

# FINAL REPORT

## Supplementation with Red Yeast Rice /CoQ10 combination and Lipid Metabolism.

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### 1.0 PURPOSE

The purpose of this study was to assess changes in cholesterol factors in subjects who used NOW Foods "Red Yeast Rice 600 mg with CoQ10 30 mg Vcaps®" for 60 days.

### 2.0 DEFINITIONS

"Cholesterol factors" include: Total Cholesterol, HDL, LDL, Triglycerides, and Total Cholesterol/HDL Ratio.

### 3.0 TEST PARAMETERS

**3.1** NOW Foods "Red Yeast Rice 600mg with CoQ10 plus Milk Thistle & Alpha Lipoic Acid" (Item # 3334) was the dietary supplement provided to subjects in this study. No other variables were monitored or controlled during this study.

**3.2** 24 subjects from the initial group of 35 volunteers finished the 60 day trial. All 24 subjects were supplied with 240 capsules of NOW Foods' "Red Yeast Rice 600mg with CoQ10 plus Milk Thistle & Alpha Lipoic Acid" (Item # 3334). 11 subjects were supplied with capsules from Lot #751206. 13 subjects were supplied with capsules from Lot #761118.

**3.3** The label states: "SUGGESTED USAGE: As a dietary supplement, take 2 Vcaps® 1-2 times daily, preferably with meals." For consistency within the group, the subjects were asked to take 2 Vcaps® with their morning meal and 2 Vcaps® with their evening meal.

**3.4** There was no "placebo" group in this test. This was a "dual-arm" study. One group of 11 subjects took Lot #751206. The other group of 13 subjects took Lot #761118. A comparison between the levels of five cholesterol factors in each subject prior to the 60-day trial and at the end of the trial was made.

**3.5** Cholesterol factors tested or calculated included Total Cholesterol, HDL, LDL, Triglycerides, and Total Cholesterol/HDL Ratio.

### 4.0 STUDY PROCEDURES

**4.1** Volunteers were solicited from all NOW Foods employees who participated in the March 2006 Wellness, Inc. Screening Program. The results the subjects received for the cholesterol factors in this screening were used as the base line or starting values.

**4.2** Subjects agreed to the following guidelines and timetables:

- Subjects must not be taking, or begin to take during the course of the study, any medication for a cholesterol-related medical condition.
- Subjects provided their cholesterol factor test results from the March 2006 Wellness, Inc. Screening Program to the Study Director.

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- Subjects agreed to have their blood tested for the same cholesterol factors at the end of the study.
- Subjects provided these second test results to the Study Director as well.
- NOW Foods paid for the second set of tests.
- Subjects took two NOW Foods Item #3334 “Red Yeast Rice 600 mg with CoQ10 30 mg Vcaps®” twice daily, preferably with meals. This serving size corresponded to the label instructions.
- NOW Foods provided 240 capsules of #3334 Red Yeast Rice Vcaps® per participant for the 60 consecutive day study period.
- NOW Foods provided these Vcaps® at no cost to the participant.
- The trial started May 19, 2006 and ran for 60 consecutive days.
- The trial ended on July 16, 2006
- The second set of cholesterol tests was scheduled for the 61<sup>st</sup> day of the study (July 17, 2006).

### 4.3 Number of Subjects, Assignment of Vcap® Lots, and Attrition

- All eligible subjects who responded to the initial request for volunteers were invited to participate in this study.
- The names of the subjects were separated into two groups by gender.
- Members of each of these two gender groups were then randomly picked for receiving either Lot #751206 or Lot #761118. This ensured equal gender ratios in each of the two groups at the start of the study.
- Initial number of subjects was 35.
- Final number of subjects who completed the study was 24.
- Three subjects started and finished one week later than the main group (May 26-July 24, with final testing July 25-28).
- Two subjects dropped out due to reasons directly related to the product (one allergy to milk thistle, one said that the pills gave them unspecified “digestive complaints”).
- Attrition unrelated to the product included: decision to try for pregnancy, not taking the capsules regularly, realized they were on a prescription cholesterol medicine, and “not really concerned about their cholesterol level.”

4.4 No other variables were monitored or controlled during this study.

4.5 Each participant signed an Informed Consent form (attached).

## 5.0 RESULTS

Table 1 shows the complete results for all 24 subjects. Table 2 shows the complete results for Lot #751206. Table 3 shows the complete results for Lot #761118.

These results are summarized in Figures 1, 2, and 2 below. A discussion of each of the five measured cholesterol related factors is given in **Section 5.2**.

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### 5.1 Summary Data

Table 1. All 24 Subjects

Average Change in 60 Days	Total Cholesterol	Triglycerides	HDL Cholesterol	LDL Cholesterol	Total Ratio Cholesterol /HDL
Numerical	-34	-44	1	-26	-0.7
Percent	-15%	-27%	2%	-19%	-15%

Table 2. LOT #751206

Average Change in 60 Days	Total Cholesterol	Triglycerides	HDL Cholesterol	LDL Cholesterol	Total Ratio Cholesterol /HDL
Numerical	-38	-24	1	-34	-0.8
Percent	-16%	-16%	2%	-23%	-17%

Table 3. LOT #761118

Average Change in 60 Days	Total Cholesterol	Triglycerides	HDL Cholesterol	LDL Cholesterol	Total Ratio Cholesterol /HDL
Numerical	-31	-61	1	-20	-0.6
Percent	-15%	-28%	2%	-16%	-14%

### 5.2 Discussion of Results for each Cholesterol Related Factor

**Total Cholesterol:** Both lots showed a significant (average values different at P >95%) decrease in Total Cholesterol at the end of the 60-day trial. Although Lot #751206 had a slightly larger lowering of average cholesterol (38 points compared to 31 points), this group also had a higher average cholesterol count at the start of the trial.

In both groups, the average 16% and 15% reductions are made up of about 1/3 of subjects who dropped 0-10%, 1/3 who dropped 11-20% and 1/3 who dropped 21-30%). One subject showed no change (Lot #761118). The greatest change was 32% (1 subject Lot #751206).

The recommended cholesterol level is <200mg/dL (Wellness Inc). The average cholesterol level for both groups of subjects was reduced from the "above recommended" range to the "recommended range" during the 60-day trial period. The average for Lot #751206 was

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reduced from 234 mg/dL to 196 mg/dL. The average for Lot #761118 was reduced from 221 mg/dL to 190 mg/dL.

**Triglycerides:** Both lots showed significant (average values different at  $P > 95\%$ ) decreases in Total Triglycerides at the end of the 60-day trial. The data are much more variable for this cholesterol factor than for Total Cholesterol. There was greater variability in Lot #761118 (from a subject with a 68% increase to a subject with a 66% decrease) than in Lot #751206 (one with a 2% increase to one with a 59% decrease).

The recommended triglyceride level is  $<150$  mg/dL (Wellness Inc).. The group that took Lot #751206 reduced their average level from 149 mg/dL (just below the recommended limit) to 125 mg/dL. The group that took Lot #761118 started with an average value of 179 mg/dL, which is above the recommended limit. The average value for this group was 120 mg/dL at the end of the 60-day trial.

**HDL Cholesterol:** The averages of the results for subjects in both lots showed small increases in HDL (high density lipoprotein) cholesterol. These results were not significant at the  $P > 95\%$  level. The average values for both groups were already in the “normal” recommended range of 40-59 mg/dL. The slight increases did not result in the averages exceeding this range. This form of cholesterol is considered the “good” form (Wellness Inc), so the increase is movement in the desired direction.

**LDL Cholesterol:** The averages of the results for subjects in both lots showed decreases in the calculated LDL (low density lipoprotein) cholesterol at the end of the 60-day trial. These decreases were significant at the  $P > 95\%$  level. The recommended range for this factor is from 0 to 100 mg/dL (Wellness Inc). The averages for both groups were above this range at the beginning of the trial. Although both groups showed decreases, both groups were still above the recommended range at the end of the 60-day trial. This decrease was -23% for those taking Lot #751206 and -16% for those taking Lot # 761118.

**Total Cholesterol/HDL Ratio:** Given the average lowering of Total Cholesterol and slight increase in HDL described above, it follows that the ratio of Total Cholesterol to HDL Cholesterol decreased in both groups of subjects. These decreases were significant at the  $P > 95\%$  level. This is movement in the desired direction, as studies show that lower Cholesterol/HDL levels are associated with lower risk of heart disease (Wellness Inc).

### 5.3 DATA PRESENTATION:

- Table 1 contains all the data collected during this Study.
- Table 2 contains just the data for subjects who took Lot #751206.
- Table 3 contains just the data for subjects who took Lot #761118.

### 6.0 CONCLUSIONS:

Under the conditions of this study, an improvement in average values of four of the five measured cholesterol factors was shown in subjects taking NOW Foods “Red Yeast Rice 600 mg with CoQ10 30 mg Vcaps®” for 60 days.

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**Figure 1. Average percentage lipid markers changes in 24 volunteers taking NOW Foods “Red Yeast Rice 600 mg with CoQ10 30 mg Vcaps®” twice a day for 60 days without implementing other dietary or lifestyle changes.**

