New Omega-3 Structure Function Claim for DHA-Rich Algae Oil

Chapel Hill, NC, October 11, 2012 --(PR.com)-- Source-Omega today forwarded new structure function claims for dietary omega-3 intake from a single algae oil. Both omega-3 docosahexaenoic acid (DHA) and omega-3 eicosapentaenoic acid (EPA) are present in their oil. As a supplier, the company has defined DHA-rich algae oil uses in very low density lipoprotein (VLDL) biology. They say the literature clearly defines DHA as the inherent structural omega-3 in the outer lipoprotein phospholipid monolayer, as inherent to the mechanism of VLDL formation and VLDL fatty acid transport in regulated physiology. They say these data are well established in the literature, although the mechanism is what Source-Omega claims they are now able to more clearly define.

“We claim DHA is the definitive omega-3 used by the liver to form VLDL. Also, DHA functions in VLDLs in the circulation to maintain steady state fatty acid transport, which is what appears to dose-dependently modify levels of plasma triglycerides in healthy individuals. We disclaim the intent to modify plasma triglyceride levels for any medical use, but medical doctors may recommend DHA-rich algae oil for this purpose. We think our methods will add compliance and basis to best practices to help guide health professionals and to inform the public health,” said Scott Doughman, PhD, CEO and Chief Scientific Officer at Source-Omega, LLC.

Recently, the company re-launched PURE ONE® DHAlicious™, newly made from the SOURCE OIL™ (DHA Chromista oil), a safe (GRAS) ingredient the company also supplies and licenses to ingredient buyers. The PURE ONE brand is included in the VLDL claims, for example.

PURE ONE DHAlicious is made in the USA as a dietary supplement using privately contracted algae oil affirmed and branded SOURCE OIL. Their pure DHA oil is derived from a 100 percent solventless extraction process.

The use of omega-3 in medical care has become confusing over time because of poorly designed, un-controlled statistical results forwarded by medical doctors, not food scientists. In addition, actionable guidance is being promoted by doctors to educate the public, without actually testing their statistical findings in real human studies.

Medical claims surrounding omega-3 are thus being rejected by medical doctors who were erroneously asking that a food supplement act like a drug in disease mitigation. This is not approved, even for medical doctors. The Source-Omega company suggests that an omega-3 used as a drug or as a food is still a food by virtue of an innate omega-3 physiology.

There is solid prevention data behind omega-3 DHA+EPA, studies clearly show, which is what the totality of the omega-3 scientific data has always demonstrated, trade groups have argued. Because DHA is not a drug, it is intended to provide quality of life benefits correlated with methods of self-care.

For structure function claims, only supplements are allowed to detail nutritive as well as non-nutritive effects. Omega-3 DHA is not a drug, although often inaccurately described as a drug by medical doctors.
Structure function claims do not imply a mitigating benefit, even if there is one. For example, the scientific literature suggests steady state doubling of omega-3 levels lowers plasma triglyceride levels in healthy people. But the company is claiming that any omega-3 benefits are physiological and not toxicological, not medical.

Permitted structure/function statements:
Source (www.fda.gov): “Dietary supplement labels or labeling may - bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims.”

Claims and General Substantiations:
DHA-rich algae oil branded SOURCE OIL™ is an ingredient used in consumer finished products. All labels and labeling associated with SOURCE OIL™ contains the following statement: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Claim: Dietary DHA in liver cells is differentially distributed into the phospholipid monolayer of very low density lipoprotein(s) (VLDL(s)).

Supply: Sufficient and well recognized substantiations have been established for what has been taught as DHA algae oil, yet these oils contain DHA+EPA. Therefore, these oils are herein referred to as DHA-rich algae oils. The literature characterizes the oils from Schizochytrium sp., edible algae of the Kingdom Chromista (Chromista oil). Chromista oil has been used by humans for nutritive value for over 20 years. The typical strain will produce DHA+EPA extracted oils that historically have concentrations of DHA at 37 to 42 percent (g/g) and EPA at 0.5 to 3 percent (g/g). All other DHA/EPA ratio formulations of Chromista oil may or may not apply to the literature referenced. DHA-rich algae oil provides named nutrients DHA and EPA as inherent to the ingredient oil, Self-Affirmed Generally Regarded as Safe (GRAS) for foods and supplements. This oil may be unblended or blended with other GRAS oils to produce a food product or dietary supplement.

Scope: DHA is incorporated into the body after differential distribution into the phospholipid monolayer of liver derived lipoproteins. Dietary DHA intake is well defined in controlled human studies using DHA-rich algae oil and from the totality of the omega-3 literature. A structure/function claim of dietary DHA is related to the internal nutrient distribution through the liver. A related non-nutrient claim is distribution of dietary DHA into and through lipoproteins, i.e. plasma lipids that exit from the liver. The scope of the claim is limited to VLDL as the lipoprotein derived from the liver cells. Thus, the claim explains how dietary DHA becomes part of the structure and function of the liver and VLDL.
Liver-VLDL mechanisms define that DHA is distributed to the body through VLDL as a structural and functional component inherent to a normal steady state liver physiology and normal steady state omega-3 physiology. No basis is forwarded in the claim in support of augmentation, mitigation, performance or change, other than to nutritive changes in steady state DHA/EPA concentrations over time. Steady state DHA/EPA concentrations may increase or decrease modestly within a range at steady state in red blood
cells, depending on background dietary intake levels. Changes in steady state omega-3 levels are inherent to changes in intake levels in the diet. Changes in steady state omega-3 levels are indirect and take place over weeks and months. It is pointed out in the science that DHA will convert to EPA in the liver to produce steady state omega-3 levels. EPA is a low abundance omega-3 in the human body and tissues, thus abundant DHA intake ensures a sufficient EPA supply. Omega-3 DHA and some EPA are inherent to the fat transport systems of the human body.

Methods: By practice of DHA-rich algae oil administration by enteral methods for both nutritive and non-nutritive purposes, there are structure/function roles for DHA to be discussed, but these are deemed correlative to any specified outcome other than to measurable steady state omega-3 levels. Fat transport function, as discussed, is not specified to be a benefit and is not based on any daily intake value that is established. Rather, sufficient literature on quantities consumed provides guidance that is within the allowable upper limits established in the United States, namely 2.0 g DHA+EPA omega-3 per day for over the counter products. This does not imply an upper limit on safety. There is an anti-deficiency effect implied by maintaining a normal intake of DHA for nutritive value. For the public health, the safety of the methodology and product is affirmed. DHA-rich algae oil, as defined above, has been published upon in meta-analysis as part of the substantiations. This basis considered qualified controlled human studies of DHA-rich algae oil. DHA+EPA are well known in human metabolism and in the composition data of various human tissues, including the liver, red blood cells, and plasma lipids.

Liver: The ratio of DHA to EPA in a normal VLDL appears dependent on the DHA/EPA ratio composition of liver cells at steady state. It is also shown that the liver incorporates dietary DHA into VLDLs in a preferential manner over other omega-3 fatty acids, regardless of whether DHA was in the diet or not. DHA is inherent to the composition of the liver and VLDL. Addition of dietary DHA adds to total DHA in nascent VLDL particles along with some EPA. Liver omega-3 concentrations may change in relation to dietary intake amounts; however, the composition ratio of DHA and EPA in the liver cells is maintained as normal.

Nutritive Basis: DHA has nutritive structure and function roles in the liver, which maintains a normal total omega-3 composition of about 70 to 80 percent DHA at all times. The liver appears to define the DHA/EPA ratio in VLDL particles. A portion of the DHA and EPA in VLDL is derived from the dietary supply during the postprandial period. A postprandial period with supplemented omega-3 includes metabolism for up to 6 hours following a meal. Over weeks and months, steady state liver omega-3 levels reflect dietary intake levels.

Non-Nutritive Basis: The total DHA on VLDL functions in a non-nutritive manner while in transport through the plasma. Dietary DHA is differentially distributed into the phospholipid monolayer of VLDLs, which is inherent to the structure and function of normal VLDL physiology. These claims inform how omega-3 intake from DHA-rich algae oil becomes incorporated into the human body. The liver is what distributes omega-3 to tissues, uncoupling dietary DHA and EPA intake from any further direct claims. The liver is where DHA is delivered after passing the intestine. In the liver drugs are metabolized. In the liver DHA and EPA are normalized and exit through VLDL to be incorporated into cells as self.
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