

Industry News

"Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States."

—FDA Commissioner, Margaret Hamburg

FDA Urges Food Companies to Correct Nutrition Labeling Violations

FDA has notified 17 food manufacturers that the labeling for 22 of their food products violates the Federal Food, Drug and Cosmetic Act. The action follows an October 2009 statement by Commissioner Margaret Hamburg, MD, encouraging companies to review their labeling to ensure that they were in

compliance with FDA regulations, and were truthful and not misleading. In an open letter to Industry dated March 3, 2010, Dr. Hamburg underscored the importance of providing nutrition information that consumers could rely on. "Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States,"

Dr. Hamburg said in the letter. She also expressed her hope that the warning letters would clarify FDA's expectations for food manufacturers as they review their current labeling. The violations cited in the warning letters include unauthorized health claims, unauthorized nutrient content claims, and the unauthorized use of terms such as "healthy," and others that have strict regulatory definitions.

GOED Tackles Recent Omega 3 Issues

A lawsuit filed in California claims that 10 types of fish oil supplements tested recently contain polychlorinated biphenyl (PCB), a toxic industrial compound, and that manufacturers and sellers need to warn consumers under the state's Proposition 65 law.

Following news of the lawsuit, industry groups attempted to reassure the public, defending the safety of fish oil products in general. According to Nutrition Business Journal, U.S. consumer sales of fish and animal oil dietary supplements totaled \$739 million, representing 18% growth in 2008.

"We have complete confidence in the safety of the fish oil supplement market, which has been validated through multiple third-party reviews by industry watchdogs on thousands of products," said Adam Ismail, executive director of the Global Organization for EPA and DHA Omega 3s (GOED). "In fact, this industry is among the highest quality and most transparent of all consumer products."

There are multiple resources in the public domain where consumers can get more information on the quality of their products, including the International Fish Oil Standards program (www.ifosprogram.com). Furthermore, a recent report by Frost & Sullivan found that 93% of the refined fish oils on the market in the U.S. are produced from anchovy and sardine oils. However, the plaintiffs only tested one of these types of oils, which actually had PCB content well within the Safe Harbor provisions of Proposition 65, according to Mr. Ismail. "While the plaintiffs raise an important issue, it is unfortunate that they are implying that most fish oils are unsafe and that the industry is hiding information on such vital nutrients," he said.



Andrew Shao, PhD, senior vice president, scientific and regulatory affairs, Council for Responsible Nutrition (CRN), Washington, D.C., said PCBs are ubiquitous within the environment, which means that all fish contain at least trace amounts. "In fact, conventional food forms of fish contain higher levels of PCBs than fish oil supplements in part because supplement fish oil products go through a refining process, which reduces PCBs and other contaminants."

FDA has established a tolerance level for PCBs in fish, which is 2.0 parts per million (ppm, also expressed as mg/kg) or 2000 parts per billion, Dr. Shao added. In comparison, the Prop 65 daily limit for PCBs for a cancer warning is 90 mg/day, which is significantly lower than what FDA deems safe.

"The lawyers are using California's Prop 65 statute to bring attention to their case by attempting to frame this as a public health concern, when in reality, fish oil has enjoyed decades of safe use," Dr. Shao noted. "The bottom line is that consumers, whether they live in California or elsewhere, should continue to feel confident in the safety and efficacy of their fish oil supplements. This lawsuit does nothing to change the strong science supporting the many health benefits of fish oil, which range from cardiovascular health to cognitive development of infants and young children, and the very low thresholds of PCBs, which apparently trigger a labeling requirement in California cannot be extrapolated to demonstrate any actual risks at those levels. The health benefits for fish oil far outweigh any suggested, and unsupported, risks."

According to Mr. Ismail, eight years ago the industry collaborated to develop strict standards to improve quality and ensure consumer safety. This standard, formerly the CRN Voluntary Monograph, is now known as the GOED Voluntary Monograph and has helped the industry grow rap-

Dr. Hamburg has made nutrition labeling a priority at FDA. The warning letters are the agency's most recent action to help improve consumers' ability to make nutritious choices. FDA will soon propose guidance regarding calorie and nutrient labeling on the front of food packages and plans to work collaboratively with the food industry to design and implement innovative approaches to front-of-package labeling that can help consumers choose healthy diets.

The Grocery Manufacturers Association (GMA) issued the following statement regarding the commissioner's open letter: "The food and beverage industry is committed to providing consumers with the products and information they need to achieve and maintain a healthy lifestyle. GMA agrees with and

supports federal laws requiring food labels to be truthful and non-misleading. As Commissioner Hamburg noted, the examples cited are not indicative of the food industry as a whole. Separately, GMA and its member companies support, and are working with, the FDA to enhance our ability to convey nutrition information clearly and consistently to consumers."

AHPA Calls for Ban of Controlled Substances

The American Herbal Products Association (AHPA), Silver Spring, MD, has adopted a policy to support federal legislation to clarify that controlled substances, as defined by the Controlled Substances Act, may not be included as ingredients in dietary supple-

ments. While no such legislation has been introduced in the U.S. Congress, AHPA plans to support this kind of direct approach to address occasional reports of products labeled as "dietary supplements" that contain anabolic steroids, a class of controlled substances that adulterate supplements and make them unlawful.

NuVal Scores Correspond with DASH Diet

Foods recommended in the popular Dietary Approaches to Stop Hypertension (DASH) diet correspond with the higher-scored items ranked by the NuVal Nutritional Scoring System, according to a study published in the American Journal of Clinical Nutrition. NuVal gives all foods a score from 1 to 100;

idly and responsibly by preemptively addressing quality issues.

GOED members must sign affidavits agreeing to manufacture and market products to the monograph standards as a condition of membership. Additionally, GOED continues to update the monograph based on all relevant legislation worldwide, including Proposition 65's No Significant Risk Levels (NSRLs) related to carcinogenic activity and Maximum Allowable Dose Levels (MADLs) related to chemicals causing reproductive toxicity.

"While NSRLs have been set for PCBs in California, MADLs have not," said Mr. Ismail. "This group is actually asserting that since no regulatory body has set a limit related to reproductive toxicity, the default level should be zero." Thus far, toxicological assessments have not supported this position, but due to the unique nature of Proposition 65, the burden of proof is on the defendants in lawsuits to establish Safe Harbor limits. "In addition, setting a MADL for PCBs appears to be of low-priority to the California Environmental Protection Agency," said Dr. Harry Rice, GOED's director of regulatory and scientific affairs. "The Office of Environmental Health Hazard Assessment (OEHHA) has assigned its lowest priority to the project, based in part on a lack of need."

In related news, the Federal Trade Commission (FTC) has sent letters to 11 companies that promote various omega 3 fatty acid supplements, telling them they should review their product packaging and labeling to make sure they do not violate federal law by making baseless claims about how the supplements benefit children's brain and vision function and development. The FTC sent letters to the companies in January, cautioning that their product packaging and advertising might be in violation of the FTC Act unless they have scientific evidence to support claims that their products boost, improve, enhance or support brain and vision function and development in children. Also included are claims relating to intelligence, cognitive function, learning ability, focus, mood, memory, attention, concentration, visual acuity and eye health. The agency warned that it might take law enforcement action if companies make health-related claims

for products without scientific proof. In its letters, the FTC described a recent investigation it conducted into similar claims made by Northwest Natural Products, Inc., the marketer of L'il Critters Omega-3 Gummy Fish, a children's omega 3 gummy vitamin. The FTC stated that in response to its inquiry, NNP quickly modified all marketing materials for Gummy Fish, including product packaging and labeling, to ensure compliance with the FTC Act.

GOED is seeking clarification from the FTC in response to the agency's concern. Dr. Rice contacted the FTC for clarification on several points, but it was not clear if FTC was concerned about claims on products containing short-chain omega 3 fatty acid, alpha-linolenic acid (ALA), compared to the long-chain omega 3 fatty acids EPA and DHA. According to the FTC, the investigation did not target one or the other, but rather claims related to omega 3 fatty acids, in general, that were not substantiated.

Second, when asked about product and population-specific trials, Dr. Rice was told the FTC does not require product-specific trials; rather, claims about an effect (e.g., brain development) need to be substantiated by science on that effect. Third, with respect to population-specific trials, the scientific evidence in support of a claim needs to be based on research conducted in the age specified in the claim. That is, if the claim is specific to toddlers two years and older, the research substantiating the claim cannot involve 1-year-olds.

While there is a large body of scientific evidence in support of claims related to EPA and DHA omega 3 fatty acids and the positive benefits related to brain health, given that the specific claims and dosages in question have not been publicly communicated, GOED said it is presently unable to comment on FTC's specific grievances. Adam Ismail, executive director of GOED, said, "We applaud the FTC's efforts to enforce claims in this area. The market for EPA and DHA omega 3s has grown as a result of investing in sound science, communicating the benefits in an ethical manner, and establishing a deep level of trust with consumers. FTC's efforts can only help ensure continued growth."

the higher the score, the higher the food's overall nutrition. According to the study, NuVal distinguished the more healthful DASH diet from the average American diet,

measured by the comprehensive National Health and Nutritional Examination Survey (NHANES, 2003-2006). The DASH diet was shown to use many items with high NuVal

scores, validating NuVal as a measure of overall nutrition quality. Another portion of the study declares that an estimated four out of five consumers can have their food-pur-



Getting Ahead of the Curve: Calcium, Vitamin D & Bioavailability

By Dr. A. Elizabeth Sloan

Nowhere is the power of the fast-emerging trend to bioavailability more impressive than in the bone health segment, breathing new life into an ailing calcium market, through promises of greater effectiveness when coupled with vitamin D.

And, enormous new positioning opportunities bioavailability will bring. Nearly nine in 10 (87%) adults are already aware that calcium supplements are capable of strengthening bones/preventing bone loss; 83% calcium-rich foods/drinks; and 76% calcium-fortified foods/beverages. Moreover, 58% of adults already believe that supplements and functional foods are "very effective" in preventing or

delaying the onset of osteoporosis (Gallup, 2009). Meanwhile, four in 10 (38%) moms are trying to increase calcium in their pre-teen's diets, unchanged since 2004 (Gallup, 2008).

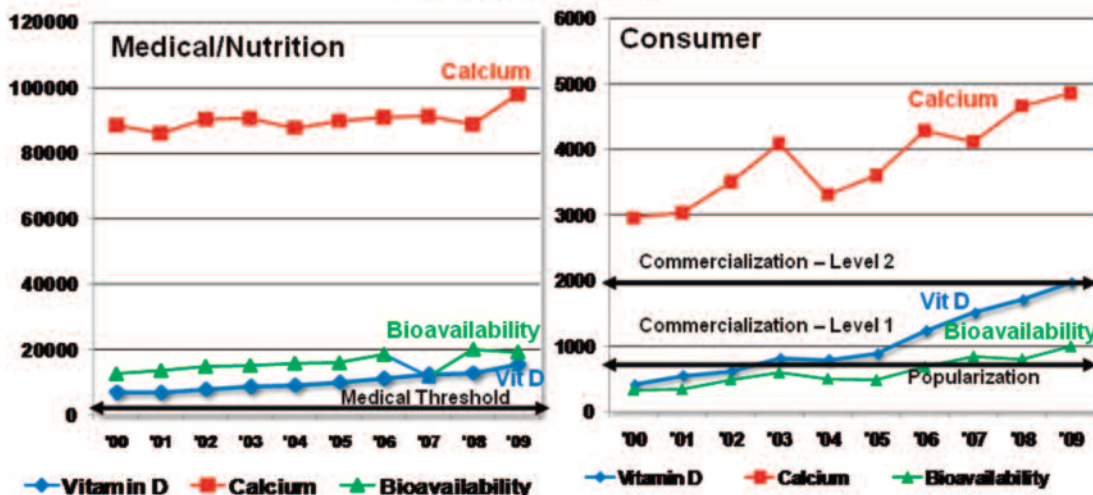
But, calcium sales have slowed in recent years. In 2007, calcium fell off the "top 10" list of the most sought after health claims on food packages (FMI, 2009). One in five (22%) consumers looked for calcium on the nutrition label, down from 2006 (IFIC, 2009). In 2007, glucosamine surpassed calcium as the second best-selling supplement in mass channels, behind various multivitamin formulas (IRI, 2008-09). And globally the introduction of new functional food/beverages with a calcium claim fell to 818 in 2009 from 981 in 2007 (Innova Market Insights, 2009).

Market Potential

According to Sloan Trends' TrendSense model, the marketability of calcium or vitamin D shows no signs of slowing down, especially given the bioavailability angle. Although enormous—100,000+ new studies per year—Medical Counts and research activity for calcium have been essentially flat over the past decade, keeping Consumer Counts relatively stable to declining, but at a large Level 2 mass-market level from 2004-2007.

However, when vitamin D became a new mass market opportunity, moving into the Commercialization Phase in late 2006/early 2007, coupled with a simultaneous crossover of the concept of

TrendSense™ Predictive Model: Calcium, Vitamin D & Bioavailability



Source: Sloan Trends Inc. 2010

* Although there are many factors that go into determining consumer trends, measuring how medical/nutrition activity levels have risen over the past decade, as well as some of the key milestones that have occurred and how these issues have been understood and embraced by the public are essential in predicting the sustainability of the Consumer trend line.

chasing habits positively influenced by NuVal scores. In consumer testing, "roughly 80% of over 800 study participants indicated that (NuVal scores) would influence their pur-

chase intent," as stated in the study. The consumer testing took place in 2007 and 2008 by the marketing research and technology firm Affinova and involved men and women be-

tween the ages of 18 and 64 who were the primary grocery shoppers for their households. The study's questions centered around the ONQI algorithm, which is the engine be-

bioavailability into the Popularization Phases (when it would become a "hot" concept for the health food channel and among very health-conscious/condition-specific consumers), the calcium market was set to benefit from its critical relationship with vitamin D.

Vitamin D and bioavailability crossed over the Medical Threshold more than a decade ago, which signaled the beginning of a long-term sustainable trend. Perhaps most exciting is that the renewed vigor in this now inter-dependant market sector has spurred significantly more research activity in the traditional calcium category, which will likely identify/solidify additional health linkages.

Growth Opportunities

- Bone health ranks 4th on the list of conditions consumers are "extremely/very concerned" about, right after mental sharpness, heart disease and cancer (HealthFocus, 2009).
- Bone health is the 4th concern for those aged 40-49, 3rd 50-64 and 2nd 65+; with 100 million Americans now over age 50, the market base is sure to accelerate (HealthFocus, 2009).
- 54% of adults made a strong effort to consume calcium, 44% vitamin D in 2009 (Gallup, 2009).
- 37% of primary grocery shoppers are extremely interested in information on calcium; 36% vitamin D (HealthFocus, 2009).
- Male osteoporosis, blood pressure, preventing bone fractures in healthy people, sarcopenia and Rx medication users represent future market potential.
- "Improved effectiveness" is one of the most important drivers of blockbuster new products in the non-food CPG segment (IRI, 2009); one third of non-users of functional foods say they don't believe they have the ingredients to be effective (Mintel, 2009).

Functional Foods & Beverages: With seven in 10 (69%) adults making a strong/some effort to eat more fortified foods—39% fortified beverages—in 2009, the market is ripe for more highly bioavailable calcium/vitamin D-enriched foods (Gallup, 2009). Mintel reports that 29% of consumers looked specifically for calcium in functional foods last year; 29% functional drinks.

Trial and regular usage are highest for calcium-fortified orange juice, cereal, milk, bars of all types and yogurt. Calcium-fortified baked goods enjoyed the highest increase vs. 2007, in terms of both trial and regular use. Regular use of calcium fortified meal replacement drinks has fallen slightly since 2007, as has bottled vitamin waters. One-third of adults ate cheese fortified with extra calcium and/or vitamin D in 2009, up 3% from 2008; 14% have tried chewing gum with calcium (Gallup, 2009).

Clearly, bioavailability claims will be an important tool in counteracting the growth of calcium-touting fortified food/drink store brands—a \$1 billion category in 2009, up 29% over 2008 (Nielsen, 2010).

Dietary Supplements: An impressive one in five (22%) supplement users took vitamin D in 2009 (Gallup, 2009). Sales of vitamin D supplements reached \$230 million in 2008, more than doubling 2007 sales; calcium supplements grew 6% in 2008 to \$1.1 billion adding \$60 million in new sales last year (Nutrition Business Journal, 2009). With 65% of adults aware that weight bearing exercise is important for improving bone strength/health, as well as 50% vitamin/mineral supplements, and interest is higher than average for bone health in health-directed dieters, those lactose intolerant and those using Rx medications, the potential for crossover products with other market segments is virtually untapped for supplement marketers, and bioavailability will be key.

Editor's Note: See Nutraceuticals World March 2010 for a TrendSense discussion of antioxidants and health linkage trends.

References furnished upon request.

About the author: Dr. A. Elizabeth Sloan is president of Sloan Trends, Inc., Escondido, CA, which is a consulting firm that offers trend-tracking and predictions, strategic counsel and business-building ideas for food, supplement and pharmaceutical marketers. Each month she will provide analysis and discuss opportunities of a particular market being covered in a given issue.

SLOAN TRENDS' TRENDSENSE is a 15-year-old trend tracking system, which identifies and quantifies trends as well as predicts the optimal timing, sustainability and life-cycle stage of ingredients, terms, product opportunities and related market issues.

The model displays medical and consumer "activity levels" based on a comprehensive analysis of five critical sources of information—consumer, trade and competitive, legal and regulatory and media coverage. The resulting charts give insight into the market's changing health issues and concerns, the ingredients that are up-and-coming and those that have just about run their course, as well as what health claims, marketing messages and products will bring your company the most success.

- **Emerging Phase** = Trends begin to appear on the radar screen. Companies should begin to collect literature and market details for those that exhibit continual growth and that might be of interest.
- **Popularization Phase** = Medical/Nutrition crossover to consumer media and marketplace; opportunity for niche or specialty markets. Marketers/manufacturers should begin a detailed evaluation of the supporting marketing and scientific data and determine if this term/trend offers a good strategic fit and is appropriate to pursue. Appropriate product development procedures should be undertaken.
- **Commercialization Phase** = Mass-market ready. Mainstream consumers have a significant degree of familiarity with the term/trend and there is opportunity for competitive advantage by getting out ahead of the competition or by providing a unique and highly innovative product positioning for success.

hind the NuVal scores. According to the survey portion of the study, NuVal's 100-point scale was preferred to systems with just four tiers by a ratio of 3-to-1. The paper also indicates that data from a Harvard study, to be published independently in the near future, directly link NuVal scores to health outcomes, including total risk of chronic disease and all-cause mortality.

EFSA Publishes More Health Claim Opinions

The European Food Safety Authority (EFSA) has published a second series of opinions on a list of "general function" health claims compiled by Member States and the European Commission (EC). Scientific experts on EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) assessed all available scientific data submitted to substantiate the 416 health claims. These opinions have been sent to the EC and to Member States, which will ultimately decide whether to authorize these claims or not. The evaluations of the NDA Panel were positive when there was sufficient "scientific evidence available to support the claim," such as those related to vitamins and

minerals. Experts issued unfavorable opinions on most of the claims in the second series due to the "poor quality of the information provided to EFSA," including: lack of information to identify the substance on which the claim is based (e.g., "probiotics"); lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of the functions of the body (e.g., food with "antioxidant properties"); or lack of human studies with reliable measures of the claimed health benefit. This is the second series of opinions on "general function" health claims and the panel is continuing its work on the remaining claims on the list.

In other developments, the EU has passed nutrition claims for omega 3s that will allow food products to claim they are either a "source of omega 3 fatty acids" or that they contain "high omega 3 fatty acids." In order to make a source claim, products must contain either 40 mg of EPA+DHA per 100 grams and kCal or 300 mg of ALA, according to the Global Organization for EPA and DHA Omega 3s (GOED). Alternatively, to make a "high" content claim, a product must contain 80 mg EPA+DHA per 100 grams and kCal or

600 mg ALA. The levels for EPA+DHA usage were based on an EFSA opinion that 250 mg of intake per day will reduce the risk of cardiovascular disease in the general population.

CRN Joins ASN as Sustaining Member & Formalizes International Presence

The Council for Responsible Nutrition (CRN), Washington, D.C., has become a "Sustaining Member" of the American Society for Nutrition (ASN), a non-profit organization that brings together nearly 4000 of the world's top nutrition researchers and clinical nutritionists to advance the knowledge and application of nutrition. CRN has been an active partner of ASN since 2008, as sponsor of the Mary Swartz Rose Awards. The awards recognize outstanding research on the safety and efficacy of bioactive compounds for human health. Joining ASN as a Sustaining Member will deepen ties between the two organizations, as they identify new ways to work together in advancing their respective missions: the expansion of nutrition science knowledge and the responsible marketing of dietary supplements.

Funds Boost Research into Cognitive Decline

The Research Partnership in Cognitive Aging, a public-private effort to promote the study of brain function with age, will award up to \$28 million over five years to 17 research grants to examine the neural and behavioral profiles of healthy cognitive aging and explore interventions that may prevent, reduce or reverse cognitive decline in



older people. The partnership, led by the National Institute on Aging (NIA), part of the National Institutes of Health (NIH), and the McKnight Brain Research Foundation (MBRF), is seeking ways to maintain cognitive health—the ability to think, learn and remember—into old age. The basic research supported by these grants will focus on the molecular, cellular, physiological and behavioral aspects of healthy aging, as well as the development and pilot testing of experimental, evidence-

based interventions. The pilot studies of behavioral strategies may eventually lead to full-scale, randomized clinical trials.

A sampling of the research supported by the partnership includes one study designed to focus on differences in how the brain encodes, consolidates, stores and retrieves memory in young and old mice. Researchers will monitor and analyze patterns of activity in the hippocampus—a part of the brain important to learning and memory—to determine age-related changes in function. These findings may lead to new therapies targeting specific components of memory loss. This project is supported by American Recovery and Reinvestment Act funds.

Another randomized, double-blind, placebo-controlled trial will examine whether dietary supplements of omega 3 fatty acids and blueberries can slow or prevent age-related cognitive decline in older adults. The study will assess changes in memory and daily functioning over one year to determine the impact of these non-pharmaceutical interventions. This study is also supported by the NIH Office of Dietary Supplements (ODS).

A pilot trial involving 90 older adults will evaluate whether cognition improves when aerobic exercise is combined with cognitive enrichment provided by a specific research-based video game. The randomized trial is aimed at finding an intervention to improve day-to-day cognitive function. (More details on this partnership and other developments in the brain health market will be provided in the May issue as part of our focus on Cognitive Function.)

In other CRN news, the organization has established a new wholly-owned subsidiary headquartered in Manno, Switzerland, to be known as the Council for Responsible Nutrition-International (CRN-I). According to Mark LeDoux, one of CRN-I's founding Board members and chairman of CRN, "This was a natural progression for CRN to formalize the work it's been doing for decades by standing up for science-based principles for dietary/food supplements worldwide. CRN-I will provide a new forum by which we can strengthen our current efforts, with a particular emphasis on promoting sound nutrition and food safety policies, and encouraging government bodies, regulators and other decision makers to make policy recommendations that are well-grounded in science. In this global economy, having a European-based platform from which to disseminate science-based policy recommendations has been imperative to maximize our influence on behalf of our multinational members doing business around the world."

The new organization's first priority is to conduct a one-day scientific symposium—"Scientific Issues Related to Codex Goals"—taking place July 3 in Geneva, Switzerland, in tandem with the Codex Alimentarius Commission meeting. The CRN-I conference will include invited international regulators and policy makers, nutrition scientists and academics to share perspectives on Codex issues relating to risk management and scientific standards for health claims.

Omega 3s Have Gone to the Dogs

A series of studies published in the *Journal of the American Veterinary Medical Association (JAVMA)* offer new insights into the possible benefits derived from feeding foods containing high omega 3 fatty acid concentrations to dogs with osteoarthritis. The results of the three studies, according to contributing author Dr. Kevin Hahn, director of research and chief medical officer at Hill's Pet Nutrition Inc., show the dogs that were fed foods fortified with omega 3s experienced less pain associated with the disease and greater mobility.

The studies, published in the January 1, 2010 and March 1, 2010 issues of *JAVMA*, included 274 dogs with osteoarthritis that took part in clinical studies at dozens of

privately owned veterinary clinics and two university veterinary clinics. The researchers focused on three areas: the effects of omega 3 fatty acids on clinical signs of osteoarthritis in dogs; the effects of omega 3 fatty acids on weight bearing in dogs with the disease; and the effects of omega 3 fatty acids on nonsteroidal anti-inflammatory drug (NSAID) dosage in dogs with osteoarthritis.

In the first study, dogs with chronic pain associated with osteoarthritis showed improvements in their ability to play and rise from rest at 6 weeks after being switched to a diet containing high concentrations of fish oil omega 3 fatty acids. The second study showed that limb strength in dogs improved with omega 3 dietary intervention, Dr. Hahn said. In the third study, veterinarians were able to reduce the dosage of carprofen, a common NSAID used for pain relief in dogs with osteoarthritis, while still providing pain relief to dogs fed food supplemented with omega 3 fatty acids.

These studies show that omega 3 fatty acids provide pain relief and improve mobility in dogs with osteoarthritis. They also indicate that proper use of a food containing a sufficient amount of omega 3 fatty acids may result in a lower dosage of medication required to manage joint pain and improve mobility in a dog with osteoarthritis. This finding is especially important because it allows veterinarians to better understand complications that may arise from pain relief medications that could be reduced when the medications are used in combination with proper nutrition.

NPA Sets 'Natural' Standard for Home Care Products

As demand for natural products continues to rise, the Natural Products Association (NPA), Washington, D.C., is extending its natural seal and standard to include home care products, such as household cleaners, laundry detergents and concentrated and ready-to-use hard surface cleaners. The standard comes amid growing consumer confusion about what makes a product natural. Under the new program, products must follow strict guidelines set out by the NPA to merit bearing the seal. The criteria include, but are not limited to: Product must be made up of at least 95% truly natural ingredients or ingredients that are derived from natural sources, excluding water; no ingredients with any suspected human health risks; no processes that significantly or adversely alter the natural ingredients; ingredients that come from a purposeful, natural source (flora, fauna, mineral); processes that are minimal and don't use synthetic/harsh chemicals; non-natural ingredients only when viable natural alternative ingredients are unavailable and only when there are absolutely no suspected potential human health risks.

Cognis Re-Submits Xangold Dossier to EFSA

Cognis Nutrition & Health, La Grange, IL, will submit a dossier to the European Food Safety Authority (EFSA) with additional new science, including studies conducted with its Xangold branded ingredient. This move follows the EFSA's recent rejection of a health claims dossier submitted by member states

Patents

Bio-Botanica has received U.S. Patent #7,658,955 for its Puresterol ingredient, which is an extract of *Pueraria candollei* var. *mirifica* A Shaw. & Suvat. *Pueraria mirifica* has been shown to be a promising phytoestrogenic and support herb for menopausal women. Bio-Botanica's patented extraction process optimizes the miroestrol component in the *Pueraria mirifica* extract, according to the company.

TSI Health Sciences, Inc. (TSI), Missoula, MT, has obtained patent #7,645,466 for its ingredients Promilin and PromilinPro. The new, broad patented claim covers the methods for deriving, isolating and/or extracting amino acid compositions from fenugreek seeds. The TSI patent covers the proprietary process for deriving novel compositions of bioactive compounds comprising 4-Hydroxyisoleucine, both for Promilin (20% 4-Hydroxyisoleucine) and PromilinPro (60% 4-Hydroxyisoleucine).

for lutein products. Cognis will submit this new information under article 13.5 of the European Commission nutrition and health claims regulation. The company is appealing the EFSA opinion cited in article 13.1 by presenting a comprehensive new submission with the new scientific data.

New Monograph for CLA Finalized in Canada

Health Canada's Natural Health Products Directorate has finalized a new monograph for conjugated linoleic acid (CLA), which is intended to serve as a guide to the Canadian

industry for the preparation of product license applications for natural health product market authorization. With this new monograph, companies will be able to communicate more effectively about the health benefits of CLA to Canadian consumers, healthcare practitioners and others interested in CLA for weight management benefits.

Investment Picks Up in Natural Personal Care Industry

A sharp rise in investment activity involving natural personal care companies is expected

in 2010, according to London, U.K.-based Organic Monitor. Improving economic conditions and easing of capital restrictions are prompting investors target this high-growth sector once again. The natural personal care industry was the darling of the investment community until the financial crisis started in 2008. After a lull period of 18 months, major deals have restarted. Shiseido has acquired Bare Escentuals in a \$1.7 billion deal, while the cosmetics company Clarins recently completed its purchase of Kibio. Organic Monitor sees more deals like this on the horizon as investors once again start pursuing natural

Recent Certifications & Approvals

Robinson Pharma Inc., (RPI), Santa Ana, CA, has received GMP certification from the Natural Products Association (NPA). The certification demonstrates that RPI is compliant with the standards outlined in 21 CFR Part 111—the current good manufacturing practices specified by the federal government under DSHEA. An NPA-authorized and qualified third party auditor conducted an exhaustive audit of the RPI facilities, practices and staff and concluded that RPI is in compliance with the regulation.

Morinaga Milk Industry Co., Ltd., Tokyo, Japan, has received a no objection letter from FDA in response to its GRAS (Generally Recognized as Safe) notification for the proprietary probiotic strain *Bifidobacterium longum* BB536. The official FDA affirmation that the ingredient is GRAS paves the way for the highly researched probiotic to be included in functional foods, according to the company. Numerous published human clinical trials have found that BB536 provides a natural defense against episodic digestive upsets, including constipation, diarrhea, abdominal discomfort, gas and bloating.

Kemin Health, Des Moines, IA, has received GMP certification from NSF International following successful completion of a facility audit that verified compliance with current dietary supplement GMPs.

ISP, Wayne, NJ, has self-affirmed that its Plasdone K-29/32 and Plasdone K-90 binders, as well as Polyplasdone XL and XL-10 disintegrants are Generally Recognized as Safe (GRAS), following a comprehensive evaluation of research and toxicology studies by a qualified, independent scientific panel. The GRAS status allows for the inclusion in nutritional and supplement products.

Burcon NutraScience Corporation, Vancouver, British Columbia, Canada, has received formal notification from FDA that the company's cruciferin-rich canola protein isolate Puratein, as well as its napin-rich canola protein isolate Supertein are Generally Recognized as Safe (GRAS) for their intended use as ingredients in a variety of food and beverage applications.

Microbia, Inc., Lexington, MA, has obtained GRAS (Generally Recognized As Safe) status for its β -carotene (beta-carotene). A three-member panel reviewed an extensive data package that included methods of preparation, compositional profile and safety and toxicology studies. The certification allows Microbia to begin marketing its β -carotene as a food ingredient in the U.S.

NSA LLC, Collierville, TN, has received certification from NSF International for its Juice Plus+ Orchard and Garden Blend and Juice Plus+ Vineyard Blend nutritional products. To achieve this certification, Juice Plus+ products met the requirements of NSF International's dietary supplements and functional foods certification program. These requirements are part of NSF/ANSI Standard 173, the only accredited American National Standard for dietary supplements and functional foods. Separately, select batches of the Juice Plus+ products have been additionally tested and certified by NSF International's Athletic Banned Substances Certification Program (Certified for Sport), which screens for more than 140 banned substances, including stimulants, narcotics, steroids and diuretics.

Best Formulations, City of Industry, CA, has obtained GMP for Sport certification from NSF International. The program requires two annual GMP for Sport facility audits and manufacturer affidavits to verify that Best Formulations does not source any ingredients on the World Anti-Doping Agency, National Football League (NFL), Major League Baseball (MLB) or Canadian Centre for Ethics in Sport (CCES) banned substances lists.

Bio Serae Laboratoires, Bram, France, has received organic certification from Ecocert SAS for its Cacti-Nea ingredient, which is made from *Opuntia ficus-indica* cactus fruit. Due to exclusive partnerships with local growers of the Mediterranean area, Bio Serae ensures the origin and the traceability of these fruits. A gentle, environmentally-friendly and chemical-free process obtains a high quality standardized ingredient, which strictly complies with the current European legislation regarding organic farming.

personal care companies. Investors are attracted by high market growth rates and profitable product categories. European companies are expected to be involved in major deals in 2010 because of the lack of “investable” companies in North America. Many leading American companies have already been acquired, leaving relatively few suitable privately-owned companies. In contrast, Europe has a high concentration of sizeable private companies.

Tomato Extract Combats Blood Clots

Provexis' Fruitflow tomato extract can be used to help combat the formation of un-

wanted blood clots, without any of the side effects associated with aspirin, according to a new study. The seven-month human trial compared the effects on platelet aggregation of Fruitflow and aspirin, which can help thin the blood but also lead to gastric ulceration and bleeding. Fruitflow showed up to 30% reduction from baseline platelet aggregation in each of three different biological pathways, while a single dose of aspirin caused up to 60% reduction in a single pathway, with lesser effects on the other two, according to the company. Fruitflow has similar results for blood thinning to aspirin without any harmful side effects. The trial also studied the interactions between

Fruitflow and aspirin, and showed no negative interactions.

Kyowa Hakko Finds Partner in Personal Care

Presperse LLC, Somerset, NJ, has established a partnership with Kyowa Hakko USA, New York, NY, to bring novel Kyowa Hakko ingredients and technologies to the personal care and cosmetic industries. The first ingredients are AHYP Natural Skin Barrier (n-Acetyl-L-Hydroxyproline) and Panadoxine P, a pro form of Pyridoxine (vitamin B6). AHYP Natural Skin Barrier is produced through the fermentation of natural sugars, and employs patented amino acid technology from Kyowa

Reports Available

The European and U.S. markets for prebiotics are projected to reach nearly \$1.2 billion and \$225 million, respectively, by the year 2015, according to a new report from Global Industry Analysts (GIA) titled “Prebiotics: A US & European Market Report.” While the European market is driven by the expansion of prebiotic ingredient manufacturers into new application areas such as meat and snack products, the U.S. market is driven by continued demand for fructans, which is the largest product segment in the U.S. prebiotic market. Prebiotics are rapidly rising in popularity within the functional food market, thanks to applications in dairy products, health drinks, nutrition bars, breakfast cereals, beverages, bakery products, meat products, mineral supplements, weight loss products, green foods, infant food and pet food. *For further information: www.strategy.com*

A new report from Business Insights explores the development of the probiotics market. “Probiotics Success Strategies in Food and Drinks: Novel applications, future R&D and consumer engagement,” indicates that probiotics have been a functional component of health foods for almost 100 years, although no legal definition exists for the term probiotic. The application of probiotics has extended to a wide range of delivery formats in food and drinks, and they are marketed on multiple health-enhancing platforms.

The mood/mind health food and drinks market is one of the most exciting and innovative in the global industry thanks to its strong growth (albeit from a small base), according to another new report from Business Insights. Titled “Innovations in Mood and Mind Health Food and Drinks: Growth Opportunities, Effective Product Strategies and Evolution in NPD,” the report indicates that more and more people show an interest in purchasing products to suit/improve their mood, improve mental acuity and target specific concerns (related to well-being and mental health). *For further information: www.globalbusinessinsights.com*

U.S. demand for food and beverage additives is expected to expand 3.5% annually to \$8.5 billion in 2014, according to a new report from The Freedonia Group. Advances will be driven by increasing consumer interest in nutritionally-enriched products and all-natural foods, which promote demand for high-value premium and natural additives, the report states. As consumers are wary of foods with artificial-sounding ingredients, processors seeking to create “clean” ingredient labels are increasingly favoring natural additives. Consumer desire for functional products that provide health benefits will also support demand for additives such as probiotics and other nutraceuticals. Flavor products and alternative sweeteners will remain the largest product types in the U.S. food and beverage additive market. *For further information: www.freedoniagroup.com*

Now in its 3rd edition, “Consumer Health & Wellness 2010”—a report from Richard K. Miller & Associates—assesses healthcare planning and decision making from a consumer/patient perspective, including how consumers view their personal health and the measures they take to maintain good health. The report presents consumers' attitudes toward their health and how they research healthcare, select hospitals for treatment and choose providers. Also included is insight into consumers' health-related behaviors and the influence of marketing on the choices they make. Hospitals, health insurers and pharmaceutical executives can use this report to better understand consumers' health needs and decision making related to their care. *For further information: www.pharma-reports.com*

The market for nutritional bars is soaring, despite the economic recession, according to analysis from Bridge2Food, which claims sales of European snack bars are growing at a 5% rate, and currently generating €1.4 billion in sales. Market expenditure, average price and frequency of purchase went up during 2009 in the U.K., however, private label share for the bar category has not grown. In the leading U.K. market, retailers own only 8% of the category. Also, adding fiber can substantially improve profitability for manufacturers. *For further information: www.bridge2food.com*

Hakko. Clinical tests have shown superior penetration of the skin, elevation of collagen synthesis, improved skin elasticity and overall strengthening of the skin's barrier properties to combat allergens and pollution. The ingredient has also shown the ability to accelerate wound healing and increase moisturization. Panadoxine P is released as vitamin B6 internally by interacting with the body's enzymes and is a useful source of vitamin B6 for skin, hair and body that provides long-term health benefits.

Adams Food Launches Functional Ingredient Range

To help food manufacturers enhance the health and nutritional values of their products, Adams Food Ingredients Limited, the functional ingredients division of The Irish Dairy Board, Leek, U.K., has launched a range of additives designed to fortify foods, reduce fat content, increase fiber content and lower levels of cholesterol and sugar. The company is also able to blend these ingredients with other functional ingredients to deliver efficiencies in cost and formulation. The range includes products such as B-CAN oat beta glucan, Züeit brand sucralose, COWCIUM natural milk calcium, Proti-GERM defatted wheat germ and FOAMEX quillaja extract powder. Applications include breakfast cereals, yogurts, beverages, healthy batters and coatings and other baked items.

Stratum Nutrition Partners with KitoZyme

Stratum Nutrition, St. Louis, MO, a Novus International business that focuses on human nutrition through functional and specialty ingredients, has entered a strategic partnership with international functional ingredients manufacturer KitoZyme. Based in Herstal, Belgium, KitoZyme manufactures a new vegetarian ingredient, chitin-glucan, which supports arterial and overall heart health. Stratum Nutrition will further advance the science, global sales and marketing of chitin-glucan.

Ganeden Biotech Signs Deal with Pathway International

Extending distribution to Australian and New Zealand markets, Ganeden Biotech, Cleveland, OH, makers of the patented probiotic

strain GanedenBC30, has partnered with Pathway International Pty Ltd. The partnership will provide growth opportunities for Ganeden Biotech through increased distribution channels and access to an exclusive international supply chain network of leading manufacturers in Australia and New Zealand.

Institut Rosell-Lallemand Acquires LAFTI Business from DSM

Adding to its portfolio of probiotics targeting specific health segments, such as gut health, immunology, women's and children's health, Institut Rosell-Lallemand has acquired the LAFTI dietary supplement business from Netherlands-based DSM Food Specialties. LAFTI is a range of probiotic strains with targeted health benefits, supported by strong scientific and clinical evidence. DSM Food Specialties will retain the dairy portion of the LAFTI business through a license agreement, reflecting the company's strategy to concentrate on food and beverage probiotic applications. The LAFTI range comprises three strains: *Lactobacillus acidophilus* LAFTI L10, *Lactobacillus casei* LAFTI L26 and *Bifidobacterium animalis lactis* LAFTI B94.

Pharmachem Unveils New Weight Control System

Building on its long-term platform of Phase 2 Carb Controller, Pharmachem Laboratories, Inc., Kearny, NJ, has launched two new weight management ingredients, Phase 1 Hunger Controller and Phase 3 Sugar Controller. Referred to as "The Three Phases of Weight Control," the ingredient system addresses the many ways consumers gain weight, whether overeating, consuming too many carbs or eating too much sugar. Phase 1 Hunger Controller is a family of flavored beverage powders containing Olibra, which has been clinically shown to promote appetite control and satiety. A study published in the *International Journal of Obesity* showed that subjects who consumed foods containing Olibra had significantly reduced food intake at subsequent meals.

Phase 2 Carb Controller is a proprietary extract of the white bean clinically shown to reduce the digestion of starches. Its efficacy and safety have been confirmed in more than 24 separate studies.

Phase 3 Sugar Controller is a powdered

formula shown to be effective in supporting healthy blood sugar levels. A new human study of Phase 3 Sugar Controller showed that 1.1 grams of the material had a significant effect on improving blood sugar and insulin levels after consumption of a beverage containing 70 grams of sugar.

Jarrow Formulas to Use Probi's Lp299v Strain in Supplements

An alliance between Sweden-based Probi, a leading player in probiotics research and a partner of Institut Rosell, and Jarrow Formulas, Los Angeles, CA, now gives the nutritional supplement company the right to sell a dietary supplement that contains Probi's bacteria, Lp299v, exclusively to U.S. health food stores. Probi's Lp299v has been shown in clinical trials to help people suffering from symptoms associated with Irritable Bowel Syndrome (IBS), which include diarrhea, constipation and abdominal cramps.

Imperial Sugar & PureCircle Enter Joint Venture

Combining the natural benefits of sugar and stevia to develop reduced-calorie, natural, sweet product solutions, Imperial Sugar Company, Sugar Land, TX, and PureCircle Limited, Oak Brook, IL, have launched Natural Sweet Ventures LLC. The product line will deliver benefits of pure cane sugar and stevia to manufacturers across North America through a broad portfolio, including liquid form for syrup, spray-on, dairy and many baking and confection applications; a variety of calorie reduction levels, allowing formulation to specific calorie levels that best suit the application; and a sugar option with the added benefits of a lower glycemic index, non-GMO (genetically modified organism), temperature and pH stable and uniform dispersion of both sugar and stevia. Natural Sweet Ventures' products will be produced at Imperial's Port Wentworth, GA, refinery and marketed across North America by the combined sales teams of Imperial and PureCircle.

Nebraska Cultures Sponsors Study on DDS-1

Walnut Creek, CA-based Nebraska Cultures Inc. is sponsoring a clinical study that will evaluate the efficacy of Dr. Shahani's DDS-1 strain of *L. acidophilus* in humans. The study, titled "Survival and persistence of

Lactobacillus acidophilus DDS-1 and other lactobacilli in human subjects," specifically seeks to determine whether healthy bacteria can survive for an extended time in the human gastrointestinal (GI) tract. Because of the low pH, the presence of bile salts and the competitive environment of the human intestinal tract, questions have arisen regarding the survivability (and therefore efficacy) of probiotics as a category. For accuracy and relevance to Dr. Shahani's original strain of probiotic, the study will employ human trial subjects who ingest controlled amounts of specified bacteria strains, and who are then tested after an extended period of time to see what, if any, of the bacteria can still be detected. The study will be conducted by the University of Nebraska, Department of Food Science and Technology, under the guidance of noted probiotic scientist Robert Hutkins, as well as Jens Walter and Steven Frese. The study will assess the ability of a commercially available, widely studied probiotic strain, Lactobacillus acidophilus DDS-1, and two other lactobacilli to survive through the stomach and persist in the human gastrointestinal tract.

Nature's Products Inc. Acquires Iceland Health Brand

Sunrise, FL-based Nature's Products Inc., a full service contract manufacturer and packager of consumer healthcare products, has acquired the Iceland Health vitamin brand and all store brand business from Nutrition 21. Iceland Health is a leading brand in the direct response and mass market channels, with a focus on omega 3 and joint care products. Nature's Products Inc. is a contract manufacturing organization in the nutritional supplement industry, and also has a presence in branded nutritional supplements.

SoluBlend Launches Novel Formulation Technology

Frankfort, IL-based SoluBlend Technologies LLC has launched a new technology that allows manufacturers of beverages as well as frozen, refrigerated, packaged and baked foods the ability to formulate healthy products with fat-soluble ingredients converted to water-soluble lipids. The company has a patented, proprietary technology that allows popular nutraceuticals such as omega 3 fatty acids, plant-based phytosterols, resveratrol, CoQ10 and natural vitamin E to be incorporated into a variety of consumables as water-soluble lipids, opening up opportunities to provide shelf-stable, value-added foods and beverages.

DVA Expands Market Presence to U.S.

DVA International has expanded its distribution of ingredients for the food, beverage and nutrition industries by opening a new U.S. subsidiary, DVA America Corp, Princeton, NJ. The firm will leverage its global buying power toward its strategic product categories, consisting of vitamin C, sweeteners, nutraceuticals and other vitamins for distribution to clients across North America. The new team is composed of health and nutrition ingredient experts in sales, marketing, quality and distribution management. Experts are trained to meet the needs of U.S. and Canadian customers in the food, feed and nutritional/OTC industries. DVA America members also actively participate in respective industry associations to support education, ingredient safety, positive regulation, innovation and quality.