 potassium
 anemia
 obesity
 osteoporosis
 impetigo

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- M. The reason for my questions is that I would like to get your opinion about MEVACOR™ OTC. The survey takes about another 40 minutes, and I think you will find it interesting. We will pay you \$20 for your time. Would you be willing to help us?
- Yes - (RECORD RESPONDENT'S NAME ON "LITERACY AUGMENT QUOTA SHEET" AND CONTINUE WITH MAIN QUESTIONNAIRE)
- No - (CONTINUE)
-
- N. We would really like your opinions, so if you can come back another day this week, we will pay you an additional \$5, that's \$25 total for your time. Would you be willing to come back and help us at another time?
- Yes – (SCHEDULE INTERVIEW ON FRONT OF SCREENER AND RECORD RESPONDENT'S NAME ON "LITERACY AUGMENT QUOTA SHEET")
- No - (TERMINATE AND TALLY) 1 2 3 4 5 6 7 8 9 0 X Y

CONTINUE WITH MAIN QUESTIONNAIRE

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Attachment C3

BRUNO and RIDGWAY Research Associates, Inc.
Lawrenceville, NJ 08648 Tel (609) 895-9889 Fax (609) 895-6669

6712
6/17/03
FINAL

LABEL COMPREHENSION STUDY
(MAIN QUESTIONNAIRE)

Respondent's Name: _____

(REMIND RESPONDENT TO WEAR GLASSES IF NEEDED FOR READING)

1. Before we continue, I'd like you to read and sign this nondisclosure agreement. (HAND RESPONDENT NONDISCLOSURE AGREEMENT AND A PEN. AFTER RESPONDENT SIGNS, CONTINUE.)

2. During the rest of this interview, I will be showing you a package being developed for MEVACOR™ OTC. You will have whatever time you feel you need to thoroughly review this package, and then we will go through a series of questions that will help us to see how the package is doing in communicating product information.

(TAKE OUT MEVACOR™ OTC BOX. DO NOT GIVE TO RESPONDENT AT THIS TIME.)

3. This is the actual package that will be used for this product when it is available in stores. This package contains no medicine or anything else inside, so please do **NOT** open it. (DO NOT LET RESPONDENT EXAMINE PACKAGE YET).
4. I would like you to read all of the information on this package. I'm going to leave you alone while you read the information on the package so you have time to concentrate. When I come back, I will ask you some questions about the product. Some of the questions will be about whether you, yourself, could use the product or not. I will also describe other people and ask whether you think they could use the product or not. You will be able to look at the package to answer my questions. I will check back in a while to see how you are doing. You will have as much time as you need to read the package. (HAND RESPONDENT PACKAGE AND LEAVE ROOM)

(COME BACK AFTER 5 MINUTES)

5. I'm looking in on you to see how you are doing. I want to make sure you have enough time to read over the package before we go on with the interview. Do you want a few more minutes to continue reading the package?

- 1 () Yes – (SAY:) I'll check back with you in a few minutes
2 () No – (CONTINUE)

→ COME BACK IN 2 MINUTES
AND RE-ASK Q. 5. GIVE MORE
TIME IF NEEDED

(LEAVE PACKAGE OUT FOR ENTIRE INTERVIEW)

6. This package has a lot of information on it, so for the remainder of the interview, you might find it helpful to look at the package to help answer my questions. Now, I'm going to ask you some specific questions about this product. This is not a test of you. It is a way for us to see how well this package communicates product information. So, again, I want to suggest that you refer to the package before you give your answers. Do not try to answer from memory. Base your answers only on the information provided on the package and not your personal beliefs.

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7. First, what is MEVACOR™ OTC used to treat? (DO NOT CLARIFY OR PROBE.)
-

8. What is the active ingredient in MEVACOR™ OTC?
-

9. The package information you have seen describes the exact characteristics of who could use this product and who must not use it. Imagine you are in your local pharmacy later today and you see MEVACOR™ OTC on the shelf. Think about your own personal and medical characteristics. Using the package information as the basis for your answer, could you, yourself, start to use MEVACOR™ OTC today, or not? Just to clarify, I'm not asking if you are interested in buying the product. I'm asking if, based on the information, you are personally qualified to use the product, or not. (HAND CARD E)

1() I could start using MEVACOR™ OTC today – (RECORD ON EXTENDED TAB AND CONTINUE)

I must not start using MEVACOR™ OTC today – (CONTINUE)

3() DON'T KNOW – (CONTINUE)

10. What specific information on the package helped you to decide that you (ANSWER FROM Q. 9)? (PROBE & CLARIFY RESPONSES)
-
-

(CHECK Q. 9. IF BOXED ANSWER (#2) MARKED, SKIP TO BOXED INSTRUCTION BEFORE Q. 14. OTHERWISE, CONTINUE.)

11. Assuming you decided you were interested in trying MEVACOR™ OTC, is there anything that you, personally, would do before starting to use it, or not?

1() Yes – (CONTINUE)

2() No – (SKIP TO Q. 13)

3() Wouldn't use product – (SKIP TO BOXED INSTRUCTIONS ABOVE Q. 14)

Y() DON'T KNOW – (SKIP TO Q.13)

12. What would you do? (PROBE ONCE:) What else?
-
-

(IF RESPONDENT SAYS "TALK TO A DOCTOR" IN Q. 12 ABOVE, SKIP TO BOXED INSTRUCTIONS BEFORE Q. 14; OTHERWISE, CONTINUE.)

13. How likely is it that you would talk to your doctor about MEVACOR™ OTC before starting to use it? Is it... (READ LIST)

1() Very likely

2() Somewhat likely

3() Not too likely, or

4() Not at all likely?

Y() DON'T KNOW – (DO NOT READ)

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CHECK EXTENDED TAB. IF "COULD START USING MEVACOR™ OTC TODAY" MARKED, SKIP TO Q. 18. OTHERWISE, CONTINUE WITH INSTRUCTIONS BELOW.

(CHECK Q. 10. IF THE ONLY REASON LISTED IS THAT THEY DON'T KNOW SOME OR ALL CHOLESTEROL NUMBERS, ASK Q. 14. OTHERWISE, SKIP TO Q. 18.)

14. Now, just for this next question, let's assume that you know all of your own cholesterol numbers and they are in the appropriate ranges to use MEVACOR™ OTC. Now think about all of your other personal and medical characteristics apart from your cholesterol numbers. Thinking about these other factors, and using the package information as the basis for your answer, could you, yourself, start using MEVACOR™ OTC today, or not? You may refer back to the package information if you like. (POINT TO CARD E AGAIN)

1() I could start using MEVACOR™ OTC today– (SKIP TO Q. 16)

2() I must not start using this product today– (CONTINUE)

Y() DON'T KNOW – (SKIP TO Q. 16)

15. What specific information on the package leads you to decide that you must not start using MEVACOR™ OTC today? (PROBE & CLARIFY RESPONSES)

_____ (SKIP TO Q. 18)

(CHECK Q. 11. IF ANSWERED, SKIP TO Q. 18)

16. Assuming you decided you were interested in trying MEVACOR™ OTC, is there anything that you, personally, would do before starting to use it, or not?

1() Yes – (CONTINUE)

2() No – (SKIP TO Q. 18)

3() Wouldn't use product -- (SKIP TO Q. 18)

Y() DON'T KNOW – (SKIP TO Q. 18)

17. What would you do? (PROBE ONCE:) What else?

(TAKE BACK CARD E)

18. Whether or not you feel MEVACOR™ OTC is right for you, I am now going to ask you about the decisions that some other people should make for themselves. Do you want a few minutes to review the package again before we start with these questions?

1() Yes – (LEAVE ROOM FOR 2 MINUTES. THEN CHECK TO SEE IF RESPONDENT NEEDS MORE TIME)

2() No – (CONTINUE)

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(TAKE OUT BLUE DECK OF CARDS. MAKE SURE THEY ARE IN ALPHABETICAL ORDER BY LETTER IN TOP RIGHT CORNER OF EACH CARD. DO NOT SHUFFLE.)

19a. Here are some statements that describe some people who are deciding whether MEVACOR™ OTC is right for them. Other than what I tell you about each person, assume these people have no other reasons not to use this product starting today. Using the package information as the basis for your answer, tell me whether each statement is true or false. (HAND BLUE CARD A). The first statement is "Alan has never had his cholesterol tested. He does not need to have his cholesterol tested before starting to use MEVACOR™ OTC." Is that statement true or false?

- 1() True
- 2(X) False
- Y() DON'T KNOW

19b. How about . . .? (TAKE BACK BLUE CARD A AND HAND BLUE CARD RED X'D BELOW. READ STATEMENT OUT LOUD). Is that statement true or false? (RECORD BELOW. TAKE BACK CARD AND HAND NEXT BLUE CARD SHOWN BELOW AND SAY:) How about (READ NEXT STATEMENT)? Is that statement true or false? (ASK FOR ALL BLUE CARDS IN ORDER INDICATED)

IF RESPONDENT SAYS "I NEED MORE INFORMATION ABOUT THIS PERSON" SAY "Other than what I read you about each person, assume these people have no other reasons not to use this product starting today."

	<u>TRUE</u>	<u>FALSE</u>	<u>DON'T KNOW</u>
() B. Ben has been swimming laps regularly and watching his diet. His cholesterol has not gone down. It's okay for him to use MEVACOR™ OTC	1(X)	2()	Y()
() D. Doris got her cholesterol tested without fasting first. It's okay that she is using these numbers to help decide if MEVACOR™ OTC is right for her	1()	2(X)	Y()
() J. Janet had her cholesterol tested 2 months ago. It's okay that she is using these numbers to help decide if MEVACOR™ OTC is right for her	1(X)	2()	Y()
() M. Melanie does not need to try a healthy diet before starting MEVACOR™ OTC because MEVACOR™ OTC will lower her cholesterol in place of the diet.	1()	2(X)	Y()
() S. Sam had his cholesterol tested 2 years ago. It's okay that he is using those numbers to help decide if MEVACOR™ OTC is right for him.	1()	2(X)	Y()

(TAKE OUT CARD F)

20. We're going to look at a few descriptions of different people who are deciding if MEVACOR™ OTC is right for them. I want you to look over the information on each card then tell me the answer on this card that applies to the person being described. (HAND CARD F AND REVIEW ANSWER CHOICES) Remember, your answers should be based only on the information from the package and not based on your own opinions or your own health information. Please remember that you can refer back to the package.

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Version 1(X)

(TAKE OUT TAN DECK OF CARDS AND SHUFFLE. HAND FIRST TAN CARD)

21. Here is some information about someone who is deciding if MEVACOR™ OTC is right for him or her. (READ MATCHING STATEMENT BELOW.) According to the package, please tell me which one answer on this card best describes what this person should do? (RECORD ANSWER NEXT TO SAME LETTER ON GRID. TAKE BACK TAN CARD AND HAND RESPONDENT NEXT TAN CARD. CONTINUE UNTIL ALL TAN CARDS HAVE BEEN ANSWERED.)

ACCORDING TO THE PACKAGE...	THIS PERSON COULD START USING RIGHT AWAY	BEFORE USING, THIS PERSON NEEDS TO ASK A DOCTOR FIRST OR GET MORE INFORMATION	THIS PERSON SHOULD NOT USE AT ALL	DON'T KNOW
(F) Francine is 61 years old. Before using MEVACOR™ OTC, her LDL "bad" cholesterol is 150. Her mother had a heart attack at age 59. Assume Francine has no other reasons not to use this product starting today.	1(C)	2(A)	3()	Y()
(J) Jane is 60 years old. Before using MEVACOR™ OTC, her LDL "bad" cholesterol is 115. She has high blood pressure. She is not taking any prescription medicines. Assume Jane has no other reasons not to use this product starting today.	1()	2(C)	3(A)	Y()
(K) Kathleen is 58 years old. She doesn't know her LDL "bad" cholesterol or her HDL "good" cholesterol numbers. Her father had a heart attack when he was 47. Assume Kathleen has no other reasons not to use this product starting today.	1()	2(C)	3(A)	Y()
(S) Steve is 47 years old. Before using MEVACOR™ OTC, his LDL "bad" cholesterol is 140. His HDL "good" cholesterol is 33. Assume Steve has no other reasons not to use this product starting today.	1(C)	2(A)	3()	Y()
(V) Victor is 59 years old. Before using MEVACOR™ OTC, his LDL "bad" cholesterol is 145. His HDL "good" cholesterol is 32. Recently he had a muscle pain side effect from taking a cholesterol lowering medicine and had to stop using it. Assume Victor has no other reasons not to use this product starting today.	1()	2(A)	3(C)	Y()

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Version 2(X)

(TAKE OUT YELLOW DECK OF CARDS AND SHUFFLE. HAND FIRST YELLOW CARD)

21. Here is some information about someone who is deciding if MEVACOR™ OTC is right for him or her. (READ MATCHING STATEMENT BELOW) According to the package, please tell me which one answer on this card best describes what this person should do? (RECORD ANSWER NEXT TO SAME LETTER ON GRID. TAKE BACK YELLOW CARD AND HAND RESPONDENT NEXT YELLOW CARD. CONTINUE UNTIL ALL YELLOW CARDS HAVE BEEN ANSWERED.)

ACCORDING TO THE PACKAGE...	THIS PERSON COULD START USING RIGHT AWAY	BEFORE USING, THIS PERSON NEEDS TO ASK A DOCTOR FIRST OR GET MORE INFORMATION	THIS PERSON SHOULD NOT USE AT ALL	DON'T KNOW
(B) Brenda is 68 years old. Before using MEVACOR™ OTC, her LDL "bad" cholesterol is 156. Her father had a heart attack at the age of 50. Assume Brenda has no other reasons not to use this product starting today.	1(C)	2(A)	3()	Y()
(C) Carol is 72 years old. Before using MEVACOR™ OTC, her LDL "bad" cholesterol is 250. She has high blood pressure. She is not taking any prescription medicines. Assume Carol has no other reasons not to use this product starting today.	1()	2(C)	3(A)	Y()
(D) David is 46 years old. Before using MEVACOR™ OTC, his LDL "bad" cholesterol is 145. His HDL "good" cholesterol is 32. Assume David has no other reasons not to use this product starting today.	1(C)	2(A)	3()	Y()
(L) Laurie is 45 years old. Before using MEVACOR™ OTC, her LDL "bad" cholesterol is 155. She has high blood pressure. She is not taking any prescription medicines. Assume Laurie has no other reasons not to use this product starting today.	1()	2(C)	3(A)	Y()
(R) Rob is 68 years old. Before using MEVACOR™ OTC, his LDL "bad" cholesterol is 160. His father had a heart attack at the age of 45. Rob is allergic to lovastatin. Assume Rob has no other reasons not to use this product starting today.	1()	2(A)	3(C)	Y()

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Version 1(X)

(TAKE BACK CARD F AND HAND CARD G)

22. I have different people I want to ask you about. All of these people would qualify to use MEVACOR™ OTC right away except that they are using a medicine or health care product. I'm going to read you what each person is using and I want you to tell me what that person should do if they want to start taking MEVACOR™ OTC. These are the answers you should choose from (READ ANSWERS ON CARD G). Assume that all these people otherwise qualify to take MEVACOR™ OTC right away. Here is the first person. (READ DESCRIPTION STARTING AT RED "X.") Which answer on this card best describes what that person should do? (CONTINUE UNTIL ALL HAVE BEEN ASKED.)

	THIS PERSON COULD START USING RIGHT AWAY	BEFORE USING, THIS PERSON NEEDS TO ASK A DOCTOR FIRST	DON'T KNOW
() Al is using a nonprescription cough drop for a mild cough	1(C)	2()	Y()
() Sara takes a prescription medicine to lower her cholesterol	1()	2(C)	Y()
() Doug takes a prescription medicine for his ulcer	1()	2(C)	Y()
() Lisa has developed a case of hemorrhoids and has started to use Preparation H for it.	1(C)	2()	Y()
() Linda takes a nonprescription fiber laxative for regularity	1(C)	2()	Y()
() Warren is taking a prescription medicine for an infection	1()	2(C)	Y()

(TAKE BACK CARD G AND HAND CARD H)

23. Let's talk about another group of people. None of these people are taking prescription medicines; however, they all have other health conditions. I'm going to tell you about each person's health condition and I want you to tell me which answer on the card best describes what that person should do if they want to start taking MEVACOR™ OTC. Here are the answers you should choose from (READ ANSWERS ON CARD H). Assume that all these people otherwise qualify to take MEVACOR™ OTC right away. Here is the first person. (READ DESCRIPTION STARTING AT RED "X.") Which answer on the card best describes what that person should do? (CONTINUE UNTIL ALL HAVE BEEN ASKED.)

	THIS PERSON COULD START USING RIGHT AWAY	BEFORE USING, THIS PERSON NEEDS TO ASK A DOCTOR FIRST	THIS PERSON SHOULD NOT USE AT ALL	DON'T KNOW
() Peter gets gas from over-eating once in a while	1(C)	2(A)	3()	Y()
() Barbara has liver disease	1()	2(A)	3(C)	Y()
() Luke had a stroke several years ago.	1()	2(C)	3(A)	Y()
() John has occasional constipation	1(C)	2(A)	3()	Y()
() Amanda's triglycerides are 450	1()	2(C)	3(A)	Y()
() Helen is breast-feeding	1()	2(A)	3(C)	Y()
() Bill was camping in the woods and got a case of poison ivy	1(C)	2(A)	3()	Y()

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Version 2(X)

(TAKE BACK CARD F AND HAND CARD G)

22. I have different people I want to ask you about. All of these people would qualify to use MEVACOR™ OTC right away except that they are using a medicine or health care product. I'm going to read you what each person is using and I want you to tell me what that person should do if they want to start taking MEVACOR™ OTC. These are the answers you should choose from (READ ANSWERS ON CARD G). Assume that all these people otherwise qualify to take MEVACOR™ OTC right away. Here is the first person. (READ DESCRIPTION STARTING AT RED "X.") Which answer on this card best describes what that person should do? (CONTINUE UNTIL ALL HAVE BEEN ASKED.)

	THIS PERSON COULD START USING RIGHT AWAY	BEFORE USING, THIS PERSON NEEDS TO ASK A DOCTOR FIRST	DON'T KNOW
() Al is using a nonprescription cough drop for a mild cough	1(C)	2()	Y()
() Sara takes a prescription medicine to lower her cholesterol	1()	2(C)	Y()
() Doug takes a prescription medicine for his ulcer	1()	2(C)	Y()
() Lisa has developed a case of hemorrhoids and has started to use Preparation H for it.	1(C)	2()	Y()
() Linda takes a nonprescription fiber laxative for regularity	1(C)	2()	Y()
() Warren is taking a prescription medicine for an infection	1()	2(C)	Y()

(TAKE BACK CARD G AND HAND CARD H)

23. Let's talk about another group of people. None of these people are taking prescription medicines; however, they all have other health conditions. I'm going to tell you about each person's health condition and I want you to tell me which answer on the card best describes what that person should do if they want to start taking MEVACOR™ OTC. Here are the answers you should choose from (READ ANSWERS ON CARD H). Assume that all these people otherwise qualify to take MEVACOR™ OTC right away. Here is the first person. (READ DESCRIPTION STARTING AT RED "X.") Which answer on the card best describes what that person should do? (CONTINUE UNTIL ALL HAVE BEEN ASKED.)

	THIS PERSON COULD START USING RIGHT AWAY	BEFORE USING, THIS PERSON NEEDS TO ASK A DOCTOR FIRST	THIS PERSON SHOULD NOT USE AT ALL	DON'T KNOW
() Peter gets gas from over-eating once in a while	1(C)	2(A)	3()	Y()
() Alice is pregnant	1()	2(A)	3(C)	Y()
() Mary had a heart attack last year	1()	2(C)	3(A)	Y()
() Bill was camping in the woods and got a case of poison ivy	1(C)	2(A)	3()	Y()
() John has occasional constipation	1(C)	2(A)	3()	Y()
() Cindy has diabetes	1()	2(C)	3(A)	Y()

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(TAKE BACK CARD H)

24. Would you like to take a quick break to stretch your legs and review the package again before we finish this interview? (MARK YES OR NO BELOW AND, IF YES, LEAVE ROOM FOR ABOUT 2 MINUTES.)

1() Yes – (LEAVE ROOM FOR ABOUT 2 MINUTES)

2() No – (CONTINUE)

25. Now I'm going to ask you some specific questions about how to use this product. You can refer to the package before you give your answers.

26. First, what is MEVACOR™ OTC supposed to do to a person's LDL cholesterol?

27. Looking at the package, and considering the directions for using the product, how many times a day should someone take MEVACOR™ OTC?

_____ (# OF TIMES – NO RANGES)

Y() DON'T KNOW

28. And, how many tablets should someone take at one time?

_____ (# OF TABLETS – NO RANGES)

Y() DON'T KNOW

29. Does the package say at what point in time someone can increase the dose of MEVACOR™ OTC on their own?

1() Yes – (CONTINUE) 2() No – (SKIP TO Q. 31) Y() DON'T KNOW – (SKIP TO Q.31)

30. According to the package, what is the point in time that someone can increase the dose of MEVACOR™ OTC on their own?

31. Does the package information say what, if anything, will happen if a person who has been using MEVACOR™ OTC stops using it?

1() Yes – (CONTINUE)

2() No – (SKIP TO Q. 33)

Y() DON'T KNOW – (SKIP TO Q. 33)

32. According to the package, what will happen if a person who has been using MEVACOR™ OTC stops using it?

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33. Is there a best time during the day to take MEVACOR™ OTC, or is one time as good as another?

- 1() There is a best time - (CONTINUE)
 2() One time is as good as another - (SKIP TO Q. 35)
 Y() DON'T KNOW - (SKIP TO Q.35)

34. When is the best time to take MEVACOR™ OTC? Is it... (READ LIST)

- 1() In the morning,
 2() At lunch time, or
 3() In the evening?
 Y() DON'T KNOW (DON'T READ)

(TAKE OUT CARD I)

35. Up until now, we have been talking about people who needed to decide if MEVACOR™ OTC is right for them. Now, we are going to talk about some people who have been taking the product for a while. They need to be sure they are following the directions to take MEVACOR™ OTC correctly. I will be asking several questions that relate to whether they are following the directions for taking MEVACOR™ OTC correctly. These are the answers you should choose from (HAND CARD I). This answer card has three choices relating to cholesterol testing (READ ANSWERS ON CARD I) Remember, you can refer to the package at any time. Here is the first person. (START AT RED "X.") Which answer on this card best describes what that person should do next? (CONTINUE ASKING UNTIL BOTH HAVE BEEN ASKED)

	GET A CHOLESTEROL TEST NOW	GET A CHOLESTEROL TEST AFTER A FEW MORE WEEKS	NO NEED TO GET A CHOLESTEROL TEST ANYTIME SOON	DON'T KNOW
() Connie has been taking MEVACOR™ OTC for 4 weeks.	1()	2(X)	3()	Y()
() Dan has been taking MEVACOR™ OTC for 8 weeks.	1(X)	2()	3()	Y()

(TAKE BACK CARD I. TAKE OUT PINK DECK CARDS.)

36. This next group of people have been taking MEVACOR™ OTC for a while. Now they need to see if MEVACOR™ OTC is working for them. Each person has already gotten his or her follow-up LDL test result. I'm going to ask you several questions about what each person should do next.

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37. Here is the first person. (HAND PINK CARD THAT IS RED X'D BELOW. AFTER READING IT ALOUD, ASK Q's A, B AND C IN ORDER FOR EACH SCENARIO. CONTINUE IN ROTATION ORDER UNTIL ALL 3 PINK CARDS HAVE BEEN ASKED)

() Card E - After taking MEVACOR™ OTC for 6 weeks, Eddie got a follow-up LDL test. His LDL test result was 115.

- A. Did Eddie get a follow-up LDL test at the appropriate time, or not?
 1(X) Yes – (CONTINUE) 2() No – (SKIP TO NEXT PINK CARD) Y() DON'T KNOW – (SKIP TO NEXT PINK CARD)
- B. Did Eddie's follow-up LDL test result fall to the right level, or not?
 1(X) Yes – (CONTINUE) 2() No – (CONTINUE) Y() DON'T KNOW – (SKIP TO NEXT PINK CARD)

(HAND CARD J. READ FOLLOWING DESCRIPTION ABOUT ANSWER CARD FOR JUST THE 1ST SCENARIO ASKED.)
 Please use this card to answer the next question about Eddie. It has 4 choices. The choices describe whether Eddie should continue using MEVACOR™ OTC or stop using it, and also whether or not he should talk to a doctor about this action. (READ ANSWERS.)

- C. Which statement on this card best describes what Eddie should do next?
 1(C) Continue to use MEVACOR™ OTC and does not need to talk to a doctor.
 2(A) Continue to use MEVACOR™ OTC but must talk to a doctor.
 3() Stop using MEVACOR™ OTC. Does not need to talk to a doctor.
 4(A) Stop using MEVACOR™ OTC. Must talk to a doctor.
 Y() DON'T KNOW

() CARD K -- After taking MEVACOR™ OTC for 3 weeks, Kevin got a follow-up LDL test. His LDL test result was 137.

- A. Did Kevin get a follow-up LDL test at the appropriate time, or not?
 1() Yes – (CONTINUE) 2(X) No – (SKIP TO NEXT PINK CARD) Y() DON'T KNOW – (SKIP TO NEXT PINK CARD)
- B. Did Kevin's follow-up LDL test result fall to the right level, or not?
 1() Yes – (CONTINUE) 2() No – (CONTINUE) Y() DON'T KNOW – (SKIP TO NEXT PINK CARD)

(HAND CARD J. READ FOLLOWING DESCRIPTION ABOUT ANSWER CARD FOR JUST THE 1ST SCENARIO ASKED.)
 Please use this card to answer the next question about Kevin. It has 4 choices. The choices describe whether Kevin should continue using MEVACOR™ OTC or stop using it, and also whether or not he should talk to a doctor about this action. (READ ANSWERS.)

- C. Which statement on this card best describes what Kevin should do next?
 1() Continue to use MEVACOR™ OTC and does not need to talk to a doctor.
 2() Continue to use MEVACOR™ OTC but must talk to a doctor.
 3() Stop using MEVACOR™ OTC. Does not need to talk to a doctor.
 4() Stop using MEVACOR™ OTC. Must talk to a doctor.
 Y() DON'T KNOW

() CARD S - After taking MEVACOR™ OTC for 6 weeks, Sophie got a follow-up LDL test. Her LDL test result was 158.

- A. Did Sophie get a follow-up LDL test at the appropriate time, or not?
 1(X) Yes – (CONTINUE) 2() No – (SKIP TO NEXT PINK CARD) Y() DON'T KNOW – (SKIP TO NEXT PINK CARD)
- B. Did Sophie's follow-up LDL test result fall to the right level, or not?
 1() Yes – (CONTINUE) 2(X) No – (CONTINUE) Y() DON'T KNOW – (SKIP TO NEXT PINK CARD)

(HAND CARD J. READ FOLLOWING DESCRIPTION ABOUT ANSWER CARD FOR JUST THE 1ST SCENARIO ASKED.)
 Please use this card to answer the next question about Sophie. It has 4 choices. The choices describe whether Sophie should continue using MEVACOR™ OTC or stop using it, and also whether or not she should talk to a doctor about this action. (READ ANSWERS.)

- C. Which statement on this card best describes what Sophie should do next?
 1() Continue to use MEVACOR™ OTC and does not need to talk to a doctor.
 2(A) Continue to use MEVACOR™ OTC but must talk to a doctor.
 3(A) Stop using MEVACOR™ OTC. Does not need to talk to a doctor.
 4(C) Stop using MEVACOR™ OTC. Must talk to a doctor.
 Y() DON'T KNOW

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(TAKE BACK PINK DECK CARDS. LEAVE ANSWER CARD J IN FRONT OF RESPONDENT. TAKE OUT ORANGE DECK OF CARDS AND SHUFFLE.)

38. The people in this group have already been taking MEVACOR™ OTC for several weeks. After I read the description of each person, I want you to tell me which answer on this same card applies to what the person should do next. To remind you, there are 4 answer choices on this card. The answers describe whether the person should continue to use MEVACOR™ OTC or stop using it, as well as whether he or she should talk to a doctor about this action. Here is the first person (HAND RESPONDENT FIRST ORANGE CARD. READ MATCHING STATEMENT BELOW) What one answer on this card best describes what this person should do next according to the package? (TAKE BACK ORANGE CARD AND HAND RESPONDENT NEXT ORANGE CARD. CONTINUE UNTIL ALL CARDS HAVE BEEN READ)

	<u>CONTINUE TO USE MEVACOR OTC AND DOES NOT NEED TO TALK TO DOCTOR.</u>	<u>CONTINUE TO USE MEVACOR OTC BUT MUST TALK TO DOCTOR.</u>	<u>STOP USING MEVACOR OTC. DOES NOT NEED TO TALK TO DOCTOR.</u>	<u>STOP USING MEVACOR OTC. MUST TALK TO DOCTOR.</u>	DON'T KNOW
(D) Diane has been taking MEVACOR™ OTC for several weeks. She didn't do any unusual physical activity and isn't feeling sick but she has started to feel pain in her leg muscles.	1()	2(A)	3(A)	4(C)	Y()
(E) Ellen has been taking MEVACOR™ OTC for several weeks. She took Tums for indigestion that she got from eating spicy foods.	1(C)	2(A)	3()	4(A)	Y()
(H) Harry has been taking MEVACOR™ OTC for several weeks. He got caught in the rain and developed a mild cold.	1(C)	2(A)	3()	4(A)	Y()
(B) Bob has been taking MEVACOR™ OTC for several weeks. One day he was digging in his garden and the next day his shoulders ached.	1(C)	2(A)	3()	4(A)	Y()
(P) Paul has been taking MEVACOR™ OTC for several weeks. He was given a prescription antibiotic medicine for pneumonia.	1()	2(C)	3(A)	4(C)	Y()
(T) Theresa has been taking MEVACOR™ OTC for several weeks. At her yearly physical, she was diagnosed with kidney disease.	1()	2(C)	3(A)	4(C)	Y()

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TAKE BACK CARD J AND PUT AWAY MEVACOR™ OTC PACKAGE.

39. (LOOK BACK AT SCREENER. MARK THE ANSWER BELOW THAT REPRESENTS RESPONDENT'S GENDER AND AGE.)

- 1() Male 44 and younger – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #1)
2() Male 45 and older
3() Female 54 and younger – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #1)
4() Female 55 and older

(HAND CARD K)

40. This card shows various conditions some people have. As I read each one, please tell me whether you, yourself, have that condition. (READ EACH CONDITION BELOW. RECORD A "YES" OR "NO" FOR EACH.)

Table with 3 columns: YES, NO, DK. Rows include: Ever had heart disease such as heart attack, angina...; Ever had any kind of stroke, including mini-strokes...; Currently have diabetes or high blood sugar?

IF ANY BOXED ANSWER MARKED, RECORD ON EXTENDED TAB INELIGIBLE: REASON #2

(TAKE BACK CARD K)

41. Do you currently have liver disease such as hepatitis, or other liver problems?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #3)
2() No
Y() DON'T KNOW

42. Are you, yourself, allergic to lovastatin [LO-va-stat-in], which is the active ingredient in MEVACOR™ OTC and prescription MEVACOR®?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #4)
2() No
Y() DON'T KNOW

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(IF RESPONDENT IS A WOMAN UNDER THE AGE OF 55, CONTINUE WITH Q. 43. OTHERWISE, SKIP TO Q. 46)

43. Are you pregnant?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #5 AND SKIP TO Q. 45)
2() No – (CONTINUE)

44. Are you currently practicing any method of birth control or not?

- 1() Yes
2() No

45. Are you breast-feeding a baby?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #5)
2() No

46. Are you currently taking any prescription drugs to lower blood lipids, cholesterol or triglycerides [try-GLISS-er-ides]?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #6 AND SKIP TO Q. 48)
2() No -- (SKIP TO Q. 48)
Y() DON'T KNOW – (CONTINUE)

(HAND CARD L)

47. Are you currently taking any of the prescription drugs to lower blood lipids, cholesterol or triglycerides that are listed on this card?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #6)
2() No
Y() DON'T KNOW

(TAKE BACK CARD L)

48. Are you currently taking any other prescription medicines, that is, medicines that have been prescribed by a doctor?

- 1() Yes – (CONTINUE)
2() No – (SKIP TO Q. 50)
Y() DON'T KNOW – (CONTINUE)

(HAND CARD M)

49. Are you currently taking any of the prescription medicines that are listed on this card?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #7)
2() No
Y() DON'T KNOW

(TAKE BACK CARD M)

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50. Are you currently taking 1000 milligrams or more of niacin [NI-a-sin] in order to lower your cholesterol or not?

- 1() Yes – (RECORD ON EXTENDED TAB INELIGIBLE: REASON #6)
 2() No
 Y() DON'T KNOW

51. Do you know your total cholesterol level?

- 1() Yes – (CONTINUE)
 2() No – (SKIP TO Q. 53)

52. What is it?

_____ -- SKIP TO Q. 55

53. Do you know if your total cholesterol level is.....(READ LIST)

- 1() Less than 200,
 2() 200 to 260, or
 3() More than 260? } SKIP TO Q. 55

4() DON'T KNOW – (CONTINUE)

54. Do you know if your total cholesterol level is . . . (READ LIST)

- 1() High,
 2() Borderline, or
 3() Okay?
 Y() DON'T KNOW

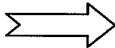
55. Prior to today, had you ever heard of LDL “bad” cholesterol?

- 1() Yes – (CONTINUE)
 2() No – (RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #8” SKIP TO Q. 60)

56. Do you know your own LDL cholesterol level?

- 1() Yes – (CONTINUE)
 2() No – (SKIP TO Q. 58)

57. What is it?

_____ -- IF 1-129 OR 171 OR HIGHER
 RECORD ON EXTENDED TAB AS
 “INELIGIBLE: REASON #9”  SKIP TO Q. 60

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58. Do you know if your LDL is ... (READ LIST)

- 1() 1-129, – (RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #9” AND SKIP TO Q. 60)
- 2() 130 TO 170, or – (SKIP TO Q. 60)
- 3() 171 or higher? – (RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #9” & SKIP TO Q. 60)
- 4() DON'T KNOW – (CONTINUE)

59. Do you know if your LDL cholesterol level is . . . (READ LIST)

- 1() Okay, or
- 2() Not okay?
- Y() DON'T KNOW

RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #8”

60. Prior to today, had you ever heard of triglycerides?

- 1() Yes – (CONTINUE)
- 2() No – (RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #10” AND SKIP TO Q. 65)

61. Do you know your own triglyceride level?

- 1() Yes – (CONTINUE)
- 2() No – (SKIP TO Q. 63)

62. What is it?

_____ --

IF 200 OR MORE RECORD ON
 EXTENDED TAB AS “INELIGIBLE:
 REASON #11”

➔

SKIP TO Q. 65

63. Do you know if your triglycerides are . . (READ LIST)

- 1() Less than 200, or -- (SKIP TO Q. 65)
- 2() 200 or more?
- 3() DON'T KNOW – (CONTINUE)

RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #11” AND SKIP TO Q. 65

64. Do you know if your triglycerides are . . . (READ LIST)

- 1() Okay, or
- 2() Not okay?
- Y() DON'T KNOW

RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #10”

65. Prior to today, had you ever heard of HDL cholesterol?

- 1() Yes – (CONTINUE)
- 2() No – (RECORD ON EXTENDED TAB AS “INELIGIBLE: REASON #12” AND SKIP TO Q. 70)

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66. Do you know your own HDL cholesterol level?

- 1() Yes – (CONTINUE)
2() No – (SKIP TO Q. 68)

67. What is it?

_____ --

IF 60 OR MORE RECORD ON
EXTENDED TAB AS "INELIGIBLE:
REASON #13"

IF 1-39 MARK THE BOX BELOW

→

SKIP TO Q. 70

68. Do you know if your HDL level is ... (READ LIST)

- Less than 40, -- (SKIP TO Q. 70)
2() 40 to 59, or -- (SKIP TO Q. 70)

3() 60 or more



RECORD ON EXTENDED TAB AS "INELIGIBLE:
REASON #13" AND SKIP TO Q. 70

4() DON'T KNOW – (CONTINUE)

69. Do you know if your HDL cholesterol level is ... (READ LIST)

- 1() Okay, or
2() Not okay?
Y() DON'T KNOW

RECORD ON EXTENDED TAB AS "INELIGIBLE: REASON #12"

70. Has your father or brother ever suffered a heart attack or angina before they were 55 years old?

- Yes
2() No
Y() DON'T KNOW

71. Has your mother or sister ever suffered a heart attack or angina before they were 65 years old?

- Yes
2() No
Y() DON'T KNOW

72. Are you a smoker?

- Yes
2() No

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73. Do you know if your blood pressure is ... (READ LIST)

- 1() High,
 2() Normal, or
 3() Low?
 Y() DON'T KNOW

74. Are you taking any medicines to treat your blood pressure?

- 1() Yes
 2() No



INTERVIEWER: CHECK Q's 67,68,70,71,72,73,74
 IF ALL 7 BOXED ANSWERS BLANK, MARK AS "INELIGIBLE: REASON #14"

75. Did you ever have muscle pain, weakness, or tenderness from taking cholesterol lowering medicine?

- 1() Yes (RECORD ON EXTENDED TAB AS "INELIGIBLE: REASON #15")
 2() No

76. What is the last grade of school you completed? (RECORD ONLY ONE ANSWER. DO NOT READ LIST.)

- 1() Elementary school only (grades 1-8)
 2() High school incomplete (grades 9-11)
 3() High school graduate (grade 12)
 () College – (PROBE:) Is that...(READ LIST)?
 4() Vocational/Technical (after high school)
 5() College incomplete
 6() Associate's degree
 7() Bachelor's degree
 8() Postgraduate/advanced college degree
 Y() Refused – (DO NOT READ)

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INTERVIEWER: CHECK EXTENDED TAB

- IF "Could start using MEVACOR™ OTC today" MARKED **AND** RESPONDENT IS INELIGIBLE (ANY REASON #), CONTINUE WITH Q. 77
- OTHERWISE, END INTERVIEW

77. According to the questions you answered earlier, MEVACOR™ OTC is not right for you because (STATE REASON(S) FOR INELIGIBILITY). Yet, when I asked if you, yourself, could begin using the product today, you said "yes."
78. So, I'd like to talk about what made you decide that you could use the product today even though the package recommends against immediate use for you. You can look back at the package to refresh your memory.

(IF MORE THAN 1 REASON MARKED ON EXTENDED TAB SKIP TO Q. 80. OTHERWISE CONTINUE)

79. Do you remember thinking about the reason for your ineligibility that I just mentioned when you were looking over any of the package information?
- 1() Yes - (SKIP TO Q. 81)
2() No - (END INTERVIEW)
3() DON'T REMEMBER/DON'T KNOW - (END INTERVIEW)
80. Do you remember thinking about any of the reasons for your ineligibility that I just mentioned when you were looking over any of the package information?
- 1() Yes - (CONTINUE)
2() No - (END INTERVIEW)
3() DON'T REMEMBER/DON'T KNOW - (END INTERVIEW)
81. Why did you decide that you could use the product today even though the package recommends against it for you because of the reason(s) I mentioned? Please be as specific as possible.

THANK YOU FOR YOUR COOPERATION. YOUR OPINION COUNTS.

INTERVIEWER: STAPLE SCREENER AND MAIN QUESTIONNAIRE TOGETHER.

THIS RESPONDENT MAY BE RECONTACTED DIRECTLY BY BRUNO AND RIDGWAY RESEARCH AS A PART OF THEIR NORMAL VERIFICATION PROCEDURES.

INTERVIEWER'S SIGNATURE: _____

X() Could start using MEVACOR™ OTC today (Q.9)

Ineligibility Reason #:

- | | |
|--|--|
| <p>1() You are too young to use MEVACOR™ OTC</p> <p>2() You cannot use MEVACOR™ OTC because of a medical condition you currently have or had in the past</p> <p>3() You currently have liver disease/liver problems</p> <p>4() You are allergic to lovastatin, which is the active ingredient in MEVACOR™ OTC and prescription MEVACOR®</p> <p>5() You are pregnant or breast-feeding</p> <p>6() You are using a medicine to lower blood lipids, cholesterol or triglycerides</p> <p>7() You are taking other prescription medicines</p> <p>8() You don't know your LDL cholesterol number</p> | <p>9() Your LDL cholesterol number is not in the appropriate range</p> <p>10() You don't know your triglycerides</p> <p>11() Your triglycerides are too high</p> <p>12() You don't know your HDL cholesterol number</p> <p>13() Your HDL cholesterol number is too high</p> <p>14() You don't have any of the listed conditions that increase heart risk</p> <p>15() You have experienced muscle problems from cholesterol medicine in the past</p> |
|--|--|

10-June-2004

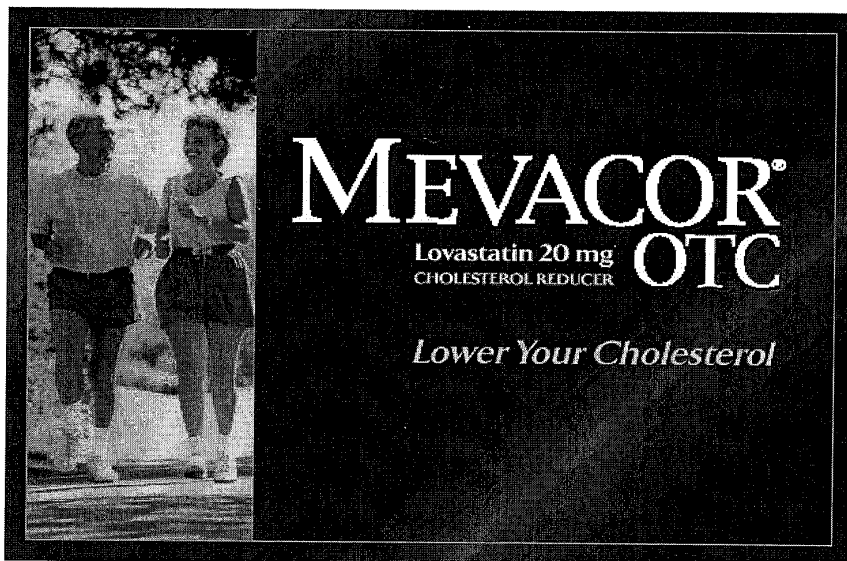
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Attachment D
QUESTIONNAIRE CHANGES BASED ON FDA FEEDBACK 6/5/02

Question #: Prior Protocol	FDA Comment	6/02 Advice Letter Page #	How Issue was Addressed in New Protocol
Screener	If concept included, make it less promotional.	3	Concept modified; references to dosing removed and package text simplified.
37-38	Education and income not necessary.	4	Income question removed. Education question retained for internal purposes.
36b	Comments on question about exercise habits.	4	Exercise question removed. Although we will get some information about prior diet and exercise during the CUSTOM Trial, we will not be using these factors to classify self-selection behavior.
Screener	Ask everyone about reading glasses, not just those who are not wearing glasses.	4	Questionnaire modified accordingly.
2b	Interviewer should not point out the wheels.	4	Wheels are no longer part of the package (also applies to comments on old Q4 series about wheels).
2b	Clarify that respondents will be able to look at package during questioning.	4	Questionnaire modified accordingly.
6 series	Leading, consider scenarios instead; Incorrect placement.	4-5	Questions changed to closed-ended scenarios and placed after self-selection (Q19a-b).
7e	Leading: questionable value.	5	Question modified to be less leading (Q13); prior open-ended question (Q12) will be given more weight in the report.
10	Modifications recommended for several scenarios; Modify heading; Include other important issues.	5	Questionnaire modified accordingly (Q21). Most important issues that are not in these scenarios are included in other question sequences.
11	Modify question so that it cannot be answered by logic alone.	5	Question eliminated.
12b	Several scenarios are unbelievable: warts, reading glasses.	6	Different, systemic "false positives" substituted for these (Q23).
13a	Change wording to "You can".	6	Question modified accordingly (Q25).
13 series	Add a false positive.	6	False positive added (Q29-30).
13g	Change format to scenario or list.	6	Format changed to list (Q33-34).
14-16	Somewhat leading; try scenarios.	6	Scenarios created (Q35-37).
17	Change "Vaseline" false positive to something more believable; clarify correct answer for LDL 165.	6	Question series has been modified to be consistent with that used in the CUSTOM Trial. Vaseline excluded (Q38).
35b	Have respondents give BP numbers; train investigators to write them correctly.	7	Because this is not a label criterion, it has not been included in the questionnaire.
39	Question about computer use not needed.	7	Question eliminated.
40	Add a sentence for clarification; allow reference to package.	7	Questionnaire modified accordingly (Q77-78).

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Attachment E**Introducing New Non- Prescription Mevacor™ OTC****The Simple Way to Lower Your Cholesterol!**

Nowadays, most of us realize that one of the best ways to reduce the risk of heart disease is to lower our cholesterol. And that's why Mevacor™ OTC was created.

New non-prescription Mevacor™ OTC has been clinically proven to lower cholesterol, which can significantly reduce your risk of heart disease. Mevacor™ OTC is a tiny tablet, so it is easy to take. And because Mevacor™ OTC was previously sold only by prescription, it's been proven safe and effective for more than a decade.

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Attachment F

NONDISCLOSURE AGREEMENT

IMPORTANT: STUDY PARTICIPANTS ARE REQUIRED TO READ, DATE AND SIGN THIS FORM.

I have agreed to participate in a Research Study ("Study") in which I will be asked to evaluate a health care product (hereinafter called "Product"). As a condition for my participation in this Study, I agree to the following:

1. I will not disclose to others, or use for any purpose other than for the performance of the Study, any information relating to the Product disclosed to me during the Study; and
2. When requested to do so, I will return to the organization conducting this Study all Product packaging and materials which may have been made available to me during the Study.

I ACCEPT AND AGREE TO THE ABOVE TERMS AND CONDITIONS.

Signature of Participant: _____ Date: _____