



NEWS GSN NEWS

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A Few Facts From the American Heart Association:

- ♥ Cardiovascular disease kills more than 2.4 million Americans per year, making it the #1 cause of death
- ♥ 61.8 million Americans have some form of cardiovascular disease (CVD)
- ♥ Americans will pay about \$352 billion in 2003 for CVD-related medical costs and disability

Just In Time for Thanksgiving Dinner—New Ideas For Cholesterol Control and Cardiovascular Health Products

Once considered dangerous ground for a marketer of dietary supplements, the FDA's recent approval of some *dietary supplement-specific* cardio health claims has suddenly made Heart Health a hot category.

Vegetable Oil Sterol/Heart Disease Claim

For the first time, the words "may reduce the risk of heart disease" can legally accompany foods or supplements that contain vegetable oil sterols. While the regulations have not been finalized, we have received clarification from FDA about the enforcement discretion that the agency will exercise until such time as the final regs are on the books.

In short, the key formulation requirement is that a qualified product provide at least 800 mg of vegetable oil sterols per day, given in two divided doses with meals.

Since different sterol materials contain varying ratios of the key phyto-sterols, it is also necessary to choose a material that meets specific guidelines ensuring that the product is in line with the research that justifies the health claim. GSN has received confirmation from FDA that the vegetable sterol powder used in

our products meets these requirements and is appropriate for the health claim.

While a similar health claim has been available for high soluble fiber products (like oatmeal or high-dose psyllium powders) for a few years, the new sterol health claim opens the door for smaller and more affordable tablet or capsule formulations.

B-Vitamin/Vascular Disease Claim

If you're a fan of articles with a theme, then you're going to be happy to hear about another FDA-approved health claim which applies to dietary supplements containing vitamin B6, B12, and/or folic acid. In this case, the sexy part of the claim announces that "Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular

disease."

Unlike the sterol claim, there are no significant formulation and/or material sourcing requirements for the B-vitamin claim, other than that the supplement be manufactured to USP guidelines for disintegration and dissolution—both of which are already automatic for any product manufactured by GSN.

While we've known about the link between these B-vitamins and circulating homocysteine levels for years—and they are therefore represented in plenty of existing cardio health formulas—we are now able to get right to the point on product labels.

About the only downside to these claims is the cumbersome disclaimer that must accompany them (see the accompanying graphic).

Here is the full text of the two referenced health claims:

- Foods containing at least 400 mg per serving of vegetable oil **sterol esters**, eaten twice a day with meals for a daily total intake of at least 800 mg, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [product] supplies __ mg of vegetable oil sterol esters.
- As part of a well-balanced diet that is low in saturated fat and cholesterol, **Folic Acid, Vitamin B6 and Vitamin B12** may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

New Regensasure™ Glucosamine

- Non-shellfish
- Non-animal
- Made from a renewable resource
- Meets USP/NF specs for D-glucosamine HCl

A Glucosamine Even Richard Gere Could Love

All right, I'll admit it—I didn't know that Richard Gere was a vegetarian (and a Buddhist vegetarian, at that) until I found him on the list at FamousVeggie.com, but I really liked the whole idea of a famous vegetarian being in the article title. The fact is, he really might get excited about Cargill's new product Regensasure™, the only commercially available brand of non-animal, non-shellfish glucosamine HCl.

While Regensasure™ is more expensive than stan-

dard shellfish-derived glucosamine, we believe that there are significant niche markets that will be happy to have a real alternative.

Besides vegans and vegetarians, the product is ideal for those concerned with shellfish allergies and those whose religious obligations prevent them from consuming shellfish. Furthermore, the growing crowd of environmentally-conscious consumers might opt for a product that is produced exclusively from renewable resources.

Since Regensasure™ is chemically identical to glucosamine HCl, the product enjoys the same high level of clinical substantiation that has made other glucosamine products so marketable. And just as significantly, it can be used in all of the same physical applications: drinks, ready-to-mix powders, effervescent tablets, capsules and more.

Please give GSN a call to see if Regensasure™ fits into your dietary supplement plan either as a new item or as a line extension.

The Evolution of Policosanol

For the past couple of years, policosanol has been gaining popularity as a natural cholesterol control aid. Until now, the commercially-available policosanol products (manufactured from sugar cane wax) have been quite expensive—a problem that has kept policosanol out of quite a few cholesterol formulas.

Because of GSN's substantial buying power, we have been able to negotiate

extremely competitive pricing on a patent-pending source of policosanol that is derived from rice bran wax. The new product will be available in mid-December.

Since our primary concern is always efficacy, our product underwent an extensive independent clinical trial which measured 34 different parameters to compare its efficacy to that of sugar cane wax-derived policosanol. The results were

encouraging, to say the least! After 16 weeks, mildly hypercholesterolemic patients who received the rice bran wax product averaged a 13% reduction in total cholesterol and 20% reduction in LDL cholesterol, which was statistically identical to the sugar cane wax group.

And by shaving nearly 50% off its current cost, we believe that policosanol may finally be accessible to all!

Regulatory Notebook

FYI—Bioterrorism Registration Deadline Is Upon Us

The NNFA provides the following background info:

"The Bioterrorism Act, which Congress passed in 2002, requires FDA to establish record-keeping and registration requirements for those who manufacture, process, pack, transport, distribute, receive, hold, or import food.

"The aim of the law is to allow FDA to quickly identify the sources and recipients of food in order to ad-

dress threats of serious adverse health consequences or death to humans or animals."

In compliance with this law, GSN—as a "domestic or foreign facility that manufactures, processes, packs or holds food for human or animal consumption in the United States"—registered with FDA well ahead of the **December 12, 2003 registration deadline**.

Of great significance to our industry friends, the Bioterrorism Act imposes registration, recordkeeping and import notification requirements that are likely to affect us all.

If you haven't done so already, we strongly urge you to go to the FDA's Bioterrorism Act Information Page for complete instructions, background and future requirements.

<http://www.fda.gov/oc/bioterrorism/bioact.html>

About Garden State Nutritionals

Dietary Supplement Industry Rallies On Capitol Hill

As you are probably aware, on October 21 approximately 130 representatives from the dietary supplement industry descended on Washington, DC to lobby various legislative representatives on two pending bills that would greatly affect the future of the industry.

The day began with a meeting designed to give attendees a detailed overview of some of the issues

confronting the industry. This was followed by a Lobbying 101-type lecture to help the legions of neophyte lobbyists to maximize their meetings with the legislators and their staff.

While responses varied from legislator to legislator, GSN's attendee was happy to report that NJ's two Senators were squarely behind the industry-backed legislation proposed by Senators Tom Harkin and

Orrin Hatch (known as SB 1538).

While neither SB 1538 nor Senator Richard Durbin's controversial bill SB 722 made it to the floor during this busy session of Congress, we believe that the Rally on Capitol Hill was an unmitigated success if for no other reason than the fact that our diverse industry put forth the most unified front since the battle for DSHEA a decade ago.

The World's Leading Custom Supplement Manufacturer

Garden State Nutritionals has built a reputation over three decades as a trusted leader in the formulation, development and manufacture of custom dietary supplements.

We pride ourselves on our ability to innovate, creating more than 2000 new products every year. Our customers have come to rely upon us to give their products the flair, effectiveness and differentiation they need to find success in the marketplace.

Our clients can also count on us to help them beyond formula development and manufacturing, as

we can offer valuable assistance in the areas of strategic marketing, product positioning, regulatory compliance and implementation from package design through distribution.

GSN has been audited and quality approved by key industry certifying bodies, including a GMP "A Rating" from the National Nutritional Foods Association (NNFA).

Our reputation for quality extends around the world to clients in 36 countries. We are one of a select group of manufacturers to have received certification and approval from Australia's Therapeutic Goods Administration

(TGA). As dietary supplements for the Australian market must be manufactured to pharmaceutical standards, TGA approval is the ultimate confirmation of superior quality.

Whether you are in need of a custom formulation, or are looking for a quality GMP manufacturer to produce your existing formula, our philosophy is the same — Garden State Nutritionals is completely committed to the success of every customer.

We welcome the opportunity to lend our experience to your business.

Professional Affiliations and Recognitions:



Certified Manufacturer

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