

ProAlgaZyme™ cholesterol management potential

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HEPI is focused on isolating and identifying the active cholesterol agents present in PAZ. A study conducted during summer 2009 at Wayne State University's Department of Nutrition and Food Science by Dr. Smiti Gupta demonstrated unequivocally that PAZ filtrates are able to lower LDL cholesterol while raising HDL cholesterol in animal subjects. This bolsters previous studies that indicated similar results in humans and animals, albeit not under the strict conditions imposed by the Wayne State University study.

HEPI launched its final push to isolate and identify the active cholesterol agents, concluding a month-long fractionation process during November and then in December distributing concentrated PAZ samples to various facilities across the US for nuclear magnetic resonance scans, high performance liquid chromatography and mass spectroscopy, to be followed by an entire series of analytical processes to sort through the instrument data and then new biological assays.

When the process is completed, HEPI will file patents and begin the process of bringing its active cholesterol agents to market.

Market background for functional foods

Americans are more interested in functional foods than ever before – a fact that is opening doors for cholesterol-lowering food makers, according to Dr Robert Harwood, principal consultant at UK-based CPL Business Consultants.

Cholesterol management has established itself in consumers' minds: Lower cholesterol and reduce the likelihood of heart disease - it's a simple and easily understood message.

But will cholesterol-lowering food ingredients ever be serious contenders in the cholesterol-lowering market given the competition with drugs and supplements?

That market will depend on:

- How well the ingredient works in lowering cholesterol
- The strength of scientific studies
- What label claims will be permitted by the FDA
- The costs per effective daily dose
- The formulation versatility - will it dissolve readily in water?

A proof-point for manufacturers is that cholesterol-lowering margarines have held margins of 3-4 times the price of conventional margarines, while high-fiber bread rarely obtains any premium at all.

Trends in cholesterol awareness

According to current US National Cholesterol Education Program (NCEP) guidelines, everyone over age 20 should have a blood lipoprotein profile at least once every five years to measure total cholesterol, LDL ('bad' cholesterol), HDL ('good cholesterol') and triglycerides. At present, about 33% all Americans' cholesterol levels are at or above the recommend maximum. Consumer awareness data would suggest there remains a lot of untapped potential in the market.

Popularity of functional foods

Historically, the US 'health' market has been based more on supplements than functional food. Consumers happily pay high prices for supplements but balk at paying even a little more for enriched foods. This may be changing – the recent marketing success of one-shot healthy drinks is the vanguard of a new trend. Recent studies show that the US accounts for 30 percent of worldwide functional product launches. This suggests an increased interest in food as a vehicle for a healthy lifestyle.

Phytosterols and phytostanols dominate the market in a range of products from fruit juices to confectionary chews – they are well researched and were one of the first to gain an FDA-endorsed health claim.

Consumer awareness of other cholesterol-reducing ingredients such as beta-glucan (oats and barely) has also increased. In fact, cholesterol-lowering properties have boosted sales of soy-based products, especially drinks, to health conscious consumers.

Innovations in functional foods and nutraceuticals

Every day there are reports of new cholesterol-lowering ingredients generally coming from three sources – new research on existing products (e.g. hydrocolloids), extracts from 'healthy' plants (e.g. algae) and novel research (e.g. [sterols](#) and stanols).

Some of the newer cholesterol lowering ingredients include rye beta glucan, sugar beet fibre, flax, HPMC, policosanol, inulin, oligofructose, hydrocolloids including pectin, guar, konjac and gum arabic, ALA (alpha linolenic acid) and GLA (gamma linolenic acid), as well as various polyphenols. Many of these ingredients are used not because they are especially healthful or efficacious, but rather because they lend themselves to current food processing technologies and they are relatively inexpensive. In some cases, there is only enough of the ingredient to justify package labeling requirements, not actual dose-dependent efficacy.

Supplements

As stated previously, Americans don't mind paying exorbitant sums for pills and powders that contain some of the very same ingredients as functional foods. The dietary supplement industry still generates \$24+ billion in sales, even in the midst of a severe recession. Like functional

foods and nutraceutical ingredients, supplements follow trends initiated by marketers and reacted to by consumers. Cholesterol, and most specifically raising HDL, is at or near the top of mind for all Americans over the age of 50, who represent more than half the population of the US and much of its personal net worth.

There are few, if any, functional foods, nutraceuticals or supplements that will effectively lower LDL and simultaneously raise HDL with the exception of ProAlgaZyme and its derivatives. This is what's driving the Company's quest to identify and then monetize the cholesterol active agents present in ProAlgaZyme – the prospect of taking the lead in a multi billion industry with a safe and effective cholesterol management food ingredient and free-standing supplement.

Health Claims

In the US, health claims can be made under Health Claims Meeting Significant Scientific Agreement (SSA); Qualified Health Claims (QHCs) and Structure/Function Claims.

Cholesterol-lowering ingredients meeting SSA standards include *Psyllium* husk, beta glucan from oats and barley, soy protein and stanols/sterols. Ingredients with QHCs include nuts, omega-3 fatty acids, B-vitamins and fatty acids.

Structure/function claims are supported by an individual company's evidence and are not pre-approved or endorsed by the FDA. A claim that an ingredient 'lowers cholesterol' requires FDA approval whereas the claim that an ingredient 'helps maintain normal cholesterol levels' can be made as a structure/function claim.

Food manufacturers want ingredients with a sound scientific basis to minimize the risk of losing consumer confidence. That's why ingredients with FDA approval dominate the market, even when that approval is not necessary to market the ingredient. There has always been some debate about whether any such ingredient actually works regardless of FDA endorsement, and whether or not it really needs to.

From the lab to the processing plant

Many studies for new ingredients are *in vitro* or have been carried out in animals. The number translating into positive human clinical trials will be significantly less. But there is a lot of justified interest and many ingredients companies have cholesterol-lowering products at the top of their 'wish list' and those with the goods in hand can capitalize on this opportunity.

Fortunately, ProAlgaZyme is in a rather unique position. Its efficacy has already been proven in humans and animals. The current scientific research underway is focused on isolating the active agents and determining the best possible means of production in large volumes.

The plan is straightforward, even as the execution is time-consuming and expensive – the active ingredient will be back-tested in biological assays and hamsters simultaneously in early-mid January of 2009. At the same time, HEPI will be approaching ingredient manufacturers to establish production and distribution arrangements.

At the mid-point of the hamster safety-toxicity study, interim results will be pulled in order to submit a Phase O application to the FDA and a human safety-toxicity study plan to Wayne State University's IRB. To save time, HEPI will also prepare for a GRAS panel review with the FDA to speed up the food ingredient marketing strategy. The Company is also aiming for the FDA's Qualified Health Claims designation and will have assembled the necessary support by early spring 2010. This is far and way superior to typical structure/function claims and will allow HEPI to command a significant pricing premium for its product.

Multiple simultaneous channels

Therefore, HEPI aims to generate revenue as a functional food ingredient, as a nutraceutical and as a dietary supplement – all available channels permitted by the FDA. In no case will HEPI attempt to market its own branded product. Rather, HEPI will function as a supplier to much larger brand-name food producers and manufacturers. These will include makers of snacks, sports beverages, functional water, medical foods, processed 'health' foods, processed 'enhanced' foods and whole foods into which processed ingredients can be lawfully introduced.

As a supplier to larger producers and marketers, HEPI is not obliged to spend huge sums on advertising, marketing, inventory, shelf-space premiums and all of the expenses associated with retailing. Rather, HEPI will promote itself as a branded ingredient, much in the same way that Super Citri-Max is positioned. This weight-loss ingredient cannot be purchased as a standalone product, yet its logo is prominently displayed on more than 400 hundred food and drink products.

In the case of HEPI's cholesterol agent, the bioactive compound will be given a 'marketing' name (its scientific name is likely to be unpronounceable by most) which is then promoted to the public and large food producers alike. Much like resveratrol enjoyed consumer awareness as an antioxidant long before it was isolated for pharmacological applications, the active agent(s) within ProAlgaZyme will be promoted as a natural ingredient for cholesterol management.