Executive Summary

Background
The purpose of a label comprehension study is to evaluate whether or not consumers can comprehend important communication objectives on a product label. When a label comprehension study demonstrates that a label conveys certain messages poorly, the sponsor can revise the label and retest it to try to improve communication. Label comprehension studies should include participants of normal literacy and a low literacy cohort.

The label iteration that respondents understand best can be used to test behavior in an actual use study, and so typically sponsors conduct label comprehension studies before starting an actual use study. This will allow the use of the label with optimal comprehension in the actual use study. For the Mevacor OTC 20 mg development program, the sponsor conducted a label comprehension study after they had started the actual use study.

The sponsor states that the label used in this label comprehension study incorporates the NCEP ATP III cholesterol treatment guidelines, advice and guidance from an academic panel of lipid experts, and feedback from FDA (June 5, 2002 Advice Letter). This label comprehension study was conducted using the package label (carton back panel) that was studied in the actual use study titled: A Consumer Use Study of OTC Mevacor (CUSTOM, Protocol 084).

Primary Objective
The sponsor describes their primary objective as the following:
"Determine the percent of respondents who demonstrate that they comprehend the Mevacor OTC package label used in the CUSTOM actual use study by being able to correctly answer questions about specific elements [communication objectives]as well as apply their understanding to "scenarios" that combine multiple elements [communication objectives].

Methodology
The study was a non-randomized design testing one label using a question-answer format with structured interviews.

The sample was recruited from shopping malls. Respondents were screened in 25 geographically and demographically dispersed malls across the country. The total sample was recruited first followed by the recruitment of additional low-literacy subjects in 17 of the 25 screening sites.

Summary of Results
Taking into account only "correct" responses and not "acceptable" responses (defined by the sponsor as those responses that ". . .did not specifically adhere to the label directions but would pose no potential safety risk".), respondents demonstrated reasonable comprehension of the following communication objectives:

- Comprehension of what condition the product is to be used for
- Dosage information
- Active ingredient in the product
- Understanding that evening is the best time of day to take it
- Scenarios that address prerequisites for using the product, specifically diet, exercise, and appropriate time frame for testing cholesterol in order to decide whether or not to use the product
- Other medications (good comprehension for prescription medications; poor comprehension for non-prescription medications) that require consultation with a health care professional prior to product use or preclude use
- Scenarios that address comprehension of the timing for follow-up cholesterol testing

Taking into account only "correct" responses and not "acceptable" responses, all respondents demonstrated lower comprehension of the following communication objectives:

- Medical conditions that require consultation with a health care professional prior to product use or preclude use (pp.10-18 of the review)
- De-selection based on scenarios that describe events that might occur during product usage that should indicate that they need to stop using the product and/or talk with a doctor (pp.22-27 of the review)
- Self-selection based on scenarios that describe combinations of age, gender, cholesterol levels, risk factors, and other factors that should alert respondents to talk to their doctors before using the product or to not use it at all (pp.28-48 of the review)
- Understanding that a person's cholesterol level will go back up if someone stops using the product (pp.27-28 of the review)
- Scenarios that explore comprehension of the goal message (pp.21-22 of the review)

One percent of the respondents who stated they could use Mevacor OTC "right away" actually self-selected correctly according to the label. Ninety-nine percent of all the respondents who reported that they could start Mevacor OTC right away, self-selected incorrectly because they had at least one contraindication or did not meet eligibility criteria for use.

Overall there was little difference between the cohorts; the Caucasian and non low-literacy cohorts tested similarly to the non-Caucasian and low-literacy cohorts.