



SOCIAL SCIENCE REVIEW

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Products

DATE: December 10, 2005

FROM: Susanna Weiss, Ph.D., J.D.
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THROUGH: Charles Ganley, M.D.
Director, Office of Nonprescription Products

RE: **NDA 21-887**
GlaxoSmithKline Healthcare
Orlistat 60 mg capsules (for weight loss)

SUBJECT: Review of label comprehension study.

BACKGROUND

Hoffmann-LaRoche, Inc. first submitted an investigational new drug application (IND) for orlistat capsules on May 12, 1988 (received May 13, 1988). Xenical® (orlistat) 120 mg capsules were subsequently approved for prescription marketing on April 23, 1999, under NDA 20-766.

On June 14, 2001 (received June 19, 2001), Hoffmann-LaRoche submitted IND 62,758, to investigate the feasibility of an over-the-counter (OTC) version of orlistat, to be marketed as Xenical® 60 mg capsules. An End of Phase II meeting was held on July 17, 2002, between representatives of Hoffmann-LaRoche, the Division of Metabolic and Endocrine Drug Products, and the Division of Over-the-Counter Drug Products (now the Office of Nonprescription Products).

GlaxoSmith Kline subsequently acquired ownership of IND 62,758 from Hoffmann-LaRoche and a Type B – Pre-NDA meeting was held on December 8, 2004 between representatives of GlaxoSmithKline, the Division of Metabolic and Endocrine Drug Products, and the Division of Over-the-Counter Drug Products (now the Office of Nonprescription Products).

During the July 17, 2002 End-of-Phase II meeting with Hoffmann-La Roche, and during the December 8, 2004 TypeB – Pre-NDA meeting with GlaxoSmithKline, several issues were raised which have a bearing on the subsequent package labeling, supplemental materials, and label comprehension study that was developed for submission under NDA 21-887 for OTC Orlistat (the amended name for the OTC product). The meeting minutes refer to the following key issues:

1. Potential drug-drug interaction, e.g., cyclosporine-orlistat must be addressed.

2. A label comprehension study would have to show that consumers who have co-morbidities contraindicated on the label, such as gallbladder disease, would know not to use the product.
3. Adequate safety in a non-obese population.
4. Safety considerations in specific populations such as pregnant women, the elderly, and renally/hepatically impaired patients.
5. Vitamin malabsorption and the waste of fat-soluble vitamins:
 - a. The need for vitamin supplementation and the potential for consumers to wrongly take vitamins concomitantly with Orlistat, instead of 2 hours before or 2 hours after taking Orlistat.
 - b. A “worst-case-scenario” whereby overweight, post-menopausal women at risk for osteoporosis might take vitamin D and Calcium at the wrong times.
 - c. Consumers who might concomitantly use Orlistat and also significantly ingest foods containing Olestra.
6. The need for consumers to understand the importance of appropriate diet and exercise in conjunction with use of Orlistat, so that they optimize and maintain their weight loss.
7. Potential misuse by those under the age of 18.
8. Potential misuse by non-overweight individuals, especially those with eating disorders such as anorexia and bulimia who abuse laxatives.

GlaxoSmithKline (GSK) provided the following responses to these concerns:

- *Long term (up to 4 years) Rx clinical trials showed that vitamin levels decrease but remain within reference ranges with orlistat usage. GSK indicated that the drug facts label will recommend vitamin use while taking orlistat. GSK also noted that data from the Actual Use Study trial demonstrates that the majority of consumers were already taking a multivitamin and, of those who were not, roughly 50% started to take one.*
- *GSK indicated that they are not aware of any clinical data describing concomitant use of Olestra and orlistat. However, they noted that Olestra products are currently formulated to include vitamins and orlistat will be labeled to encourage vitamin use. In the event that gastrointestinal effects are additive, GSK believes it is unlikely that consumers would elect to use them together.*
- *In the ‘worst case scenario’ of vitamin deficiency, i.e., if orlistat was used chronically by overweight, post-menopausal women at risk for osteoporosis, or persons taking vitamin D and calcium at the wrong times, GSK referred to the 4 year Xenos study which demonstrated that patients experienced an initial decrease in vitamin levels during the first 1 to 2 months of use, after which they re-established a new steady state vitamin level.*
- *GSK believes that use in those under 18 should be under physician supervision.*
- *GSK described the incidence of reported misuse and abuse from Rx experience as negligible, even in the environment of internet availability. GSK noted that only four cases of abuse by bulimic patients using Xenical® have been reported worldwide. Among these four cases, there were no clinically significant safety issues or adverse health consequences. GSK also noted that Orlistat is not a good cathartic and only inhibits fat absorption.*

STUDY OVERVIEW

This was a multi-site (13 geographic locations) mall-intercept study. Interviewing began on January 31, 2005 and ended on February 11, 2005. A total of 410 interviews were conducted.

Primary Objectives

1. To measure consumers' understanding of the key label objectives – uses, warnings, directions for use, and the front panel information indicating inside-package components.
2. To measure consumers' understanding of where to locate additional information included in the package.

Study Population

Inclusion/Exclusion Criteria:

- Male/Female of any race/ethnicity.
- At least 18 years of age.
- Expressed an interest (“somewhat” or “very interested”) in weight loss.

Two cohorts of individuals:

1. General Population of 304 subjects, 18% of which qualified as Low Literate and were also counted in Cohort #2 (the low literacy group).
2. Low Literacy group of 160 subjects, 54 of which were from the General Population group and 106 of which were specifically recruited as low literate subjects.

Gender Breakdown:

- General Population – 36% male and 64% female.
- Low Literacy – 39% male and 61% female.

Race/Ethnicity:

General Population

75% Caucasian/White
18% African American/Black
1% Native American
1% Asian
5% Other

Low Literacy Group (REALM test)

39% Caucasian/White
52% African American/Black
----% Native American
----% Asian
----% Other

Reviewer Comments

There is no specific mention of Hispanic/Latino Americans, even though this is the fastest growing segment of the U.S. population and constitutes almost 14% of the population according to latest census figures. It may also be worth noting, although this is just an observation, that 84 (53%) of the 160 subjects in the Low Literacy cohort reported that they had completed high school, and 19 (12%) reported that they had completed some college or technical school, even though their REALM scores indicated that they read at about a seventh-to-eighth-grade level.

The Questionnaire and Interviewing

Scenarios were developed to test consumers’ understanding of product package labeling. The questions following those scenarios were open-ended. A variety of question structures were used to minimize subjects’ opportunity to detect correct response patterns. Additional questions were deployed to measure the respondents’ ability to locate information in the Table of Contents materials for the various Guides that are included inside the product package.

Reviewer Comments

Review of the questionnaire and the interviewing scripts and methods indicate that questions and techniques were objective, non-leading, and were conducted to minimize opportunity for bias.

Data Reporting

Coding Problems -- Reviewer Comments

There are some problems with the Sponsor’s coding of “correct” vs. “acceptable” vs. “incorrect” responses, as well as with the presentation of the results. These issues are described in the table that runs from pages 7-22 of this document.

Tabulated Data -- Reviewer Comments

When first submitted, data was reported by Sponsor only as percentages. At FDA request, new tables were submitted in which results were reported by number of subjects as well as percentages. For purposes of exemplification only, the breakdowns in the tables were requested to be as follows:

Base: Total Responding	General Population N = 304		Low Literacy N = 160	
	N	%	N	%
Correct (total)	?	?	?	?
<i>Correct initially Q90</i>				
Not okay	?	?	?	?
Ask her doctor	?	?	?	?
<i>Correct after probe Q91</i>				
Ask a doctor first	?	?	?	?
Ask a doctor/pharmacist	?	?	?	?
Acceptable (total)	?	?	?	?
<i>Acceptable initially Q90</i>				
Call the 800#	?	?	?	?
<i>Acceptable after probe Q91</i>				
Look in User Guide	?	?	?	?
Incorrect (total)	?	?	?	?
Is not contraindicated	?	?	?	?
Okay to use	?	?	?	?
Package does not mention	?	?	?	?
Lower dosage	?	?	?	?
Don’t know	?	?	?	?

STUDY RESULTS

Coding and Data Reporting Flaws

The primary objective of this label comprehension study was to measure consumers' understanding of key label objectives contained in the Drug Facts Label – particularly Warnings and Directions – as well as additional information contained in the package panels, such as the front panel information indicating supplementary materials contained inside the package.

Bearing this in mind, and given the fact that the study participants were specifically informed that: (A) this was a test of the package labeling; (B) they would not be questioned about previous knowledge or commonsense but about what has been learned from reading the information in the package labeling; (C) they should respond according to the information in the label, and (D) they would be able to view and read all the package labeling throughout the test, it is not justifiable (with very few exceptions) to code responses that are not based precisely on the label information as “acceptable” or, worse still, “correct.”

For example, it is not appropriate to inflate the label's comprehension value by coding the “default” response – “*ask a doctor, pharmacist or healthcare professional*” – as an “acceptable” answer, unless that instruction was given in the label. OTC medicines are rarely designed to be purchased or used with concurrent or frequent input from healthcare professionals (other than limited advice from a doctor or pharmacist, and only where specified in the label instructions).

However, this being said, the study contained some scenarios and questions which called for responses based on information that was not presented in the Drug Facts Label or other areas of package labeling. In those particular instances, then, it was understandable and acceptable that subjects would defer to “I don't know,” or “it's not mentioned anywhere on the box,” or “she/he should talk to a doctor or pharmacist.” These particular issues are described in detail later in this review.

Sponsor's Results tables were organized into three sections, based on the communication objectives of the package labeling. A similar organizational system has been followed by this reviewer.

Drug Facts Label – Product Usage and Warnings.

Drug Facts Label – Directions and Product Information.

Front Panel and Guides – Tables of Contents of the User's Guide, the At Home Guide, and the Away from Home Guide.

Summary of Results

- 26 scenarios and accompanying questions were designed to elicit responses concerning information contained specifically in the **Drug Facts Label** portion of the packaging.
 - 18 of those scenarios achieved scores of 85%-100% in the General Population, and 15 achieved scores of 80%-100% in the Low Literate group. However, four of those scenarios and their accompanying questions provided mixed results in both groups that need additional explanation and will be discussed in detail later in this review.
 - 6 scenarios and accompanying questions achieved scores of 72%-84% in the General Population and 67%-77% in the Low Literate group.
 - 2 scenarios/questions achieved scores of 47%-48% in the General Population; 5 scenarios/questions achieved scores of 34%-64% in the Low Literate group). Two of these three scenarios warrant additional discussion because they deal with important safety concerns.
- 10 scenarios and questions were designed to elicit responses about information contained in the **supplementary educational materials**.
 - 6 achieved correct responses ranging from 65% to 90% in the General Population (GP).
 - 4 achieved correct responses ranging from 37% to 43% for the General Population (GP).

<u>Drug Facts Scenario / Information Issue</u>	Sponsor		Reviewer	
	GP%	LL%	GP%	LL%
<u>Product Use</u>				
Correct	97	94	97	93
Acceptable	3	6	2	6
Total	100	100	100	100
<u>Not okay to use Orlistat if allergic</u>				
Correct	97	94	97	94
Acceptable	2	3	0	0
Total	99	97	97	94
<u>Not okay to use Orlistat if under 18 years old.</u>				
Correct	96	95	96	95
Acceptable	2	3	0	0
Total	98	98	96	95
<u>Okay to take Orlistat if not currently taking any other medication for weight loss</u>				
Correct	96	94	96	94
Acceptable	2	4	?	?
Total	98	98	96	94
<u>Not okay to use while breastfeeding</u>				
Correct	95	92	95	92
Acceptable	1	1	0	0
Total	96	93	95	92
<u>Changing your eating patterns before starting Orlistat</u>				
Correct	55	34	54	34
Acceptable	41	58	40	52
Total	96	92	95	86
<u>Recommended dosage to start taking Orlistat</u>				
Correct	93	87		
Start with 1			38	34
1-2 each meal			54	53
Total	93	87	92	87
<u>Not okay to use Orlistat while taking cyclosporine</u>				
Correct	91	89	91	91
Acceptable	5	1	0	0
Total	96	90	91	91

<u>Drug Facts Scenario / Information Issue</u>	Sponsor		Reviewer	
	GP%	LL%	GP%	LL%
<u>Not okay to use Orlistat if having gallbladder problem</u>				
“Ask doctor” / Correct	60	45	60	45
“Not okay” / Acceptable	38	50	38	50
Correct after probe	1	2	1	2
Total	99	97	99	97
<u>Not okay to use Orlistat if currently taking medicine for diabetes</u>				
“Ask doctor or pharmacist”	45	39	45	39
“Not okay”	50	56	50	56
Acceptable	2	2	2	2
Total	97	97	97	97
<u>Not okay to use Orlistat if had kidney stones in the past</u>				
Correct = “Ask doctor”	53	44	53	44
Not okay / Acceptable	38	47	38	47
Correct after probe #1	4	2	4	1
Correct after probe #2	2	4	2	4
Total	97	97	97	96
<u>Not okay to use Orlistat while taking Warfarin</u>				
“Ask doctor or pharmacist”	28	22	28	22
“Not okay” / Acceptable	65	71	65	71
Total	93	93	93	93
<u>Okay to use Orlistat if experiencing problems sleeping</u>				
Correct	87	79	87	79
Acceptable #1	6	12	6	12
Acceptable #2			4	3
Total	93	91	97	94
<u>Okay to use Orlistat if experiencing a headache</u>				
Correct	80	66	80	66
Acceptable	10	11	10	11
Total	90	77	90	77

<u>Drug Facts Scenario / Information Issue</u>	Sponsor		Reviewer	
	GP%	LL%	GP%	LL%
<u>Okay to continue using Orlistat if experiencing loose stool and bowel changes</u>				
Correct	86	74	86	74
Acceptable	7	11	1	3
Total	93	85	86	74
<u>How Orlistat works to promote weight loss</u>				
Correct	82	61	82	61
Acceptable	3	3	3	3
Total	85	64	85	64
<u>Maximum capsules of Orlistat in one day</u>				
Correct	84	64	84	64
Total	84	64	84	64
<u>Timeframe of when to expect results when taking Orlistat</u>				
Correct	80	64	80	64
Acceptable	2	5	2	5
Total	82	69	82	69
<u>Where to find information using Orlistat</u>				
Correct	81	75	81	75
Total	81	75	81	75
<u>Not okay to take Orlistat if not overweight</u>				
Correct	78	74	78	74
Acceptable	1	3	1	3
Total	79	77	79	77
<u>Weight loss goal not met after 6 months</u>				
Correct	75	64	75	64
Acceptable	3	11	1	3
Total	78	75	76	67
<u>How to decrease the likelihood of loose stool and bowel changes</u>				
Correct	72	48	72	48
Total	72	48	72	48
<u>Recommended timing for taking a multivitamin</u>				
Correct	48	34	48	34
Acceptable	31	31	0*	0*
Total	79	66	48	34
<u>Concern about vitamin absorption</u>				
Correct	69	50	47	36
Acceptable	24	38	0*	0*
Total	93	88	47	36

<u>Scenarios and Questions Concerning Supplementary Educational Materials: Results Listed in Descending Order From Positive to Negative for the General Population Group</u>	<u>Sponsor</u>		<u>Reviewer</u>	
	<u>GP % correct</u>	<u>LL % correct</u>	<u>GP % correct</u>	<u>LL % correct</u>
<u>Information on fast food restaurants</u>	90	90	90	90
<u>Information on setting realistic goals</u>	89	87	89	87
<u>Why weight loss amount will vary per person</u>	83	65	83	63
<u>Information on understanding personal eating habits</u>	81	76	81	75
<u>Information on snacking tips</u>	79	70	77	70
<u>Information on learning to navigate the grocery store</u>	67	65	65	63
<u>Information on the food and activity tracker</u>	45	44	43	41
<u>Information on fat and calories</u>	74	57	42	26
<u>Information on preparing meals</u>	84	63	42	24
<u>Information on what to order when dining out</u>	75	57	37	23

GENERAL OBSERVATIONS AND COMMENTS

Comprehension of information contained in the Drug Facts Label

The ability of the Drug Facts Label to transfer information to the reader was generally good. Results from this study show that, for the most part – i.e., with the exception of six sets of responses – most GP and even LL respondents grasped the basic concepts, warnings and directions contained in the label. The GP group scored at or above 90% on 14 out of 26 scenarios/questions (as mentioned earlier, four of those require further explanation); from 81% to 89% on seven of the scenarios/questions; from 72% to 79% on three of the scenarios/questions, and scored poorly – in the 47th and 48th percentiles – on two scenarios/questions. The latter two scenarios also require additional explanation. LL respondents scored above 90% on 11 scenarios; 81%- 87% on four scenarios; 64%-77% on eight scenarios, and 34%-48% on three.

Where to find information in the supplementary educational materials

With regard to understanding where to find information about specific weight/diet/calorie topics in the supplementary educational materials, GP subjects scored from 81%-90% on four out of the 10 scenarios/questions; 65% and 77% on two of the scenarios/questions, and between 37%-43% on the four remaining scenarios/questions. LL subjects scored 70%-90% on four scenarios; 63% on two scenarios; 41% on one, and 23%-26% on three scenarios.

General observations

The overall number of “incorrect” responders in the study was fairly small on most of the scenarios, but there appear to be three broad types of “incorrect” responders: (1) those who state that key information points are not present anywhere in the package labeling, even though they are in fact there, (2) those who read information in the label but who do not understand and/or do not recall it accurately, and (3) those who, despite reading certain instructions in the Drug Facts Label, ignore those instructions and instead construct their own rationalizations or internal narratives as to why it would be “okay” to behave contrary to the label instructions. These nuances in the data may need further exploration and explanation in future.

Organization of the Following Analysis and Discussion of Results

Pages 11-26: Table summarizing and analyzing results, comments, observations and open-ended (verbatim) responses for each of the scenarios and study questions (26 concerning information contained in the Drug Facts Label and outer package panels, and 10 concerning information contained in the supplementary educational booklets inside the box).

Pages 27-29: Discussion of results concerning proper use of Orlistat, particularly the possible use by consumers who are not overweight.

Pages 29-31: Discussion of results for warnings concerning cyclosporine, problems absorbing food, and allergies to ingredients in the drug.

Pages 31-33: Discussion of results concerning warnings associated with kidney stones, gallbladder problems, and concomitant use of Warfarin, or medications for diabetes, or other weight loss drugs.

Pages 33-34: Discussion of the two lowest sets of scores, i.e., those concerning vitamin absorption, and those concerning the recommended timing for taking a multivitamin. These are important safety issues.

Page 36: Discussion of results concerning the warning not to use Orlistat is pregnant or breastfeeding.

Pages 37-38: Discussion of results for the two scenarios designed to test extrapolation of information from the label, i.e., can Orlistat be used if you have problems sleeping and/or if you have a headache?

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments and Observations, Including Open-Ended Responses
<p>Table A / Card A</p> <p><u>Product Use</u></p> <p>Q1 Based on the package labeling, what is the product used for?</p>	<p><u>Sponsor</u></p> <p>Correct 97 Acceptable 3 Total 100</p> <p><u>Reviewer</u></p> <p>Correct 97 Acceptable 3 Total 100</p>	<p><u>Sponsor</u></p> <p>Correct 94 Acceptable 6a Total 100</p> <p><u>Reviewer</u></p> <p>Correct 94 Acceptable 6 Total 100</p>	<p>Responses coded as “acceptable” were appropriate based on the label language/content.</p> <p><u>Acceptable Responses:</u></p> <ul style="list-style-type: none"> • For dieting. • To block/prevent/decrease fat absorption.
<p>Table B / Card C</p> <p><u>Okay to use Orlistat if experiencing problems sleeping.</u></p> <p>Lisa is overweight and is interested in losing a few pounds. She has been having problems sleeping lately. Lisa is thinking about using Orlistat for weight loss.</p> <p>Q4/Q5 Based on the package labeling, is it okay or not okay for Lisa to use Orlistat?</p> <p><u>Note: This concomitant condition is not mentioned in the label.</u></p>	<p><u>Sponsor</u></p> <p>Correct 87b Acceptable 6 Total 93</p> <p><u>Reviewer</u></p> <p>Correct 87b Acceptable* 6 Acceptable** 4 Total 97</p>	<p><u>Sponsor</u></p> <p>Correct 79 Acceptable 12a Total 91</p> <p><u>Reviewer</u></p> <p>Correct 79 Acceptable* 12a Acceptable** 3 Total 94</p>	<p>The purpose of this scenario was to test subjects’ ability to think logically and extrapolate that, if there is no warning on the label against taking Orlistat while having sleep problems, then it would be okay to take the medication.</p> <p>* Since problems with sleep and use of Orlistat are not mentioned in the label, a response such as “ask a doctor, healthcare professional or pharmacist” may be an acceptable and understandable response for this scenario. Nine subjects gave this response.</p> <p>** 13 subjects (8 GP and 5 LL) who were coded by the Sponsor as responding “incorrectly” actually gave a logical and technically correct response that the package/label does not mention anything about sleeping problems.</p> <p>It is interesting that another 12 respondents gave completely incorrect answers, including a couple who said that the label specifically indicated not to take Orlistat if you are having trouble sleeping. In fact the label does not mention anything at all about sleep problems.</p> <p><u>Examples of incorrect responses:</u></p> <ul style="list-style-type: none"> • It says if you have problems sleeping, don’t take it until you consult your doctor. • Sleeping disorders – you can’t take it. It says on the label. • Sleeping problems will affect it. • May be causing her sleep loss if not eating right. • The medicine might keep her up all night. • The insomnia might get worse with it and it doesn’t say otherwise. •

<p>Table C / Card H</p> <p><u>Not okay to use Orlistat if not overweight</u></p> <p>Jane is 25 years old and not overweight. Jane is considering using Orlistat.</p> <p>Q15/Q16 Based on the package labeling, is it okay or not okay for Jane to use Orlistat?</p> <p>Although the label states that Orlistat is for <i>“weight loss in overweight adults”</i> the Drug Facts panel does not indicate what constitutes being overweight. There may, therefore, be room for subjective interpretation of whether or not it is appropriate to take Orlistat. Much would depend on the individual’s perception of whether their weight is “overweight” or not.</p> <p>Ask a doctor, pharmacist or healthcare professional may be an acceptable response in this scenario. Many of the responses that were coded as “incorrect” were quite logical given the label content.</p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>78</td></tr> <tr><td>Acceptable</td><td>1</td></tr> <tr><td>Total</td><td>79</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>78</td></tr> <tr><td>Acceptable</td><td>1</td></tr> <tr><td>Total</td><td>79</td></tr> </table>	Correct	78	Acceptable	1	Total	79	Correct	78	Acceptable	1	Total	79	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>74</td></tr> <tr><td>Acceptable</td><td>3</td></tr> <tr><td>Total</td><td>77*</td></tr> </table> <p>(Sponsor’s table gives total for LL as 78%)</p> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>74</td></tr> <tr><td>Acceptable</td><td>3</td></tr> <tr><td>Total</td><td>77</td></tr> </table>	Correct	74	Acceptable	3	Total	77*	Correct	74	Acceptable	3	Total	77	<p>The “Jane” scenario and question (Card H, Q15/Q16) were designed to test the concept that it is not okay to use Orlistat if a person is not overweight. However, the scenario and question present information that is a little ambiguous and leaves room for subjective interpretation.</p> <p>78% of the General Population respondents gave the hoped-for answer that it is NOT OKAY. A few respondents suggested that Jane should consult her doctor or healthcare professional first, but just over 20% of the study participants offered a variety of reasons why it would be “okay” for Jane to use Orlistat.</p> <p>One general train of thought was that, since there is no specific warning on the box stating that non-overweight people should not take Orlistat, and if the purchaser is over 18, then it’s okay to take it:</p> <ul style="list-style-type: none"> • <i>Is not contraindicated / Package/label does not mention (25)</i> • <i>Don’t have to be overweight to use (3)</i> • <i>Over 18 years old/old enough (13)</i> • <i>Okay to use / Healthy/isn’t sick / Safe to use / Other (22)</i> <p>Another set of responses reflected the idea that it would be good for <i>maintaining</i> desired weight:</p> <ul style="list-style-type: none"> • For weight loss/weight control/overweight (6) • Use to maintain weight (6) <p>There were a variety of interesting open-ended responses:</p> <ul style="list-style-type: none"> • <i>If she really wants to go for that Calista Flockhart look, she can. It doesn’t say pecifically not to, and it probably won’t be any worse for her than if she just goes bulimic.</i> • <i>Some people may want to lose weight no matter what they weigh. Nowhere on this box does it say for those that are overweight only.</i> • <i>There’s nothing on the box that says not overweight people can’t take it. There’s no warning.</i> • <i>It might be unhealthy, but it doesn’t explicitly say not to.</i> • <i>If she wants to maintain her weight, it’s fine to use it.</i> • <i>It could help her not to be overweight.</i> • <i>I think it’s good for everyone even if they are not really overweight. It could help them to maintain.</i> • <i>If she uses it moderately, it will help her maintain her weight.</i> • <i>It could help her stay thin.</i> • <i>She might just want to keep her weight the way it is.</i>
Correct	78																										
Acceptable	1																										
Total	79																										
Correct	78																										
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Acceptable	3																										
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Correct	74																										
Acceptable	3																										
Total	77																										
<p>Table D / Card I</p> <p><u>Okay to use Orlistat if experiencing a headache</u></p> <p>Frank is overweight and would like to use Orlistat. Frank has a headache</p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>80b</td></tr> <tr><td>Acceptable</td><td>10</td></tr> <tr><td>Total</td><td>90b</td></tr> </table>	Correct	80b	Acceptable	10	Total	90b	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>66</td></tr> <tr><td>Acceptable</td><td>11</td></tr> <tr><td>Total</td><td>77</td></tr> </table>	Correct	66	Acceptable	11	Total	77	<p><u>Note: This concomitant condition is not mentioned in the label.</u></p> <p>Experiencing a headache at the same time as wanting to take Orlistat is not mentioned in the label. A response such as “ask a doctor, pharmacist or healthcare professional” is, therefore, an acceptable and understandable response for this scenario. 10% GP and 11% LL gave this response.</p>												
Correct	80b																										
Acceptable	10																										
Total	90b																										
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Acceptable	11																										
Total	77																										

<p>today and is not sure if he should start taking Orlistat.</p> <p>Q17/Q18 Based on the package labeling, is it okay or not okay for Frank to start taking Orlistat today?</p>	<p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>80b</td></tr> <tr><td>Acceptable 1</td><td>10</td></tr> <tr><td>Acceptable 2</td><td>2</td></tr> <tr><td>Total</td><td>92b</td></tr> </table>	Correct	80b	Acceptable 1	10	Acceptable 2	2	Total	92b	<p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>66</td></tr> <tr><td>Acceptable 1</td><td>11</td></tr> <tr><td>Acceptable 2</td><td>3</td></tr> <tr><td>Total</td><td>80</td></tr> </table>	Correct	66	Acceptable 1	11	Acceptable 2	3	Total	80	<p>Sponsor coded as “incorrect” respondents who said that the label does not mention this concomitant condition.</p> <p>However, since neither the package labeling nor the Guides refer to headaches, the study subjects cannot be faulted for choosing to respond that the package/labeling does not mention headaches when, indeed, it does not.</p>								
Correct	80b																										
Acceptable 1	10																										
Acceptable 2	2																										
Total	92b																										
Correct	66																										
Acceptable 1	11																										
Acceptable 2	3																										
Total	80																										
<p>Table E / Card L</p> <p><u>Okay to continue using Orlistat if experiencing loose stool and bowel changes.</u></p> <p>Peggy is overweight and has been taking Orlistat for 1 week. She has noticed that she is having loose stool and bowel changes.</p> <p>Q 21/Q22 Based on the package labeling, is it okay or not okay for Peggy to continue using Orlistat?</p> <p><u>Correct responses after probe Q22:</u></p> <ul style="list-style-type: none"> • It is related to how the product works. • It is related to how the product works and usually lessens in a few weeks. • It will lessen in a few weeks. • This will happen after high fat meals. • Side effect / reaction to drug. • Normal / what to expect. 	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>86b</td></tr> <tr><td>Acceptable</td><td>7</td></tr> <tr><td>Total</td><td>93</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>86b</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>86</td></tr> </table>	Correct	86b	Acceptable	7	Total	93	Correct	86b	Acceptable	0	Total	86	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>74</td></tr> <tr><td>Acceptable</td><td>11</td></tr> <tr><td>Total</td><td>85</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>74</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>74</td></tr> </table>	Correct	74	Acceptable	11	Total	85	Correct	74	Acceptable	0	Total	74	<p>The label specifically describes these symptoms/side effects, explains that they are related to how the product works, and will lessen in a few weeks. The default response “ask a doctor, pharmacist or other healthcare professional” is therefore NOT an acceptable response for this scenario and should be coded as “incorrect.”</p> <p>14% of GP respondents and 26% of LL respondents gave incorrect responses which seem to indicate that they <i>completely missed</i> the point on the label that loose stools and bowel changes are related to how the product works, usually lessen in a few weeks, and you can reduce the likelihood of these effects by reducing the fat in your diet.</p> <p><u>Examples of incorrect responses:</u></p> <ul style="list-style-type: none"> • It could mean something serious. • . . . it means something is wrong in your system. • . . . Don’t think it would be healthy. • I don’t think it’s good for your body... I would quit using it. • Maybe it’s an allergic reaction. • It doesn’t seem to agree with her. • Not healthy. • That is an adverse reaction. • Problems absorbing food will mess with the bowels.
Correct	86b																										
Acceptable	7																										
Total	93																										
Correct	86b																										
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Acceptable	11																										
Total	85																										
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Acceptable	0																										
Total	74																										
<p>Table F / Card BB</p> <p><u>Not okay to use Orlistat if under 18 years old.</u></p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>96</td></tr> <tr><td>Acceptable</td><td>2</td></tr> <tr><td>Total</td><td>98</td></tr> </table>	Correct	96	Acceptable	2	Total	98	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>95</td></tr> <tr><td>Acceptable</td><td>3</td></tr> <tr><td>Total</td><td>98</td></tr> </table>	Correct	95	Acceptable	3	Total	98	<p>The label states in Directions: “for overweight adults 18 years and older.” Therefore, the only correct response for this scenario and question is “not okay.”</p>												
Correct	96																										
Acceptable	2																										
Total	98																										
Correct	95																										
Acceptable	3																										
Total	98																										

<p>Stacey is 16 years old and overweight. Stacey is interested in trying Orlistat to lose weight.</p> <p>Q44/Q45 Based on the package labeling, is it okay or not okay for Stacey to use Orlistat?</p>	<p><u>Reviewer</u></p> <p>Correct 96</p> <p>Acceptable 0</p> <p>Total 96</p>	<p><u>Reviewer</u></p> <p>Correct 95</p> <p>Acceptable 0</p> <p>Total 95</p>	<p>Ask a doctor or pharmacist is NOT an acceptable response for this scenario. The label specifically states that Orlistat is for overweight adults 18 years and older.</p> <p>For clarity and emphasis, it may be helpful to move this instruction to the top of the Drug Facts Label under the heading “Uses.”</p> <p>For example: Use . . . promote weight loss in overweight adults 18 years and older, when used along with a reduced calorie and low fat diet.</p>
<p>Table G / Card D</p> <p><u>Not okay to use Orlistat if diagnosed with problems absorbing food.</u></p> <p>Jenna is overweight and wants to reduce her weight. Jenna has previously been diagnosed as having problems absorbing food.</p> <p>Q6/Q7 Based on the package labeling, is it okay or not okay for Jenna to use Orlistat?</p> <p>The label states in the Warnings section: Do not use . . .</p> <ul style="list-style-type: none"> if you have been diagnosed with problems absorbing food. 	<p><u>Sponsor</u></p> <p>Correct 90</p> <p>Acceptable 3</p> <p>Total 93</p> <p><u>Reviewer</u></p> <p>Correct 90</p> <p>Acceptable 0</p> <p>Total 90</p>	<p><u>Sponsor</u></p> <p>Correct 86</p> <p>Acceptable 3</p> <p>Total 89</p> <p><u>Reviewer</u></p> <p>Correct 86</p> <p>Acceptable 0</p> <p>Total 86</p>	<p>The label specifically states in the Warnings section: Do not use if you have been diagnosed with problems absorbing food.</p> <p>Ask a doctor or pharmacist is NOT an acceptable response for this scenario.</p> <p>The overall “correct” response rate on the food absorption scenario was fairly high (86%-90%) but 8 respondents incorrectly said that the warning about problems absorbing food was not mentioned on the box/package/label, even though it is clearly stated in the Drug Facts Label. A further 21 subjects gave explanations which seemed to imply that Jenna’s wish to lose weight was more important than her inability to absorb food, or that it’s okay for Jenna to use Orlistat even though she has problems absorbing food. Some examples of incorrect responses include:</p> <ul style="list-style-type: none"> <i>It’s good for dieting if you eat the right food.</i> <i>It might help her.</i> <i>It doesn’t have anything to do with absorbing food problems.</i> <i>It won’t make her sick or interfere with the program.</i> <i>She can take only part of the dosage and see what happens.</i> <i>The drug helps with absorption.</i> <i>This product could help your digestion.</i> <i>I’ve never heard of not absorbing food.</i>
<p>Table H / Card E</p> <p><u>Not okay to use while breastfeeding.</u></p> <p>Marsha had a baby two months ago and is currently breastfeeding. She would like to use Orlistat to help her get rid of the extra baby weight.</p>	<p><u>Sponsor</u></p> <p>Correct 95</p> <p>Acceptable 1</p> <p>Total 96</p>	<p><u>Sponsor</u></p> <p>Correct 92</p> <p>Acceptable 1</p> <p>Total 93</p>	<p>Although 95% of the General Population group and 92% of the Low Literacy group correctly responded that it is “not okay” to use Orlistat if breastfeeding, 12 subjects responded that the label did not warn against taking Orlistat if breastfeeding, and 8 subjects offered a variety of their own rationalizations why it would be okay to take Orlistat even though the label states (perhaps not clearly enough) that breastfeeding is contraindicated:</p>

<p>Q8/Q9 Based on the package labeling, is it okay or not okay for Marsha to start using Orlistat?</p> <p><u>Note:</u> The Drug Facts Label states: “If pregnant or breast-feeding, do not use.”</p> <p>This warning should be moved higher up in the Warnings section.</p> <p>Ask a doctor or pharmacist is NOT an acceptable response for this scenario.</p>	<p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>95</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>95</td></tr> </table>	Correct	95	Acceptable	0	Total	95	<p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>92</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>92</td></tr> </table>	Correct	92	Acceptable	0	Total	92	<ul style="list-style-type: none"> • She just wants to lose weight. • She couldn’t use it when pregnant, but can use it now. • She isn’t really sick or nothing. She just wants to lose weight. • It’s not a danger to her. • She’s not high risk, baby out of her, and not old. • After 6 to 8 weeks you can diet to lose baby fat. <p><u>Note:</u> In trying to understand the reasons for these incorrect responses, several questions and possible explanations come to mind:</p> <ul style="list-style-type: none"> • Were the “incorrect” responses predominantly given by male respondents? Males may have overlooked a warning referring to pregnancy and breastfeeding, saying to themselves that the warning doesn’t pertain to them so they can skip over the information. Younger, unmarried males may be especially likely to ignore the warning. • If women were among the “incorrect” respondents, and particularly if there were women who are mothers or who are of childbearing potential, this is a serious issue and we need to know and ask “why?” would they ignore such an important warning. • Perhaps certain consumers do not comprehend the nature of systemic drugs – they don’t realize that if a drug is in the blood stream it is also in the mother’s milk. • Perhaps there are some cultural markers that influenced the thinking in this set of responses • Perhaps the urge to be thin (e.g., lose the extra pounds gained during pregnancy) is more important in a person’s mind than the health of a baby. • Perhaps there is a lack of understanding as to <i>why</i> it’s not good for a baby to ingest breast milk laced with Orlistat, and if the consequences were explained to people, the nature of their thinking would change. 												
Correct	95																										
Acceptable	0																										
Total	95																										
Correct	92																										
Acceptable	0																										
Total	92																										
<p>Table I / Card M</p> <p><u>Not okay to use Orlistat while taking cyclosporine.</u></p> <p>Bob is overweight and is interested in trying Orlistat to lose weight. He has been taking cyclosporine.</p> <p>Q 24/Q25 Based on the package labeling, is it okay or not okay for Bob to use Orlistat?</p> <p><u>Note:</u> Since the label specifically states: “Do not use if you are taking cyclosporine . . .” the response “ask a doctor or healthcare professional” is NOT acceptable for this scenario.</p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>91</td></tr> <tr><td>Acceptable</td><td>5</td></tr> <tr><td>Total</td><td>96</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>91</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>91</td></tr> </table>	Correct	91	Acceptable	5	Total	96	Correct	91	Acceptable	0	Total	91	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>89</td></tr> <tr><td>Acceptable</td><td>1</td></tr> <tr><td>Total</td><td>90</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>89</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>89</td></tr> </table>	Correct	89	Acceptable	1	Total	90	Correct	89	Acceptable	0	Total	89	<p>Even though the label states under Warnings: Do not use if you are taking cyclosporine (a drug given after organ transplant), several respondents completely missed or misunderstood the warning, and 9 of those respondents said there was nothing on the package/label about cyclosporine. Examples of some incorrect responses:</p> <ul style="list-style-type: none"> • I can’t find anything that says he cannot take it if he takes cyclosporine. • Not on package saying not to. • It doesn’t say anything about cyclosporine that I can see. • Don’t see anything on the package about this medication. • It didn’t mention cyclosporine. • He doesn’t have any kidney problems. • He has no problem with bladder or kidney stones. • It won’t make any difference because he has been taking the other medicine for a while.
Correct	91																										
Acceptable	5																										
Total	96																										
Correct	91																										
Acceptable	0																										
Total	91																										
Correct	89																										
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Total	90																										
Correct	89																										
Acceptable	0																										
Total	89																										

<p>Table J / Card Q</p> <p><u>Not okay to use Orlistat if allergic.</u></p> <p>Sharon is overweight and would like to use Orlistat for weight loss. She is allergic to Orlistat.</p> <p>Q 29/Q30 Based on the package labeling, is it okay for Sharon to use Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct 97</p> <p>Acceptable 2</p> <p>Total 99</p> <p><u>Reviewer</u></p> <p>Correct 97</p> <p>Acceptable 0</p> <p>Total 97</p>	<p><u>Sponsor</u></p> <p>Correct 94</p> <p>Acceptable 3</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Correct 94</p> <p>Acceptable 0</p> <p>Total 94</p>	<p>The label states under Warnings: “Do not use if you are allergic to any of the ingredients in Orlistat capsules.”</p> <p>Ask a doctor or pharmacist is NOT an acceptable response for this scenario.</p>
<p>Table K / Card G</p> <p><u>Not okay to use Orlistat if had kidney stones in the past.</u></p> <p>Kate is overweight and has had kidney stones in the past. She would like to start taking Orlistat to help her lose weight.</p> <p>Q11/Q12/Q13/Q14 Based on the package labeling, is it okay or not okay for Kate to use the product?</p>	<p><u>Sponsor</u></p> <p>Ask doctor 53</p> <p>Correct 2 4</p> <p>Correct 3 2</p> <p>Not okay 38</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Ask doctor 53</p> <p>Correct 2 4</p> <p>Correct 3 2</p> <p>Acceptable 38</p> <p>Total 97</p>	<p><u>Sponsor</u></p> <p>Ask doctor 44</p> <p>Correct 2 2</p> <p>Correct 3 4</p> <p>Not okay 47</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Ask doctor 44</p> <p>Correct 2 2</p> <p>Correct 3 4</p> <p>Acceptable 47</p> <p>Total 97</p>	<p>The label specifically states: Ask a doctor before use if you have gallbladder problems or kidney stones, yet 5 respondents said that the package/label did not mention this point, and one respondent said it would be okay to take Orlistat because “She isn’t really sick. She just has a kidney problem.”</p> <p>It is <u>not</u> acceptable to answer “ask a pharmacist first.” The answer should be “ask a doctor.” Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable.</p> <p>Note that strictly CORRECT responses per label instructions are low (50%-59%).</p>
<p>Table L / Card Y</p> <p><u>Not okay to use Orlistat if having gallbladder problems.</u></p> <p>Ben is overweight and is considering using Orlistat. He has been having problems with his gallbladder.</p> <p>Q40/Q41 Based on the package labeling, is it okay or not okay for Ben to use Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct 1:</p> <p>Ask doctor 60b</p> <p>Correct 2 1</p> <p>Not okay 38</p> <p>Total 99</p> <p><u>Reviewer</u></p> <p>Correct 60</p> <p>After Probe 1</p> <p>Acceptable 38</p> <p>Total 99</p>	<p><u>Sponsor</u></p> <p>Correct 1:</p> <p>Ask doctor 45</p> <p>Correct 2 2</p> <p>Not okay 50a</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Correct 45</p> <p>After Probe 2</p> <p>Acceptable 50</p> <p>Total 97</p>	<p>The label specifically states: Ask a doctor before use if you have gallbladder problems or kidney stones.</p> <p>It is <u>not</u> acceptable to answer “ask a pharmacist first.” The answer should be “ask a doctor.” Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable.</p> <p>Note that strictly CORRECT responses per label instructions are low (47%-61%).</p>

<p>Table M / Card B</p> <p><u>Not okay to use Orlistat while taking Warfarin.</u></p> <p>Jim is overweight and suffered a mild heart attack. As a result, his doctor put him on Warfarin, a prescription blood thinning medication. Jim has just purchased Orlistat and would like to start taking it as a weight loss aid.</p> <p>Q2/Q3 Based on the package labeling, iss it okay or not okay for Jim to start using Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct:</p> <p>Ask dr/ph 28</p> <p>“Not okay” 65</p> <p>Total 93</p> <p><u>Reviewer</u></p> <p>Correct 28</p> <p>“Not okay” 65</p> <p>Total 93</p>	<p><u>Sponsor</u></p> <p>Correct:</p> <p>Ask dr/ph 22</p> <p>“Not okay” 71</p> <p>Total 93</p> <p><u>Reviewer</u></p> <p>Correct 22</p> <p>“Not okay” 71</p> <p>Total 93</p>	<p>The label specifically states: Ask a doctor or pharmacist before use if you are taking Warfarin (blood thinning medicine), yet 13 respondents said there was nothing about this restriction/contraindication on the label/package; others missed the connection between a heart attack and taking Warfarin, and still others confused the warning about transplant medication with the Warfarin warning.</p> <p>Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable.</p> <p>Note that strictly CORRECT responses per label instructions are very low (22%-28%).</p>
<p>Table N / Card S</p> <p><u>Not okay to use Orlistat if currently taking medicine for diabetes.</u></p> <p>Charlie is overweight and would like to lose weight. He is diabetic and takes a prescription medicine to treat his condition.</p> <p>Q32/Q33 Based on the package labeling, is it okay or not okay for Charlie to use Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct:</p> <p>Ask dr/ph 45</p> <p>“Not okay” 50</p> <p>Acceptable 2</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Correct 45</p> <p>“Not okay” 50</p> <p>Acceptable 2</p> <p>Total 97</p>	<p><u>Sponsor</u></p> <p>Correct:</p> <p>Ask dr/ph 39</p> <p>“Not okay” 56</p> <p>Acceptable 2</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Correct 39</p> <p>“Not okay” 56</p> <p>Acceptable 2</p> <p>Total 97</p>	<p>The label specifically states: Ask a doctor or pharmacist before use if you are taking medicine for diabetes. Your medication dose may need to be adjusted during weight loss. Yet 8 respondents missed this warning on the package label.</p> <p>Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable.</p> <p>Note that strictly CORRECT responses per label instructions are very low (39%-45%).</p> <p>Acceptable responses after two probes included answers where subject said either “adjust diabetic medicine” or “ask a doctor/pharmacist first.”</p>

<p>Table O / Card V</p> <p><u>Okay to use Orlistat if not currently taking any other medication for weight loss.</u></p> <p>Kevin is overweight and is interested in trying Orlistat to lose weight. Kevin has tried other weight loss products in the past, but is not using any other drugs for weight loss at this time.</p> <p>Q 36/Q37 Based on the package labeling, is it okay or not okay for Kevin to use Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct 96</p> <p>Acceptable 2</p> <p>Total 98</p> <p><u>Reviewer</u></p> <p>Correct 96</p> <p>Acceptable 0</p> <p>Total 96</p>	<p><u>Sponsor</u></p> <p>Correct 94</p> <p>Acceptable 4</p> <p>Total 98</p> <p><u>Reviewer</u></p> <p>Correct 94</p> <p>Acceptable 0</p> <p>Total 94</p>	<p>The label specifically states: “Ask a doctor or pharmacist before use if you are taking other weight loss drugs.”</p> <p>But notice that the scenario specifically states that Kevin is NOT using any other drugs for weight loss at this time. The correct response, then, is that it is “okay” for Kevin to take Orlistat.</p> <p>For this particular question, is it “acceptable” to respond “ask a doctor or pharmacist?” Probably not, given the specific wording of the scenario.</p>
<p>Table P / Card F</p> <p><u>Maximum capsules of Orlistat in one day.</u></p> <p>Q10 Based on the package labeling, what is the most number of Orlistat capsules that you should take in one day?</p>	<p><u>Sponsor</u></p> <p>Correct 84b</p> <p><u>Reviewer</u></p> <p>Correct 84b</p>	<p><u>Sponsor</u></p> <p>Correct 64</p> <p><u>Reviewer</u></p> <p>Correct 64</p>	<p>Open-ended responses reveal that 72 respondents answered this question incorrectly, and 66 out of those 72 incorrect respondents apparently confused the per-meal maximum dose (2 tablets per meal) with the maximum daily dose of 6 tablets. <u>It is disturbing that even simple numeric instructions are easily mixed up.</u></p> <p>These low percentages of correct responses are worrying considering the label specifically states: “do not exceed 6 capsules daily.” No answer other than “6” or “no more than 6” or “up to 6” or “maximum of 6” is correct or acceptable.</p>
<p>Table Q / Card K</p> <p><u>Recommended dosage to start taking Orlistat.</u></p> <p>Ellen is overweight and would like to start taking Orlistat.</p> <p>Q20 Based on the package labeling, what is the recommended dose for Ellen to start taking Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct 93b</p> <p><u>Reviewer</u></p> <p>Start w/1 38</p> <p>1-2 each meal 54</p> <p>Total 92</p>	<p><u>Sponsor</u></p> <p>Correct 87</p> <p><u>Reviewer</u></p> <p>Start w/1 34</p> <p>1-2 each meal 53</p> <p>Total 87</p>	<p>The Drug Facts Label clearly states in the Directions: “start with 1 capsule. After you have gained experience with choosing meals that contain less than 30% fat, you can increase to 2 capsules with each meal for maximum weight loss.”</p> <p>The question specifically asks about the <u>starting</u> dose. Therefore any other dose other than the starting dose, “start with 1 capsule,” is NOT a correct response.</p> <p>The general dose direction in the Drug Facts Label is: “1 to 2 capsules with each meal.” This is the dose that was referred to by more than half of all respondents. It is disturbing that several study participants mistook the general per-meal dose for the recommended starting dose.</p> <p>Nine subjects gave responses such as: “1 per day,” “2 per day,” and “1-2 per day.”</p>

<p>Table R / Card O</p> <p><u>Concern about vitamin absorption.</u></p> <p>Terry is overweight and would like to use Orlistat for weight loss. She is concerned that she will not be able to absorb the vitamins in the food if she starts taking Orlistat.</p> <p>Q 27 Based on the package labeling, what, if anything, should Terry do about this concern?</p> <p>The order in which information is presented is an important factor in whether or not it is noticed, read at all, and/or recalled. In order to boost the likelihood that consumers will read the crucial instruction about taking a daily multivitamin, 2 hours before or 2 hours after taking Orlistat, it might be better to move the instruction higher up in the “Directions” section, or even move it into the “When using this product” section.</p>	<p><u>Sponsor</u></p> <p>Correct 69b Acceptable 24 Total 93</p> <p><u>Reviewer</u></p> <p>Correct 47 Acceptable 0* Total 47</p> <p>Per the label instructions, the <u>only correct</u> answer for this scenario and question is: “take a multivitamin once a day, 2 hours before or 2 hours after taking Orlistat.”</p> <p>*I might be willing to consider some of the responses coded by GSK as “acceptable” upon verification and further explanation of the actual responses.</p>	<p><u>Sponsor</u></p> <p>Correct 50 Acceptable 38a Total 88</p> <p><u>Reviewer</u></p> <p>Correct 36 Acceptable 0* Total 36</p> <p>Per the label instructions, the <u>only correct</u> answer for this scenario and question is: “take a multivitamin once a day, 2 hours before or 2 hours after taking Orlistat.”</p> <p>*I might be willing to consider some of the responses coded by GSK as “acceptable” upon verification and further explanation of the actual responses.</p>	<p>The Drug Facts Label states in the Directions section: “to ensure adequate vitamin absorption, you should take a multivitamin once a day, 2 hours before or after taking Orlistat capsules.”</p> <p>The purpose of this instruction is to ensure that fat-soluble vitamins are not wasted by being excreted if taken at the same time as Orlistat. Hence it is crucial for consumers to understand not only the importance of taking a multivitamin each day, but also to realize that the multivitamin must be taken and digested 2 hours before or 2 hours after taking Orlistat (NOT any closer in time to taking Orlistat).</p> <p>The issue/information conveyed in the scenario is vital for proper health while taking Orlistat. It is, therefore, worrying that correct response rates are so low – only 47% among the GP group and only 36% among the LL group.</p> <p>* Although 22% of GP and 14% of LL subjects mentioned the need to take a multivitamin, they did not include the essential directive about the timing of taking the multivitamin. Clarification is required on these responses before they can be counted as “acceptable.” The remaining respondents said things such as:</p> <ul style="list-style-type: none"> • <i>She shouldn’t take it.</i> • <i>Lower dosage.</i> • <i>Look at the warnings and side effects.</i> • <i>Don’t use the product.</i> • <i>Call the 1-800#.</i> • <i>Look in User’s Guide/Manual/Directions on label / Reference Card.</i> • <i>Ask a doctor/pharmacist</i> • <i>Eat a well-balanced meal.</i>
<p>Table S / Card P</p> <p><u>Recommended timing for taking a multivitamin.</u></p> <p>Q28 Based on the package labeling, what is the recommended timing for taking a multivitamin to ensure adequate vitamin absorption?</p>	<p><u>Sponsor</u></p> <p>Correct 48b Acceptable 31 Total 79b</p> <p><u>Reviewer</u></p> <p>Correct 48 Acceptable 0* Total 48</p>	<p><u>Sponsor</u></p> <p>Correct 34 Acceptable 31 Total 66</p> <p><u>Reviewer</u></p> <p>Correct 34 Acceptable 0* Total 34</p>	<p>Per the label instructions, the <u>only</u> correct answer for this question is: “2 hours before or 2 hours after taking Orlistat.”</p> <p>The purpose of the instruction is to ensure that fat-soluble vitamins are not wasted by being excreted if taken at the same time as Orlistat. It is crucial for consumers to understand not only the importance of taking a multivitamin each day, but to realize that the multivitamin must be taken and digested 2 hours before or 2 hours after taking Orlistat (NOT any closer in time to taking Orlistat).</p> <p>The information sought in this question is vital for proper health maintenance while taking Orlistat. It is, therefore, worrying that correct response rates are so low: only 48% among the GP group and only 34% among the LL group.</p>

			<p>* 21% of GP and 16% of LL subjects gave responses that partially fit the correct answer – “2 hours before,” “2 hours after” “once a day 2 hours before.” However, because they did not specify 2 hours before or after taking orlistat, further clarification is needed before these responses can be counted as “acceptable.”</p> <p><u>None of the Sponsor’s other so-called “correct” responses, nor any of the Sponsor’s other so-called “acceptable” answers, are valid.</u> How could it possibly be “correct” to answer: “<u>one</u> to two hours before meals?” Similarly, how could it possibly be “acceptable” to answer the question with any of the following?</p> <ul style="list-style-type: none"> • Daily for six months, once a day. • Before a meal. • Six months. • After you eat. 																								
<p>Table T / Card X</p> <p><u>Weight loss goal not met after 6 months.</u></p> <p>Melissa has been using Orlistat for 6 months to reduce her weight. She has not yet reached her weight loss goal.</p> <p>Q 39 Based on the package labeling, what, if anything, should Melissa do now?</p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>75b</td></tr> <tr><td>Acceptable</td><td>3</td></tr> <tr><td>Total</td><td>78</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>75b</td></tr> <tr><td>Acceptable</td><td>1</td></tr> <tr><td>Total</td><td>76</td></tr> </table>	Correct	75b	Acceptable	3	Total	78	Correct	75b	Acceptable	1	Total	76	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>64</td></tr> <tr><td>Acceptable</td><td>11</td></tr> <tr><td>Total</td><td>75</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>64</td></tr> <tr><td>Acceptable</td><td>3</td></tr> <tr><td>Total</td><td>67</td></tr> </table>	Correct	64	Acceptable	11	Total	75	Correct	64	Acceptable	3	Total	67	<p>The correct response based on the label is “talk to your doctor.”</p> <p>An acceptable response would be to call the 1-800 phone number for advice.</p> <p>Given the very simple and straightforward nature of this instruction, it is hard to understand the relatively low correct response rates: 76% for GP and 67% for LL. I am inclined to think that the point may have been overlooked because of its positioning relatively far down in the drug facts label – many consumers simply don’t read all the way to the end of a set of instructions. However, it probably needs to stay where it is because other instructions may deserve greater weight and prominence in the list than this particular one.</p>
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Acceptable	3																										
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Correct	64																										
Acceptable	11																										
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<p>Table U / Card AA</p> <p><u>When to increase dosage from 1 capsule to 2.</u></p> <p>Valerie is overweight and would like to lose weight. She has been using 1 capsule of Orlistat with each meal for 3 weeks.</p> <p>Q43 Based on the package labeling, when could Valerie increase her dose from 1 capsule to 2 capsules with each meal?</p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>80b</td></tr> <tr><td>Acceptable</td><td>9</td></tr> <tr><td>Total</td><td>89b</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>76b</td></tr> <tr><td>Acceptable</td><td>12</td></tr> <tr><td>Total</td><td>88</td></tr> </table>	Correct	80b	Acceptable	9	Total	89b	Correct	76b	Acceptable	12	Total	88	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>61</td></tr> <tr><td>Acceptable</td><td>19a</td></tr> <tr><td>Total</td><td>80</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>55</td></tr> <tr><td>Acceptable</td><td>26a</td></tr> <tr><td>Total</td><td>81</td></tr> </table>	Correct	61	Acceptable	19a	Total	80	Correct	55	Acceptable	26a	Total	81	<p>The correct response according to the label is: “After gaining experience choosing meals that contain less than 30% fat.”</p> <p><u>Note:</u> The label instructions are somewhat ambiguous in terms of a particular time frame, hence there was quite a lot of variation in the responses. Several responses coded as “correct” are not strictly correct per the label but may be moved into the “acceptable,” category or range.</p> <p>Again, given the relatively straightforward nature of this instruction, it is hard to understand why strictly “correct” response rates were fairly low: 80% for GP and 61% for LL. The nature of the question vis-à-vis the rather ambiguous time-frame in the instruction may have something to do with this. As mentioned, a large percentage of responses were very varied, which indicates poor questioning or terminology.</p>
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Acceptable	9																										
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Correct	76b																										
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Total	81																										

<p>Table V / Card CC</p> <p><u>Where to find information on using Orlistat.</u></p> <p>Ron has purchased Orlistat. He has read the labels on the package but still has some questions about this product.</p> <p>Q46 Based on the package labeling, where could Ron find information?</p>	<p><u>Sponsor</u> Correct 81</p> <p><u>Reviewer</u> Correct 81</p>	<p><u>Sponsor</u> Correct 75</p> <p><u>Reviewer</u> Correct 75</p>	<p>The Drug Facts Label specifically states in the Directions section: “before using this product, read the enclosed User’s Guide for complete directions and other important information.” The label also includes a toll free telephone number for “Questions or comments?”</p> <p>The “ask a doctor/pharmacist” response is not technically wrong, but when used as the <u>default</u> option (as opposed to being a specific label instruction) it is not appropriate for OTC products. 8% of the GP subjects and 10% of the LL subjects used this response and were inappropriately coded as “acceptable.”</p> <p>The scenario specifically states that Ron “has read the labels on the package” but still has questions. Why, then, would it be “acceptable” for the respondents to say that if Ron wants to find more information, he can find it on the back of the box or in the questions and comments section, which is what he has already done?</p>
<p>Table W / Card L</p> <p><u>How to decrease likelihood of loose stool and bowel changes.</u></p> <p>Peggy is overweight and has been taking Orlistat for 1 week. She has noticed that she is having loose stool and bowel changes.</p> <p>Q23 Based on the package labeling, What, if anything, should Peggy do to decrease the likelihood of this happening?</p>	<p><u>Sponsor</u> Correct 72</p> <p><u>Reviewer</u> Correct 72</p>	<p><u>Sponsor</u> Correct 48</p> <p><u>Reviewer</u> Correct 48</p>	<p>The Warnings section of the Drug Facts Label specifically explains that: “You can decrease the likelihood [of loose stool and bowel changes] by reducing the fat in your diet.” Based strictly on the label language, then, only a response that says Peggy should “reduce the fat in her diet” is the correct response.</p> <p>The responses coded by Sponsor as “acceptable” are NOT appropriate. Also, the “ask a doctor/pharmacist” response is a weak default option and is not favored for OTC products. 2% GP and 8% LL of subjects used this default response and were coded “acceptable.”</p> <p>There were some very interesting “incorrect” open-ended responses, for example:</p> <ul style="list-style-type: none"> • She should drink more fluids / Drink a lot of water / Increase water intake. • Take a multivitamin. • Eat less calories/ Eat less. • Take something to firm her up / Take other medication to help with this problem. • She should take less fiber, not prune juice/ Cut back on fruit because it irritates your bowels.
<p>Table X / Card R</p> <p><u>How Orlistat works to promote weight loss.</u></p>	<p><u>Sponsor</u> Correct 82 Acceptable 3 Total 85</p>	<p><u>Sponsor</u> Correct 61 Acceptable 3 Total 64</p>	<p>These are rather low “correct” and “acceptable” response rates, given that the question is based on fairly straightforward information.</p>

<p>Q31 Based on the package labeling, how do Orlistat capsules work to promote weight loss?</p>	<p><u>Reviewer</u> Correct 82 Acceptable 3 Total 85</p>	<p><u>Reviewer</u> Correct 61 Acceptable 3 Total 64</p>	
<p>Table Y / Card T</p> <p><u>Changing your eating patterns before starting Orlistat.</u></p> <p>Normally Tim eats foods that are high in fat and calories. Tim realized that he is getting overweight and has decided to start using Orlistat to reduce his weight.</p> <p>Q34 What, if anything, should Tim do with his eating patterns before he begins taking Orlistat?</p>	<p><u>Sponsor</u> Correct 55b Acceptable 41 Total 96</p> <p><u>Reviewer</u> Correct 55b Acceptable 40 Total 95</p>	<p><u>Sponsor</u> Correct 34 Acceptable 58a Total 92</p> <p><u>Reviewer</u> Correct 34 Acceptable 52a Total 86</p>	<p>The question specifically calls for the response that is pulled from the Drug Facts Label and provides the following instructions: “you should follow a well-balanced diet that is reduced in calories and contains 30% or less. Try starting this diet before you begin taking Orlistat capsules. See enclosed User’s Guide for information and tips on how to follow a well-balanced diet that it low in calories and fat.”</p> <p>Many of the responses coded by Sponsor as “acceptable” are not strictly in accordance with the label language, but are reasonably appropriate for that category, for example:</p> <ul style="list-style-type: none"> • Try a low fat diet • Follow diet plan / Guide for well balanced diet • Look in User’s Guide / Manual / Directions on the label / Reference card • Eat better foods / more balanced diet / Watch diet <p>However, “ask a doctor/pharmacist” is NOT acceptable.</p>
<p>Table Z / Card W</p> <p><u>Timeframe of when to expect results when taking Orlistat.</u></p> <p>Gina is overweight and has started taking Orlistat today.</p> <p>Q38 Based on the package labeling, how soon can Gina expect to begin seeing weight loss?</p>	<p><u>Sponsor</u> Correct 80b Acceptable 2 Total 82</p> <p><u>Reviewer</u> Correct 80b Acceptable 2 Total 82</p>	<p><u>Sponsor</u> Correct 64 Acceptable 5a Total 69</p> <p><u>Reviewer</u> Correct 64 Acceptable 5a Total 69</p>	<p>The Drug Facts Label states: “you should start to lose weight within the first two weeks. How much weight you lose will depend on how closely you follow the recommended diet and the Orlistat program.”</p> <p>Correct responses included: “Within the first two weeks” and “In two weeks.”</p> <p><u>Acceptable responses included:</u></p> <ul style="list-style-type: none"> • Within a few weeks. • One week. • Two to three weeks. • A week or two. <p>“Correct” response rates are low considering the information is so straightforward. <u>The vast majority of “incorrect” responses were: “Six months,” which is actually the directed maximum length of time that the product should be used as an OTC medicine. Participants confused the two time frames.</u></p>

<p>Table AA / Card Z</p> <p><u>Why weight loss amount will vary per person.</u></p> <p>Diane and her friend Bev are both overweight and started taking Orlistat at the same time. After taking Orlistat for 4 weeks, Diane is frustrated since she has not lost the same amount of weight as Bev.</p> <p>Q42 Based on the package labeling, what, if anything, is the reason why Diane is not losing the same amount of weight as Bev?</p>	<p><u>Sponsor</u></p> <p>Correct 79b Acceptable 4 Total 83</p> <p><u>Reviewer</u></p> <p>Correct 79b Acceptable 3 Total 82</p>	<p><u>Sponsor</u></p> <p>Correct 58 Acceptable 7 Total 65</p> <p><u>Reviewer</u></p> <p>Correct 58 Acceptable 5 Total 63</p>	<p><u>Correct responses include:</u></p> <ul style="list-style-type: none"> • Not closely following the program • Not following the recommended diet • Not reducing calories and fat • Not taking Orlistat with each meal • Not taking Orlistat as much • Eating more fat/Too much fat in diet • Taking in more fat and calories <p><u>Acceptable responses include:</u></p> <ul style="list-style-type: none"> • Not following User’s Guide correctly • Eating too much • Not taking it correctly/not doing it right • Differences in diet and exercise • Different diets/eating habits <p><u>Note: “Didn’t ask doctor/should ask doctor” is <u>not</u> an acceptable response.</u></p> <p><u>Incorrect responses include:</u></p> <ul style="list-style-type: none"> • Metabolism breaking down fat at different speed (5) • Different body mass/weight (10) • Not exercising/not as active (4) • Need to take multivitamin (2) • Label doesn’t mention (1) • Every body/system is different (24) • Different fat absorption (3) • Bowel changes (1) • Other (2)
<p>Table BB / Card J</p> <p><u>Information on what to order when dining out.</u></p> <p>Steve is overweight. He has been using Orlistat. Steve is going out to dinner tonight but is not sure what would be best for him to order.</p> <p>Q19 Based on the package labeling, where could Steve find information?</p>	<p><u>Sponsor</u></p> <p>Correct 35b Acceptable 40 Total 75</p> <p><u>Reviewer</u></p> <p>Correct 35b Acceptable 2 Total 37</p>	<p><u>Sponsor</u></p> <p>Correct 19 Acceptable 38 Total 57</p> <p><u>Reviewer</u></p> <p>Correct 19 Acceptable 4 Total 23</p>	<p><u>The accurate response is: “Away from Home Guide” which clearly states that it covers “Dining Out” issues. Some variations are acceptable:</u></p> <ul style="list-style-type: none"> • Dining Out Guide. • In the little restaurant guide. • Calorie/fat counter/diet cards. <p>“Ask a doctor/pharmacist” is NOT an acceptable answer, nor are a number of other responses coded by Sponsor as “acceptable.” The following are so general as to be no better than default answers:</p> <ul style="list-style-type: none"> • In the booklet • In the packet • Inside the box

			<p>The large number of incorrect responses is worrying in view of the straightforward nature of the scenario and question. Some examples of incorrect responses:</p> <p>42 respondents gave answers such as:</p> <ul style="list-style-type: none"> • Back of package/on back in drug facts / Directions on box/label/ directions / On the label/box <p>4 respondents said:</p> <ul style="list-style-type: none"> • From restaurant/ ask the waiter / restaurant / consult the restaurant <p>Other respondents said Steve should look in the “When using this product” section of the label; or “In the inactive ingredients” section of the label; or in the “Activity tracker;” or at “The bottom of the label.”</p>																								
<p>Table CC / Card N</p> <p><u>Information on preparing meals.</u></p> <p>Laura is overweight and has been using Orlistat. She would like to prepare meals for the week and wants to make sure she has the right ingredients on hand.</p> <p>Q26 Based on the package labeling, where could Laura find information?</p> <p><u>Acceptable responses include:</u> Call the toll free 800 number. Inside the box/Guide inside the box.</p>	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>42</td></tr> <tr><td>Acceptable</td><td>42</td></tr> <tr><td>Total</td><td>84</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>42</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>42</td></tr> </table>	Correct	42	Acceptable	42	Total	84	Correct	42	Acceptable	0	Total	42	<p><u>Sponsor</u></p> <table border="0"> <tr><td>Correct</td><td>24</td></tr> <tr><td>Acceptable</td><td>39</td></tr> <tr><td>Total</td><td>63</td></tr> </table> <p><u>Reviewer</u></p> <table border="0"> <tr><td>Correct</td><td>24</td></tr> <tr><td>Acceptable</td><td>0</td></tr> <tr><td>Total</td><td>24</td></tr> </table>	Correct	24	Acceptable	39	Total	63	Correct	24	Acceptable	0	Total	24	<p>The accurate response is: “At Home Guide” which states that it covers “Food Preparation.” It would be better to use the phrase “Preparing meals” rather than “Food Preparation.” Also correct is the response “Meal Planner / Balance Your Meal Plan” since these are relevant sections of the “At Home Guide.”</p> <p>The following were coded by Sponsor as “acceptable” but are either incorrect or are so general as to be no better than default answers:</p> <ul style="list-style-type: none"> • User’s Guide • Call the Toll Free 800 number • Inside the box/Guide inside box • Questions or Comments section • Food chart • Diet book <p>Examples of incorrect responses include:</p> <ul style="list-style-type: none"> • Back of package/on back in drug facts / Directions on box/label/ directions / On the label/box/bottom of box/label / On warning label (34) • Questions or Comments section; Ingredients section (5) • Ask a doctor/pharmacist (4) <p>Correct rates are low. The scenario calls for information that can be found in the “At Home Guide,” which states that it covers meal plans, sample menus, shopping lists, and navigating the grocery store.</p>
Correct	42																										
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<p>Table DD / Card U</p> <p><u>Information on fat and calories.</u></p> <p>Tina is overweight and has been using Orlistat. She would like to eat lunch tomorrow at a fast food restaurant. Tina wants to find out how much fat and calories are in the meal she usually orders.</p> <p>Q35 Based on the package labeling, where could Tina find information?</p>	<p><u>Sponsor</u></p> <p>Correct 42 Acceptable 32 Total 74</p> <p><u>Reviewer</u></p> <p>Correct 42 Acceptable 0 Total 42</p>	<p><u>Sponsor</u></p> <p>Correct 23 Acceptable 34 Total 57</p> <p><u>Reviewer</u></p> <p>Correct 23 Acceptable 3 Total 26</p>	<p>The accurate response is: “Away from Home Guide” which clearly states that it covers “Fast Food Restaurants.” The variations “Dining Out Guide” and “Calorie/fat counter/diet cards” are acceptable alternative response..</p> <p>A number of responses coded by Sponsor as “acceptable” are either incorrect or are so general as to be no better than default incorrect answers:</p> <ul style="list-style-type: none"> • User’s Guide. • Call the toll free 800 number. • Inside the box/Guide inside box. • Meal planner/Balance Your Meal Plan. • Questions or Comments Section. • Activity Tracker. <p>The large number of incorrect responses is worrying in view of the straightforward nature of the scenario and question. Examples of incorrect responses include:</p> <ul style="list-style-type: none"> • Back of package/on back in drug facts; Directions on box/label/ directions; On the label/box; Bottom of box/label; Front of package (28) • When using this product section; Ingredients section; Food packages (3) • At the restaurant (31)
<p>Table EE / Card DD</p> <p><u>Information on snacking tips.</u></p> <p>Q47 Based on the materials in front of you, when using Orlistat where would you look to find information on snacking tips?</p>	<p><u>Sponsor</u></p> <p>Correct 77 Acceptable 2 Total 79</p> <p><u>Reviewer</u></p> <p>Correct 66 Acceptable 11 Total 77</p>	<p><u>Sponsor</u></p> <p>Correct 69 Acceptable 1 Total 70</p> <p><u>Reviewer</u></p> <p>Correct 61 Acceptable 9 Total 70</p>	<p>The accurate response is: “At Home Guide” which states that it covers “Snacking Tips.” The variations “Balance Your Meal Plan” or “Meal Planner” are acceptable alternative responses.</p> <p>Responses coded by Sponsor as “acceptable” are so general as to be nothing more than default incorrect answers:</p> <ul style="list-style-type: none"> • Table of contents • Inside box/Guide inside box <p>Again, the large number of incorrect responses (around a third of all responses) is worrying in view of the straightforward nature of the scenario and question.</p>
<p>Table FF / Card EE</p> <p><u>Information on fast food restaurants.</u></p> <p>Q48 Based on the materials in front of you, when using this product where would you look to find information on fast food restaurants?</p>	<p><u>Sponsor</u></p> <p>Correct 90</p> <p><u>Reviewer</u></p> <p>Correct 90</p>	<p><u>Sponsor</u></p> <p>Correct 90</p> <p><u>Reviewer</u></p> <p>Correct 90</p>	<p>The accurate response is: “Away from Home Guide” which clearly states that it covers “Fast Food Restaurants.” The variation “Dining Out” is a correct alternative response.</p> <p>Sponsor listed “Table of Contents” as an acceptable answer which is NOT appropriate.</p>

<p>Table GG / Card FF</p> <p><u>Information on setting realistic goals.</u></p> <p>Q49 Based on the materials in front of you, when using this product where would you look to find information on setting realistic goals?</p>	<p><u>Sponsor</u></p> <p>Correct 89</p> <p>Acceptable 0</p> <p>Total 89</p> <p><u>Reviewer</u></p> <p>Correct 89</p> <p>Acceptable 0</p> <p>Total 89</p>	<p><u>Sponsor</u></p> <p>Correct 86</p> <p>Acceptable 1</p> <p>Total 87</p> <p><u>Reviewer</u></p> <p>Correct 86</p> <p>Acceptable 1</p> <p>Total 87</p>	<p>The accurate response is: “User’s Guide/ The Orlistat Approach to Weight Loss” which states in the Table of Contents under the subheading “Prepare for Success” that it includes information on how to set realistic goals. An alternative correct response is: “Prepare for Success.”</p> <p>An acceptable response is: “Approach to Weight Loss.”</p>
<p>Table HH / Card GG</p> <p><u>Information on learning to navigate the grocery store.</u></p> <p>Q50 Based on the materials in front of you, when using this product where would you look to find information on learning to navigate the grocery store?</p>	<p><u>Sponsor</u></p> <p>Correct 65</p> <p>Acceptable 2</p> <p>Total 67</p> <p><u>Reviewer</u></p> <p>Correct 65</p> <p>Acceptable 0</p> <p>Total 65</p>	<p><u>Sponsor</u></p> <p>Correct 64</p> <p>Acceptable 1</p> <p>Total 65</p> <p><u>Reviewer</u></p> <p>Correct 63</p> <p>Acceptable 0</p> <p>Total 63</p>	<p>The accurate response is: “At Home Guide” which contains a section titled “Learn to Navigate the Grocery Store.” An alternative correct response is: “Take Charge” (the subheading in the Guide’s table of contents).</p> <p>“Meal Plan and Food Preparation” is not a correct response.</p> <p>Correct response rates are low considering that subjects could look at the package labeling and the table of contents of the guides while answering the question.</p>
<p>Table II / Card HH</p> <p><u>Information on understanding personal eating habits.</u></p> <p>Q51 Based on the materials in front of you, when using this product where would you look to find the information on understanding your eating habits?</p>	<p><u>Sponsor</u></p> <p>Correct 81</p> <p>Acceptable 0</p> <p>Total 81</p> <p><u>Reviewer</u></p> <p>Correct 81</p> <p>Acceptable 0</p> <p>Total 81</p>	<p><u>Sponsor</u></p> <p>Correct 76</p> <p>Acceptable 0</p> <p>Total 76</p> <p><u>Reviewer</u></p> <p>Correct 75</p> <p>Acceptable 0</p> <p>Total 75</p>	<p>The correct response is “User’s Guide/The Orlistat Approach to Weight Loss.” An alternative correct response is: “Manage Your Eating Behavior” (the subheading in the Guide’s table of contents).</p> <p>Correct response rates are low considering that subjects could look at the package labeling and the table of contents of the guides while answering the question.</p>
<p>Table JJ / Card II</p> <p><u>Information on the food and activity tracker.</u></p> <p>Q52 Based on the materials in front of you, when using this product where would you look to find a food and activity tracker?</p>	<p><u>Sponsor</u></p> <p>Correct 43</p> <p>Acceptable 2</p> <p>Total 45</p> <p><u>Reviewer</u></p> <p>Correct 43</p> <p>Acceptable 0</p> <p>Total 43</p>	<p><u>Sponsor</u></p> <p>Correct 41</p> <p>Acceptable 3</p> <p>Total 44</p> <p><u>Reviewer</u></p> <p>Correct 41</p> <p>Acceptable 0</p> <p>Total 41</p>	<p>The correct response is “Away From Home Guide.”</p> <p>Contrary to Sponsor’s coding, the response “Table of Contents” is NOT an acceptable answer.</p> <p>Correct response rates are low considering that subjects could look at the package labeling and the table of contents of the guides while answering the question.</p>

Results Relating to Drug Facts Label – Use

Three questions directly concerned the use of Orlistat (per the Drug Facts Label) and were designed to test consumers’ understanding that:

- The product is intended to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet.
- Not okay to use Orlistat if under 18 years old.
- Not okay to use Orlistat if not overweight.

Scores for Question 1 (Table A / Card A) concerning the product’s intended use, and Questions 44/45 (Table F / Card BB) testing the concept that it is not okay to use Orlistat if under 18 years of age, were very positive – 100% and 95%, respectively.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304)		Low Literacy (n=160)		Comments, Observations, and Open-Ended Responses
		%		%	
Table A / Card A <u>Product Use</u> Q1 Based on the package labeling, what is the product used for?	<u>Sponsor</u> Correct 97 Acceptable 3 Total 100 <u>Reviewer</u> Correct 97 Acceptable 3 Total 100		<u>Sponsor</u> Correct 94 Acceptable 6 Total 100 <u>Reviewer</u> Correct 94 Acceptable 6 Total 100		Responses coded as “acceptable” were appropriate based on the label language/content. <u>Acceptable Responses:</u> For dieting. To block/prevent/decrease fat absorption.
Table F / Card BB <u>Not okay to use Orlistat if under 18 years old.</u> Stacey is 16 years old and overweight. Stacey is interested in trying Orlistat to lose weight. Q44/Q45 Based on the package labeling, is it okay or not okay for Stacey to use Orlistat?	<u>Sponsor</u> Correct 96 Acceptable 2 Total 98 <u>Reviewer</u> Correct 96 Acceptable 0 Total 96		<u>Sponsor</u> Correct 95 Acceptable 3 Total 98 <u>Reviewer</u> Correct 95 Acceptable 0 Total 95		The label states in Directions: “for overweight adults 18 years and older.” Therefore, the only correct response for this scenario and question is “not okay.” Ask a doctor or pharmacist is NOT an acceptable response for this scenario. The label specifically states that Orlistat is for overweight adults 18 years and older. For clarity and emphasis, it may be helpful to move this instruction to the top of the Drug Facts Label under the heading “Uses.” For example: Use . . . promote weight loss in overweight adults 18 years and older, when used along with a reduced calorie and low fat diet.

The “Jane” scenario and Questions 15/16 (Table C / Card H on the next page) were designed to test the concept that it is not okay to use Orlistat if a person is not overweight. The lower scores on this scenario – 79% of the General Population and 77% of the Low Literates answered correctly that it is NOT okay to use Orlistat if a person is not overweight – may be due to the slightly ambiguous label instructions, which leave room for some subjective interpretation. A small percentage of all respondents (4%) suggested that Jane should consult her doctor first, but a fairly large percentage of the study participants (44%) offered a variety of reasons why it would be “okay” for Jane to use Orlistat even though she is not overweight, suggesting that consumer perceptions of what may be “overweight” or “not overweight” are quite subjective and lead to a host of interesting responses about who is an appropriate candidate for Orlistat.

The verbatim responses reveal some interesting trains of thought. One was that, since there’s no specific warning on the box stating that non-overweight people can not take Orlistat, then it’s okay to take it:

- *Some people may want to lose weight no matter what they weigh. Nowhere on this box does it say for those that are overweight only.*
- *There's nothing on the box that says not overweight people can't take it. There's no warning.*
- *It might be unhealthy, but it doesn't explicitly say not to.*
- *If she really wants to go for that Calista Flockhart look, she can. It doesn't say specifically not to, and it probably won't be any worse for her than if she just goes bulimic.*

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304)		Low Literacy (n=160)		Comments, Observations and Open-Ended Responses
		%		%	
Table C / Card H	<u>Sponsor</u>		<u>Sponsor</u>		The "Jane" scenario and question (Card H, Q15/Q16) were designed to test the concept that it is not okay to use Orlistat if a person is not overweight. However, the scenario and question present information that is ambiguous and leaves room for subjective interpretation.
	Correct	78	Correct	74	
	Acceptable	1	Acceptable	3	
<u>Not okay to use Orlistat if not overweight</u>	Total	79	Total	77	
Jane is 25 years old and not overweight. Jane is considering using Orlistat.	<u>Reviewer</u>		<u>Reviewer</u>		It is hardly surprising that only 78% of the General Population respondents gave the hoped-for answer that it is NOT OKAY. A small percentage of respondents (4%) suggested that Jane should consult her doctor or healthcare professional first, but a fairly large percentage of the study participants offered a variety of reasons why it would be okay for Jane to use Orlistat.
	Correct	78	Correct	74	
	Acceptable	1	Acceptable	3	
Q15/Q16 Based on the package labeling, is it okay or not okay for Jane to use Orlistat?	Total	79	Total	77	
Although the label states that Orlistat is for " weight loss in overweight adults " it requires reading the supplemental materials in order to learn what constitutes being overweight. There may, therefore, be room for subjective interpretation of whether or not it is appropriate to take Orlistat, depending upon the individual's perception of whether their weight is "overweight" or not).					One general train of thought was that, since there is no specific warning on the box stating that non-overweight people should not take Orlistat, then it's okay to take it:
Ask a doctor, pharmacist or healthcare professional may be an acceptable response in this scenario. Many of the responses that were coded as "incorrect" were quite logical given the label content.					<p><i>"If she really wants to go for that Calista Flockhart look, she can. It doesn't say specifically not to, and it probably won't be any worse for her than if she just goes bulimic."</i></p> <p><i>Some people may want to lose weight no matter what they weigh. Nowhere on this box does it say for those that are overweight only.</i></p> <p><i>There's nothing on the box that says not overweight people can't take it. There's no warning.</i></p> <p><i>It might be unhealthy, but it doesn't explicitly say not to.</i></p> <p>Another set of responses reflected the idea that it would be good for <u>maintaining</u> desired weight:</p> <ul style="list-style-type: none"> • <i>If she wants to maintain her weight, it's fine to use it.</i> • <i>It could help her not to be overweight.</i> • <i>I think it's good for everyone even if they are not really overweight. It could help them to maintain.</i> • <i>If she uses it moderately, it will help her maintain her weight.</i> • <i>It could help her stay thin.</i> • <i>She might just want to keep her weight the way it is.</i>

Another set of verbatim responses reflected the idea that it would be good for maintaining desired weight:

- *If she wants to maintain her weight, it's fine to use it.*
- *It could help her not to be overweight.*
- *I think it's good for everyone even if they are not really overweight. It could help them to maintain.*
- *If she uses it moderately, it will help her maintain her weight.*
- *It could help her stay thin.*
- *She might just want to keep her weight the way it is.*

Other responses reflected the sentiment that if a person is over 18, then it's up to the consumer to decide whether to use the product or not. Another category of responses reflected the notion that as long as a person is healthy, then there shouldn't be any problems taking Orlistat, regardless of whether the person is overweight or not. All of these consumer rationalizations ignore the label instruction which clearly states that orlistat is for *overweight adults* and that it is intended *for use along with a reduced calorie and low fat diet*. Furthermore, the supplementary educational booklets contain information about what constitutes being "overweight" and describes numerous helpful ways to maintain a low fat, reduced calorie diet. Nevertheless, the "incorrect" results indicate that some 21% (GP) to 23% (LL) of consumers maintain subjective perceptions of what constitutes being "overweight" and believe that it is up to individual purchasers to determine what their weight should be and whether or not they should use Orlistat.

Results Relating to Drug Facts Label – Warnings – Do not use . . .

Three questions directly concerned the Drug Facts Label warnings against using Orlistat . . .

- If you are taking cyclosporine (a drug given after organ transplant)
- If you have been diagnosed with problems absorbing food
- If you are allergic to any of the ingredients in Orlistat capsules

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304)		Low Literacy (n=160)		Comments, Observations and Open-Ended Responses
		%		%	
Table I / Card M <u>Not okay to use Orlistat while taking cyclosporine.</u>	<u>Sponsor</u>		<u>Sponsor</u>		Even though the label states under Warnings: Do not use if you are taking cyclosporine (a drug given after organ transplant) , 28 respondents (some possibly overlapping) completely missed or misunderstood the warning, and 6 of those respondents said there was nothing on the package/label about cyclosporine. Examples of some incorrect responses: <ul style="list-style-type: none"> • I can't find anything that says he cannot take it if he takes cyclosporine. • Not on package saying not to. • Doesn't say anything about cyclosporine that I can see. • Don't see anything on the package about this medication. • It didn't mention cyclosporine. • He doesn't have any kidney problems. • He has no problem with bladder or kidney stones. • It won't make any difference because he has been taking the other medicine for a while.
	Correct	91	Correct	89	
	Acceptable	5	Acceptablen	1	
	Total	96	Total	90	
Bob is overweight and is interested in trying Orlistat to lose weight. He has been taking cyclosporine.	<u>Reviewer</u>		<u>Reviewer</u>		
	Correct	91	Correct	89	
Q 24/Q25 Based on the package labeling, is it okay or not okay for Bob to use Orlistat?	Acceptable	0	Acceptable	0	
	Total	91	Total	89	
<u>Note:</u> Since the label specifically states: "Do not use if you are taking cyclosporine . . ." the response "ask a doctor or healthcare professional" is NOT acceptable for this scenario.					

The "Bob" scenario (Table I / Card M above) indicates that although 91% of all the respondents correctly answered that it is NOT OKAY to use Orlistat if taking cyclosporine, 9 individuals incorrectly responded that this warning was not mentioned on the box/package/label, even though it is stated in the Drug Facts Label. Six other individuals confused other aspects of the label and other contraindications with the particular warning about cyclosporine, for example:

- *He doesn't have any kidney problems.*
- *He has no problem with bladder or kidney stones.*
- *It won't make any difference because he has been taking the other medicine for a while.*

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304)		Low Literacy (n=160)		Comments, Observations and Open-Ended Responses
		%		%	
Table G / Card D <u>Not okay to use Orlistat if diagnosed with problems absorbing food.</u>					The label specifically states in the Warnings section: Do not use if you have been diagnosed with problems absorbing food. Ask a doctor or pharmacist is NOT an acceptable response for this scenario.
Jenna is overweight and wants to reduce her weight. Jenna has previously been diagnosed as having problems absorbing food.	<u>Sponsor</u> Correct Acceptable Total	90 2 92	<u>Sponsor</u> Correct Acceptable Total	86 3 89	The overall “correct” response rate on the food absorption scenario was fairly high (86%-89%) but as with the scenario about cyclosporine, several respondents incorrectly said that the warning about problems absorbing food was not mentioned on the box/package/label, even though it is clearly stated in the Drug Facts Label. Several subjects gave explanations which seemed to imply that Jenna’s wish to lose weight was more important than her inability to absorb food, and several respondents provided a variety of reasons why it’s okay for Jenna to use Orlistat even though she has problems absorbing food. Examples of incorrect responses include:
Q6/Q7 Based on the package labeling, is it okay or not okay for Jenna to use Orlistat?	<u>Reviewer</u> Correct Acceptable Total	90 0 90	<u>Reviewer</u> Correct Acceptable Total	86 0 86	<ul style="list-style-type: none"> • <i>It’s good for dieting if you eat the right food.</i> • <i>It might help her.</i> • <i>It doesn’t have anything to do with absorbing food problems.</i> • <i>It won’t make her sick or interfere with the program.</i> • <i>She can take only part of the dosage and see what happens.</i> • <i>The drug helps with absorption.</i> • <i>This product could help your digestion.</i> • <i>I’ve never heard of not absorbing food.</i>
The label states in the Warnings section: Do not use . . . <ul style="list-style-type: none"> • if you have been diagnosed with problems absorbing food. 					

The “Jenna” scenario (Table G / Card D above) indicates that the “correct” response rate on the food absorption scenario was fairly high (86%-89%) but as with the scenario about cyclosporine, several respondents – in this case 8 – incorrectly said that the warning about problems absorbing food was not mentioned on the box/package/ label, even though it is clearly stated in the Drug Facts Label. A further 6 subjects gave explanations which seemed to imply that Jenna’s wish to lose weight was more important than her inability to absorb food, and the remaining 15 respondents provided a variety of rationalizations why it’s okay for Jenna to use Orlistat even though she has problems absorbing food. Examples include:

- *It’s good for dieting if you eat the right food.*
- *It might help her.*
- *It doesn’t have anything to do with absorbing food problems.*
- *It won’t make her sick or interfere with the program.*
- *She can take only part of the dosage and see what happens.*
- *The drug helps with absorption.*
- *This product could help your digestion.*
- *I’ve never heard of not absorbing food.*
- *It doesn’t say anything under warnings about it.*
- *I didn’t read it.*
- *I don’t see anywhere that it is a red flag.*
- *Well, the box does not say anything about absorbing food.*
- *I didn’t see anything about it not being okay.*
- *Only if she has trouble absorbing fat.*
- *She wants to lose weight.*
- *This is supposed to be good for weight loss.*

The “Sharon” scenario (Table J / Card Q below) indicates that 97% of the GP and 94% of the LL subjects clearly understood that it is “not okay to use Orlistat if allergic” to the drug.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
Table J / Card Q Not okay to use Orlistat if allergic. Sharon is overweight and would like to use Orlistat for weight loss. She is allergic to Orlistat. Q 29/Q30 Based on the package labeling, is it okay for Sharon to use Orlistat?	<u>Sponsor</u> Correct 97 Acceptable 2 Total 99 <u>Reviewer</u> Correct 97 Acceptable 0 Total 97	<u>Sponsor</u> Correct 94 Acceptable 3 Total 97 <u>Reviewer</u> Correct 94 Acceptable 0 Total 94	The label states under Warnings : “Do not use if you are allergic to any of the ingredients in Orlistat capsules.” Ask a doctor or pharmacist is NOT an acceptable response for this scenario.

Results Relating to Drug Facts Label – Warnings – Ask a doctor before use if you have . . .

Two scenarios were designed to test understanding of the important warning that a doctor must be consulted before using Orlistat if the consumer has gallbladder problems or kidney stones.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
Table K / Card G Not okay to use Orlistat if had kidney stones in the past. Kate is overweight and has had kidney stones in the past. She would like to start taking Orlistat to help her lose weight. Q11/Q12/Q13/Q14 Based on the package labeling, is it okay or not okay for Kate to use the product?	<u>Sponsor</u> Ask doctor 53 Correct 2 4 Correct 3 2 Not okay 38 Total 97 <u>Reviewer</u> Ask doctor 53 Correct 2 4 Correct 3 2 Acceptable 38 Total 97	<u>Sponsor</u> Ask doctor 44 Correct 2 2 Correct 3 4 Not okay 47 Total 97 <u>Reviewer</u> Ask doctor 44 Correct 2 2 Correct 3 4 Acceptable 47 Total 97	The label specifically states: Ask a doctor before use if you have gallbladder problems or kidney stones , yet 5 respondents said that the package/label did not mention this point, and one respondent said it would be okay to take Orlistat because “She isn’t really sick. She just has a kidney problem.” It is <u>not</u> acceptable to answer “ask a pharmacist first.” The answer should be “ask a doctor.” Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable. Note that strictly CORRECT responses per label instructions are low (49%-59%).

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
Table L / Card Y Not okay to use Orlistat if having gallbladder problems. Ben is overweight and is considering using Orlistat. He has been having problems with his gallbladder. Q40/Q41 Based on the package labeling, is it okay or not okay for Ben to use Orlistat?	<u>Sponsor</u> Correct 1: Ask doctor 60 Correct2 1 Not okay 38 Total 99 <u>Reviewer</u> Correct 60 After Probe 1 Acceptable 38 Total 99	<u>Sponsor</u> Correct 1: Ask doctor 45 Correct 2 2 Not okay 50 Total 97 <u>Reviewer</u> Correct 45 After Probe 2 Acceptable 50 Total 97	The label specifically states: Ask a doctor before use if you have gallbladder problems or kidney stones . It is <u>not</u> acceptable to answer “ask a pharmacist first.” The answer should be “ask a doctor.” Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable. Note that strictly CORRECT responses per label instructions are low (47%-61%).

With regard to the “kidney stones in the past” scenario (Table K / Card G), although only 59% of the GP and 49% of the LL group gave the truly correct answer “ask a doctor,” it could be argued that the 38% and 47%, respectively, who said that it would NOT be okay to take the product gave acceptable answers, since no harm would come to consumers who assimilated the notion that it is “not okay” to take Orlistat if you have had kidney stones in the past, rather than following the label directive to “ask a doctor.” Either way, the safety concern is avoided.

Similarly, on the issue about gallbladder problems (Table L / Card Y) although only 61% of the GP and 47% of the LL group gave the truly correct answer “ask a doctor,” again, the 38% and 50%, respectively, who responded that it would not be okay to take Orlistat, brings the total of correct/acceptable answers to above the 95th percentile, which alleviates the safety concern on this issue.

Results Relating to Drug Facts Label – Warnings – Ask a doctor or pharmacist before use if you are ...

- taking medicine for diabetes. Your medication dose may need to be adjusted during weight loss.
- taking Warfarin (blood thinning medicine).
- taking other weight loss drugs.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
<p>Table M / Card B</p> <p><u>Not okay to use Orlistat while taking Warfarin.</u></p> <p>Jim is overweight and suffered a mild heart attack. As a result, his doctor put him on Warfarin, a prescription blood thinning medication. Jim has just purchased Orlistat and would like to start taking it as a weight loss aid.</p> <p>Q2/Q3 Based on the package labeling, is it okay or not okay for Jim to start using Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct 1:</p> <p>Ask d/p 28</p> <p>Not okay 65</p> <p>After Probe 1</p> <p>Total 93</p> <p><u>Reviewer</u></p> <p>Correct 28</p> <p>After Probe 1</p> <p>Acceptable 65</p> <p>Total 93</p>	<p><u>Sponsor</u></p> <p>Correct 1:</p> <p>Ask d/p 22</p> <p>Not okay 71</p> <p>After Probe 0</p> <p>Total 93</p> <p><u>Reviewer</u></p> <p>Correct 22</p> <p>After Probe 0</p> <p>Acceptable 71</p> <p>Total 93</p>	<p>The label specifically states: Ask a doctor or pharmacist before use if you are taking Warfarin (blood thinning medicine), yet 13 respondents said there was nothing about this restriction/contraindication on the label/package; others missed the connection between a heart attack and taking Warfarin, and still others confused the warning about transplant medication with the Warfarin warning.</p> <p>Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable.</p> <p>Note that strictly CORRECT responses per label instructions are very low (22%-28%).</p>
<p>Table N / Card S</p> <p><u>Not okay to use Orlistat if currently taking medicine for diabetes.</u></p> <p>Charlie is overweight and would like to lose weight. He is diabetic and takes a prescription medicine to treat his condition.</p> <p>Q32/Q33 Based on the package labeling, is it okay or not okay for Charlie to use Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct:</p> <p>Ask d/p 45</p> <p>Not okay 50</p> <p>Acceptable 2</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Correct 45</p> <p>Not okay 50</p> <p>Acceptable 2</p> <p>Total 97</p>	<p><u>Sponsor</u></p> <p>Correct:</p> <p>Ask d/p 39</p> <p>Not okay 56</p> <p>Acceptable 2</p> <p>Total 97</p> <p><u>Reviewer</u></p> <p>Correct 39</p> <p>Not okay 56</p> <p>Acceptable 2</p> <p>Total 97</p>	<p>The label specifically states: Ask a doctor or pharmacist before use if you are taking medicine for diabetes. Your medication dose may need to be adjusted during weight loss. Yet 6 respondents missed this warning on the package label.</p> <p>Strictly speaking, it should not be acceptable to answer “Not okay,” since that is not the information provided in the label. However, since no harm would come to a consumer who selects NOT to take the product, this response could be acceptable.</p> <p>Note that strictly CORRECT responses per label instructions are very low (39%-45%).</p> <p>Acceptable responses after two probes included answers where subject said either “adjust diabetic medicine” or “ask a doctor/pharmacist first.”</p>

Table M / Card B and Table N / Card S (above) indicate results similar to those revealed in the kidney stone and gallbladder scenarios, which required consumers to “ask a doctor” before choosing to use Orlistat. In the “Jim” and “Charlie” scenarios, concerning the directive to “ask a doctor or pharmacist” before using Orlistat if you are either diabetic or you are currently taking Warfarin for heart problems, between 50% to 71% of the respondents did not assimilate the “ask a doctor or pharmacist” instruction. However, they said that it would not be okay to take Orlistat in these situations, which may alleviate the safety concern in these cases. The combination of the correct response “ask a doctor or pharmacist before use” and the acceptable response “not okay to use Orlistat” brings the scores above the 90th percentile.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
<p>Table O / Card V</p> <p><u>Okay to use Orlistat if not currently taking any other medication for weight loss.</u></p> <p>Kevin is overweight and is interested in trying Orlistat to lose weight. Kevin has tried other weight loss products in the past, but is not using any other drugs for weight loss at this time.</p> <p>Q 36/Q37 Based on the package labeling, is it okay or not okay for Kevin to use Orlistat?</p>	<p><u>Sponsor</u></p> <p>Correct 96</p> <p>Acceptable 2</p> <p>Total 98</p> <p><u>Reviewer</u></p> <p>Correct 96</p> <p>Acceptable 0</p> <p>Total 96</p>	<p><u>Sponsor</u></p> <p>Correct 94</p> <p>Acceptable 4</p> <p>Total 98</p> <p><u>Reviewer</u></p> <p>Correct 94</p> <p>Acceptable 0</p> <p>Total 94</p>	<p>The label specifically states: “Ask a doctor or pharmacist before use if you are taking other weight loss drugs.”</p> <p>But notice that the scenario specifically states that Kevin is NOT using any other drugs for weight loss at this time. The correct response, then, is that it is “okay” for Kevin to take Orlistat.</p> <p>Is it “acceptable” to respond “ask a doctor or pharmacist?”</p> <p><u>Note:</u> We need to develop a consistent policy on whether or not <u>only</u> the strictly called-for “correct” response to the scenario and question is the sole CORRECT answer, or if we will accept alternative responses as either correct or acceptable.</p>

The “Kevin” scenario (Table O / Card V above) yielded correct responses above the 90th percentile, indicating that respondents clearly understood the directive that they should “ask a doctor or pharmacist” before using Orlistat if they are currently taking any other medication for weight loss.

Directions – The Need to Take a Multivitamin Each Day at Specific Times

Table R / Card O (below) reports results for what could be regarded as one of the six most important scenarios and issues examined in this study – the need to understand the importance of taking a daily multivitamin, either 2 hours before or 2 hours after taking Orlistat. The key information transfer element is this: Orlistat can rob the body of fat soluble vitamins, therefore it is important for those taking Orlistat to supplement their diets with a daily multivitamin, but the vitamin supplement will be wasted (literally) if not taken in the precise time-frame instructed in the label.

Only 47%-48% of the General Population group and 34%-36% of the Low Literacy group correctly responded that in order to ensure adequate vitamin absorption, a multivitamin should be taken once a day, 2 hours before or 2 hours after taking Orlistat, even though this instruction is clearly stated in the Directions section of the Drug Facts Label.¹ Approximately a quarter to a third of all respondents reverted to “default” answers such as “ask a doctor” or “ask a doctor or pharmacist” or “call the 1-800#” on the package labeling or “look in the User’s Guide/Manual/ Reference Card” in answering the questions about vitamin absorption. About a third of all the subjects could not state correctly the instruction about taking the multivitamin either 2 hours before or 2 hours after taking the Orlistat capsule.

¹ I might be willing to consider 22 GP and 14 LL responses coded by Sponsor as “acceptable for Question 27, and 21 GP and 15 LL responses coded by Sponsor as “acceptable” on Question 28, if additional verification and explanation of these responses were provided by GSK. It would also be helpful to know whether the information was simply overlooked in the label, or if it was misunderstood. Perhaps recognition and recall may have been better if the instruction were placed in a more prominent position in the label.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
<p>Table R / Card O</p> <p><u>Concern about vitamin absorption.</u></p> <p>Terry is overweight and would like to use Orlistat for weight loss. She is concerned that she will not be able to absorb the vitamins in the food if she starts taking Orlistat.</p> <p>Q 27 Based on the package labeling, what, if anything, should Terry do about this concern?</p> <p>The order in which information is presented is an important factor in whether or not it is noticed, read at all, and/or recalled. In order to boost the likelihood that consumers will read the crucial instruction about taking a daily multivitamin, 2 hours before or 2 hours after taking Orlistat, it might be better to move the instruction higher up in the “Directions” section, or even move it into the “When using this product” section.</p>	<p><u>Sponsor</u></p> <p>Correct 69</p> <p>Acceptable 24</p> <p>Total 93</p> <p><u>Reviewer</u></p> <p>Correct 47</p> <p>Acceptable 0</p> <p>Total 47</p> <p>Per the label instructions, the <u>only</u> correct answer for this scenario and question is: “take a multivitamin once a day, 2 hours before or 2 hours after taking Orlistat.”</p> <p><u>None</u> of the Sponsor’s other so-called “correct” responses, nor any of the Sponsor’s so-called “acceptable” answers, are valid.</p>	<p><u>Sponsor</u></p> <p>Correct 50</p> <p>Acceptable 38</p> <p>Total 88</p> <p><u>Reviewer</u></p> <p>Correct 36</p> <p>Acceptable 0</p> <p>Total 36</p> <p>Per the label instructions, the <u>only</u> correct answer for this scenario and question is: “take a multi-vitamin once a day, 2 hours before or 2 hours after taking Orlistat.” <u>None</u> of the Sponsor’s other so-called “correct” responses, nor any of the Sponsor’s so-called “acceptable” answers, are valid.</p>	<p>The Drug Facts Label states in the Directions section: “to ensure adequate vitamin absorption, you should take a multivitamin once a day, 2 hours before or after taking Orlistat capsules.”</p> <p>The purpose of this instruction is to ensure that fat-soluble vitamins are not wasted by being excreted if taken at the same time as Orlistat. Hence it is crucial for consumers to understand not only the importance of taking a multivitamin each day, but also to realize that the multivitamin must be taken and digested 2 hours before or 2 hours after taking Orlistat (NOT any closer in time to taking Orlistat).</p> <p>The issue/information conveyed in the scenario is vital for proper health while taking Orlistat. It is, therefore, very worrying that correct response rates are so low – only 47% among the GP group and only 36% among the LL group.</p> <p>The fact that more than half to almost two thirds of the subjects responded to this question incorrectly indicates that they completely missed the information/ instruction in the label and this is worrying. They said such things as:</p> <ul style="list-style-type: none"> • Do nothing • Lower dosage • Look at warnings and side effects • Don’t know • Call 1-800# • Look in User’s Guide/Manual/Reference Card • Ask a doctor/pharmacist • Eat a more balanced diet
<p>Table S / Card P</p> <p><u>Recommended timing for taking a multivitamin.</u></p> <p>Q28 Based on the package labeling, what is the recommended timing for taking a multivitamin to ensure adequate vitamin absorption?</p>	<p><u>Sponsor</u></p> <p>Correct 48</p> <p>Acceptable 31</p> <p>Total 79</p> <p><u>Reviewer</u></p> <p>Correct 48</p> <p>Acceptable 0</p> <p>Total 48</p>	<p><u>Sponsor</u></p> <p>Correct 34</p> <p>Acceptable 31</p> <p>Total 66</p> <p><u>Reviewer</u></p> <p>Correct 34</p> <p>Acceptable 0</p> <p>Total 34</p>	<p>Per the label instructions, the <u>only</u> correct answer for this question is: “2 hours before or 2 hours after taking Orlistat.”</p> <p>The purpose of the instruction is to ensure that fat-soluble vitamins are not wasted by being excreted if taken at the same time as Orlistat. It is crucial for consumers to understand not only the importance of taking a multivitamin each day, but to realize that the multivitamin must be taken and digested 2 hours before or 2 hours after taking Orlistat (NOT any closer in time to taking Orlistat).</p> <p>The information sought in this question is vital for proper health maintenance while taking Orlistat. It is, therefore, very worrying that correct response rates are so low: only 48% among the GP group and only 34% among the LL group.</p> <p><u>None</u> of the Sponsor’s other so-called “correct” responses, nor any of the Sponsor’s so-called “acceptable” answers, are valid. How could it possibly be “correct” to answer: “<u>one</u> to two hours before meals?” or “<u>one</u> to two hours before or after meals?” Similarly, how could it possibly be “acceptable” to answer the question with any of the following?</p> <ul style="list-style-type: none"> • Daily for six months, once a day. • Before a meal. • Six months. • Once a day, 2 hours before. [Before what?] • After you eat.

For the scenario in Table W / Card L, designed to test comprehension of how to decrease likelihood of loose stool and bowel changes, comprehension levels were low, especially in the low literacy group: only 72% of GP and 48% of LL subjects understood that “You can decrease the likelihood [of loose stool and bowel changes] by reducing the fat in your diet.” There were several idiosyncratic verbatim responses for this scenario, including: “She should drink more fluids/ Drink a lot of water/ Increase water intake.” “Eat less calories/ eat less.” “Take a multivitamin.” “Take something to firm her up/ Take other medication to help with this problem.” “She should take less fiber, not prune juice/ cut back on fruit because it irritates your bowels.” For the Table T / Card X scenario, concerning what to do if the weight loss goal is not met after 6 months of using Orlistat, comprehension levels were in the 70th percentile for both the GP and LL groups. This may be adequate but is not particularly good, given the straightforward nature of the label instruction to “talk to your doctor” about the situation. An acceptable response was to call the 1-800 phone number for advice.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
<p>Table W / Card L</p> <p><u>How to decrease likelihood of loose stool and bowel changes.</u></p> <p>Peggy is overweight and has been taking Orlistat for 1 week. She has noticed that she is having loose stool and bowel changes.</p> <p>Q23 Based on the package labeling, What, if anything, should Peggy do to decrease the likelihood of this happening?</p>	<p><u>Sponsor</u> Correct 72</p> <p><u>Reviewer</u> Correct 72</p>	<p><u>Sponsor</u> Correct 48</p> <p><u>Reviewer</u> Correct 48</p>	<p>The Warnings section of the Drug Facts Label specifically explains that: “You can decrease the likelihood [of loose stool and bowel changes] by reducing the fat in your diet.” Based strictly on the label language, then, only a response that says Peggy should “reduce the fat in her diet” is the correct response.</p> <p>The responses coded by Sponsor as “acceptable” are NOT appropriate. Also, the “ask a doctor/pharmacist” response is a weak default option and is not favored for OTC products. 2% GP and 8% LL of subjects used this default response and were coded “acceptable.”</p> <p>There were some very interesting “incorrect” open-ended responses:</p> <ul style="list-style-type: none"> • She should drink more fluids/ Drink a lot of water/ Increase water intake. • Take a multivitamin. • Eat less calories/ eat less. • Take something to firm her up/ Take other medication to help with this problem. • She should take less fiber, not prune juice/ cut back on fruit because it irritates your bowels.

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304) %	Low Literacy (n=160) %	Comments, Observations and Open-Ended Responses
<p>Table T / Card X</p> <p><u>Weight loss goal not met after 6 months.</u></p> <p>Melissa has been using Orlistat for 6 months to reduce her weight. She has not yet reached her weight loss goal.</p> <p>Q 39 Based on the package labeling, what, if anything, should Melissa do now?</p>	<p><u>Sponsor</u> Correct 75 Acceptable 3 Total 78</p> <p><u>Reviewer</u> Correct 75 Acceptable 1 Total 76</p>	<p><u>Sponsor</u> Correct 64 Acceptable 11 Total 75</p> <p><u>Reviewer</u> Correct 64 Acceptable 11 Total 75</p>	<p>The correct response based on the label is “talk to your doctor.”</p> <p>An acceptable response would be to call the 1-800 phone number for advice.</p> <p>Given the very simple and straightforward nature of this instruction, it is hard to understand the relatively low correct response rates: 75% for GP and 64% for LL. I am inclined to think that the point may have been overlooked because of its positioning relatively far down in the drug facts label – many consumers simply don’t read all the way to the end of a set of instructions. However, it probably needs to stay where it is because other instructions may deserve greater weight and prominence in the list than this particular one. (See studies on recall and comprehension based on the ordering and/or saliency of information).</p>

It's Not Okay to Take Orlistat While Breastfeeding

Information Transfer Objectives, Scenario and Study Questions	General Population (n=304)		Low Literacy (n=160)		Comments, Observations and Open-Ended Responses
		%		%	
Table H / Card E					
<u>Not okay to use while breastfeeding.</u>	<u>Sponsor</u>		<u>Sponsor</u>		Although 95% of the General Population group and 92% of the Low Literacy group correctly responded that it is “not okay” to use Orlistat if breastfeeding, 12 subjects responded that the label did not warn against taking Orlistat if breastfeeding, and 10 subjects offered a variety of their own rationalizations why it would be okay to take Orlistat even though the label states (perhaps not clearly enough) that breastfeeding is contraindicated: <ul style="list-style-type: none"> o She just wants to lose weight. o She couldn't use it when pregnant, but can use it now. o She isn't really sick or nothing. She just wants to lose weight. o It's not a danger to her. o She's not high risk, baby out of her, and not old. o After 6 to 8 weeks you can diet to lose baby fat.
	Correct	95	Correct	92	
	Acceptable	1	Acceptable	1	
Total	96	Total	93		
Marsha had a baby two months ago and is currently breastfeeding. She would like to use Orlistat to help her get rid of the extra baby weight.	<u>Reviewer</u>		<u>Reviewer</u>		
	Correct	95	Correct	92	
	Acceptable	0	Acceptable	0	
Total	95	Total	92		
Q8/Q9 Based on the package labeling, is it okay or not okay for Marsha to start using Orlistat?					
Note: The Drug Facts Label states: “If pregnant or breast-feeding, do not use.”					

The Drug Facts Label states: **“If pregnant or breast-feeding, do not use.”** Although 95% of the General Population group and 92% of the Low Literacy group correctly responded that it is “not okay” to use Orlistat if breastfeeding, 12 subjects responded that the label did not contain the warning and 10 subjects offered a variety of their own rationalizations why it would be okay to take Orlistat even though the label states (perhaps not clearly enough) that breastfeeding is contraindicated:

- *She just wants to lose weight.*
- *She couldn't use it when pregnant, but can use it now.*
- *She isn't really sick or nothing. She just wants to lose weight.*
- *It's not a danger to her.*
- *She's not high risk, baby out of her, and not old.*
- *After 6 to 8 weeks you can diet to lose baby fat.*

In trying to understand the reasons for these incorrect responses, several questions and possible explanations come to mind:

- Were the “incorrect” responses predominantly given by male respondents? Males may have overlooked a warning referring to pregnancy and breast-feeding, saying to themselves that the warning doesn't pertain to them so they can skip over the information. Younger, unmarried males may be even more likely to ignore the warning.
- If women were among the “incorrect” responders, and particularly if there were women who are mothers or who are of childbearing potential, this is a serious issue and we need to know and ask “why?” would they ignore such an important warning.
- Perhaps certain consumers do not comprehend the nature of systemic drugs – they don't realize that if a drug is in the blood stream it is also in the mother's milk.
- Perhaps there are some cultural markers that influence certain people to ignore or override serious warnings.
- Maybe the urge to be thin (e.g., lose the extra pounds gained during pregnancy) is more important in a person's mind than the health of a baby.
- Perhaps there is a lack of understanding as to *why* it's not good for a baby to ingest breast milk laced with Orlistat, and if the consequences were explained to people, the nature of their thinking would change.

Answers to some of these questions might be obtained by examining “who” (gender/age/marital status/ethnicity) gave “incorrect” responses, and then by asking follow-up questions to delve more deeply into “why” they answered as they did.

SCENARIOS DESIGNED TO ENCOURAGE EXTRAPOLATION

The study had the good intention of including a couple of scenarios that would require the subjects to extrapolate from the label information and make the kinds of *ad hoc* decisions that often face consumers of OTC drugs in the real world. The subjects did reasonably well on these scenarios – Questions 4/5 and 17/18 (GP scores were GP 87% and 80%; LL scores were 79% and 66%, respectively). However, the two scenarios and questions generated some unforeseen problems which are described in detail below.

1. Okay to use Orlistat if experiencing problem sleeping (Card C scenario in Table B):

Lisa is overweight and is interested in losing a few pounds. She has been having problems sleeping lately. Lisa is thinking about using Orlistat for weight loss.

Q4/Q5 Based on the package labeling, is it okay or not okay for Lisa to use Orlistat?

Subjects were specifically told by the study interviewers (per their script) that it is the content of the package labeling that is being tested, not previous experience or common sense. The scenario was designed to test whether or not consumers would realize that it is alright to take Orlistat even if a person is having trouble sleeping, in other words, insomnia is not generally a contraindication for using Orlistat. Neither the Drug Facts Label, nor anything in the Tables of Contents for the various Guides, disclosed any directions or information concerning insomnia and the use of Orlistat. That being the case, a correct answer to the scenario question is, in fact, that **the package/label does not mention this**. Yet the subjects who gave that response were coded as having answered incorrectly.

There are actually two correct responses to this question:

1. The first is the response that the Sponsors were looking for, which would have been something like this: “It doesn’t mention anywhere in the labeling that you shouldn’t take Orlistat if you are having trouble sleeping, therefore it would be **okay** for Lisa to take Orlistat even if she’s been having problems sleeping lately.”
2. The second correct response is actually that none of the packaging, labeling or guides mention anything about this issue (insomnia). A total of 13 respondents gave CORRECT variations on this answer but were coded as “INCORRECT.” Examples coded as “incorrect” include:
 - Don’t see anything about sleeping.
 - I couldn’t find on the back of the package where the information is stated.
 - I don’t remember reading anything about that.
 - Didn’t see it on the box.
 - It doesn’t say anything about problems with sleeping.

An “acceptable” alternative to the latter response would have been one supplemented with additional caveats such as: “The labeling doesn’t say anything about trouble sleeping. She should check with her doctor or a pharmacist in case she’s taking some medication to help her sleep that might not be good to take along with Orlistat.”

What *should* have been coded as “incorrect” but was, in fact, coded as “acceptable” was a response which fabricates something which is NOT in the labeling at all: **“It says if you have problems sleeping, don’t take it until you consult your doctor.”** It is just as worrying that respondents make up things that are not in the labeling as it is that they forget or ignore things that are there.

2. Okay to use Orlistat if experiencing a headache (Card I scenario in Table D):

Frank is overweight and would like to use Orlistat. Frank has a headache today and is not sure if he should start taking Orlistat.

Q17/Q18 Based on the package labeling, is it okay or not okay for Frank to start taking Orlistat today?

Obviously, this scenario was designed to elicit the response that it would be “okay for Frank to start taking Orlistat today” because headaches are not mentioned anywhere in the labeling as a contraindication for Orlistat. However, although neither the label nor guides mentions headaches, several respondents erred on the side of caution when answering this question and, in fact, provided logical and rational reasons for their responses. The open-ended responses revealed three predominant trains of thought:

1. The cause of the headache is unknown, it might be a symptom of something more serious, and Frank should first find out from a doctor what’s causing the headache before starting to take Orlistat.
2. People who suffer from headaches, particularly migraine headaches, often take medicine for the pain. If Frank is taking medicine for his headache he should check with a doctor or pharmacist before starting Orlistat, in case there is a potential drug interaction problem.
3. Frank should wait until his headache has gone before starting to use Orlistat.

Since neither the package labeling nor the Guides refer to headaches, an OTC consumer could hardly be faulted for taking the precautionary steps described above, nor can the study subjects be faulted for choosing to respond that the package/labeling does not mention headaches when, indeed, it does not. Several responses originally coded as “incorrect” should therefore be switched to “acceptable.”

THE DRUG FACTS LABEL

Some elements of the Drug Facts Label may need to be edited/changed:

1. The drug Warfarin, needs to be spelled with a capital “W” (Warfarin) since it is a “Proper Noun.”
2. The warning that orlistat should not be used by women who are pregnant or breastfeeding should be moved into the section directly underneath the heading **Warnings** and **Do not use**, as follows:

Warnings

Do not use

- if you are pregnant or breastfeeding
 - if you are taking cyclosporine (a drug given after organ transplant)
 - if you have been diagnosed with problems absorbing food
 - if you are allergic to any of the ingredients in Orlistat capsules
3. In the **Uses** section, it might help to state the age factor, as follows, since this is an important element of the appropriate use (and purchase) of the drug:

Use

- Promote weight loss in overweight adults, 18 years and older, when used along with a reduced calorie and low fat diet.