

PRESS RELEASE

New Clinical Study Affirms Plant Sterol/Stanol Liquid Softgel Supplement as Effective Means of Lowering Cholesterol Levels

Sterol/Stanol Softgels Offer a Convenient Way to Improve Cholesterol Levels

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January 22, 2014 (Northridge, CA) – A research study published this month in the Journal of the Academy of Nutrition and Dietetics demonstrates the effectiveness of a sterol/stanol ester softgel capsule for lowering low-density lipoprotein (LDL) cholesterol in individuals with high cholesterol levels. Plant sterols and stanols occur naturally in plant-based foods and have been shown to decrease cholesterol levels by reducing absorption in the intestinal tract. Pharmavite LLC, makers of Nature Made® brand dietary supplements, provided the sterol/stanol esters used in this study in the form of its CholestOff® softgel dietary supplement. These study results reinforce the findings of earlier similar research and provide reproducible clinical data that healthcare professionals may find useful in making lifestyle recommendations for their patients.

Throughout this study, all subjects followed a heart healthy (National Cholesterol Education Program) diet. In a crossover fashion, all subjects received a sterol/stanol softgel for 6 weeks and a placebo for 6 weeks with the order of treatments randomly assigned. After taking the sterol/stanol softgels for six weeks, reductions were significant versus the placebo period ($P < 0.01$) for LDL cholesterol (-4.3%), non-HDL cholesterol (-4.1%) and total cholesterol (-3.5%).

“This is a significant contribution to our understanding of an esterified plant sterol and stanol based dietary supplements’ role in the reduction of cholesterol levels,” said Dr. Kevin Maki of Biofortis, the clinical research arm of Merieux NutriSciences in Chicago. “Our results show that a softgel capsule can be an effective and convenient way to provide plant sterol/stanol

esters in a non-food matrix.”

The softgel supplement in this study provided 1.8 grams of esterified plant sterols and stanols in two softgels taken twice daily with meals. This dosage is within the range for which positive changes in cholesterol levels in individuals with high cholesterol have been observed in previous studies. Many individuals consuming a typical Western Diet consume as little as 200 milligrams of plant sterols and stanols each day, a level unlikely to change blood cholesterol levels.

“When Nature Made developed the CholestOff dietary supplement we worked to ensure that the dose provided was consistent with the scientific literature that showed a reducing effect on cholesterol levels,” said Dr. James Brooks, Vice President, Science and Technology, Pharmavite, LLC. “Previously, a study was published showing that the tablet form of CholestOff lowered cholesterol levels significantly. This new study of our softgels adds to the assurance consumers can have using this product.”

The randomized, double-blind, placebo-controlled, crossover study involved 30 non-smoking, men and women. Study participants followed the National Cholesterol Education Program (NCEP) Therapeutic Lifestyle Changes (TLC) diet throughout the duration of the study, starting five weeks before the plant sterol/stanol capsules and placebo capsules were administered. The TLC diet is a low saturated fat, low cholesterol diet developed by the National Institutes of Health (NIH) to reduce cholesterol levels to help reduce heart disease risk. Five weeks after starting the TLC diet, subjects were randomly assigned, in a double-blinded manner, to receive either Cholestoff softgels or a placebo softgel that contained only soybean oil and medium-chain triglycerides for six weeks each. Throughout the study, subjects were restricted from consuming any dietary supplements as well as plant sterol and stanol fortified foods.

These study findings demonstrate the effectiveness of plant sterols and stanols from CholestOff softgel capsules for lowering cholesterol levels as part of the NCEP TLC diet in subjects with high cholesterol. The softgel plant sterol and stanol ester capsules are a convenient and appealing option for individuals managing their cholesterol. For some individuals, this option may help with compliance during long-term use. For more information about Nature Made® CholestOff, please visit NatureMade.com.

About Pharmavite LLC

For more than 40 years, Pharmavite LLC has earned and maintained the trust of healthcare professionals, consumers, and retailers by manufacturing high-quality vitamins, minerals and other dietary supplements, and all-natural foods under its Nature Made® and SOYJOY® brand names. Based in Northridge, California, Pharmavite LLC operates as a subsidiary of Otsuka Pharmaceutical Co., Ltd. For more information, please visit Pharmavite.com.

About Mérieux NutriSciences

As part of Institut Mérieux, Mérieux NutriSciences is dedicated to advancing global public health by delivering a wide range of services to the food, nutrition and environment value chains.