Nutrition INDUSTRY EXECUTIVE®

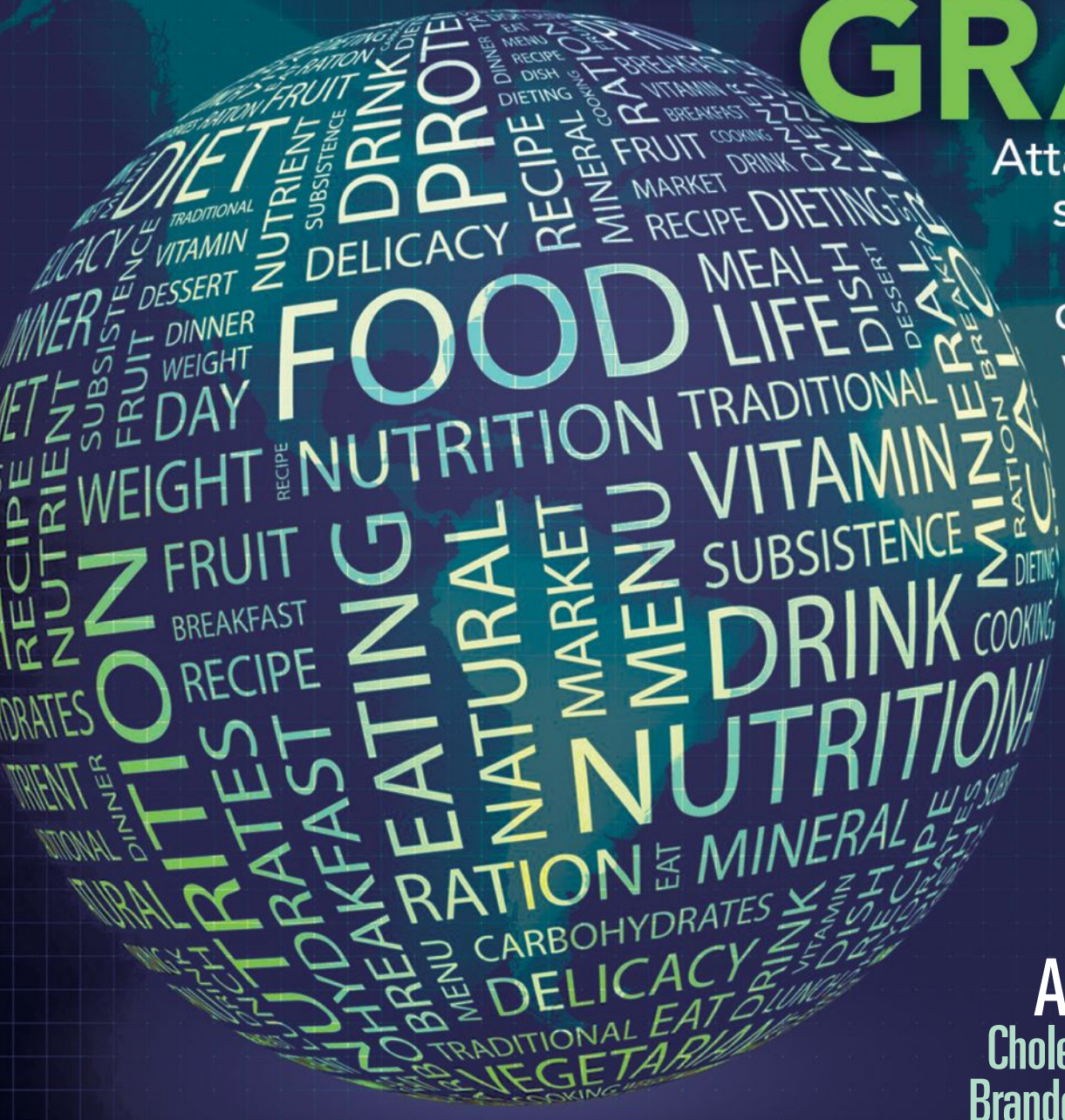
THE BUSINESS MAGAZINE FOR DIETARY SUPPLEMENT & FUNCTIONAL FOOD MANUFACTURERS

www.niemagazine.com

December 2011

GREAT TO BE GRAS

Attaining the status and the role it could play with NDIs



Also Inside:

- Cholesterol Control
- Branded Ingredients
- Tart Cherry
- Halal Certifications

PRSRT STD
US POSTAGE
PAID
VITAMIN
RETAILER, INC

Vitamin Retailer Magazine Inc., 431 Cranbury Road, Suite C, East Brunswick, NJ 08816


Silbinol™
SABINSA'S LINE OF STILBENOLS:
> Silbinol®5%
> Silbinol®Super 30%
> Silbinol®90%
> PteroWhite™ 90% (cosmetic)
RELAX. IT'S NATURAL.
A plant once synthesized pterostilbene to ward off stress. . . and science established its benefits in supporting health and wellness. Silbinol®, carefully extracted from the heartwood of *Pterocarpus marsupium*, captures natural pterostilbene in a convenient, stable, powder form for use in dietary supplements and functional foods. With validated efficacy and safety from cell based and *in vivo* studies, Silbinol® is the natural choice in supplements to support a healthy inflammatory response, cardiovascular health and wellness, a healthy body weight and composition, and normal metabolic functions. Ask about our White Paper for more details.
SABINSA CORPORATION
www.sabinsa.com | info@sabinsa.com
732.777.1111 | 801.465.8400

Stevia FSE™

natural sweetener

USDA Organic / GRAS / KOSHER
Enzyme-Treated for Superior Formulations
Clean Sweet Taste / Zero Calories
Does Not Require Flavor Enhancers or Sugar Alcohols
60 –100 Times Sweeter than Sugar
Best Value Available / Full-Spectrum Herb

USDA ORGANIC

Healthco℠

Healthco℠ brings your vision to reality
offering bulk ingredients, supplements, personal care and private labeling services
630.545.9095 / 800.477.3949 / Fax 630.545.9080 / www.healthco-intl.com

"A" Rated GMP Manufacturing Facility
Organic Certified by QAI
OTC Registered
Low Minimums

Large Selection of Finished Goods and Raw Materials
Liquid Supplement Manufacturing
Stevia and Xylitol Packet Manufacturing
Trademarked Quality Ingredients

Table of Contents

Nutrition Industry Executive®
THE BUSINESS MAGAZINE FOR DIETARY SUPPLEMENT & FUNCTIONAL FOOD MANUFACTURERS
VOLUME 16, NO. 10
December 2012

FEATURES

ALSO INSIDE

COLUMNS

Visit Our Magazine Online at www.niemagazine.com!

2012 Media Planner Now Available! Circulation Increase In 2012 • Ask about our unique advertising opportunities

Connecting Advertisers with the Nutrition Industry in Print and Online!

January/February 2012 Editorial Topics...

- Plant Capacity
- Heart Health
- Digestive Wellness
- Certifications
- Astaxanthin
- Licorice Extract
- Osteoporosis

Ad Closing: 12-30-2011

Nutrition Industry Executive
Delivering your brand message in print and digitally to over **14,000** readers each issue and **GROWING!**

NIE Website
Online resource for dietary supplement and functional food manufacturers.

e-Newsletter
Sent bi-weekly to over **7,000** nutrition industry members!

Contact One of Our Ad Specialists Today:

Russ Fields at 732-432-9600 ext. 102 or e-Mail RussF@niemagazine.com
Roy Kieffer at 719-358-9838 or e-Mail RoyK@niemagazine.com
Scott Blackburn at 303-993-3812 or e-Mail ScottB@niemagazine.com

From Cooperation Back to Conflict

While the industry and the FDA haven't always seen eye to eye, at the beginning of 2011, all signs pointed to a no-nonsense, but cooperative year between the two.

Starting with FDA's Commissioner Margaret A. Hamburg's letter at the close of 2010 announcing the agency's intention to crack down on products marketed as dietary supplements but that contain the same active ingredients as FDA-approved drugs, and the FDA pledging to work with industry trade associations. This industry had no objection to eliminating the bad actors masquerading as quality supplements; the two sides seemed to share a common goal that they could work together to achieve.

From there was the re-launching of the Congressional Dietary Supplement Caucus for the 112th Congress earlier this year. Remember the positive air around the AHPA, CRN, NPA and UNPA collaboration to facilitate discussions among lawmakers about the benefits of dietary supplements, and promoting research into health care saving provided by dietary supplements? Were we wrong to think that bringing Congressional attention to supplements' role in health promotion and disease prevention, and addressing supplement industry regulation was a turning point where there wasn't so much contention between the entities, but a recognition of the industry's inherent value to consumers' well-being?

However, as the mid-year mark hit, the connection began to dissolve.

One such example: June and the year anniversary of industry-wide GMP compliance. While the FDA's assessment at SupplySide East showed 25 percent of facility audits showed deficiencies in manufacturers of all sizes, the responsibility for these shortcomings was split. On one hand, yes, *some* manufacturers took a "wait-and-see" attitude, but many more pointed to ambiguities in the regulations and the unevenness of auditors' experience and approach. Still, others noted that the FDA took its far too long finalizing the cGMP rule.

Then, amidst the industry's uproar over Senator Durbin's Dietary Supplement Labeling Act, the FDA issued its NDI Draft Guidance. Even though FDA's Daniel Fabricant, PhD has been quite vocal about how the NDIs should "come as no surprise," they have been nothing short of a bombshell at every turn, and have further proven FDA's indifference to working with the industry.

Ever since the Draft Guidance was issued, the industry has labored to get a handle on what it would mean if it passed as it stood, and how it could make the FDA aware of the changes that needed to be adopted. The associations worked to inform the industry about the guidance, while collecting comments so they could be submitted in the allotted timeframe.

It quickly became obvious that this mission was far too big to tackle in the window FDA had granted, so petitions for comment extension were sent to the Agency. In addition, Jarrow Formulas Inc. submitted Freedom of Information Act (FOIA) requests so the industry could, in fact, make informed comments based on the FDA's intentions.

While FDA saw fit to give an NDI comment extension, putting us at December 2nd, it has not complied with Jarrow's FOIA requests. Instead, the FDA has given the company, and the industry as a whole, a time-wasting runaround (see pg 8).

Standing on Shaky Ground

As this issue goes to press, we're mere days away from the cutoff for comments regarding the NDI Draft Guidance. Trade associations are working to complete their coordinated comments so the FDA can take into account the industry's concerns, while the Citizens for Health has made a tireless campaign to get 10,000 signatures to get the FDA to withdraw the Guidance altogether. (The last report showed that it had acquired 7,000 in just seven days with a handful of days to go.)

From here the industry is forced to wait until the Agency publishes its final guidance. CRN's Duffy MacKay has said that the "FDA is not obligated to respond within a certain timeframe or necessarily publish a final guidance. But we absolutely don't want this to just sit around as a draft for years … it would be unfair to leave the industry in limbo."

Unfair is an understatement.

Unfortunately, as the industry has worked to comply with FDA, the agency has refused to reciprocate. Together, we'll see what 2012 will hold, with a clear line drawn in the sand and back on opposing sides.

Kate Quackenbush

Nutrition Industry Executive
THE BUSINESS MAGAZINE FOR DIETARY SUPPLEMENT & FUNCTIONAL FOOD MANUFACTURERS

Publisher/Editorial Director
Daniel McSweeney

Associate Publisher
Russ Fields

Advertising Sales Manager
Roy Kieffer

Editor-in-Chief
Kate Quackenbush

Managing Editor
Janet Poveromo

Associate Editor
Shari Barbanel

Assistant Editor
Rajiv Leventhal

Contributing Writers
Paul Bubny

Art Director/Production Manager
Christopher DeCellio

Circulation Manager
Yoko McSweeney

Printing
Quad/Graphics
1700 James Savage Road
Midland, MI 48642

A PUBLICATION OF VITAMIN RETAILER MAGAZINE, INC.

President
Daniel McSweeney

ZYCHROME™

A new generation of chromium has arrived

Research-based ingredients. Uncompromised quality. *Trusted.*

InterHealth Nutraceuticals Incorporated

Improvement for the Irritable

By Rajiv Leventhal

Irritable bowel syndrome (IBS) is the most common functional gastrointestinal (GI) disorder with worldwide prevalence rates ranging from nine to 23 percent, and U.S. rates generally in the area of 10 to 15 percent. Most people with IBS have mild symptoms, though many of them don't recognize IBS symptoms. Yet, IBS is one of the most common disorders seen by physicians.

According to the Rome Foundation, IBS is characterized by abdominal pain or discomfort associated with disordered bowel movement, bloating and distension. Specific causes of IBS are yet to be found, but there are various theories, such as stress, food sensitivity, weakened immune system and a consequence of other intestinal disorders. However, it cannot be predicted accurately what will stop IBS from occurring. Though it does not damage the colon or other parts of the digestive system, IBS is a severe condition that needs to be taken seriously.

"Presently, there is no consensus as to the causes of IBS," said Dallas Clouatre, PhD, consultant for R&D at Jarrow Formulas (Los Angeles, CA). "Low-grade inflammation, altered gut microbiota and changes in the gut immune system likely contribute to the pathogenesis of IBS. [But] there is no one-size-fits-all solution. For instance, bloating, flatulence and abdominal pain may be improved with some approaches that actually lead to a slight increase in the urgency for bowel movements and have no impact at all on other symptoms."

A Mixed Market

While fibers, laxatives and, in some cases, antibiotics are often prescribed for IBS, probiotics for digestive health continue to remain a strong solution.

Lesaffre Human Care (Milwaukee, WI) has launched a new probiotic yeast, Lynside® Pro GI+, to help people maintain digestive comfort. Lynside Pro GI+ is a *Saccharomyces cerevisiae* yeast selected from more than 6,000 proprietary strains. Many preclinical trials and one large clinical trial with 200 volunteers were conducted successfully with Lynside Pro GI+ and two other clinical trials are underway. According to Adeline Cheong, PhD, the company's senior business manager, research concluded that Lynside Pro GI+ at 4 x109 CFU conveniently delivered once daily by one capsule is well-tolerated and reduces abdominal discomfort.

Additionally, a little more than a year ago, Jarrow Formulas launched Ideal Bowel Support, which employs the Institut Rosell-Lallemand's (Montreal, QC, Canada) *Lactobacillus plantarum* 299v strain and contains 10 billion CFU per vegetarian capsule, said Clouatre.

Further, a new study echoes results from adult studies showing that a high-potency lactic acid bacteria supplement may ease the symptoms of IBS in children.

A daily dose of VSL Pharmaceuticals, Inc.'s (Gaithersburg, MD) VSL#3® branded probiotic was found to reduce measures of abdominal pain and discomfort and levels of bloating and gassiness, according to findings published in the *Journal of Pediatric Gastroenterology and Nutrition*. "There is evidence that some probiotics […] have a beneficial role in the dietary management of children and teenagers suffering from IBS," said Stefano Guandalini, MD, lead researcher and professor at the University of Chicago.

"This has the potential to make a real difference for kids who suffer from pain, bloating and discomfort of IBS."

Guandalini and his co-workers conducted their randomized, double-blind, placebo-controlled, crossover study with children aged 4 to 18 years. The children and adolescents were randomly assigned to receive placebo or the probiotic supplement (450 billion CFU) for six weeks. At the end of the intervention, the children underwent a two-week washout period and then crossed over for six weeks of the other intervention. The data showed that, for the 59 children who completed the study, the placebo "was effective in some of the parameters and in as many as half of the patients." However, the probiotic was "significantly superior to it in the primary endpoint, the subjective assessment of relief of the symptoms."

With the continued success of probiotics for IBS, ingredient suppliers also offer other methods of treatment, including herbal. "A number of herbs have demonstrated benefits in IBS," said Clouatre. "Peppermint oil (enteric coated) has been shown to reduce pain via a spasmolytic effect on the smooth muscles in the digestive tract. Other herbs that may provide benefits are turmeric extract, artichoke leaf extract, and a number of herbal combinations."

Furthermore, Chinese herbs support IBS symptoms by helping to maintain normal colon function, added Kathy Birkner, CRNA, PhD, CNC of Pain & Stress Center (San Antonio, TX). "[Manufacturers] should be obtaining good Chinese herbs that do not contain contaminants combined with amino acids." According to the National Center for Complementary and Alternative Medicine, a systematic review of clinical trials for 71 herbal remedies found limited evidence suggesting that some of these herbal remedies might help improve IBS symptoms including abdominal pain, constipation and diarrhea.

Some studies have indicated that prebiotics plus probiotics are more effective than probiotics alone, especially if constipation is involved, said Clouatre. Among fiber supplements, much work has been performed on psyllium. One study found that this partly soluble fiber provided significant pain relief for IBS patients with constipation and/or diarrhea, he said.

Obstacles to Overcome

There are a number of challenges that companies face when formulating ingredients for IBS. For one, multi-strain probiotic products are not a matter of simply mixing up probiotic powders, said Clouatre. "Many otherwise beneficial probiotic bacteria do not play well together. Similarly, many herbs should not be combined with probiotics because they lead to reduced viability. Careful selection of probiotic strains and matching for compatibility therefore are musts," he explained.

Other challenges include claims that can be understood by the consumer and still meet FDA and FTC guidelines, as well as testing and documentation to meet NDI and GMP standards, said Lesaffre's Cheong. "We also have to overcome hurdles [through] collaboration of industrial members and communication to governing authorities."

Nevertheless, natural alternatives are becoming a constant in the IBS category. "A major problem with pharmaceutical and allopathic approaches to IBS is that the rate of treatment success is not high and there are significant side effects," said Clouatre. "Natural treatments tend to offer benefits similar to or better than allopathic treatments, yet avoid the side effects. Doing no harm is always the place to start." **NIE**

FORMOREINFORMATION:

- Jarrow Formulas, (800) 726-0886
- Lesaffre Human Care, (800) 558-7279
- Pain & Stress Center, (800) 669-2256
- VSL Pharmaceuticals, Inc., (866) 438-8753

FDA Takes Action Against Dietary Supplement Maker

The U.S. Food and Drug Administration (FDA) took legal action on November 23 against a dietary supplement maker and owner for substituting ingredients and products without noting the changes on the final product labels. The permanent injunction, filed on behalf of the FDA by the U.S. Department of Justice, would stop the defendants from making and distributing more than 400 products for being in violation of the Federal Food, Drug and Cosmetic Act.

The FDA requested the permanent injunction against ATF Fitness Products Inc. (ATF), Manufacturing ATF Dedicated Excellence, Inc. (MADE), and James G. Vercellotti of Oakmont, PA, owner and operator of both companies. The cGMP regulations require manufacturers to ensure quality in their dietary supplements by controlling all aspects of their processes and procedures. MADE makes more than 400 dietary supplements, including vitamins and minerals, under the brands "Sci-Fit," "Nature's Science" and "For Store Only." ATF purchases dietary supplements exclusively from MADE and distributes them throughout the United States.

This is the first time FDA has taken legal action against a dietary supplement manufacturer of this size for failure to comply with the dietary supplement current good manufacturing practice (cGMP) regulations. The cGMPs for dietary supplements went into effect in 2007, in a stepped process based on company size. This company's compliance date came into effect in 2010, and they did not meet the relevant cGMP requirements after that date.

Dara Corrigan, associate commissioner for regulatory affairs, said the injunction reinforces a commitment to ensuring that supplements meet the cGMP requirements the law establishes.

The government's complaint, filed in the U.S. District Court for the Western District of Pennsylvania, alleges that in addition to "adulterating" and "misbranding" final products, the manufacturer and its owner failed to report serious adverse events associated with products. In one case, an individual who consumed one of the products reported experiencing a spike in blood pressure, hospitalization and a subsequent mild heart attack.

ATF responded in a written statement: "We find it surprising and regrettable that after months of ongoing contact and cooperation with the FDA and the U.S. Attorney's Office to address their concerns with respect to our good manufacturing practices, the FDA found it necessary on the eve of the Thanksgiving holiday to not only file a civil complaint against us, but to issue a press release publishing their allegations. This is despite our ongoing discussions toward an amicable resolution, which addresses the alleged GMP non-conformity in the form of a Consent Decree.

"We would like to clarify that although the press release infers that there is an injunction against the manufacturing company, MADE, this is absolutely not true. In reality, as part of general due process there has been a civil complaint filed, however, ATF has not yet even been served with a copy of the complaint. If, despite good faith efforts, we were unable to resolve this matter with a Consent Decree and the matter proceeded to litigation, we would we have an opportunity to answer the allegations in the complaint before a ruling was made. As has been the case with many manufacturers who have been subject to a GMP inspection, the FDA noted areas where they allege we were not compliant with the cGMPs. We have in the eight months posted inspection and will continue to diligently address those allegations of non-compliance.

"At this juncture, ATF fully anticipates that this matter will be resolved with a Consent Decree and has absolutely no expectations that the terms of the decree will affect the inventory of our vendors and distributors."

For more information, visit www.fda.gov.

FDA Avoids Key Questions in Jarrow Formulas' FOIA

On September 8, 2011 Jarrow Formulas, Inc. (JFI, Los Angeles, CA) sent the FDA a 128-item Freedom of Information Act (FOIA) Request in connection with the New Dietary Ingredient (NDI) Draft Guidance that was issued on July 1.

Since sending the letter, JFI said it has received four responses. The first and third were comments in the form of letters from the public in reaction to the Agency's July Draft Guidance. JFI said the letters were entirely non-responsive to its FOIA Request. The second FDA response was correspondence to the FDA from U.S. Senators Orrin Hatch and Tom Harkin. In its fourth response, the FDA stated that it has no information on 11 of JFI's FOIA Requests, including the statement that the Agency has no earlier drafts of the NDI Draft Guidance. The FDA also stated it had no information on its decision to regard any new formulation, or even a minor change in an existing formulation, as an NDI.

"To date, FDA has offered no meaningful response to JFI's September 8, 2011 FOIA Request," said food and drug attorney Scott Polisky. "The Agency has only sent us information that was already in the public domain."

JFI has recently sent FDA a letter objecting to the non-responsive documents sent, and informing the Agency that its lack of response jeopardizes JFI's ability to submit comprehensive comments before the December 2, 2011 NDI Draft Guidance comment period deadline.

"FDA has a legal obligation to respond to these FOIA Requests in a timely manner," said Jarrow L. Rogovin, founder and president of JFI. "We are simply not going to allow FDA to sidestep answering these crucial questions."

For more information, call (310) 204-6936 or visit www.jarrow.com.

AHPA: CSPI Call for St. John's Wort Labeling Redundant

On November 10, the Center for Science in the Public Interest (CSPI) submitted a petition to the FDA to require cautionary statements on the labels of dietary supplements containing St. John's wort.

In a press release, the organization noted that this popular herb might interfere with a number of drugs and petitioned FDA to require a black box warning to caution against use of any St. John's wort product when taking any medication.

The American Herbal Products Association (AHPA) established a Guidance Policy in 2000 recommending that St. John's wort products be labeled to suggest that consumers seek the advice of their physician if taking any prescription drug.

Additionally, AHPA established a related Guidance Policy in October 2001 that recommends consumers disclose the use of any herbal supplements to their health care provider. As part of this policy, AHPA encourages health care providers to seek out accurate and truthful information about herbs.

"CSPI has not discovered any new information, but is only acknowledging what AHPA has known for many years with regard to the possibility for some St. John's wort ingredients to interact with certain drugs," commented Michael McGuffin, AHPA's president. "But this information is already disclosed through the broad use in the herbal trade of AHPA's labeling policy for St. John's wort, and we do not agree that a black box warning—generally limited to only the most dangerous drugs—is warranted."

"Prescribers of medications need to inform patients of possible food-drug and herb-drug interactions," added Steven Dentali, PhD, AHPA's chief science officer. "Although specific drugs are not identified on the labels of grapefruit juice, leafy greens or St. John's wort extracts, it is widely known that these can affect drug metabolism. In the case of St. John's wort, this concern is limited to certain constituents, as there is no indication that low-hyperforin products cause clinically significant drug interactions."

For more information, visit www.ahpa.org.

WILD Welcomes European Parliament's Approval of Stevia

WILD Flavors GmbH (Erlanger, KY) has reported the recently announced official EU-wide approval of steviol glycosides in foodstuffs. With its global presence and stake in the stevia manufacturer, Sunwin International, WILD stated it is already prepared for a great demand of the calorie-free sweetener from natural sources.

"Early on, we expected a positive EFSA opinion stating that stevia is a safe ingredient in food, and, therefore, we put all of our efforts into developing our high-quality Sunwin Stevia portfolio," said Michael Ponder, CEO of WILD Flavors GmbH. "Our stake in Sunwin International, one of the leading stevia producers, gives us clear-cut advantages. We are optimally prepared for bulk stevia requests as well as product formulation of low calorie products."

WILD has developed Taste Optimization Technology that eliminates the characteristic licorice nuance and bitter aftertaste often associated with stevia.

For more information, call (888) WILD-FLAVORS or visit www.wildflavors.com.

DSM North America to Host 2012 Tribute to Women and Industry

DSM North America (Parsippany, NJ) will serve as Host Company for the 33rd Annual Tribute to Women and Industry Awards Dinner to be held on Wednesday, April 18, 2012 at the Hanover Marriott Hotel in Parsippany. The company will donate $45,000 in cash and services to the YWCA of Central New Jersey's TWIN (Tribute to Women and Industry) Program to help the organization provide career and mentoring services to the women it serves.

"DSM has been part of the TWIN program for many years," said Hugh C. Welsh, president and general counsel of DSM, and honorary chair of the event. "We are honored to host this year's TWIN Awards Dinner and are proud of our decades-long relationship with a program that supports and mentors women throughout central New Jersey, and helps to promote a more diverse and inclusive business environment."

A national and international awards program of the YWCA, TWIN annually recognizes outstanding businesswomen and their companies. Its mission is to honor women who have excelled in their fields and made significant contributions to industry in executive, managerial and professional roles, as well as to salute corporations whose policies and practices encourage high achievement by women and who promote equal advancement opportunities for women of diverse background.

For more information, visit www.ywca-cnj-twin.org or www.dsm.com.

LycoRed Opens New Plant in China

LycoRed Ltd. (Beer Sheva, Israel) has announced the opening of a new plant in Changzhou, China, which will be available for commercial production by the end of 2011. The facility will produce a wide range of premixes for the food and beverage industry for nutritional fortification covering the Asian market. Research conducted by LycoRed shows a growing demand for nutritional premixes in Asia Pacific, in addition to accelerated demand for Lyc-O-Mato® in China, Japan and Thailand. These finding encouraged LycoRed management to build the new facility in China, and to allow the company to establish and develop closer partnerships with key suppliers and provide comprehensive healthy ingredient and premix solutions.

"Building this new plant in China, coupled with our extensive plant in the UK, is in line with our goal to strengthen our position in the Asia-Pacific market and become a preferred supplier of natural functional ingredients to food and beverage companies worldwide," said Morris Zelkha, president and CEO of LycoRed Ltd.

With ecological responsibility in mind, the construction, materials and plant systems used and installed in the plant were selected to minimize energy requirements and optimize the use of water during plant and equipment clean-downs. LycoRed currently is completing equipment validation and securing the necessary quality certifications for production, including FSSC and MUI Halal.

For more information, visit www.lycopene.com.

Naturex Awarded for Successful Integration; Acquires Burgundy Botanical Extracts

Naturex (Avignon, France) received the "Best Acquisition" award at the European Outsourcing Awards ceremony organized in Frankfurt as part of the CPhI trade show held in October. The prize recognizes the company's successful integration of the natraceutical ingredients division into its various business units. Francis Dumont, director of supply chain sourcing of Pfizer, presented the award at a gala dinner event celebrating outsourcing excellence within the pharmaceutical community, and recognized flourishing companies for their outstanding contributions throughout the year.

"The success of this integration is the result of our dynamic team inspired by the same spirit of reactivity. It is a great honor for us to accept this award. We are pleased that our efforts have been recognized this way," said Jacques Dikansky, president and CEO of Naturex. The integration completed the Naturex portfolio, brought a balanced geographical presence between Europe and the U.S., and more than doubled the number of plants worldwide, according to the company.

In other news, Naturex recently announced the acquisition of Burgundy Botanical Extracts, a French manufacturer and supplier of plant extracts for the nutraceutical, pharmaceutical and cosmetics industries.

Flagship brands and products developed by Burgundy over the last 10 years include grape seed and cranberry extracts; UTIrose™, a patented hibiscus extract for use in combating urinary infections; and Iridoforce™, an extract of harpagophytum used in the prevention of arthrosis and joint diseases.

The addition of Burgundy will enable Naturex to strengthen its industrial base and capacities to meet customer needs by developing its expertise in nutraceutical, pharmaceutical and personal care. Burgundy's products will, in turn, benefit from Naturex's industrial and technological expertise in addition to its global sourcing capacity, innovation and the strength of its worldwide commercial network.

"This acquisition fits perfectly with Naturex's strategy for pursuing growth in its different markets. It is an excellent development opportunity in terms of both manufacturing capacity and commercial positioning," said Dikansky.

"Combining the forces of Burgundy with Naturex will contribute to developing the industrial and scientific strengths of both these two entities," said Christophe Magnin, chairman of Burgundy. "Naturex's proactive commercial network will promote greater customer proximity and enhance service quality."

For more information, visit www.naturex.com.

Health Canada Revises Guidelines on *p*-Synephrine Use

Health Canada, a counterpart to the U.S. Food and Drug Administration (FDA), has relaxed and redefined its guidelines for the use of *p*-synephrine, the dominant amine in Advantra Z®, a patented bitter orange extract and the industry's leading natural thermogenic ingredient. The agency's report states that:

1 to 50mg of *p*-synephrine per day for healthy adults is now classified as a Type III health risk: "a situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences."

Products providing up to 40mg of *p*-synephrine in combination with a maximum of 320mg of caffeine per day also have Type III classifications.

Products containing greater amounts of these ingredients are now classified as Type II: "a situation in which use of, or exposure to, a product may cause temporary adverse consequences or where the possibility of serious adverse health consequences is remote."

Health Canada will require cautionary label statements on products containing more than 50mg *p*-synephrine, noting that this dosage should be avoided by children, women who are pregnant and nursing, and people who take blood pressure and/or thyroid medications, sympathomimetics or monoamine oxidase inhibitiors (MAOIs).

Previously, Health Canada's "Guidelines for the Use of Synephrine" limited daily intake of *p*-synephrine to 30mg. Products containing both p-synephrine and caffeine were prohibited without extensive human clinical studies.

"This is very good news for makers of weight management, sports nutrition and energy supplements. Not only because Health Canada's report validates the safety of Advantra Z and *p*-synephrine, but also because this government agency has looked past the hype and evaluated the scientific data behind this tried-and-true thermogenic ingredient," said Bob Green, president of Nutratech, Inc., exclusive distributor of Advantra Z.

Health Canada's "Guidelines for the Use of Synephrine" came to the attention of many U.S. manufacturers and ingredient suppliers in January 2011, when the agency issued advisories in conjunction with product recalls. However, the product recalls were issued because the manufacturers did not obtain the proper licenses from Health Canada—and did not result from any adverse event reports connected to *p*-synephrine, Advantra Z or bitter orange.

For more information, visit www.hc-sc.gc.ca.

InterHealth Presents Weight-Loss Survey and Research Findings

InterHealth Nutraceuticals (Benicia, CA) recently announced the results of a 2011 survey of 45 medical doctors, physician's assistants, nurse practitioners and registered dietitians at the 61st Annual Obesity and Associated Conditions Symposium in Las Vegas, NV. More than 88 percent of health care professionals surveyed believe that weight-loss supplementation is one of many components in a successful weight-management program.

"Many physicians, including bariatricians, believe that surgery is really the last resort for weight loss," said Francis Lau, PhD, FACN, and InterHealth's lead scientist. "Diet, exercise and a focus on lifestyle changes are often the first approach. While exercise and eating right are the best ways to manage weight, 82 percent of those surveyed currently recommend dietary supplements for weight loss."

At the Symposium, InterHealth also presented preliminary data from two randomized, double-blind, placebo-controlled studies on its latest weight-loss ingredient, Merastin™ (the combination of *Sphaeranthus indicus* and *Garcinia mangostana*). Research shows that Merastin works in two weeks to significantly reduce body weight as well as reduce hip and waist circumference. Preliminary results from the second clinical study demonstrate weight loss of 11.5 pounds and waist and hip reduction of 4.7 inches and 2.5 inches, respectively.

"This was an excellent opportunity for InterHealth to reach key targeted influencers in weight-management research and practice. There was a lot of interest in Merastin, many wanting further information on the clinical research and inquiring about finished products containing Merastin," said Lau.

For more information, call (800) 783-4636 or visit www.interhealthusa.com.

Ethical Naturals Inc. Granted U.S. Patent

Ethical Naturals Inc. (ENI, San Anselmo, CA), developer of GreenGrown® vegetable glucosamine, has announced that the United States Patent and Trademark Office (USPTO) has granted a patent for their method of testing and identifying the unique markers that differentiate between shellfish and vegetable based glucosamine.

Lora Xiong, MS, ENI director of research and development and quality control, developed the newly patented process by using the Isotopic Signature Carbon Tracing Method (ISCTM).

"Purified glucosamine, whether from a shellfish or vegetable base, appears identical when using typical high-performance liquid chromatography analysis," said Xiong. "The uses of both products are essentially the same, however, for many people there is a vital difference between the two materials. GreenGrown vegetable glucosamine offers distinctive benefits ideal for those who are allergic to shellfish, vegetarians, and individuals who do not consume shellfish for religious reasons. With this analytical method [ISCTM] we are now able to objectively identify the source of the material as vegetable or shellfish."

GreenGrown®

Ethical Naturals®
nature verified by science®

For more information, call (866) 459-4454 or visit www.ethicalnaturals.com.

You're Hired

Michael Ceranski will become senior vice president of BASF's (Lampertheim, Germany) global business unit human nutrition, effective January 1, 2012. Ceranski is currently vice president of business management crop protection for Germany, Austria, Switzerland and Benelux.


Rend Al-Mondhiry

Renowned scientist and noted expert on krill and the krill fishery, **Dr. Stephen Nicol**, has joined Aker BioMarine (Oslo, Norway) Antarctic's Science Board (ASB). Nicol holds degrees in zoology, oceanography and biology, and worked for more than 20 years with the Australian Antarctic Division as a research scientist and program leader. He directed four major research voyages to the Antarctic and participated in five additional voyages, and his extensive study and research on krill, the krill fishery and the Southern Ocean ecosystem has led to over 200 published articles including the recently published article in *Fish and Fisheries*.


Louis Vintro

Main Street Ingredients (La Crosse, WI) recently announced that **Shawn Wegner**, the company's plant manager since 2008, has become the director of operations. Wegner has worked in a variety of capacities including lab testing, process development, production management and operations management.

Rend Al-Mondhiry has joined The Council for Responsible Nutrition's (CRN) staff to serve as the trade association's regulatory counsel. Most recently, Al-Mondhiry worked as state legislative counsel for the Consumer Healthcare Products Association (CHPA).

Louis Vintro will join Key Technology (Walla Walla, WA) as senior vice president of business development and global operations. Vintro will be responsible for planning and managing all aspects of Key's operations.

Vitiva (Slovenia) has appointed **David Howard** as the UK regional sales director to serve the company's UK food and beverage manufacturing market. Howard worked the last five years in manufacturing for industrial and marketing companies with Huegli UK Ltd.


David Howard

GCI Nutrients (Foster City, CA) has appointed **Michael Solomon** vice president of sales and marketing. Solomon has been in the industry for many years and has worked for GCI in the past in various capacities.

Rochem International Inc. (Ronkonkoma, NY) has expanded its sales and distribution focus with the addition of **Lionel Bannelier** as sales director for Europe, Middle East and Africa. Bannelier joins Rochem after having most recently worked for SPI Pharma in France where he managed key accounts.

Deacom Inc. (Wayne, PA) has hired **Stephanie Eaves** as marketing communications specialist. Eaves will generate sales support materials, coordinate company events and maintain the company website.

Study Reveals Magnesium Deficiency Found in Alzheimer's Patients

In a recent study published in *Magnesium Research* (2011 September 1;24(3):115-21), Italian researchers examined the magnesium status of people with mild-to-moderate Alzheimer's disease (AD). They found those with low-ionized magnesium levels had the most impaired cognitive function as compared to the control group.

The magnesium "ion test" in the study showed low magnesium levels in AD, whereas serum total magnesium levels didn't show a deficiency. "This serves to confirm that magnesium deficiency overexcites the brain's neurons and results in less coherence and reduced cognitive function," said Carolyn Dean, MD, ND, magnesium expert and medical director of the nonprofit Nutritional Magnesium Association. "The study also validates the fact that serum magnesium levels are a poor way to diagnose magnesium deficiency and that magnesium ion testing is a far more valid way of testing for magnesium deficiency. Magnesium in the blood does not correlate with the amount of magnesium in other parts of your body."

In spite of, or perhaps because of, all the metabolic processes that rely on magnesium, less than one percent of the body's total magnesium can be measured in our blood; the rest is busily occupied in the cells and tissues or holding our bones together.

This makes it virtually impossible to make an accurate assessment of the level of magnesium in various body tissue cells using a routine serum magnesium test. This test is often called a total serum magnesium test, which one might imagine relates to all the magnesium in your body, but actually it does not. Most magnesium evaluations done in hospitals and in laboratories use the antiquated serum magnesium test, according to the Nutritional Magnesium Association.

The connection between magnesium deficiency, the presence of heavy metals and AD cannot be overlooked. As far back as 1990, world-renowned magnesium researcher, Dr. Jean Durlach stated, "Magnesium depletion, particularly in the hippocampus (that part of the brain associated with short- and long-term memory), appears to represent an important pathogenic factor in Alzheimer's disease. It is associated with high aluminum incorporation into brain neurons."

"Alzheimer's disease is often misdiagnosed," said Dean. "Half the people diagnosed with it may, in fact, not have this condition but suffer from brain toxicity due to a lifelong accumulation of toxins, chemicals, poisons and nutrient deficiencies that prevents normal detoxification. While allopathic medicine tries to find the 'one cause' for Alzheimer's and the 'one drug' that will cure it, alternative medicine practices detoxification and supplementation to effectively treat this condition."

For more information, visit www.nutritionalmagnesium.org.

Obese Adolescents Benefit From High-Dose Vitamin D

Vitamin D deficiency is common in Americans, and especially in overweight and obese adolescents, according to the National Institutes of Health. University of Missouri (MU) researchers have found that providing obese adolescents with a high daily dose of vitamin D3 is safe and effective in improving their vitamin D status.

"Obese adolescents face an increased risk for deficiency because they tend to absorb vitamin D in their fat stores, which prevents it from being utilized in their blood," said Catherine Peterson, associate professor of nutrition and exercise physiology. "We found that a daily dose of 4,000IU of vitamin D3, the maximum intake level set by the Institute of Medicine (IOM), is both safe and effective at improving vitamin D status in obese adolescents."

Vitamin D is obtained by eating certain foods, taking supplements and through sunlight exposure. It is essential for maintaining healthy bones, muscles, nerves and immunity. The IOM recently set new dietary reference intakes for vitamin D. They recommend 600IU daily, with a tolerable upper intake of 4,000IU. Based on the guidelines, it is important to determine the effects of a vitamin D dose that is equivalent to the upper limit, especially in understudied groups, such as obese adolescents, Peterson said.

In the study, participants from the MU Adolescent Diabetes and Obesity Clinic were randomly selected to receive a placebo or 4,000IU/day of vitamin D3 for six months as part of their standard treatment. All obese participants initially were deficient or insufficient in vitamin D status. Participants supplemented with vitamin D3 had significantly greater increases in concentrations of 25OHD, the main indicator of vitamin D status, compared to those who received the placebo.

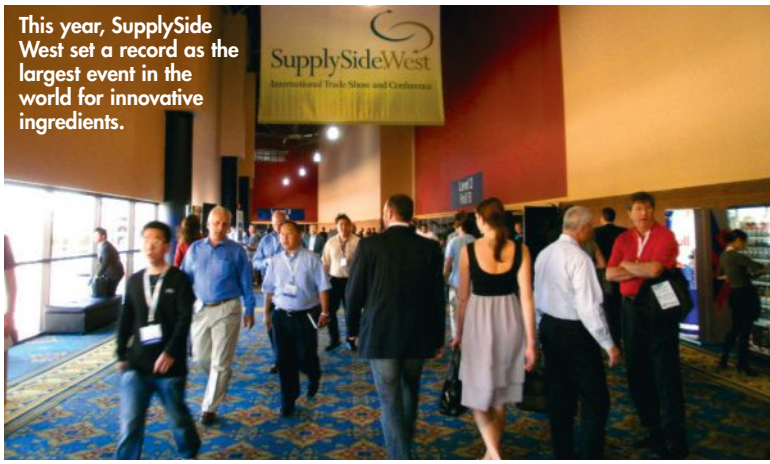
Obese adolescents are only about half as efficient at using vitamin D as their lean counterparts. For example, in lean adolescents it only takes about 100IU to increase their serum 25OHD levels by 1ng/ml. In obese adolescents, it takes about 200IU to achieve the same increase.

"If obese adolescents only consumed the recommended 600IU, they would be in trouble," said Peterson. "It takes 4,000IU to raise their vitamin D status within a sufficient range. This is much higher than the currently recommended daily amount for this age group. This indicates that physicians need to carefully evaluate the vitamin D status in their overweight and obese patients."

For more information, visit www.missouri.edu.

New Ingredients, NDI Concerns Highlight SupplySide West

In a record-setting 15th anniversary event, more than 9,700 dietary supplement, food/beverage and cosmeceutical executives from 64 countries met October 10-14 at The Sands Exposition Center and The Venetian Resort Casino for SupplySide West 2011. This year's exhibit hall featured 1,340 booths—a nine percent increase over the record set in 2010, confirming SupplySide West as the world's largest event for healthy and innovative ingredients.



This year, SupplySide West set a record as the largest event in the world for innovative ingredients.

Education

Attendees at this year's SupplySide West took advantage of the three-day, four-track education program, sponsored by BASF, which featured more than 40 education sessions covering hot topics in the nutraceutical, food/beverage and cosmeceutical industries, as well as pre- and post-conference workshops.

Featured speaker Joy Bauer, MS, RD, CDN outlined manageable steps for people to improve their diets, telling attendees to cut out all fried foods, nix sugary beverages and incorporate produce at every meal. Bauer made it clear to the audience that it is easy to eat healthy if you come up with five healthy and quick meals that you can prepare in 20 minutes or less. "If you always have ingredients for two of these meals on hand," Bauer said, "you won't fall apart at dinner." Bauer suggested water, flavored natural seltzer, unsweetened iced tea, hot tea and high-volume protein snacks as between-meal healthy snack and drink options, and turkey meat, stir fry and whole wheat pasta as healthy dinner options. At all costs, Bauer advised, avoid soda, hot dogs and starchy breakfast pastries.

The NDI Town Hall was one of the most well-attended and talked about events at SupplySide this year.

Additionally, Greg Stephens from Windrose Partners, presented "Key Success Factors for Nutraceutical Products." "The increasing investment required to launch products and sustain existing products requires well-planned and well-executed product development and marketing initiatives," he said.

Stephens outlined three main representative key success factors for dietary supplements and functional food: consumer (Does the product address an met consumer need? Is existing awareness of the benefit high or are acceptable claims available? Does the product fit into existing eating patterns, convenient to purchase, etc.?); product/ingredient (Is the product safe? Does the product deliver on the benefit claim? Does the product impart superior taste, texture, color and smell characteristics?); and market (Does the product offer acceptable value for the cost incurred? What are the issues and opportunities in the market?)

During the presentation titled "Top Trends Driving Innovation," Steve French, executive vice president and managing partner at Natural Marketing Institute, predicted that three themes will continue to drive future industry growth: health and wellness, healthy aging and sustainability. "Pure, natural and simple will be the growing mantra of an ever-evolving and increasingly savvy consumer," French said, adding that more than 75 percent of consumers feel that healthy eating helps them feel in control of their lives.

The concept of "healthy aging," according to French, was once exclusive to Baby Boomers and matures, but has now been embraced across the entire demographic spectrum. "While agelessness may be the cultural ideal, the reality is that healthy aging is getting younger."

French then discussed sustainability, which he called "the balance of personal and planetary health." Those who value protecting the environment are far more likely to exercise, be a healthy weight and eat healthy or organic foods," he said. "The deepening of this linkage over time has fueled an entire industry of products and services."

New Ingredients

A number of innovative ingredients were launched at the show:

Glanbia Nutritionals (Fitchburg, WI) unveiled its new ingredient solution for sugar reduction. OptiSol™ 2000 is a unique binding system, which reduces sugar by up to 50 percent, providing a highly desirable alternative to lecithin and other binders. The new ingredient easily replaces lecithin thanks to its high performance emulsification properties. OptiSol 2000 allows for efficient formulation of chewy granola bars, baked bars and cereal clusters, without the higher costs associated with alternative emulsifying agents containing high levels of sugar.

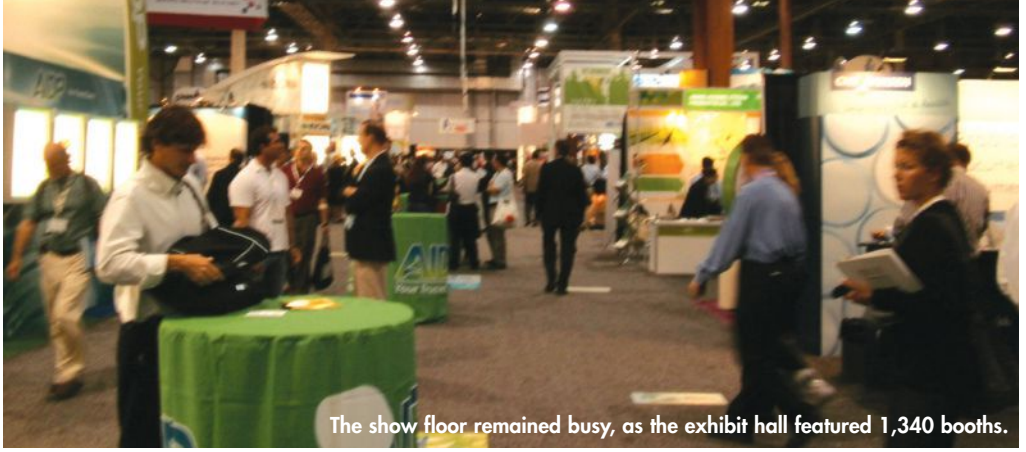
Continuing in the hot trend of coconut products, NP Nutra's (Rancho Dominguez, CA) CocoJiva™ and organic Coconut Water freeze dried drew strong interest at the show. Also of note was the plethora of omega-3 sources, from chia, blackcurrant and sea buckthorn to NP Nutra's own SachaOmega™, a proprietary organic cold pressed Sacha Inchi Oil with 92 percent essential fatty acids omega 3,6,9.

The industry also showed strong interest in vitamin K2. Nattopharma, a Norwegian raw material supplier, offers MenaQ7®, which provides natural vitamin K2 as a fermentation extract whereby vitamin K2 is manufactured using bacillus subtilis natto. It is documented that adding MenaQ7 will increase activation of osteocalcin, so the conditions for improved bone health are


NDI Panel of Speakers L to R: Harry Rice, UNPA; Steve Mister, CRN; John Gay, NPA; Michael McGuffin, AHPA; Daniel Fabricant, FDA

met. Likewise, accumulating evidences show the importance of MenaQ7 activated matrix-gla protein in inhibiting calcium deposits in arteries thus contributing to better cardiovascular health.

Additionally, InterHealth Nutraceuticals' (Benicia, CA) Zychrome™ brand chromium dinicocysteinate is a unique, patent-pending, next generation chromium complex for diabetes management. This new form of chromium has been studied in preliminary clinical research to be twice as effective as chromium picolinate in maintaining insulin function and healthy insulin levels trending toward normal range.


The show floor remained busy, as the exhibit hall featured 1,340 booths.

NDI Update

Perhaps nothing at SupplySide West was as highly anticipated or well-attended as the NDI Town Hall event. The industry has disagreed on many of the new dietary ingredient notification (NDIN) requirements present in the NDI Draft Guidance, which was submitted by FDA in July. A panel of speakers gave their respective thoughts on the issue. They included: Daniel Fabricant, PhD, director of dietary supplement programs, FDA; Michael McGuffin, president, American Herbal Products Association (AHPA); John Gay, executive director and CEO, Natural Products Association (NPA); Harry Rice, United Natural Products Alliance (UNPA); and Steve Mister, president, Council for Responsible Nutrition (CRN).

There was also a brief introductory video recording from Senator Orrin Hatch (R-UT). Hatch was clearly on the industry's side, urging them to take action against the NDIN requirements. "As long as I'm in the U.S. Senate, I will work hard to defend the Dietary Supplement Health and Education Act of 1994 (DSHEA)," said Hatch.

Fabricant said FDA's Draft Guidance was about "preventative control" in terms of dietary supplement regulation. However, he did little to reassure the audience that FDA sympathized with the industry's concerns, often declining to respond to hypothetical situations. "We don't want to pass something and find out what's in it later," said Professor Rich Kreider of Texas A&M after posing a question to Fabricant. Jarrow Formulas' Jarrow Rogovin added that the existing Draft Guidance "should be shredded."

McGuffin was perhaps the most vocal of the speakers, as he said the grandfathered ingredient burden is misplaced in the Draft Guidance, adding that DSHEA doesn't say product manufacturers need to show a dietary supplement was marketed prior to October 15, 1994.

McGuffin also said FDA is incorrect in its definition of dietary supplement. He said DSHEA defines them, but makes no mention of "in the diet of man," as the Draft Guidance contends. McGuffin was confident in his criticisms of the Draft Guidance, adding, "if we ever have a final Guidance, I believe we'll have a significantly different one than what we see now."

Gay, meanwhile, focused on the issue of requiring notifications for each new supplement and for each new ingredient. "We believe it was not the intent of Congress to have notifications for each supplement, but for each new ingredient," he said. With all the added time and resources, Gay said this will present a huge burden and could have "a costly price tag that will lead to overwhelming paperwork and a clogging of FDA's system."

One thing FDA and the industry associations agreed on was that the industry needs to submit comments, which they were allowed to do through December 2. Fabricant said FDA wants substantive, data-driven comments, but couldn't answer when they would all be reviewed, saying, "it depends on the comments."

Hatch urged how important it is to be a part of the solution in his video recording. "Make sure each of your voices are heard. Make sure you all submit comments," he said. McGuffin also strongly encouraged comments, adding that companies should either submit comments through their trade organizations, on their own or in a combination of both if their business would be impacted.

HeardattheShow

With the NDI Draft Guidance on nearly everyone's mind at SupplySide, *NIE* took the pulse of various industry members' thoughts on the controversial document.

"I know a lot of people are concerned over the NDI guidance. We were concerned too, which is why we submitted our NDI prior to the guidance coming out. That way, we could have it completed and not be as concerned. Now our customers have peace of mind knowing that EpiCor has the appropriate regulatory documentation for the product they may want to develop."
— Paul Faganel, president, Embria Health Sciences (Ankeny, IA)

"Obviously the NDI regulation was at the top of everyone's minds. It is certainly a critical time in this industry and my hope is that we will all band together and present a united front to the regulatory agencies."
— John Jarmul, marketing manager, Kaneka Nutrients (Pasadena, TX)

"We guarantee banned, drug-free products and that's the way the industry is going, but more regulation causes us more work. Some regulations are good, but the biggest problem is interpretation."
— Joe Archer, vice president of sales and marketing, All American Pharmaceuticals (Billings, MT)

Save the Date!

Next spring, SupplySide East expands into SupplySide MarketPlace and will be unveiled in New York City, from May 8-10, with the exhibit hall open May 9-10. SupplySide West 2012 is slated for November 5-9 at The Venetian & Sands Expo in Las Vegas.

Indena's Grape Seed Extracts Receive Kosher Certification

Indena (Milan, Italy) has received kosher certification from the Kashrut Division of the London Beth Din (KLBD) for its Leucoselect® and Enovita® grape seed extract ingredients. The company has worked extensively with KLBD in London for a number of years and has certified a number of its ingredients. The kosher certification for Indena's grape seed extracts required extensive site inspections by Rabbi Akiva Padwa, director of certification, reviewing the entire process from harvest, through preparation of the seeds to the extraction of the polyphenols.

"KLBD, as the largest kosher agency in Europe, is very pleased to have kosher certified Indena's grape seed extracts," said Russell Brown, KLBD commercial consultant. "This is a culmination of several years of hard work; a team effort between their production people and our rabbinical experts."

According to a recent study conducted by Mintel International, consumers are increasingly purchasing kosher-certified products based on food quality, general healthfulness and food safety. Supplements containing grape seed extracts have long been available in the market and functional foods have been introduced in recent years. Grape seed extracts are a rich source of a complex mixture of polyphenols, containing a characteristic signature of catechins, procyanidins and proanthocyanidins.

"We were delighted to go through the auditing process because KLBD is recognized by our customers as an international kosher agency," said Christian Artaria, marketing director and head of functional food development for Indena. "Certification is opening up markets and helping to make business easier."

For more information, visit www.indena.com.

POM Wonderful Expands Into Nutritional Ingredient Market

POM Wonderful (Los Angeles, CA) recently announced that it is offering POMx to nutrition companies globally as an ingredient to enhance a wide variety of nutritional products, including dietary supplements and functional foods.

POMx is an all natural, concentrated source of polyphenol antioxidants from Wonderful variety pomegranates. Available in both powder and liquid forms, POMx contains a broad spectrum of pomegranate polyphenol antioxidants.

Multiple parts of Wonderful variety pomegranates, including the peel, membrane and juice sacs, are rich in polyphenol antioxidants. In 2005, POM Wonderful developed a patent-pending process to harness the high concentration of polyphenols found in all of these parts of the fruit. The result was POMx, which until recently was only available in POM Wonderful products.

"We chose to enter this market due to the tremendous response POMx received from supplement and food manufacturers," said Brad Paris, vice president of global produce. "As a completely vertically integrated pomegranate company, we are well positioned to offer the finest pomegranate ingredients in the market."

To support this new venture, POM Wonderful has hired Kyle Redfield in the role of industrial sales manager. Redfield has been in the dietary supplement ingredient business for the last five years, and his knowledge and experience will ensure that POM Wonderful operates as a high quality ingredient manufacturer.

For more information, call (310) 966-5800 or visit www.pomwonderful.com.

BioCell Technology Rebrands Flagship Ingredient

BioCell Technology LLC (Newport Beach, CA) recently announced that it has rebranded its flagship ingredient "BioCell Collagen II®" to "BioCell Collagen®," and BioCell Collagen is also issuing a new logo to go along with its rebrand. The main change to the logo is a new font, which is specifically designed to be easier to read on a product label.

The original name, "BioCell Collagen II," made reference to one of the ingredient's integral component parts, type II collagen. The designation made sense during the early years of BioCell Collagen, mainly because of the strong association between type II collagen and joint health. However, as more studies were conducted on BioCell Collagen, the data repeatedly pointed in one direction: BioCell Collagen is much more than a joint health ingredient. The single-source, all natural ingredient contains a naturally existing matrix of hydrolyzed collagen type II, hyaluronic acid and chondroitin sulfate, all of which are highly-bioavailable.

The completion of the first human skin study on BioCell Collagen was announced on June 23, 2011. The study suggested that BioCell Collagen stimulates dermal fibroblasts, which are responsible for skin collagen (primarily collagen types I and III) production. With that, the BioCell Technology team said the name "BioCell Collagen II" limited the product's perception in the marketplace and failed to elucidate the ingredient's multiple benefits.

"It was well established that hydrolyzed collagen type II, a key constituent of BioCell Collagen, stimulated the biosynthesis of collagen type II from the cartilage-building chondrocytes, raising a possibility of cartilage regeneration by the ingestion of hydrolyzed collagen," said Dr. Joosang Park, vice president of scientific affairs of BioCell Technology LLC. "The recently completed human skin study on BioCell Collagen showed a significant increase in collagen content in the skin dermis. This and earlier studies demonstrate the unique biological properties of BioCell Collagen to support the dermal matrix containing collagen types I and III as well as the cartilage containing type II."

For more information, call (714) 632-1231 or visit www.biocelltechnology.com.

Embria Health Sciences Completes NDI Process for EpiCor

Embria Health Sciences (Ankeny, IA), manufacturer of the immune-balancing ingredient EpiCor®, has successfully completed the Food and Drug Administration's (FDA) NDI (new dietary ingredient) Notification process. Kevin Boot, regulatory counsel for Embria Health Sciences, believes this accomplishment will have far-reaching benefits for the ingredient supplier and its customers.

"The clean acknowledgement letter Embria received from the FDA signifies the successful completion of the NDI process, which is something many suppliers and manufacturers are still struggling to attain," said Boot. "EpiCor received a clean acknowledgement letter that means all populations can take EpiCor year round. The safety of EpiCor confirmed there's no concern about immune fatigue, which can be a concern for other immune ingredients."

Since EpiCor was covered under the FDA's grandfather clause, completing the NDI Notification process was not a requirement for the ingredient supplier. However, Embria said it was confident that completing the NDI process would be an added benefit to their customers and manufacturing partners.

"Combined with the large body of clinical studies demonstrating EpiCor's ability to support year-round immune health, this milestone will give Embria's partners added confidence to take a quality product to market," added Boot.

For more information, call (877) 362-7421 or visit www.embriahealth.com.

Immuno Medic's Beta Glucan Ingredient Coming to North America

Immuno Medic (Oslo, Norway) is preparing to launch its ultra pure beta 1,3/1,6 glucan ingredient, Betox-93™, in the North American market. Betox-93 yields a purity of 93 percent, one of the highest in the market compared to the typical claims of purity levels of up to 75 percent. It offers higher bioavailability due to the high purity and micronization of particles, making it suitable for a wide range of formulations.

Beta glucan is a complex sugar molecule, or polysaccharide, primarily used to stimulate the immune system as well as to manage blood cholesterol concentration levels. The most common source of beta glucans are higher fungi, baker's yeast cell walls and grains of some cereals.

Betox-93 is without any proteins, fats, taste or odor. This patented ingredient is produced under strict quality control and its origin is certified organic oyster mushroom (*Pleurotus ostreatus,* or hiratake).

"We are thrilled to bring this new, high purity and high bioavailability beta glucan to the North American market," said Morten Sundsto, president and CEO of Immuno Medic. "The beta glucan market in the U.S. and Canada is expected to grow rapidly in the coming years. Beta glucan is increasingly gaining attention as a natural and effective ingredient for wide range of applications, including supplements, functional foods, skincare and wound care."

As its next development and commercialization phase, Immuno Medic is identifying distribution partners and key customers in the North American market.

For more information, call +47-950-61860 or visit www.immunomedic.com.

Burcon Develops New Technology and Introduces Peazazz

Burcon NutraScience Corporation (Vancouver, BC, Canada) has developed a novel pea protein isolate branded as Peazazz™.

Peazazz is 100 percent soluble and transparent in low pH solutions with clean flavor characteristics and is heat stable permitting hot-fill applications. Burcon's Peazazz can be used in a variety of consumer product applications and should be of interest to companies looking for a great-tasting functional alternative plant protein ingredient.

Pea protein is a relatively new, vegetable-based, functional protein ingredient valued for its emulsifying properties. Pea proteins currently available in the market are sold for use in a variety of food products including: snacks and cereals; diet products (high-protein foods); gluten-free and vegetarian and vegan foods.

"Our team of scientists and engineers has once again proven their ability to push the envelope in developing unique plant protein ingredients with our first protein from a source other than oilseeds," said Johann F. Tergesen, president and COO of Burcon. "Our new Peazazz protein offers yet another platform for Burcon to monetize our technology."

Burcon has also announced that it is engaged in discussions with a potential partner to commercialize Peazazz™ and the associated protein extraction technology. In that regard, Burcon has entered into a confidentiality and material transfer agreement to facilitate these discussions.

Burcon has filed patent applications with the U.S. Patent and Trademark Office to protect its newly developed novel processes for the production of pea protein isolates, as well as to protect Peazazz, the product derived there from, and to protect the functional and nutritional applications of Peazazz as an ingredient in consumer products. Consistent with Burcon's previous patents and patent applications, the company has also filed for protection internationally under the patent cooperation treaty of the World Intellectual Property Organization to protect these new inventions. Burcon has 174 issued patents worldwide including 30 U.S. patents, and in excess of 300 additional patent applications, 70 of which are U.S. patent applications.

For more information, call (604) 733-0896 or visit www.burcon.ca.

AHPA Updates Botanical Authentication Program

The American Herbal Products Association (AHPA) has added star anise *(Illicium verum)* fruit to its Guidance on Known Adulterants, part of its *Botanical Authentication Program*, with Japanese star anise *(Illicium anisatum)* fruit identified as the known adulterant, effective immediately.

The action follows a vote by the organization's Board of Trustees at its most recent meeting to help industry confirm the identity of *Illicium verum* as differentiated from *Illicium anisatum*.

Created in 1997, AHPA's Guidance on Known Adulterants identifies herbs and potential adulterants that are known to be in trade. The list identifies safety-related substitutions, such as *Digitalis lanata* leaf for plantain leaf *(Plantago lanceolata)*, and safety- and economic-based substitutions, such as red dye #2 (amaranth dye) for bilberry fruit extract. The current list of articles of trade and their known adulterants is available on the AHPA website.

Also, as noted in the *AHPA Update* of November 4 titled "FTC Settles Case Against Marketers of 'Not Authentic' Hoodia," AHPA has made available on its website since 2007 microscopic, high-performance thin-layer chromatographic (HPTLC) and high-performance liquid-chromatographic (HPLC) analytical techniques to differentiate between authentic and inauthentic hoodia.

Under its *Botanical Authentication Program*, AHPA has developed methods of ingredient identification and analysis for four botanicals, a toxic constituent and a supplement ingredient, including:

- Aristolochic acid
- Bilberry fruit extract
- Black cohosh *(Actaea racemosa* syn. *Cimicifuga racemosa)* root /rhizome
- Eleuthero *(Eleutherococcus senticosus)* root
- *Hoodia gordonii* stem
- Glycerin

"With this latest listing of star anise, AHPA expands its 14-year leadership in the area of identifying adulterants and creating standards for ingredient authentication under the *AHPA Botanical Authentication Program*," said Michael McGuffin, AHPA president. "With the active participation and input from our membership and the in-depth work of three AHPA committees, we will continue to expand the knowledge base around these most important concerns for the trade."

For more information, visit www.ahpa.org.

NPA Counsel Writes the Book on Dietary Supplement Regulations

The Food and Drug Law Institute (FDLI) is publishing *Dietary Supplement Regulation: A Comprehensive Guide*. Edited by Scott Bass, a partner at Sidley Austin in Washington, D.C., who serves as the chief counsel for the Natural Products Association (NPA), the book will serve as a valuable resource to dietary supplement stakeholders.

"The book recognizes that dietary supplements are the new playing field not only for the original marketers of vitamins and minerals, but also today for big pharma and big food," said Bass. According to Bass, as the dietary ingredient market continues to expand globally, and pharmaceutical manufacturers, major food processors and marketing companies offer more functional food products, herbal and natural-source supplements, this up-to-date resource is all the more critical to the dietary supplement community.

"The Natural Products Association is pleased that the Food and Drug Law Institute has teamed up with Scott Bass and Sidley Austin to offer a powerful new resource for the dietary supplement industry. Scott is a pioneer in the industry whose work on protecting supplement makers from onerous regulations is second to none," said John Gay, NPA executive director and CEO. "Scott's deep level of knowledge and experience on dietary supplement regulations is a key asset to helping NPA meet the challenge of any regulatory overreach by the government. This important new guide offers a complete overview of federal regulations, valuable for anyone involved in making and selling dietary supplements."

FDLI's *Dietary Supplement Regulation: A Comprehensive Guide* includes easy-to-understand explanations of key dietary supplement issues, including: regulatory status and formulation; product claims and intended use; dietary supplement marketing and safety; good manufacturing practices and foreign regulation.

For more information, visit www.fdli.org.

AHPA Board Votes to Establish Tea Products Committee

At a meeting on October 11, the American Herbal Products Association (AHPA) Board of Trustees voted to create a Tea Products Committee and also voted to appoint Wilson Lau, of nuherbs Co., currently an AHPA board trustee, as the chair of the new committee.

The new Tea Products Committee is chartered to promote and protect responsible commerce of herbal products marketed as teas and with responsibilities that include maintaining attention to regulatory issues related to tea products and ingredients; creating best practices and appropriate standards for the manufacture, labeling, and marketing of tea products, as needed; and developing active relationships with other organizations that represent marketers of tea products and ingredients.

"AHPA is pleased to announce the establishment of this newest committee," noted Michael McGuffin, AHPA president. "The committee will provide the association and its members and the industry at large with a new forum for marketers in the tea products category to identify and address issues of mutual interest and ensure its continued viability and growth."

For more information, visit www.ahpa.org.

New Trade Association in Early Stages

The Dietary Supplement Manufacturers and Marketers Association (DSMMA) is a new trade association proposed by Jarrow Rogovin, president and chairman of the board of Jarrow Formulas, Inc., at this year's Expo East in Baltimore, MD, that will be focused on aggressively pursing regulatory reform on behalf of dietary supplement manufacturers and marketers. The DSMMA will be legally and politically focused on preventing the FDA from regulatory over-reach to ensure consumers' continued access to innovative dietary supplements.

"The General Counsel for the new association is Todd A. Harrison, Esq., a partner at Venable LLP's Washington D.C. headquarters," said James J. Gormley, spokesman for the DSMMA. "In addition, attorneys Scott Polisky and Susan Brienza have been instrumental in moving the association forward from concept to reality in a very short period of time. The bylaws are in the process of being drafted and the organization is in the process of being incorporated."

The mission statement, business plan and other foundational documents are also being drafted. When that is completed, the DSMMA will announce its founding members and make its mission statement public.

For more information, contact James J. Gormley at (202) 695-2027 or jamesgormley01@gmail.com.

Combining Tradition With Modern Science

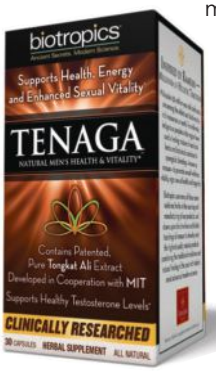
BIOTROPICS MALAYSIA BERHAD
Level 52, Menara TM
Jalan Pantai Baharu
50672 Kuala Lumpur
Phone: +603-2245-8000
Fax: +603-2245-8008
e-Mail: info@biotropicsmalaysia.com

BIOTROPICS U.S. INC.
P.O. Box 62012
1620 Pinetree Dr.
Pittsburgh, PA 15241
Phone: (412) 833-6826
Fax: (412) 831-2274
e-Mail: us@biotropicsmalaysia.com
Website: www.biotropicsUS.com

In 2007, Biotropics Malaysia Berhad was incorporated as a government-linked corporation to develop and commercialize Malaysia's bio-resources into natural health products. Malaysia has some of the world's oldest tropical rain forests and the company was created "to explore, harness and develop products utilizing nature's gifts for the benefit of consumers around the world in a sustainable approach," said Sami Khan, senior director business development for Biotropics Malaysia.

Biotropics Malaysia utilizes both the biological resources and traditional wisdom and combines them with modern science. Its product range includes proprietary standardized extracts; all natural dietary supplements; and ingredients for nutraceutical, functional food and cosmeceutical applications. In addition, the company is continuously developing herbal medicines and botanical drugs, and its aim is to ensure that all of its ingredients and products are scientifically tested and verified to meet the highest quality, safety and efficacy standards.

As the company has entered its second year in the U.S. market, Biotropics Malaysia offers three flagship products:



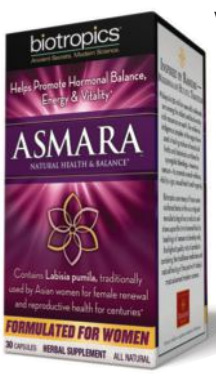
- **Tenaga**: The only men's product on the market to contain Physta, a clinically tested and patented form of tongkat ali—the only tongkat ali developed in partnership with the Massachusetts Institute of Technology (MIT). Tenaga supports men's health, energy and sexual vitality.
- **Asmara**: Asmara, which means 'love,' delivers a pure measure of *Labisia pumila* extract, a traditional herb used by generations of Malaysian women to help promote hormonal balance, energy and vitality.
- **Super Antioxidant Chews**: A proprietary blend of seven tropical fruits including mangosteen parapet extract. Every chew has the antioxidant power of 2.5 cups of blueberries.

Commitment to Excellence

Biotropics Malaysia stresses the importance of quality control in all of its extracting processes, research, product development and manufacturing activities to ensure that its products are always at their highest quality. All incoming raw materials and extracts are analyzed for authenticity and purity as well as tested for heavy metals, pesticides, aflatoxins and microbial levels to comply with applicable standards. Continual monitoring and testing is also conducted throughout all stages of processing and manufacturing based on international reference standards and validated testing methods.

The company also believes that extensive analysis, chemical profiling and toxicological studies followed by clinical trials conducted to provide validated and scientific proof are needed for all of its products. Additionally, Biotropics Malaysia uses the latest technology to discover the chemical structures of plant metabolites and their biological activities, as well as traditional knowledge, to identify potential leads and generate proprietary compound and novel product candidates from the rain forests of Malaysia.

The company's good manufacturing practices (GMP) facility in Malaysia is licensed by the National Pharmaceutical Control Bureau, Ministry of Health, Malaysia. The facility is custom designed and fully equipped with high power encapsulation, blister packing, bottling lining, labeling and cartoning machines. Biotropics Malaysia also utilizes state-of-the-art extraction and drying technologies and maintains quality control for the purity and consistency of its standardized extracts. In addition, Biotropics Malaysia is committed to the sustainability of Malaysia's rain forests through the company's standard operating procedures; the company uses responsible agricultural and collection practices. Further, an in-house, small-scale cultivation was developed to produce only the best high yield plant species.



Looking Forward

As Biotropics Malaysia continues to grow, the company would like to educate health food retailers, health care professionals and the public about the health impact of low testosterone levels and high cortisol levels, including loss of vigor and stamina, as well as natural ways to support healthier testosterone levels using age-old rain forest secrets with modern clinical research to validate their safety and effectiveness.

To achieve these goals, the company's website was recently redesigned to make research, product and related lifestyle information more accessible. Biotropics Malaysia is also using social media to encourage engagement with its target audience.

But what Biotropics Malaysia wants to get across most is that its products are safe and effective. "Researchers and key influencers are actively conducting media interviews that deliver favorable messaging, reassuring the industry, health care professionals and consumers that our products are safe, trusted, proven and effective," said Khan.

Branded ingredients have gained distinction as ingredient manufacturers have invested in clinical trials and consumer marketing, as well as formed partnerships with major product manufacturers. For manufacturers, the benefits of a high-quality branded ingredient can be significant. Below are six examples of branded ingredients on the market, as *NIE* details how the companies behind them provide support and clarity.

pTeroPure From Chromadex, Inc.

pTeroPure® was founded as a high-quality brand of ChromaDex, Inc (Irvine, CA) to provide high purity pterostilbene to the dietary supplement, food, beverage, cosmetic, animal health and pharmaceutical industries. pTeroPure is a nature-identical 99 percent pure all-trans pterostilbene. Pterostilbene, like resveratrol, is a natural compound found in small berries that acts as part of the plant's defense system, and, according to Jeremy Bartos, PhD, senior product development manager at Chromadex, it has shown clinical promise in several health markets, including heart health, aging, cognitive function, memory and metabolism.

In one study published by the United States Department of Agriculture (USDA) in 2005, both pterostilbene and resveratrol were tested for the ability to induce PPAR-alpha activation. PPAR-alpha is involved in fatty acid and lipid catabolism and its activation leads to decreased triglyceride and very low-density lipoprotein (VLDL) synthesis; for example, the fibrate family of pharmaceuticals acts to decrease cholesterol levels through PPAR-alpha activation. The study showed that pterostilbene activated PPAR-alpha *in vitro* better than all compounds tested, including both resveratrol and the pharmaceutical ciprofibrate. Subsequent structural and *in vivo* studies confirmed the correlation between pterostilbene's activation of PPAR-alpha and cholesterol lowering.

According to Bartos, pTeroPure is the only pterostilbene on the market with completed safety and toxicity studies. This has led to self-affirmed generally recognized as safe (GRAS) status, demonstrating the safety of the ingredient, with a maximum daily allowable dose of 1,890mg; the average recommended daily amount of pTeroPure ranges between 50mg and 150mg, Bartos said.

"With pTeroPure, manufacturers have access to the intellectual property that ChromaDex has licensed, including the right to market the products in the heart health, cognitive function, aging and anti-anxiety markets. With the culmination of the first human study on cholesterol finishing up and another planned, ChromaDex is planning to pursue a qualified health claim for pTeroPure and cholesterol, in a similar manner as the phytosterols qualified health claim for lowering cholesterol."

As such, Jarrow Formulas (Los Angeles, CA) features pTeroPure in its standalone pterostilbene, in Resveratrol Synergy™ and in Resveratrol Synergy™ 200. It also will be included in an upcoming combination formula to be released later this year, said Dallas Clouatre, PhD, consultant for R&D at Jarrow.

Clouatre said that it has been very difficult to find a reliable generic source of the ingredient. "Even when the quality control has been adequate, there have been supply issues. Jarrow made its choice partially in terms of simple reliability of supply and quality."

Undoubtedly, Jarrow also believes in products that are backed by science and continued research. pTeroPure has been and will continue to be the object of a growing volume of research, especially clinical research, said Clouatre. "With commodities, which is to say generic sources of ingredients, the emphasis typically quickly deteriorates to mere questions of price. In contrast, branded ingredients are supported by investments in science and quality control. The name of a branded ingredient is something of value and the defense of this value is insurance for those who use branded ingredients."

Advantra Z From Nutratech, Inc.

Advantra Z®, distributed worldwide exclusively by Nutratech, Inc. (West Caldwell, NJ), is an ingredient for energy, weight management and sports nutrition, and works by increasing thermogenesis—a proven method of weight loss and toning—to help burn calories and fat. It does this without causing

Brands With Backing

As the popularity of branded ingredients continues to increase, *Nutrition Industry Executive* examines what makes them effective and why manufacturers are eager to use them.

BY RAJIV LEVENTHAL

negative cardiovascular and central nervous system side effects.

Advantra Z is derived from bitter orange, which has been used for a variety of medicinal and dietary purposes for thousands of years. The ingredient primarily stimulates beta 3 receptors, which are found on every cell wall and are responsible for triggering thermogenesis. Thermogenesis increases the resting metabolic rate and the rate at which fat is released from body stores and broken down to help burn calories.

The only branded bitter orange extract on the market, Advantra Z's superiority over generic bitter orange extracts is clear, according to Bob Green, president of Nutratech. Green explained that in contrast to branded bitter orange extracts, generic extracts have many deficiencies, including: they tend to isolate a single constituent; they may include m-synephrine, which has the potential for raising blood pressure in humans; they may incorporate synthetic synephrine; and there is inconsistent quality, unreliable supply and no clinical support.

"There is a wealth of research—more than 20 double-blind, placebo-controlled studies—supporting Advantra Z's safety and efficacy," said Green. "In fact, bitter orange is one of the most studied ingredients in the natural products industry. Most of these studies have used Advantra Z rather than generic bitter orange extracts because of its consistent quality."

A big challenge Nutratech has had to overcome with Advantra Z is dealing with the media, who, according to Green, have made bitter orange one of their favorite "whipping boys," with its safety frequently called into question.

Green said that this notion should be dispelled now that researchers have published a definitive scientific analysis of the chemistry and safety of Advantra Z/bitter orange, drawn from 59 clinical research studies and reference sources. (The Safety of Bitter Orange [Citrus aurantium] and *p*-Synephrine, *HerbalGram*, 2011). The article concludes that, based on current research and the extensive ingestion of products containing bitter orange, Advantra Z is safe for human consumption and that challenges to the safety of this ingredient are without scientific basis, said Green. "The researchers go so far as to state that those who question the safety of the patented bitter orange extract, Advantra Z, 'either lack understanding of the chemistry of bitter orange or have failed to carefully review the scientific literature.'"

Manufacturers can maximize the use of Advantra Z in their formulas by featuring the logo on packaging. "It's a clear marketing advantage," said Green. "The Advantra Z logo tells both retailers and consumers that research, quality controls/testing and patents back this branded ingredient. Plus, companies that place the Advantra Z logo and patent/trademark statement on the product label can receive a marketing allowance."

Zychrome From InterHealth Nutraceuticals

Interhealth Nutraceuticals (Benicia, CA) is a company that believes in branding as a key strategy. "It helps to differenti-

ate our products in a crowded environment," said Paul Dijkstra, Interhealth's CEO. The company's key brands are backed by strong clinical research that support unique and value-added product claims. "Lack of science in a tough market like this can be detrimental, especially in an environment of rising regulation. I've seen many brands introduced into the market without adequate efficacy or safety data necessary to support long-term success."

Interhealth's Zychrome™ is a unique, patent-pending chromium complex consisting of chromium, niacin and L-cysteine (chromium dinicocysteinate). Published preclinical research demonstrates that Zychrome increases blood sugar control and insulin regulation, and decreases inflammatory markers and oxidative stress. Decreasing these markers ultimately increases insulin control and increases glucose transport into cells.

Zychrome was examined in a randomized, double-blind, placebo-controlled study to determine its effect on insulin, insulin resistance and other benefits compared to chromium picolinate. Subjects took Zychrome, chromium picolinate (each providing 400mcg of elemental chromium) or a placebo daily for 12 weeks. Preliminary results from this clinical study showed that Zychrome significantly reduced fasting insulin levels at week 12 over baseline, resulting in a 30 percent reduction, said Dijkstra.

Dijkstra expressed he feels strongly that Zychrome will reinvigorate the blood sugar market as the next generation in chromium supplementation. "Manufacturers are searching for something that is effective, safe and has significant impact on consumer's health. The clinical results we've seen as well as the published preclinical data are very promising. This is a step in the right direction in managing insulin function and ultimately blood sugar control for millions of Americans."

Wellmune WGP From Biothera

According to Richard Mueller, president and CEO of Biothera (Eagan, MN), Wellmune WGP® is a one-of-a-kind technology. "This proprietary compound has more than $300 million invested in research and development. This investment has demonstrated safety and efficacy, making it a premium ingredient worthy of its own brand."

Wellmune WGP is a natural food, beverage and supplement ingredient that is clinically proven to safely enhance the immune system and help keep the body healthy. Derived from a proprietary strain of yeast, Wellmune WGP is a gluco polysaccharide that mobilizes billions of innate immune cells that are part of the body's natural defenses. This unique immune health ingredient helps increase the effectiveness of these immune cells without stimulating the immune system, Mueller said.

Once swallowed, immune cells in the gastrointestinal tract take up Wellmune WGP and transport it throughout the body. Fragments bind to receptors on all neutrophils, which are the most abundant immune cells in the body, accounting for over half of all immune cells. Activated by Wellmune WGP, the neutrophils are now primed for activity. Priming means the neutrophil (immune system) will not be stimulated and does not act differently until a challenge is present. Then, with Wellmune WGP, the neutrophil will more quickly navigate to the site of a challenge in the body and more effectively kill it, Mueller explained.

There is plenty of research backing Wellmune WGP, including eight clinical studies that consistently show the ingredient's ability to strengthen the immune system even during periods of high physical or lifestyle stress. "Wellmune WGP is safe and designed for daily consumption, making immune support a year-round activity rather than a seasonal product," said Mueller.

Mueller added that manufacturers can maximize the use of Wellmune WGP just by use of the brand name. "More than 80 percent of the products containing Wellmune show the Wellmune brand logo on their packaging. Highlighting Wellmune WGP demonstrates for consumers the real, clinically proven immune health benefits of the finished product."

Fast-C From Scientific Food Solutions, LLC

Fast-C™ from Scientific Food Solutions, LLC (Fairfield, CA) is a premium, faster absorbing and well-retained vitamin C ingredient, which has been the subject of two U.S.-based, double-blind, randomized, crossover clinical trials. One double-blind, crossover human clinical study performed at a pharmaceutical lab in the U.S. demonstrated that Fast-C was absorbed faster and showed a higher rise in blood vitamin C with equal to better retention.

The ingredient utilizes a unique, patent-pending composition that provides a buffered and 90 percent+ acid neutralized vitamin C, delivering this vital nutrient with greater speed and excellent retention in an easily tolerated formulation that fosters greater consumer compliance. Fast-C contains BioPerine®, the patented bioavailability enhancement ingredient from Sabinsa Corporation, through a semi-exclusive licensing agreement.

According to Gretchen Reese, president of Scientific Food Solutions, the company entered the branded ingredients market due to a "desire to formulate superior ingredients that are truly efficacious with science to back the claims." The ingredient enjoys significant intellectual property in the forms of patents, human clinical data and superior formulas, she said.

Manufacturers such as Purchase, NY-based Quality of Life Labs have found successful use of Fast-C. The company features the ingredient in its AdvaSorb™ Vitamin C, which is used to improve antioxidant status, detoxify a range of pollutants and provide an immune boost during the winter months, said Dan Lifton, COO of Quality of Life Labs. "Fast-C is better than the leading brand of vitamin C because it delivers 28-54 percent more vitamin C into the tissues in the first two hours (relative to baseline vitamin C levels) yet is equally retained by the body."

When asked why the company chose branded ingredients over generic ones, Lifton pointed to clinical research and scientific backing. "Branded ingredients usually have clinical research because the manufacturers have a financial incentive to conduct human studies. For obvious reasons, manufacturers of commodity ingredients have a harder time justifying an investment in research when the spoils of their investment go to other manufacturers. Since clinical research is

How does Speed Stack stay LEAN and MEAN?

Speed Stack® is the industry's best-selling performance-enhancing beverage. After ten years on the market, it still enjoys significant annual growth. So when American Body Building reformulated Speed Stack in 2004, it demanded the industry's most potent thermogenic ingredient – inside and out: **Advantra Z®**.

"We only deal with the best – especially since bitter orange knock-offs may not provide the same benefits," said Jay Jacobsen, American Body Building marketing manager. "By aligning Speed Stack with Advantra Z, we are confident about the science behind its potency, purity, efficacy and reliability.

"Our customers know this. They are serious athletes – and incredibly discriminating. They will buy Speed Stack as long as it consistently delivers the results they demand and expect. Seeing Advantra Z on the bottle gives them that assurance. Using Advantra Z, we know we'll never let them down."

Advantra Z® is a proprietary bitter orange extract and the leading patented, all-natural thermogenic ingredient for weight management and sports nutrition. Companies that place the Advantra Z logo and patent statement on the product label can receive a marketing incentive. Call today for details. And, visit our web site for the latest research, patent and license information.

Exclusively available through

nutratech

973 882 7773

www.nutratechinc.com

Zhishin Capital has licensed Citrus aurantium patents to Nutratech, Inc., the exclusive worldwide distributor and owner of the trademark, Advantra Z®. Nutratech is a trade name and trademark of Nutritech.

American Body Building Products, LLC, is a wholly owned subsidiary of Optimum Nutrition, Inc.

such a core focus for us, branded ingredients deliver value with the clinical research they bring."

Lifton added that branded ingredients also help differentiate the product—often allowing companies to tell a unique story and positing them as a "better than" version of existing commodity ingredients.

Capismax From OmniActive Health Technologies

According to Dr. Jayant Deshpande, CTO of OmniActive Health Technologies (Maharashtra, India), the company chose to enter the branded ingredients market because "its products are unique and have a great deal of brand appeal, thus allowing manufacturers to capitalize on the reputation that our brand brings."

OmniActive's patent-pending Capsimax™ is a new development in capsicum technology that allows manufactures to include the beneficial amounts of capsicum, red hot peppers, to their weight management and sports nutrition formulas.

Capsimax utilizes OmniBead, OmniActive's breakthrough beadletting technology, to deliver a fiery thermogenic pump without the burn. Each beadlet starts with an inert core, which is coated with premium, highly concentrated natural capsicum, followed by a controlled release outer coating that releases in the intestines and not the stomach. Using a proprietary matrix of excipients and coatings, Capsimax capsicum extract gives users the maximum effectiveness of capsacinoids without any oral or gastric irritation, thus solving the problem of capsicum compliance, said Deshpande.

"There is a notable trend happening toward ingredients that are scientifically validated and safe, showing a definitive shift from weight management and sports nutrition products that are either dangerous or that just don't work. Manufacturers will be able to include an effective and safe ingredient with Capsimax."

Additionally, unlike many ingredients, capsicum and capsacinoids have a long line of history, said Deshpande. "Not only have capsicum and capsacinoids been a dietary mainstay around the world for hundreds of years, but in the past 30 years, they have also gained an increasingly impressive reputation as safe and effective ingredients to support weight management and sports nutrition. In animal and human studies, capsicum and capsaiciods have been shown to help manage appetite, support healthy metabolism by burning calories, help induce thermogenesis (increase in energy expenditure in the body), and support lipolysis." **NIE**

Extra! Extra!

Visit www.niemagazine.com to view crucial questions companies should ask before contemplating an ingredient branding strategy.

FORMOREINFORMATION:

- Biothera, (877) 699-5100
- Chromadex, (949) 419-0288
- Interhealth Nutraceuticals, (707) 751-2800
- Nutratech, Inc., (973) 882-7773
- Omni Active Health Technologies
- Scientific Food Solutions, (866) 447-0875

pTeroPure®
Pterostilbene

The *Breakthrough*...Pure, Potent, Proven

pTeroPure® is now GRAS

If you like the benefits of resveratrol, it's time to try pTeroPure® Pterostilbene (*tero-STILL-bean*)

- pTeroPure® is pure (>99%) all trans-pterostilbene with four patents pending
- pTeroPure® is the only pterostilbene currently undergoing human clinical trials*
- Pterostilbene is a natural analog of resveratrol found in blueberries
- pTeroPure® has significant advantages over resveratrol:
  - Superior bioavailability - 80% vs. 20%
  - 7 Times longer half-life in the body
  - Greater oral absorption & metabolic stability

*More information at www.clinicaltrials.gov/ct2/show/NCT01267227

pTeroPure®

Brought to you by:

ChromaDex®

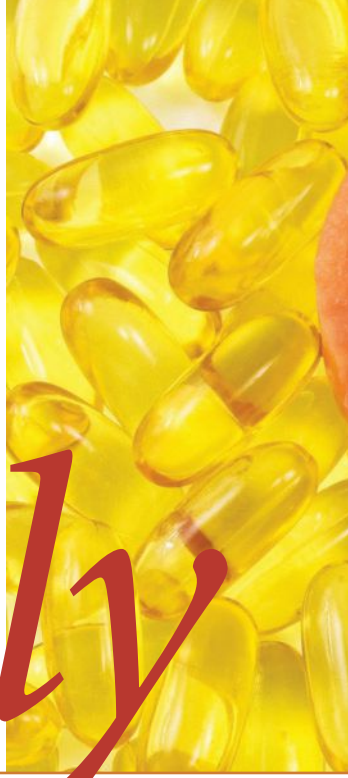
A premier provider of unique, innovative, and novel phytochemical ingredients.

Please contact:

10005 Muirlands Blvd., Suite G
Irvine, CA 92618 USA
Tel: 1-949-600-9694 | Fax: 1-949-600-9699
sales@pteropure.com
www.pteropure.com

Recipient of the Frost & Sullivan 2010 Most Promising Ingredient of the Year Award

Keeping Cholesterol Balanced Naturally



By Janet Poveromo

According to the Center for Disease Control (February 9, 2010), "approximately one in every six adults—17 percent of the U.S. adult population—has high blood cholesterol."

Because of heightened consumer awareness due to the inundation of the marketing of statins by the major pharmaceutical markets, according to Mike Uckele, CN, CEO Uckele Health & Nutrition (Blissfield, MI), the demand for cholesterol control supplements is also very high. "[Statins] have become the top-selling prescribed medication in the world. However, it's now being understood that targeted nutritional support works well to maintain healthier cholesterol levels, along with a healthy diet."

Uckele's Chief Science Officer Jack Grogan, CN, said the market has become more interested in natural methods of balancing cholesterol since studies have shown that statin medications can deplete CoQ10, which has shown to be critical in maintaining normal energy production in the heart muscle. "They're looking for methods to balance cholesterol that will not deplete other necessary cardiovascular support," he said.

The future of the category lies in recent scientific studies that point to the importance of balancing the ratios of the different forms of cholesterol, rather than simply lowering cholesterol levels. "In the past, the emphasis of the discussion about maintaining healthy cholesterol levels was based on simply lowering the total and LDL cholesterol values," Uckele said. "Also, triglycerides are now deservedly getting more acknowledgement in the role that they play as a major risk factor for health issues independently of the cholesterol values, as well as their relationship to healthy HDL and LDL cholesterol levels."

Drugs and Alternatives

Steve Holtby, president and CEO of Soft Gel Technologies, Inc. (Los Angeles, CA), noted that many people are familiar with the terms "bad cholesterol" and "good cholesterol," and correctly think of them as being related to heart disease risk. "Triglycerides are another type of fat in the blood. It is associated with fat from foods, such as animal fats, and can be stored in cells to use for energy," he said. "Similar to high 'bad cholesterol' (LDL) and low 'good cholesterol' (HDL), current research reveals elevated triglycerides may contribute to hardening the artery wall, which increases risk for stroke, heart attack and heart disease. High triglycerides should be viewed as a danger signal, as they are often associated with low levels of HDL cholesterol and indicate a problem that causes the body to carry fat particles in the blood that do cause vascular disease. Very high levels of triglycerides can also cause pancreatitis, an inflamed pancreas."

Though some scientists believe they are overused, there is a place for statin drugs. David Peters, director of sales and marketing with Biovelop AB (Kimstad, Sweden), pointed out that the National Institute for Health and Clinical Excellence (NICE) recommends that those patients with a significantly above-average chance of suffering a heart attack, stroke or heart disease over the next 10 years should be prescribed statins. "However, the case for those at lower risk or with only slightly elevated cholesterol levels is far less clear-cut, and in the light of the negative press around statins, it is not surprising to find that these individuals are increasingly looking to alternative, more natural ways of lowering their cholesterol," he said. "This represents a great opportunity for food and drink manufacturers to create functional products from natural ingredients which target cholesterol reduction as part of a healthy diet and lifestyle.

"Some patients will continue to require statins to reduce the risk of future heart-related health issues, but many could reduce their cholesterol to—and maintain it at—normal levels by incorporating the power of nature into their diets," Peters added. "Faced with increasing pressure from government to produce healthier foods, the food and drink industry has an ideal opportunity to demonstrate that nutraceutical ingredients can mean healthier sales figures as well as healthier consumers."

Natural Ingredients & Product Offerings

Cholesterol lowering supplements, such as red yeast rice, phytosterols, policosanol, guggul, polymethoxylated flavones and tocotrienols, help prevent atherosclerosis and associated diseases. "Too much cholesterol in the bloodstream leads to nar-

Heart health and cholesterol are top concerns for health-conscious consumers. Fortunately, the benefits of natural products (as well as healthier lifestyle choices) for those issues are also well known and in a position to flourish.

rowing and blockage of the arteries that greatly increases the risk of stroke, coronary heart disease and heart attacks," said Holtby. "Additionally, vitamins C and E, niacin and grape seed extract—all of which are believed to have a dilating effect on blood vessels—may help to get the blood flowing. Certain niacin forms may cause uncomfortable flushing. Magnesium supplements may help dilate vessels and alleviate arterial spasms. Omega-3 fatty acids have been shown to decrease high blood triglyceride (fat) levels."

Having moved beyond commodity ingredients, many suppliers favor branded offerings to address cholesterol that are backed by science. One such product by Soft Gel is Sytrinol®, a patented formulation consisting of palm fruit and citrus extracts that contain polymethoxylated flavones and tocotrienols, and has been clinically proven to help maintain healthy cholesterol levels. "People now have a natural dietary supplement that has been shown in multiple clinical studies to lower total cholesterol, LDL cholesterol and triglyceride levels," said Holtby. In a clinical trial, soft gels manufactured by Soft Gel Technologies, Inc. exhibited enhanced bioavailability of the key active ingredients found in Sytrinol—specifically, the two polymethoxylated flavones (PMFs) tangeretin and nobiletin. Compared to powder-filled, two-piece hard shell capsules, the soft gel form of Sytrinol was four times more bioavailable.

Sytrinol was shown in several clinical trials to lower total cholesterol by 20 percent, LDL-cholesterol by 22 percent and triglycerides by 28 percent. PMFs modulate lipoprotein and lipid metabolism directly in the liver by decreasing apoprotein B needed for endogenous synthesis of LD-cholesterol, and by inducing the suppression of diacylglycerol acyltransferase—an enzyme required for triglycerides synthesis.

Oat beta glucan is one of the very few ingredients approved by EFSA (European Food Safety Authority), Health Canada and the FDA for cholesterol-reduction health claim purposes, Biovelop AB's Peters pointed out. "It is the backing of these substantiated health claims that gives the consumer the confidence to purchase products containing it," he said.

The company's PromOat™ is an oat beta glucan-rich, soluble fiber ingredient produced in Sweden using locally grown, non-GMO oats. PromOat is naturally separated from the oat bran using a patented, chemical-free technology, and can be added to a wide range of food, drinks and nutritional supplements to bestow the health benefits of oats on those products without the taste, color or graininess usually associated with oats.

W.H. Leong, vice president with Carotech Inc. (Edison, NJ), said the company's Tocomin SupraBio® patented and bioenhanced palm tocotrienol complex is the emerging (and synergistic) ingredient for the category. "There is a stark difference between Tocomin SupraBio and any other conventional tocotrienol preparation in that the absorption of tocotrienols from Tocomin SupraBio is guaranteed to be at least 250 percent better for each individual tocotrienol." Leong noted a recently reported clinical study that showed that when tocotrienol levels in the blood are significantly raised, reduction in total cholesterol and LDL-cholesterol levels is achieved (*Functional Foods in Health and Disease*, 3, 106-117 (2011)).

Headquartered in Denmark, Danisco Health & Nutrition introduced PinVita™ Phytosterols this year to keep the heart and arteries in shape by lowering the level of unfavorable LDL cholesterol in the blood by reducing cholesterol absorption.

Derived from a natural and sustainable pine source, PinVita is easy to formulate, and provides food manufacturers potential access to a cardiovascular health claim, according to the company. Peter Wisler, Danisco business development director, said, "It is well documented that lowering LDL cholesterol reduces the risk of cardiovascular health conditions. With PinVita, we provide an ingredient that helps reduce that risk and, it is therefore no exaggeration to state that PinVita comes with 'science at heart.'"

Gary Walker, president of Sylvan Bio, Inc. (Kittanning, PA), the only U.S. grower of red yeast rice, stressed that ingredients

Keeping Cholesterol Balanced Naturally

for maintaining healthy cholesterol are not enough; that consumers need to make conscious lifestyle choices: Eating healthy foods such as fresh fruits and vegetables, grains, fish oil and omega-3s, and nuts such as walnuts and almonds; regular exercise; and not smoking. "Smoking weakens the walls of the arteries and makes them more prone to the buildup of cholesterol," he said.

ny. "This is a balanced formula that includes nutrients, enzymes and plant extracts that can supply factors to directly support the liver's ability to properly metabolize HDL and LDL cholesterol balance and healthy fat metabolism," said Grogan. The product includes vitamins C and B5, guggul, red yeast rice, bromelain, taurine, pancreatin, CoQ10, policosanol and octacosanol.

Other Considerations, News

With regards to government regulations, an FDA mandate, set to go into effect on February 21, 2012, may mean that supplements claiming to reduce cholesterol and cause damage and create other cardiovascular issues."

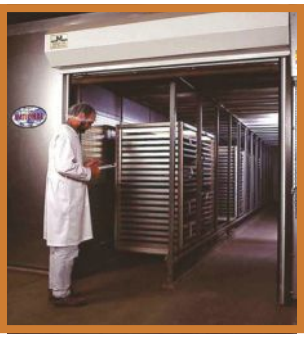
Ultimately, even with new knowledge of heart health, a healthy lifestyle can't be replaced with pills. "Modern medications have come a long way in helping to control blood cholesterol levels and high blood pressure, but making diet and lifestyle changes, including regular physical activity, are the best way to help prevent heart disease," stressed Holtby. "Patients tend not to think about what they eat or maintaining an exercise regime if they are on drug therapy for elevated cholesterol levels, or those who have elevated

Photo Credit to Sylvan Bio Inc.

Red Yeast Rice/ *Monascus purpureus*

Red Yeast Rice Manufacturing Process

Incubation



Drying

Processing

"We understand that quality and consistency are two very important factors for consumers when faced with making decisions with regards to their health," Walker added. The company will be introducing its new line, Synergia Wellness, in the first quarter of 2012. The Synergia Wellness Organic red yeast rice is U.S. grown and USDA Certified Organic. It is also a red yeast rice/vegetarian CoQ10 combination product, and a standalone vegetarian CoQ10, Walker noted. "When we produce red yeast rice, we keep it in its natural state. It appears that the combination, or cocktail, of natural metabolites in red yeast rice works effectively in cholesterol management."

Another finished product, Uckele's Lipisterin, has been very well received in the marketplace, according to the company. "This is a balanced formula that includes nutrients, enzymes and plant extracts that can supply factors to directly support the liver's ability to properly metabolize HDL and LDL cholesterol balance and healthy fat metabolism," said Grogan. The product includes vitamins C and B5, guggul, red yeast rice, bromelain, taurine, pancreatin, CoQ10, policosanol and octacosanol.

Other Considerations, News

With regards to government regulations, an FDA mandate, set to go into effect on February 21, 2012, may mean that supplements claiming to reduce cholesterol and that contain free forms of phytosterols will have to be pulled from shelves, Leong pointed out. "The proposed rule would ban cardiovascular disease risk reduction claims on supplements containing non-esterified phytosterols. Esterified phytosterols are not affected."

Another change is that the blanket fear of high cholesterol has been replaced. Holtby noted that it is known that as the size of cholesterol particles decreases, the cardiovascular risks increase. "Normal cholesterol results aren't necessarily reliable measures of risk," he said. "There are now tests that screen a far broader spectrum of risk factors that show up in the blood. One of the most important metabolic markers is a small, dense form of LDL. Their small size makes it easier to enter the arterial walls, where they can cause damage and create other cardiovascular issues."

Ultimately, even with new knowledge of heart health, a healthy lifestyle can't be replaced with pills. "Modern medications have come a long way in helping to control blood cholesterol levels and high blood pressure, but making diet and lifestyle changes, including regular physical activity, are the best way to help prevent heart disease," stressed Holtby. "Patients tend not to think about what they eat or maintaining an exercise regime if they are on drug therapy for elevated cholesterol levels, or those who have elevated risks for heart disease and stroke. Nobody can 'eat anything they want' and stay heart healthy, particularly since foods that contain high levels of saturated fat and/or trans fat contribute to high blood cholesterol." **NIE**

Extra! Extra!
Visit www.niemagazine.com to read about a new cholesterol-lowering drug study recently presented to the AMA.

FORMOREINFORMATION:

- Biovelop AB, +46 42 341230
- Carotech Inc., (732) 906-1901
- Danisco, +45 3266 2000
- Soft Gel Technologies, Inc., (800) 360-7484
- Sylvan Bio Inc., (866) 352-7520
- Uckele Health & Nutrition, (800) 248-0330

Science of Note:

***NIE* asked article participants what studies and research regarding cholesterol was most impactful to them.**

Soft Gel's Holtby: Both cholesterol and CoQ10 share a common biosynthetic pathway, which involves the formation of mevalonate compound with the aid of 3-hydroxy-methylglutaryl coenzyme A (HMG-CoA) reductase. Inhibition of HMG-CoA reductase by statin drugs at the mevalonate level will inevitably decrease the levels of both cholesterol and CoQ10. Human studies revealed a significant decrease in CoQ10 serum levels as a result of HMG-CoA reductase inhibitor treatment. In a double-blind, randomized clinical trial, hypercholesterolemic patients received either Lovastatin or Pravastatin over a period of 18 weeks. At the end of the study period, the total serum level of CoQ10 declined by about 25 percent in the Lovastatin and Pravastatin groups. (Mortensen SA et al. Dose-related decrease of serum coenzyme Q10 during treatment with HMG-CoA reductase inhibitors. *Mol Aspects Med* 1997; 18:S137).

Sylvan Bio's Walker: Dr. Becker, a cardiologist affiliated with Chestnut Hill Hospital, University of Pennsylvania School of Medicine in suburban Philadelphia, has conducted some of the most recent studies. One of his studies was published in the *Annals of Internal Medicine*: "Red Yeast Rice for Dyslipedemia in Statin-Intolerant Patients."

Carotech's Leong: We have recently completed the largest-ever human clinical trial on tocotrienols—"Neuroprotective and Cardioprotective Effects of Palm Vitamin E Tocotrienols," in which Tocomin SupraBio was used. The study results are expected to be published soon and preliminary findings are very positive.

nhiondemand.com
Health & Wellness Trade Site

- *Reaching out to over 15,000 eNewsletter industry members daily and growing!*

NHI's now thru Feb Limited Time Offer!

Start 2012 off making a real difference!

Save & Make a Difference Promotion

Save 25% off any NHI eNewsletter ad PO & we will match it with a donation to the cause of your choice.

Together everyone wins!

NHI is pleased to support:

American Botanical Council · CRN · AHPA American Herbal Products Association · Natural Products Association · Organic Trade Association · The Organic Center · Susan G. Komen Race for the Cure · vitamin angels

At NHI, our focus is on you & your success!

"We look forward to customizing your advertising package needs with the best online marketing programs in our industry to maximize your ROI"

Follow NHI on:

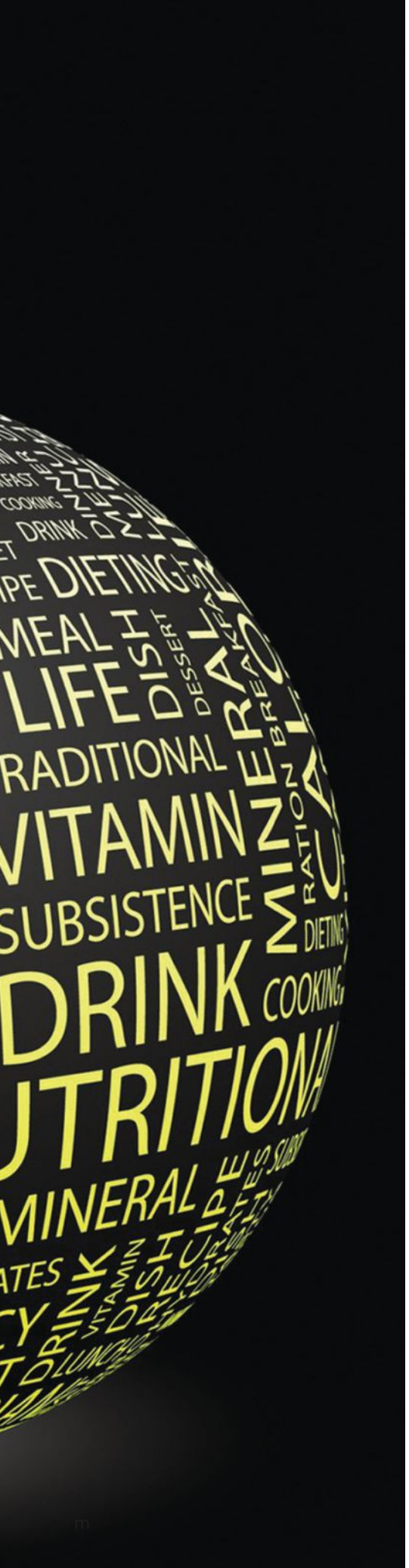
Sponsored by: Vitamin Retailer · Nutrition Industry Executive

For advertising information eMail admanager@nhiondemand.com

Great to be GRAS

With increased ingredient safety concerns and an exploding global functional food and beverage market, ingredient suppliers and experts talk about the importance and process of attaining GRAS status, and the role it could potentially play with NDIs.

By Kate Quackenbush



According to the U.S. Food and Drug Administration (FDA), under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by the FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS (generally recognized as safe) either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

"Prior to 1997, the FDA had to be petitioned to 'affirm' that a substance is GRAS, and was getting backed up with reviewing GRAS petitions," said John R. Endres, ND, CSO with AIBMR Life Sciences, Inc. (Puyallup, WA), a consulting firm that has been working with the natural products industry since its founding in 1978, and significantly increased its services to the functional foods industry in 2007. "On April 17, 1997, the FDA proposed a voluntary procedure whereby the Agency could be notified of a determination (the self-affirmation) that a substance is GRAS." While this proposed rule is yet to be finalized, all ingredients added to foods must have GRAS or Food Additive status.

Self-Affirmed GRAS

GRAS notification to the FDA is a voluntary process and not required, according to Endres. "Self-affirmation is accomplished according to the aforementioned FDA proposal. Companies hire a firm, such as AIBMR Life Sciences, to prepare a safety dossier generally based upon scientific procedures and corroborated by a history of human exposure. Finally, a panel of experts is assembled," he said, adding that AIBMR usually has two to three staff physician scientists as panel members, and the chair being a PhD toxicologist retired with 40 years experience with the FDA and EPA. "The expert panel must be qualified by training and experience to evaluate the safety of food ingredients, and must agree with the basis of the determination that the intended use of the ingredient is GRAS."

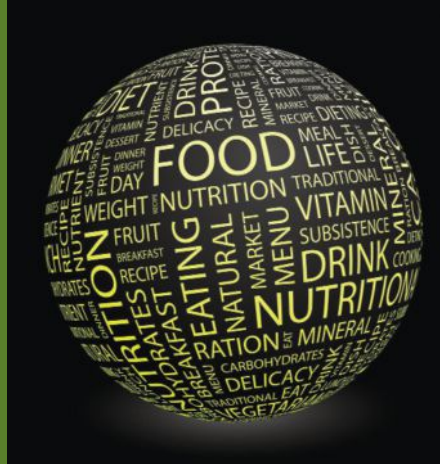
This was a route began in earnest in 2009 by Trace Minerals Resources International, Inc. (TMR, Ogden, UT). "We wanted to continue gathering scientific data giving validity to our trace mineral ingredient, ConcenTrace Trace Mineral Drops," said Ryan Fisher, the company's general manager. "As our company has grown over the last decade, we have had more international interest as well as larger food companies inquire about our minerals as a method to improve their products and add significant mineral claims to their products supplement facts. GRAS affirmation was required by some of them and encouraged by all of them. We wanted to make our product available to new markets and increase the availability of our product throughout the world."

TMR first looked at working individually with the required experts, but later decided to use the services of AIBMR. The estimated cost for GRAS affirmation is $75,000 and the time frame was approximately two years to complete, which was a completely worthwhile investment, according to Fisher.

"We saw an immediate impact with our potential client list after the process was complete," he said. "Companies who had interest in our products before but had held off purchasing from us began to bring our products in. Other current customers expanded the amount of business they were doing with us because of the extra level of confidence that they gained with us."

Another company that has seen markets open up after securing self-affirmed GRAS in late summer 2011 for its patented cognitive health ingredient Magtein™ is City of Industry, CA-based AIDP, Inc. "This compound has large market potential for a broad number of conditions," said Kathy Lund, director of business development. "By securing self-affirmed GRAS, AIDP can assure customers of Magtein's safety. It indicates an investment behind the product and a commitment to market development. GRAS helps to open several market channels that would not otherwise consider a non-GRAS ingredient, such as beverages, which require a GRAS status."

Suzanne McNeary, president of NutraGenesis LLC (Brattleboro, VT), shared that her company's choice, as with many companies, for self-affirmed GRAS was deliberate. "Our company has always preferred self-affirmed GRAS and we are not alone—the majority of GRAS determinations are self-GRAS in order to protect the proprietary information of an ingredient from competitors," she said, adding that NutraGenesis has worked with RS McQuate & Associates and GRAS



Great to be GRAS

Associates attaining GRAS self-affirmation for the company's Wellberry®, Wellberry® Trim, WellBody•365™ and Capros® ingredients. "We like working with those firms because the principals of both are former FDA safety officers and FDA toxicologists. Working with a firm or firms that have former FDA officers on staff can provide a company undertaking GRAS with a higher degree of confidence because these individuals know the inner workings, culture and mindset of the FDA, and they know what the information requirements will be in order to truly satisfy the FDA standard of GRAS."

No Objections

As soon as an ingredient is self-affirmed as GRAS it can be added to foods according to the GRAS dossier, said AIBMR's Endres. "For most companies, this is fine up to the point that they discuss selling the ingredient to the larger multinational companies. These larger companies most often require the manufacturer to get the 'no objection letter' from the FDA before they will buy the ingredient to add to their products."

Healthco (Bloomingdale, IL), the raw material and private label division of NOW Foods, made the decision to seek self-affirmed GRAS status for its enzyme treated stevia, brand named Stevia-FSE™, about three years ago. Once that was successfully done, the company began the process for FDA-notified GRAS status. "We made the decision to go through the process because we felt our full spectrum whole leaf extract was an extraordinary product, with potential in many food and beverage applications," said Peter Sokoloski, the company's private label manager. "We submitted a GRAS notification for Stevia-FSE to the FDA voluntarily. We made the business decision to do this because we believe that this product will have many food and beverage applications and thus having a no objection from the FDA would be very valuable."

Sokoloski explained that while the process was significant, preparation and actively asking questions made a great deal of difference. "We hired consultants familiar with this process and developed a scientific strategy for the information required. The big piece initially was complete characterization of the product. This took us into the most sophisticated chemical analytical technologies available today," he said. "We then met with the FDA and they suggested that we also complete a metabolic study, which we then did. With all this information we prepared a self-affirmed GRAS and also submitted to the FDA.

"The FDA process was straightforward, especially since we met with them early on and knew what was required. They had minor questions, which we answered," Sokoloski added. "The frus-

GOING FOR GLOBAL RANKINGS

Bergstrom Nutrition (Vancouver, WA), producer of OptiMSM®, started considering GRAS status in 2003. According to Rodney Benjamin, director of technical development, "We saw GRAS status as a natural progression for MSM. GRAS requires a higher level of toxicology and safety data on an ingredient than what is required for the dietary supplement market. We felt that GRAS would accomplish two goals, a stronger safety profile for our ingredient and allow entry into the additional market of functional food and beverage."

Bergstrom's final decision to proceed was in late 2004, early 2005, after an acute and sub-chronic toxicity study had been completed and an additional data gap analysis had been performed on OptiMSM. "This identified the additional studies that would be needed and gave us a rough idea of costs," said Benjamin. "I say rough because we actually exceeded initial estimates by about 50 percent. The entire process cost several hundred thousand dollars and took about three years."

In addition, Bergstrom made the choice to submit the dossier and expert panel opinion to FDA-CFSAN and received the FDA's no-objection letter.

Afterwards, the company took it a step further in deciding to follow the Global Food Safety Initiate (GFSI) program, which provides a framework for a system of independent certification that a supplier's food safety and quality management system complies with international and domestic food safety regulations.

"(GFSI) was pursued in part because of the need to be able to ensure to customers that all precautions are being taken to ensure the safest product possible is being made. The process for obtaining the GFSI certification was a lengthy one, which started with the implementation of the ISO 9001:2008 program and subsequent registration. Once that benchmark was achieved, the building of the FSSC22000 program was simpler than it would have been had we not established the ISO 9001:2008 program," said Wendi Reymore, Bergstrom's director of quality and regulatory affairs, adding that the reason for that was because the GFSI program the company chose, FSSC22000, takes many requirements right from the ISO 9001:2008 standard and adds a requirement for a HACCP plan and a few other in-depth programs to ensure product safety. "And since Bergstrom Nutrition had many of the controls already in place, it was relatively simple to write the program and put the required documentation into the daily practices.

"Going forward we see this as an opportunity to prove to our customers that we are dedicated to making a high quality and very safe product," Reymore concluded.

tration was that it took a long time; longer than it should."

Beyond the consultants and direct interaction with the FDA, Sokoloski said that having the right internal resources didn't hurt. "Because of Healthco's access to NOW Foods' technical staff with their testing and regulatory expertise, as well as some of the most sophisticated labs in the business, we had a good understanding of what was required and the capacity to do it," he said.

"Although there are two different pathways for GRAS—self-affirmation and FDA no objection—and both pathways end up in an ingredient legal for food use, many food manufacturers will not accept a self-affirmation; they want an opinion from the FDA," added Michael Lelah, technical manager with NOW Foods. "This further protects them from the FDA disagreeing with a self-affirmation at some future date, which could happen."

AIBMR's Endres acknowledged this line of thinking, but offered another side. "There is the perception that the FDA 'no objection letter' is the best that can be obtained," he said. "GRAS self-affirmations, if properly prepared and reviewed, should be thorough enough to cause the FDA to not question the basis of the GRAS determination."

One company confidently banking on this is Kemin Health L.C. (Des Moines, IA), which began its GRAS self-affirmation review in October 2010 for AssuriTEA Wellbeing™ and worked steadily on the review up through the time the Expert Panel was convened in September 2011.

"If a company makes a self-determination, FDA may challenge that determination on the basis that the product is an illegal food additive," said Debbie Trinker, Esq., vice president of regulatory and legal affairs with Kemin. "However, Kemin is not aware of any situation where FDA has challenged the GRAS status of a substance that has been self-affirmed after a thorough, documented scientific finding of GRAS status was confirmed by an qualified and independent scientific experts, such as was done for AssuriTEA."

The company's confidence is well placed, according to Trinker, as Kemin has carefully followed FDA regulations at 21 CFR 170.30 on GRAS status that require "common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food ..." "The GRAS determination of the proposed uses of AssuriTEA Wellbeing was based upon 'scientific procedures' as described in the regulation, as corroborated by history of safe use of green and black teas," Trinker explained. "Kemin was able to rely upon the history of safe use of tea, because its ingredient is a water extract that qualitatively and quantitatively compares compositionally to brewed tea. Unlike some commercial tea ingredients, AssuriTEA Wellbeing is not extracted with alcohol and its green tea component is not concentrated to EGCG or any other constituent, making reliance upon the history of safe use of tea appropriate."

Kemin's AssuriTEA Wellbeing review has taken a year and cost tens of thousands of dollars in external consulting fees, as well as required extensive use of the company's internal resources. Other discussions on the GRAS process estimate $75,000 in fees from external consultants, and six months of review time. "The amount of time and money a company will spend will depend on the ingredient, the proposed food applications and usage levels," said Trinker. "Based on Kemin's experience with a number of ingredients, companies can easily expect to pay in the six figures and for the GRAS review process to take considerably longer than six months."

GRAS and NDIs

With the door closing on the FDA's acceptance of comments regarding its

(Continued on page 39)

The Veggie Alternative

As consumer awareness of EFA importance grows, many are opting for omega-3 fatty acids from vegan or vegetarian sources.

BY SHARI BARBANEL

Essential fatty acids (EFAs) are a necessary part of a person's diet. Omega-3 fatty acids support the immune, nervous, cardiovascular and reproductive systems as well as eye and brain health. Further, more studies and research are being conducted to discover additional benefits of consuming EFAs.

There are three main types of EFAs: alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Further, omega-3 EFAs fall into two major categories: plant-derived and marine-derived. ALA is found in plant-based sources such as flax seed, chia seed, walnuts and dark green leafy vegetables, while EPA and DHA are most commonly found in cold-water marine animals such as cod, krill, sardines, mackerel and anchovies.

When plant-sourced EFAs are consumed, the body converts ALA to EPA and then eventually to DHA. Even though the process of conversion can be very slow in some people, the plant-based option is essential for those living a vegan or vegetarian lifestyle, and is seen a good alternative for those with fish allergies or who choose not to consume marine-based EFAs. "ALA is a crucial dietary source of omega-3 fatty acids and its inclusion in the diet is critical to maintain long-chain omega-3 tissue levels," said Dean Mosca, president of Proprietary Nutritionals Inc. (PNI, Kearny, NJ). "However, a number of factors are responsible for the low consumption of these essential fatty acids, and greater intake of omega-3 fatty acids is hard to achieve by the general population, due to the occidental modern diet."

Natural Sources

The body is unable to produce EFAs on its own, so they must be consumed from other sources. While many consumers opt for marine-based EFAs, others who are not necessarily restricted to a vegan or vegetarian diet may worry about digesting toxins and contaminants that can be found in fish (such as mercury), and prefer a supplement that isn't as heavily processed.

"Beyond the strict vegan demand need, general consumers want to be able to logically link the food/supplement ingredient to a known natural source," said Walter Postelwait, vice president of sales and marketing for BI Nutraceuticals (Long Beach, CA). "The image of pressing fish by-products to make fish oil does not resonate as a natural process to most everyday consumers. Additionally, the medical research on EFAs is ever increasing and showing more benefits. This will only continue to drive the demand along with the demographics of the aging population."

There are a number of plant-based EFAs including flax, chia and hemp seeds, walnuts, soybeans, and some leafy green vegetables and plant foods. While there is also a growing interest in lesser-known plant sources of ALA such as sacha inchi (a native plant of the Amazon rainforests) seeds and perilla seeds, the two most popular plant-based EFA sources are flax and chia.

Seeds of the flax plant, flaxseeds can provide a rich source of ALA (containing more than 50 percent of ALA), and is also a good source of fiber. Flax can be added in various types of foods, beverages as well as supplements. The popularity of adding flax to products is growing rapidly, as the Flax Council estimates that close to 300 new flax-based products were launched in 2010 in the U.S. and Canada.

Like flax, chia is an oil seed that is rich in ALA. In fact, 63 percent of total fatty acids in chia seeds are omega-3 EFAs. In addition, chia provides other nutrients including antioxidants; fiber; vitamins B1, B2 and B3; as well as minerals such as phosphorus, calcium, potassium, iron, zinc and copper.

Benexia™ Omega-3 Chia from PNI is organic, gluten-free and a rich source of omega-3 fatty acids. Typically, chia seeds contain 20 percent protein, 34 percent oil and 25 percent dietary fiber. Benexia is also a super antioxidant, delivering a higher ORAC value than fresh blueberries. The health benefits include cardiovascular, brain and immune system support, as well as support of a healthy inflammatory response. Benexia Chia is the only GAP, GMP, HACCP and ISO certified source for highest purity and quality. It is available in bulk seed, sprouted seed, milled seed, flour and oil. According to the company, it is ideal for drink mixes, bars and incorporates easily into other foods.

BI Nutraceuticals offers Steam Sterilized Chia Seeds, which are a complete vegan source of protein, have no gluten or cholesterol, offer a comprehensive range of nutrients, vitamins, minerals, antioxidants and essential amino acids, and contain the highest levels of total omega-3 fatty acids by weight of any common foods, according to the company.

"BI only wants to offer products which truly bring value to our customers," said Postelwait. "This is why we chose chia seeds. Our proprietary steam sterilization technology provides us the ability to sterilize the seeds and guarantee a level of safety that no other supplier of this ancient grain can provide today." BI Nutraceuticals's Steam Sterilized Chia Seeds can be used in various applications including cereals, breads, soups, salad dressings and nutrition bars, and can be mixed with liquids to create beverages.


Chia plant

Setbacks and the Sustainable Future

Although the popularity of plant-sourced EFAs is growing and consumers are embracing them more, Postelwait said he believes that there is still confusion and misconceptions about plant-based EFAs. "I am not so convinced that the majority of end consumers are truly aware of how each of the different types of the vegetarian EFAs are made and therefore, I don't believe they fully understand the scientific

credibility each offering has," he explained. "Yes, they most likely are aware of the original source of the vegetarian EFA (algae, ancient grain, flax, etc.), but it is not clear that they fully understand how they are derived and the different benefits of each."

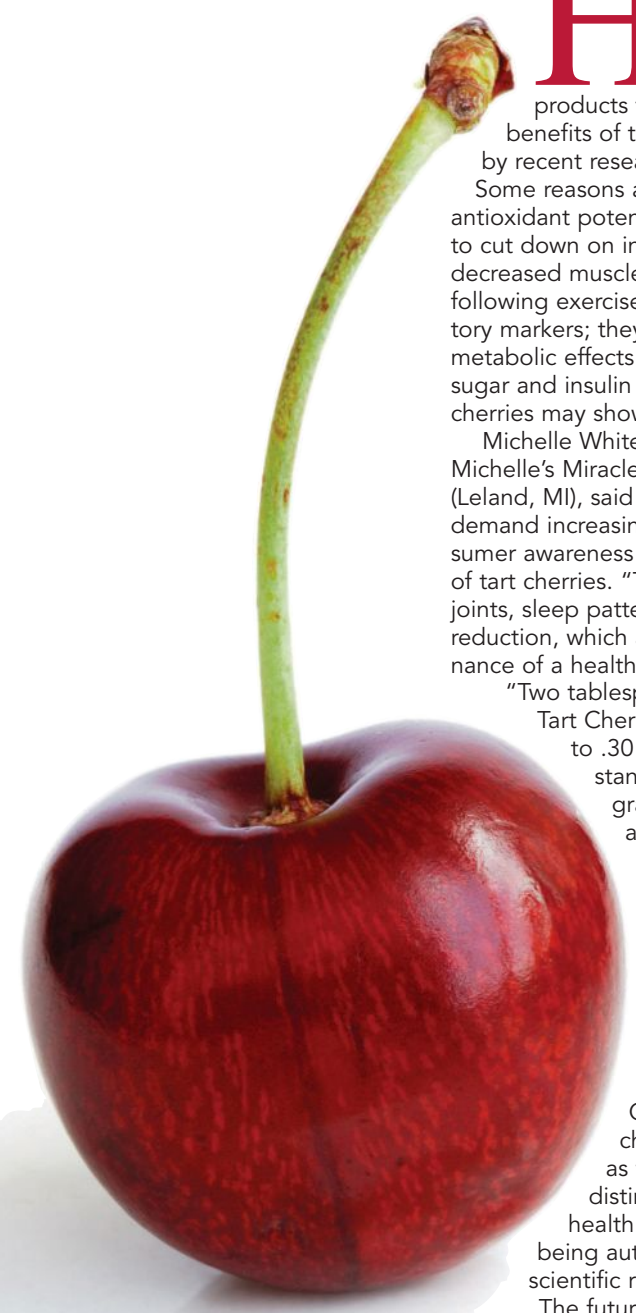
But what manufacturers and consumers are taking into consideration is, unlike fish sources, vegan and vegetarian EFA sources seem to be more sustainable in the long run. "We believe that the sustainability of the omega-3 supply is the big challenge in this category of products," said Mosca. "As EPA and DHA continue to grow in sales and in demand, sustainability is becoming more crucial. The fish stock is not endless and the needs for omega-3s are huge for the global human population. ALA is the only sustainable source of omega-3 for humanity in the long term. The world's population is increasing and is becoming more aware of the huge requirements for omega-3s, and the health problems resulting from its deficiencies in human nutrition." **NIE**

FORMOREINFORMATION:

- BI Nutraceuticals, (310) 669-2100
- Proprietary Nutritionals Inc., (800) 526-0609

Untapped Potential for a Tart Super Fruit

By Janet Poveromo



Having found delicious new ways to capture the energy of tart cherries, conscientious companies are creating products to bring consumers health benefits of the super fruit that is backed by recent research.

Some reasons are: tart cherries have high antioxidant potential; they have been shown to cut down on inflammation including decreased muscle soreness, greater strength following exercise and decreased inflammatory markers; they have important beneficial metabolic effects such as decreasing fat, sugar and insulin levels in the blood; and tart cherries may show helpful effects on sleep.

Michelle White, founder and president of Michelle's Miracle Tart Cherry Concentrate (Leland, MI), said the market is booming with demand increasing due to the influx of consumer awareness on the measurable benefits of tart cherries. "Tart cherries support healthy joints, sleep patterns and inflammation reduction, which also supports the maintenance of a healthy heart.

"Two tablespoons of Michelle's Miracle Tart Cherry Concentrate is equivalent to .30 grams of aspirin, whereas a standard aspirin tablet is .325 grams—all adding in anti-inflammation. As we know, inflammation is the root of many health problems," she said.

"Red tart cherries are a hot commodity in today's marketplace," agreed Bob Underwood, president of Cherry Capital Services/ Underwood Fruit (Traverse City, MI). "Although the tart cherry has long been known as the "pie cherry," that distinction is changing as the health benefits of the fruit are being authenticated through scientific research."

The future of this ingredient is bright as ongoing research is offering compelling evidence of health benefits, making the message clear to consumers that tart cherries will aid in maintaining good health, Underwood noted. In addition, he expressed the antioxidant benefits in tart cherries are virtually untapped and present a huge growth opportunity for farmers, producers, processors and manufacturers. "I believe the cherry industry in this country has room to expand and flourish as the nutraceutical and food applications become better known and interest increases in the emerging area of medicinal foods," Underwood added.

What Consumers Know

Tart cherry knowledge continues to grow with the health benefits being touted by health authorities including Dr. Oz. "Evidence of this is significant with a doubling of sales during a down economy over the past nine months," said White.

"The initial 'wives tale' of generations past is now being supported by real research," she added. "And while the consumer awareness is significantly more than in years past, it is important to continue to educate consumers of all ages who are concerned about maintaining a healthy lifestyle without using medications with dangerous side effects."

From Word-of-Mouth to Research

Anecdotal evidence about tart cherries is the reason Underwood's nutraceutical, functional food company was launched 12 years after he spent his entire career as a fruit farmer, processor and as a farm market retailer. "It was the many comments from customers about the palliative effects of tart cherries on their hurts and sore muscles that initiated my efforts to make tart cherries available year round in a convenient form."

Since then, the company's CherryFlex has been the subject of several scientific clinical trials, the most recent dealing with muscle fatigue following strenuous exercise. The American College of Sports Medicine accepted and published the finding that show CherryFlex speeds relief of muscle fatigue

Pain Relief and Tart Cherries

Michelle's Miracle provides a list of notable published research compiled into one user-friendly document for consumers. Here's a sample of two studies:

• Oregon's Hood to Coast relay is a 197-mile race involving 1,000 relay teams. In 2009, scientists from Oregon's Health and Science University studied the impact of tart cherry juice on pain in athletes participating in the race. Participants drank 10.5-oz. of tart cherry juice twice daily for a week prior to the race and then every eight hours during the race. Other runners received placebo juice. At the end of the race the cherry drinkers had less pain and faster muscle recovery.

• A European research team set out to discover the effects of anthocyanins in living animals. They found that a type of tart cherry worked in a way that is very similar to aspirin. Not only that, but tart cherry juice also has antioxidant power in the blood and livers of mice.

The study group found that tart cherry juice increased the activity of a free radical scavenger called superoxide dismutase. Glutathione peroxidase, another powerful player in the antioxidant pathway, also surged in the liver when researchers gave mice tart cherry juice. While the type of cherry affects the amount of different beneficial antioxidants, all tart cherries have some of the most powerful kinds, such as cyanidin-3-glucoside.

due to strenuous exercise. Other studies by the Cherry Marketing Institute have verified the long-held health benefits attributed to the fruit. The FDA allows statements regarding the positive effects of tart cherries on joints and muscles, cardiovascular health and the immune system.

"Great progress has been made in the past five years, but research studies need to continue as science strives to unravel the natural phytonutrient puzzle that is helping so many people live healthier lives," said Underwood. "We are one of the few small companies to invest in scientific studies and we are very proud of that fact. Not only does it verify our products, but it helps with the awareness of the entire cherry industry."

Products in Demand

In addition to Underwood Fruit's human products, CherryFlex has just entered the animal products world with CherryFlex for Horses (squeeze pouches of cherry paste with apple concentrate) and CherryFlex for Dogs (natural beef-flavored cherry paste soft gels).

"After years of testing, research and tracking our customers' successes, we know that CherryFlex is beneficial for joint and muscle health and it speeds relief of sore muscles," said Underwood. "Animals also have similar joint and muscle issues as their owners, so it only makes sense that whole red tart cherries would be beneficial for them, too."

New products for Michelle's Miracle include special proprietary formulations for joint relief and sleep, as well as tablets for convenience for travel, with more to come, said White. "What's in demand is high-quality, potent, 100 percent tart cherry concentrate that is GMO and gluten-free."

"We think producing quality fruit products using only U.S.-grown, made in America cherries is extremely important," added Underwood, admitting that tart cherries' health benefits remain largely a mystery. "Scientific research is just beginning to understand what they contain and how their compounds interact. The best part is CherryFlex is just fruit that's very safe without side effects … and we all should be eating more fruit, especially super fruits." He stressed that Underwood Fruit will continue to explore, innovate and create new products and markets with the mission of improving the quality of life for people and animals.

"It is important to understand just how easy and tasty tart cherry concentrate is to use in your daily diet," added White. The company offers seasonal and family recipes that utilize the juice at www.michelle@michellesmiracle.com. "I have developed recipes from tasty breakfast fare to dinner, desserts and drinks—all served up with healthy benefits!" **NIE**

"Great progress has been made in the past five years, but research studies need to continue as science strives to unravel the natural phytonutrient puzzle that is helping so many people live healthier lives."

— Bob Underwood, President of Cherry Capital Services/ Underwood Fruit

FOR MORE INFORMATION:

- Cherry Capital Services/ Underwood Fruit, (231) 947-8764
- Michelle's Miracle, (800) 939-3199

Faith-Based Certification

Halal accreditation can serve both the growing Muslim customer base globally and those who look to certification as a symbol of quality regardless of their religion

By Paul Bubny

The fact that upwards of two billion people around the world—including more than nine million in North America—practice Islam is compelling enough reason to seek halal certification for ingredients and/or finished products. There's also the fact that this consumer base is growing rapidly, both domestically and internationally; Islamic Services of America (ISA, Cedar Rapids, IA) reported the growth rate has exceeded 30 percent annually for the past several years, while the Park Ridge, IL-based Islamic Food and Nutrition Council of America (IFANCA) said that American Muslims alone spend about $20 billion per year on food and noted an 80 percent increase in the number of halal products worldwide since 2005. Yet there's another, less obvious consumer base, according to IFANCA: "millions of health-conscious non-Muslims who chose to eat halal-certified products because these products are inherently clean and manufactured in a compassionate manner with respect to the treatment of slaughtered animals."

A number of ingredient suppliers and branded manufacturers alike have already gotten the memo about the reach of halal certification beyond the Muslim faith. When BI Nutraceuticals (Long Beach, CA) received IFANCA certification in 2007 for hundreds of its ingredients, George Pontiakos, the company's president, noted that the importance of the Muslim demographic to his company and added, "Demand from manufacturers for Halal certified ingredients is growing exponentially, especially as Halal certified products continue to be sought out not only by the Muslim community, but also by a diverse group of individuals who view the certification as a symbol of superior quality."

Similarly, when Sabinsa Corp. (East Windsor, NJ) announced a year later that more than two dozen of its ingredients had been certified halal, Shaheen Majeed, the company's director of marketing, commented that the certification would "not only allow us to enter different world markets, but also help our customers meet regulatory requirements and demand from the Muslim community."

In 2010, branded manufacturer and bulk supplier Trace Minerals Research International, Inc. (TMR, Ogden, UT) received halal certification for its ConcenTrace Mineral Drops and Utah Sea Minerals. Ryan Fisher, general manager of TMR, predicted that the IFANCA acknowledgement "will foster even more confidence in our products to our current and future customers because of the strict standards and qualifications required for Halal certification."

Meeting the Mandate

As part of the certification process for all three companies, IFANCA inspected their manufacturing facilities. Other major certifying agencies, which similarly mandate a rigorous inspection and investigation process, include ISA and the Muslim Consumer Group (MCG, Huntley, IL).

An Arabic word meaning "lawful" or "permitted," halal refers to the Muslim dietary standard, and more generally a code of behavior and lifestyle. Along with proscribing the consumption of animals that were slaughtered in an inhumane manner, halal also prohibits eating pork and its by-products, carnivorous animals, birds of prey or land animals without external ears. Conversely, fish and all fruits and vegetables are considered halal. This has implications in terms of what ingredients can and cannot be used in halal-certified supplements and nutraceuticals.

Some food products have been certified as both kosher and halal, and ISA noted that in practice many kosher consumers use halal products and vice versa. But while there is some overlap, kosher and halal are not synonymous.

One important difference pertaining to supplement ingredients is the kosher provision of istikhala, or transformation. It allows for the consumption of gelatin made from pork bone—even though pork products are prohibited in a kosher diet as well—because the bone is no longer what it once was. There is no such provision in halal. "Something haram [unlawful] cannot

become halal even though halal can become haram," according to ISA. In this instance, vegetarian gel capsules would be called for.

Halal certification is not a strictly one-size-fits-all procedure, and the agencies said that they look at product categories differently. Take nutraceuticals, for example: "This is a growing market that includes vitamins, whole food supplements, proteins and minerals," according to ISA. The agency said it will investigate "the ingredients and the sources for halal compliance. Once compliance is established, the product will be certified and can carry the ISA halal logo."

As with organic certification or any other accreditation, the process of achieving recognition as halal begins with a request for an application. This initial contact with the halal certifying body includes a discussion of the prospects for certification and what steps the manufacturer or supplier would need to take to get there.

The application itself includes details on the ingredients and is followed by arranging for an auditor to tour the facility or facilities. Next, the company would provide the agency with the required information, "such as specification sheets, labels, flow charts, cleaning procedures, etc.," according to IFANCA.

The application is then reviewed by the agency; once everything is in place, a contract is signed and an invoice is sent. Once certification is granted in writing, the company may use the agency's symbol on its products.

What happens after certification is granted varies according to both the type of product being certified and the agency. IFANCA, for example, issues certification that's good for a year, while ISA requires annual re-inspection of facilities to ensure compliance. The agency may also provide halal training for key personnel, which can then be passed on to other members of the company's team.

It's important to note that other accreditation processes can be compatible with halal. Hazard Analysis Critical Control Point (HACCP), for example, "is an important quality management system for the food industry and fits in well with the concept of halal," according to IFANCA. "Implementing HACCP demonstrates the producer's desire for safe products. When implementing a halal certification program, the certifying agency will incorporate specific halal procedures within the greater HACCP procedures."

Similarly, IFANCA noted that ISO 9000 fits in well with halal, demonstrating the producer's desire for consistent quality. As with HACCP, IFANCA stated, "ISO alone does not make a product halal, and a halal product can be made without ISO." **NIE**

FORMOREINFORMATION:

- BI Nutraceuticals, (310) 669-2100
- Islamic Food and Nutrition Council of America, (847) 993-0034
- Islamic Services of America, (319) 362-0480
- Muslim Consumer Group, (847) 515-1008
- Sabinsa Corp., (732) 777-1111
- Trace Minerals Research International, Inc., (800) 624-7145

Great to be GRAS

(Continued from page 33)

New Dietary Ingredient (NDI) Draft Guidance, *NIE* asked: "Might GRAS status negate a company's need to submit an NDI notification (NDIN)?"

"Technically, GRAS is a higher standard than NDI because the standard for safety is higher for GRAS than for the NDI. GRAS can negate the need for an NDI, but the regulatory landscape is quite complex," said NOW Foods' Lelah.

"GRAS status is typically considered to require an ingredient to meet a higher standard of safety than the standard that applies when obtaining an NDIN, i.e., that the ingredient does not present an unreasonable risk of illness or injury when used under its intended conditions of use," explained Kemin's Trinker. "Also, FDA's 'acknowledgment' letters to an NDIN expressly state that FDA is merely accepting the notification for filing and the acknowledgment is not a finding by the FDA that the NDI or supplement that contains the NDI are safe or not adulterated. The Draft Guidance recognizes that new dietary ingredients may be exempt from an NDIN submission if the GRAS substance has been used in the food supply. According to the Draft Guidance, a GRAS substance (including substances self-affirmed as GRAS) can be used as new dietary ingredients without notification if the intake levels of the new dietary ingredient recommended are the same or lower than the intake level reviewed in the GRAS determination. So, if there is adequate information to provide reasonable assurances that the use of the GRAS substance as a NDI in a dietary supplement will not present a significant or unreasonable risk of illness or injury, then yes, the GRAS status could 'negate' the need for an NDIN submission."

A point concurred by NutraGenesis's McNeary: "I think it remains to be seen as to what will ultimately come out of the NDI Draft Guidance, but in the short term I believe that many companies may pursue GRAS status if they are at all unsure as to their ODI/NDI situation. My understanding of the current law is that GRAS status does indeed negate the need for an NDI."

"The FDA's recent guidance on NDIs allows companies to use an ingredient in their supplement without filing for NDI if that ingredient has GRAS status," said Wendi Reymore, director of quality and regulatory affairs with Bergstrom Nutrition (Vancouver, WA), producer of OptiMSM®. "GRAS requires that pivotal information be published and in the public domain, whereas information to support the safety of an NDI need not be published. GRAS also requires an expert panel to review safety data, whereas the proof for NDI safety only need be provided by the company filing for the NDI."

In closing, AIBMR's Endres has been working closely with the FDA and had this to offer: "It is difficult to anticipate what the FDA may be thinking. I have been asked a few times in meetings with the FDA in person regarding GRAS notices how I felt the voluntary program is working. My opinion is that it is working well." **NIE**

Extra! Extra!
Visit www.niemagazine.com to get participants' thoughts on what ingredient suppliers need to keep in mind when pursuing GRAS status.

FORMOREINFORMATION:

- AIBMR Life Sciences, Inc., (253) 286-2888
- AIDP, Inc, (866) 262-6699
- Bergstrom Nutrition, (888) 733-5676
- Healthco, (800) 477-3949
- Kemin Health, L.C., (800) 777-8307
- NutraGenesis LLC, (802) 257-5345
- Trace Minerals Resources International, Inc., (800) 624-7145

Equipment&Packaging

Low-Cost, High-Speed Packaging Option Enters Market

Tekni-Plex (Somerville, NJ) has announced the full commercial availability of ALU-LOOK™ blister films for pharmaceutical and nutraceutical applications. ALU-LOOK (Aluminum Look) blister films represent a versatile, high-speed packaging option for health care industry customers when compared to other options such as cold-form foil and aluminum strip packaging. Even though ALU-LOOK can be used as a mono film with no substantial changes in properties as compared to clear poly-vinyl-chloride (PVC), its primary application is for laminations to PCTFE films (Aclar® or VapoShield), giving it superior moisture barrier properties to protect hygroscopic contents. It thus offers all the benefits of conventional PCTFE laminates, such a wide barrier range and the ability to run on standard thermoforming equipment, and provides protection from UV and visible light. Most important, though, it mimics the visual characteristics of cold-form foil, but without the need for cold-form foil's larger blister formats, expensive tooling and reduced packaging speeds.
Contact Tekni-Plex, Inc. at (484) 690-1520 or visit www.tekni-plex.com.

New Ultrasonic Guillotine Cutter From Bosch

Bosch Packaging Technology (Farmington Hills, MI) has launched the new WRQ 0400 US ultrasonic cross-cutting guillotine device for bar production. Particularly suitable for products that are difficult to cut such as bars, cakes and pet food, the WRQ 0400 US uses ultrasonic technology to cut product arriving in mass ropes into individual bars, and applies minimum stress and pressure while cutting to preserve product quality. Due to its high-speed micro vibration, the technology results in clean cuts with sharp edges and smooth surfaces for further quality benefits. The ultrasonic-powered knife ensures that the product does not stick to the surface of the blades. Thus, the system is ideal for difficult cutting applications such as sensitive, sticky, laminated or layered products.
Contact Bosch Packaging Technology at (248) 876-1000 or visit www.boschpackaging.com.

O.Berk's Syrup Bottles Handle Sticky Situations

O.Berk's (Union, NJ) heavy-duty amber colored laboratory bottles are ideal for storing and handling viscous fluids such as cough and other syrups, as well as concentrated flavors and fragrances. With 28mm necks, O.Berk's Laboratory Syrup Bottles are easy to fill and pour, and tamper-proof design keeps contents safe and secure. Available in a range of 13 different capacities from 30mL through 1L, all with interchangeable closures, the amber color is ideal for light sensitive liquids. Self-adhesive labels adhere readily to smooth glass, easy-to-grip surface so contents can be quickly and easily identified. Their screw-on plastic closures can even be silk screened with a corporate logo or other graphics.
Contact O.Berk Company at (908) 851-9500 or visit www.oberk.com.

AdvertiserIndex

ADVERTISER	PAGE	PHONE	WEBSITE
Biothera	24	(651) 675-0300	www.biothera.com
Chemi Nutra	C4	(866) 907-0400	www.cheminutra.com
Health & Nutrition Show	29	(805) 646-4246	www.healthandnutritionshow.com
Healthco	1	(800) 477-3949	www.healthco-intl.com
Interhealth Nutraceuticals, Inc.	5	(800) 783-4636	www.interhealthusa.com
Nutraceutix, Inc.	7	(425) 883-9518	www.nutraceutix.com
Nutratech, Inc.	23	(973) 882-7773	www.nutratechinc.com
pTeroPure	25	(949) 600-9694	www.pteropure.com
Sabinsa Corp	C2	(732) 777-1111	www.sabinsa.com
Soma Labs, Inc	11	(802) 383-5719	www.somalabsvt.com
Trace Minerals Research	33	(800) 624-7145	www.traceminerals.com

IndustryEvents

December 1-January 31
Health & Nutrition Virtual Show
www.healthandnutritionshow.com

February 8-12, 2012 • Integrative Healthcare Symposium • Hilton New York, NY • (972) 943-4773
www.ihsymposium.com

February 14-16, 2012
WestPack 2012 • Anaheim Convention Center • Anaheim, CA
www.westpackshow.com

February 22-25, 2012
Focus on the Future Conference
Hyatt Regency Scottsdale Resort and Spa • Scottsdale, AZ
(480) 990-1101 x1171
www.focusonthefuture.net

March 8-11, 2012 • Natural Products Expo West • Anaheim Convention Center • Anaheim, CA
www.expowest.com

Energy this. Energy that.

Let's face it. The consumer is bombarded with way too many beverages and shots. Fact is, they are basically the same kind of spin on energy drinks.

Isn't it time for a change?

AlphaSize®

Alpha-Glyceryl Phosphoryl Choline

AlphaSize® A-GPC is widely used in dietary supplements. And look around. Use in functional beverages and shots is exploding. Why? Because AlphaSize® A-GPC is a natural, safe, GRAS ingredient that is science-proven.

- **Tasteless, water soluble & stable:** Excellent performance in all liquid applications.
- **Boosts mental energy, concentration & focus:** The brain is the true gatekeeper of the body's energy.
- **Improves neurological function:** Shown to speed reaction time & agility.

Mental energy is key to true human performance.

To learn more about AlphaSize® A-GPC and how to add it to your truly functional beverages and shots, contact Chemi Nutra – world leader in specialty nutraceuticals for healthy natural products.

Scan this code with a QR-Code reader with your smart phone to visit our mobile optimized website.

CHEMI Nutra

Toll-free 866.907.0400 • www.cheminutra.com