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January/February 2013
Vol. 16, No. 1

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INGREDIENTS TO WATCH
Ten to Bet On, p. 38

FIBER'S FUTURE
The Promise of Inulin, p. 44

HEART HEALTH
Beating High Blood Pressure, p. 48

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January/February 2013
Vol. 16, No. 1

What's In Tomorrow's Energy Drink?

Ingredients to court the health-conscious consumer, p. 26

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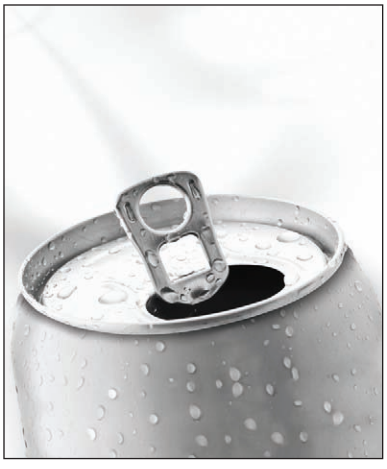
JANUARY/FEBRUARY 2013
VOLUME 16, ISSUE 1

48

69

75



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310/445-4200 • Fax: 310/445-4299

Brand Director . . . . . Tim Baudler
310/445-3757 • tim.baudler@ubm.com
Editor-in-Chief . . . . . Jennifer Grebow
310/445-3763 • jennifer.grebow@ubm.com
Associate Editor . . . . . Robby Gardner
310/445-3792 • robby.gardner@ubm.com
Account Executive . . . . . Beth Berner
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Should We Label Caffeine Content?

Barely a week goes by without some media headline about energy drinks. In recent months, coverage—particularly on caffeine products—reached fever pitch. (Turn to our timeline on page 28 for a closer look.)

The underlying concern is whether energy drinks—as well as energy supplements—are used safely. Worries include the potential danger of combining caffeine and alcohol, as well as consumption by minors.

These days, scrutiny has shifted to yet another aspect of energy products: how/whether products are labeled to disclose caffeine content.

Under current food and dietary supplement rules, energy drinks and energy supplements must disclose the presence of added caffeine by listing caffeine as an ingredient. ("Added" caffeine is considered differently than caffeine contributed naturally to a formula by, say, botanical ingredients—such as guarana or yerba mate—inherently containing caffeine.)

In the case of both energy drinks and energy supplements, however, disclosing the precise *quantity* of caffeine is optional. Dietary supplements, for instance, do not need to list a specific caffeine amount if the caffeine is considered part of the company's proprietary ingredient blend.

All energy drinks and supplements *should* be required to disclose their caffeine amounts, argue those worried that some products contain unsafe, high caffeine levels.

Also of concern is whether companies that do choose to list caffeine levels do so accurately. In recent months, *Consumer Reports*—as well as NSF International, Harvard Medical School, and the Uniformed Services University—reported that a number of products they tested contained higher levels of caffeine than the levels listed on their product labels, sometimes exceeding 20% the levels listed.

More energy drink and energy supplement companies may begin voluntarily disclosing caffeine amounts, however. In light of negative press on caffeine and energy drinks, companies may prefer to be exceedingly forthright with customers about what their products contain.

On the industry's side, one leading association encourages its own members to label caffeine content. As part of its code of ethics, the American Herbal Products Association (AHPA; Silver Spring, MD) recommends that product labels not only disclose the presence of added caffeine in a dietary supplement but also disclose the "quantity of caffeine per recommended serving, stated in both (1) milligrams per serving and (2) in equivalent approximate cups of coffee, where 100 mg of caffeine represents one cup of coffee."

According to AHPA president Michael McGuffin, the goal is to give consumers as much information as possible. "Many consumers benefit from caffeine-containing products. They are most informed to make their purchase decisions when they know [how much] caffeine is present in the products they use," he says.

There's another reason why companies may choose to list caffeine levels, adds Justin Prochnow, attorney and shareholder at Greenberg Traurig LLP (Denver). "I've talked to a lot of people who feel it's a benefit to disclose the amount of caffeine, specifically because if customers are looking for a good caffeine boost, they'll know the product has the amount they want," he says.

"I think it's a benefit both ways," Prochnow continues. "I do think that more disclosure of caffeine content would help people make more informed decisions about how much caffeine they actually want from a product. For instance, if they know a product contains 180 mg of caffeine, and they know they will be drinking two of them, for a total of 360 mg, then maybe they'll say, 'That's enough for me.'"

Jennifer Grebow
Editor-in-Chief

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*According to the New York City Department of Health

Groups Submit Comments on Proposed Codex Standard for Fish Oil

January 15 was the deadline to submit comments on a finalized draft of the Codex Alimentarius Commission's proposed standards for fish oil. Members of the project's electronic working group, including the Council for Responsible Nutrition (CRN; Washington, DC), shared their comments.

If successful, this standard will be the first Codex Alimentarius standard created for fish oils. The proposed standard applies to oil from fish—as well as from marine sources shellfish and krill—used in food and food supplements.

Next, the Codex Committee on Fats and Oils (CCFO), which oversees the project, will discuss the proposed draft to determine next steps at its meeting coming up in Malaysia in late February.

One controversial portion of the draft is an extensive table listing the fatty acid composition of oils that purportedly should be present in specific fish species. CRN questioned the accuracy of this list and its range of suggested values because it has not been vetted nor confirmed by any third-party entity. In fact, fatty acid profile might not be the best tool for confirming a fish's species because fatty acid profiles can fluctuate due to such factors as a fishery's geographic location, food sources, and environmental and seasonal conditions, says Douglas MacKay, ND, CRN's vice president of scientific and regulatory affairs. "If anchovies typically have 18% EPA present, but global warming causes their EPA levels to eventually fall to 12%, according to the table, can we still call them anchovies?" he asks.

Another argument is that sections of the draft listing appropriate processing methods are restrictive because they may not account for all methods used now or in the future.

"Some members believe this standard is ahead of its time in the sense that it can set a standard of what fish oil is today, which means not only the oil but the fatty acid content plus the preservatives that are allowed to be used and the types of concentration processing that are allowed. But veterans of the dietary supplement industry know that this has big possibilities to inhibit innovation in the future," MacKay says. For instance, he explains, if industry invents new, better preservatives for fish oil in five years, those preservatives either would not meet Codex standards if they are not on the list, or Codex would need to go through the arduous process of adding them to the standard.

CRN, as well as other commenters such as the Federation of European Specialty Food Ingredients Industries (ELC; Brussels), pointed out other problem areas as well, related to which food additives are allowed in fish oil, as well as oxidation parameters for flavored fish oils.

When asked what's likely to happen to the draft following February's CCFO meeting, MacKay says it all depends on what happens at the meeting. "If numerous member states say they have a problem with this draft, the Commission will have to decide on what next steps to take," he says.

USP Grows Food Fraud Database

The U.S. Pharmacopeial Convention (USP; Rockville, MD) has added nearly 800 new records of fraud to its Food Fraud Database. The new additions reflect records from 2011–2012 and point to additional food fraud categories: seafood, clouding agents, and lemon juice.

The Food Fraud Database documents foods most vulnerable to fraudulent manipulation in the food supply, based on reports in both scholarly journals and general media. When first compiled, the database contained 1,300 records of food fraud published between 1980 and 2010. These records showed milk, vegetable oils, and spices among the top categories for fraud.

USP scientists say those categories remain leading problems, in addition to newer fraud trends recorded in 2011–2012 for seafood (fish, shrimp), clouding agents, and lemon juice. Also vulnerable are saffron, honey, coffee, tea, black pepper, turmeric, chili powder, and maple syrup.

USP calls fraud involving clouding agents "the 2011 equivalent to the melamine scandal involving Chinese milk products from a few years ago." Clouding agents are commonly used in fruit juices to improve visual appearance and make products look freshly squeezed. Reports include use of the plasticizer Di(2-ethylhexyl) phthalate (DEHP) in fruit juices, jams, and other products, in place of more expensive palm oil. "The scope of this fraud was vast: 877 food products from 315 companies were involved; 206 products were exported to as many as 22 countries; and there were roughly 4,000 potential victims in Taiwan," USP says.

Other examples of fraud include watered-down and urea-adulterated fluid milk in India; dilution of milk powder with fillers such as maltodextrin in South America; replacement of olive oil with less-expensive vegetable oils; and dilution or replacement of spices with less-expensive spices or fillers.

USP defines "food fraud" as "the deliberate substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging, or false and misleading statements made about a product for economic gain." N

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FDA GRAS NOD FOR ALPHASIZE A-GPC

FDA has no questions about a GRAS notification for AlphaSize, an alpha-glyceryl phosphoryl choline (A-GPC) ingredient from Chemi Nutra (White Bear Lake, MN). AlphaSize targets mental and exercise performance, improving mental clarity and combating dementias and improving muscular strength, power, and reaction. The GRAS standing indicates AlphaSize—which is already used in dietary supplements—is safe for conventional food and beverages.

Chemi Nutra describes AlphaSize as a "safe, natural, and rapidly absorbed form of choline that has been shown to raise free plasma choline levels much faster than other choline precursors." In particular, A-GPC is a precursor of acetylcholine, the primary neurotransmitter involved in all brain functions and muscular contraction functions.

Black Currant Extract Self-Affirmed GRAS

Cyvex Nutrition Inc. (Irvine, CA) reports that its European black currant extract is now self-affirmed GRAS and can be incorporated in functional foods and beverages. Cyvex's black currant extract is standardized for 25% anthocyanins, making it "one of the most potent berry extracts available on the market."

Natoli Founds Tablet Engineering Program

Natoli Engineering Company, Inc., (St. Charles, MO), a specialist in tablet compression parts and services, is partnering with Long Island University to found a program to advance knowledge of pharmaceutical oral dosage engineering. The Natoli Engineering Institute will find a home on Long Island's Brooklyn campus. It's scheduled to open in September 2013.

"Work will focus on understanding many of the long-time problems of sticking and picking associated with the compression of tablets; the development of formulations for new and existing molecules; and the measurements required to ensure proper delivery of formulations to the tablet press and the control of the tablet press," the firm says.

SIDI Releases Supplier Qualification Guidelines

The Standardized Information on Dietary Ingredients (SIDI) Work Group has made available supplier qualification guidelines for dietary supplement manufacturers. This and other self-regulatory tools are available for download at www.sidiworkgroup.com.

SIDI created the supplier qualification guidelines to help manufacturers achieve supply chain integrity. Instead of just relying on a Certificate of Analysis, companies can use the new guidelines to establish their own methods for building relationships with the right partners. The document should be useful to all companies, regardless of their size.

The SIDI Work Group is made up of the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA).

Ganeden Brings Lab to Cleveland Headquarters

Ganeden Biotech (Cleveland) has relocated its state-of-the-art probiotics laboratory from Miami to its headquarters in Mayfield Heights, OH. The 4000-sq-ft facility features a 3130 Genetic Analyzer and a 2100 Bioanalyzer for verifying each lot of Ganeden BC30 probiotics by PCR and genetic sequencing.

"In addition to the standard freezers, refrigerators, sterilizers, freeze dryers, incubators, and bio-safety hoods typically found in a modern microbiology lab, we also have a full kitchen area used for preparing our customers' products as a final consumer would do, before we test for viability of Ganeden BC30," says lead scientist Howard Cash, PhD.

Ocean Spray's First International Acquisition

In a move to increase its global market share, Ocean Spray Cranberries Inc. (Lakeville-Middleboro, MA) has acquired Agrícola Cran Chile Limitada (Cran Chile), one of South America's leading cranberry growers.

The Cran Chile acquisition covers an estimated 12 million lb of yearly cranberry production and gives Ocean Spray an immediate presence in an important cranberry growing region and a counter-seasonal supply of cranberries.

DSM Acquires Swedish Oat Fiber

DSM Nutritional Products (Parsippany, NJ) has acquired Swedish Oat Fiber (Bua, Sweden), a specialty producer of oat bran rich in beta-glucans. Swedish Oat Fiber will still produce its ingredients, but DSM will assume sales and marketing activities.

Beta-glucans have a favorable reputation among various health agencies, with EFSA and FDA offering their own health claims for beta-glucans. Available from multiple food sources, beta-glucans have been associated with potential for cholesterol reduction, blood glucose control, and gastrointestinal health.

Swedish Oat Fiber distributes its OatWell brand ingredients throughout North America under Oat Ingredients LLC (Boulder, CO).

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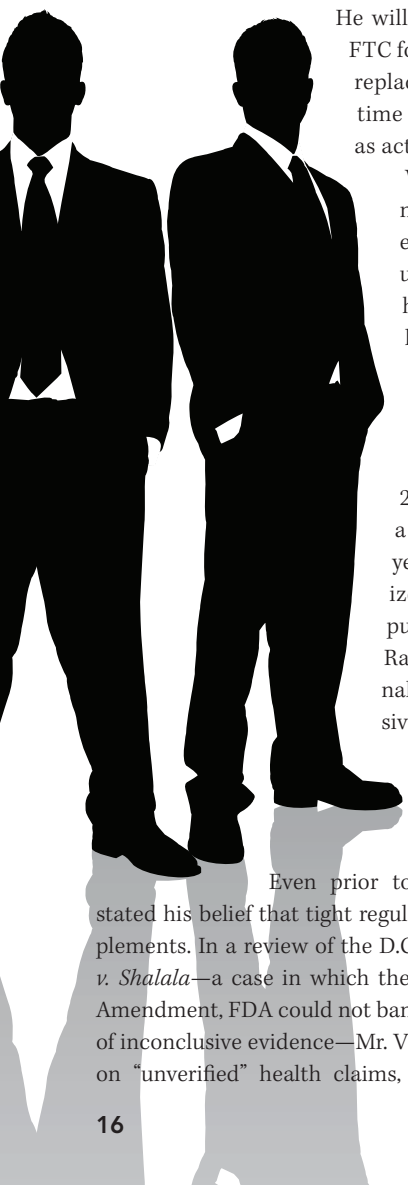
Fresh Start at the FTC?

As bureau director David Vladeck exits the FTC, will his mission endure to bring dietary supplements under tighter regulation?

BY JOHN E. VILLAFRANCO, PARTNER, KELLEY DRYE & WARREN LLP

This December, David Vladeck completed his tenure as director of the FTC's Bureau of Consumer Protection, with plans to return to academic life at Georgetown University Law Center. He will continue as a consultant to the FTC for the indefinite future and will be replaced by Charles A. Harwood, longtime FTC staff attorney, who will serve as acting bureau director.

While at the FTC, Mr. Vladeck made it clear that he believes dietary supplements should come under tight regulation. Now that he's leaving the FTC, what will his legacy leave behind?



A History of Cracking Down on Supplements

Mr. Vladeck arrived at the FTC in 2009 with impressive credentials as a consumer advocate, including 30 years of experience with Public Citizen Litigation Group, a prominent public interest law firm founded by Ralph Nader. The appointment signaled that the FTC would be aggressive in policing claims. No industry segment was more concerned by this aggressiveness than marketers of dietary supplements—and for good reason.

Even prior to his appointment, Mr. Vladeck stated his belief that tight regulation was needed for dietary supplements. In a review of the D.C. Circuit court's ruling in *Pearson v. Shalala*—a case in which the court ruled that under the First Amendment, FDA could not ban health claims simply on the basis of inconclusive evidence—Mr. Vladeck criticized the courts' views on "unverified" health claims, consumers' abilities to evaluate claims, and the "ineffective" use of disclaimers. He also argued that the D.C. Circuit misconceived basic First Amendment commercial speech principles and, consequently, placed the public at undue risk. "The tragic result of the *Pearson* [decision] is that consumers again will be exploited by health claims riddled with half-truths and distortions and duped into taking products that may jeopardize their health," he said.

Mr. Vladeck argued that all unverified health claims are misleading, and that health or nutrition claims that are unsupported by "significant scientific agreement" are unreliable and deceptive. He criticized the *Pearson* court for placing the burden of verifying claims in the hands of consumers, and explained that disclaimers would serve no role in filling the "informational void" for products that do not have significant scientific support. He stated, "nothing in the disclaimers envisioned by the *Pearson* court tell the consumer whether the product is safe—that fact is unknown; alert the consumer to the product's risks—the risks are unknown; tell the consumer whether the product works—that fact is unknown; and tell the consumer whether the product is more or less effective than a conventional remedy—that fact is unknown."

If there was any doubt about Mr. Vladeck's feelings toward the dietary supplements industry, doubt was dispelled at his May 2008 Commencement address to Georgetown University Law Center graduates. During his speech, he explained that he accepted the position with the FTC because he believes consumer fraud is "out of control" and that he intends to fight against those who prey upon the public with "snake oil supplements that promise a cure and deliver nothing."

Mr. Vladeck also made clear that the Bureau of Consumer Protection would not limit its review to bottom-feeders and unscrupulous marketers. In an October 2009 speech to the National Advertising Division, Mr. Vladeck said that the Bureau would have a renewed focus on national advertising, going after large companies that advertise widely and put forth deceptive or unsubstantiated claims, not just small companies perpetrating direct fraud. He specifically indicated that the Bureau would focus on health claims in advertising.

Both were promises he would keep.

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Once at the FTC, it was apparent that Mr. Vladeck would not be any ordinary bureau director, as he actively directed the Commission's position on appeal in *Lane Labs*. In that case, the FTC convinced the district court to reverse its earlier ruling and hold the defendants in contempt of their prior consent order with the FTC. (The district court initially concluded that the company made a good faith effort to comply with the original consent order by retaining experts and reasonably relying on the experts' opinions.)

Following *Lane Labs,* Mr. Vladeck pushed through a more rigorous substantiation standard in subsequent consent orders for other companies. Those consent orders had a profound effect on risk analysis in the supplements industry. Consent orders began to include mention of new "FDA approval provisions" that generally require, 1) FDA preapproval for the affected types of claims, and 2) new two-trial provisions that require, for the affected types of claims, at least two randomized, double-blind, placebo-controlled human clinical trials conducted by different researchers independently of each other.

These provisions are now common in consent orders and were included in orders or proposed orders involving such companies as Iovate Health Sciences, Nestlé, Dannon, and Beiersdorf. And while the FTC denies that these provisions form the *de facto* standard for companies seeking safe harbor for health claims, there is no question that the consent orders inform counsel of the FTC staff's opinion of the level of substantiation that is now required.

Mr. Vladeck made clear that the Bureau of Consumer Protection would not limit its review to bottom-feeders and unscrupulous marketers.

Most recently, the FTC's opinion was stated in an appeals case involving pomegranate juice and dietary supplement marketer POM Wonderful, which appealed a May 2012 decision by Administrative Law Judge D. Michael Chappell that the company made unsubstantiated, deceptive health claims. In a final order issued on January 10 of this year, the FTC Commission ruled that two randomized, well-controlled, human clinical trials are required to substantiate claims that a food can treat, prevent or reduce the risk of "serious diseases." As stated in the order: "Competent and reliable scientific evidence shall consist of at least two randomized and controlled human clinical trials (RCTs) of the Covered Product that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies. Such studies shall also yield statistically significant results, and shall be double-blinded unless Respondents can demonstrate that blinding cannot be effectively implemented given the nature of the intervention." (*Nutritional Outlook*'s March issue will feature more on the FTC's final POM Wonderful decision.)

New Director, Same Agenda?

What changes should the industry expect following Mr. Vladeck's exit? Probably not many.

As an initial matter, Vladeck was enormously popular with FTC staff and is widely viewed as having reinvigorated the Bureau's consumer protection mission through daring initiatives, aggressive enforcement, and effective advocacy.

The industry should expect this to continue under acting bureau director Harwood. He is a career FTC staffer who has served as a deputy director under Mr. Vladeck since November 2009. Thus, Mr. Harwood was largely responsible for implementing the Vladeck agenda.

Meanwhile, Mr. Harwood's tenure at the FTC's Seattle regional office included his own past actions against supplements. Throughout the 1990s, under the direction of Mr. Harwood, the Seattle regional office brought several complaints against dietary supplement manufacturers and marketers and joined "Operation Waistline," the FTC crackdown on weight-loss claims that resulted in settlements with seven dietary supplement manufacturers nationwide. The Seattle regional office led the investigation of two of these companies—KCD Inc. and Interactive Medical Technologies (IMT)—and settled with the companies and their principals for a total of $205,000 in consumer redress over allegations that KCD and IMT made false and unsubstantiated claims about supplement products SeQuester and Lipitrol. The companies claimed the products reduced cellulite and prevented or reduced the body's absorption of fat from food, respectively.

In 1999, following an investigation by the Seattle regional office, the FTC filed a complaint against Rose Creek Health Products, Inc., alleging that the company made false and unsubstantiated claims that its Vitamin O dietary supplement could cure and prevent cancer, lung disease, chronic headaches, and infections by enriching the bloodstream with supplemental oxygen.

Due to the Seattle regional office's efforts under Mr. Harwood, the FTC also settled with Positive Response Marketing Inc. and National Media Corp. for $275,000 each in consumer redress, resolving allegations that the companies made false claims about the dietary supplements marketed in their infomercials. Positive Response Marketing made unsubstantiated weight loss, hair growth, and impotency claims about EuroTrym Diet Patch, Foliplexx, and Y-Bron, respectively, while National Media Corp. claimed that Crystal Power could cure breast cancer and Cosmetique Francais could reduce or eliminate cellulite.

Under Mr. Harwood's direction, the FTC's eyes will remain fixed on the dietary supplement industry. Risk-averse companies should continue to closely scrutinize their marketing messages to avoid FTC action. N

John E. Villafranco *is a partner in the advertising and marketing practice at Kelley Drye & Warren LLP in Washington, DC. Villafranco is highly respected for offering comprehensive legal advice that emphasizes risk analysis and sound business practices for corporations involved in advertising and marketing. He can be reached at jvillafranco@kelleydrye.com.*

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Regulatory Changes in Canada

Crucial transition periods related to Canada's Natural Health Products Regulation.

BY TOBEY-ANN PINDER AND JACINTHA ROBERTS, DICENTRA

In 2013, Canada's Natural Health Products (NHP) Regulation will see a number of significant transition periods end. First, December 31, 2012, marked a significant deadline in the transition of food-like NHPs by Health Canada. It was the date by which all NHP-related submissions—i.e., exemption numbers (EN) and natural product numbers (NPN)—of transitioned food-like NHP products were set to expire. Second, February 4, 2013, marked the end of the Unprocessed Product License Applications Regulations (UPLAR) developed by the Natural Health Products Directorate (NHPD) to address the backlog of NHP applications.

Food-Like Products Move Out of NHPs

Health Canada defines an NHP—under the NHP Regulations—as "vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids." NHPs—which are non-prescription items—must apply for a product license and undergo premarket approval before entering Canada's market. But, on April 17, 2012, Health Canada formally announced it would transition products that more appropriately fit the definition of a food away from the NHP Regulations. Health Canada's reasoning was that certain products regulated as NHPs are packaged, perceived, represented—and thus, consumed by end users—as food. Such products include energy drinks, beverages, bars, and soups.

During the transition period from NHP to food, marketers of food-like NHPs were required to apply for Temporary Marketing Authorization (TMA) to permit their products' continued sale in the market. TMAs allow eligible products to be temporarily marketed under specific conditions, while industry collects and provides to the Food Directorate specific required data to assist in regulatory amendment to the *Food and Drug Regulations (FDR).* These food-like NHPs will meet an entirely different set of regulations once they are classified as food. For instance, companies are not required to have site licenses for food products as they would if the products were NHPs, and they also may not have to provide such extensive efficacy information on ingredients for substantiation. A TMA food, however, faces stricter regulation on fortification levels or ingredients allowed in some food categories, and may have stricter controls on related health claims.

By December 31, 2012, all food-like NHPs—excluding any case-by-case exceptions—were required to have a final TMA letter authorizing their sale under the food regulatory sphere. December 31, 2012, also marked the expiry of any NHP-related submission numbers or authorizations that any food-like NHPs had received prior, such as ENs or NPNs. Health Canada continues to issue documentation—e.g., Notice of Refusals, NPN Revocation—noting cancellation of any associated NHP submissions or authorizations for these transitioned products.

To date, most products at the food-NHP interface have been transitioned via TMA letters. Some products, however, did not require TMAs because they: 1) were already compliant as food, 2) were not eligible for TMAs without first being reformulated, or 3) remained classified as NHPs but first needed to change their marketing and other representation so as not to be confused with a food product.

Going forward, Health Canada announced it will develop category-specific TMA guidance documents, which it anticipates finalizing by the middle of this year. These documents will outline requirements for marketing data reporting, incident reporting, and other pertinent information for TMA food products. The Food Directorate has signaled that there will be a reasonable transition period for companies to bring their food-like NHPs into compliance with the TMA requirements and expects

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enforcement to be minimal during this reasonable transition period.

For new food-like NHPs that have not previously been in the NHP queue, the passing of the transition deadline marks the opportunity for new product TMA submissions to be reviewed by the Food Directorate. As we entered 2013, the Food Directorate continued to accept and review submissions of new eligible TMA food products.

UPLAR Expires

Another transition period that ended relates to UPLAR, the Unprocessed Product License Applications Regulations. The NHPD enacted UPLAR on August 4, 2010, to ensure NHPs backlogged in the queue for premarket review can, in the meantime, be legally sold. Products granted this temporary license status received a preliminary assessment for safety and efficacy and were assigned an EN while they awaited full review. UPLAR was created as a temporary solution, however, and expired on February 4, 2013. Thereafter, the legislation was repealed.

Once UPLAR expired, what happened to pre-UPLAR submissions that were still awaiting premarket review? The good news is that, at the time of this writing, NHPD appeared to be on track with clearing its backlog of pre-UPLAR NHP assessments by February 4. Of the 10,885 pre-UPLAR submissions—considered to be any new submission or amendment received by the NHPD prior to August 5, 2010—86% of them completed NHP review by October 2012. As a result, these products were either approved, refused, or withdrawn by the applicant.

As we approached the end of UPLAR, 1534 pre-UPLAR applications still awaited assessment. Although this number sounds quite large, the NHPD was working steadfastly to meet its goal of clearing the backlog, with 1593 pre- and post-UPLAR applications assessed in October 2012 alone. Furthermore, the NHPD was meeting its 180-day and 60-day review time performance targets (79% of the time for non-traditional, traditional, and homeopathic applications; and 100% of the time for compendial and labeling standards) for all new (post-UPLAR) applications. This efficiency was due to a number of NHPD initiatives, including the publication of 30 new monographs in 2012 and such strategies as "batching," in which products and/or ingredients of the same type are assessed in batches to expedite review time and provide consistency in reviewer decisions.

At the end of the [NHP] tunnel will be marketplace fairness. [And] Canadian consumers will receive products that they know to be safe and effective—a good image for our industry.

After UPLAR's expiry on February 4, no products should remain in the assessment queue with an EN; by this date, all NHP applications should have received a decision. Many in the industry questioned what to expect regarding compliance and enforcement once UPLAR expired. The NHPD has clearly indicated that it will maintain its compliance and enforcement risk-based approach and is quick to emphasize that the end of UPLAR does not signal a change in its approach to compliance and enforcement activities. Furthermore, NHPD recently met with stakeholders and reviewed industry feedback regarding appropriate transition timelines and a compliance promotion period for transitioning to full-fledged compliance and enforcement of non–market authorized products.

Canada's Natural Health Products Directorate plans to start phasing out products without NHP market authorization on March 1, 2013.

At this time, the NHPD plans to begin phasing out products without NHP market authorization starting on March 1, 2013. By December 1, 2013—nine months from the start of the transition—the NHPD expects that all manufacturers, packagers, and labelers will have completed stock turnover and should not be selling unlicensed products. Retailers and distributors will receive an additional nine months from this time—until September 1, 2014—to finish selling their stock of non–market authorized products. After this time, the Compliance and Enforcement Policy (POL-0044) will come into full effect, and products without market authorization should not be sold.

In the end, we believe full-scale enforcement of the NHP Regulation will be good for industry. For companies that have diligently worked with the NHPD process—as flawed as the process has been at times—at the end of the tunnel will be marketplace fairness. Those that comply with the regulations and produce high-quality NHPs for the public will be rewarded for their patience. In turn, Canadian consumers will receive products that they know to be safe and effective—a good image for our industry. N

Tobey-Ann Pinder *is the resident food regulatory expert at Dicentra. She is both a licensed naturopathic doctor and a lawyer.* ***Jacintha Roberts*** *works in regulatory affairs for natural health products at Dicentra. She is a biomedical engineer who has worked in site licensing at the NHPD.*

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Can the Market Mature?

Thus far, the antiaging category hasn't grown much beyond antioxidants.

BY INNOVA MARKET INSIGHTS

Healthy aging remains a key trend for product development and marketing in 2013. However, marketing to this audience is complicated. Instead of labeling products specifically as "antiaging," for instance, many marketers focus more generally on overall health maintenance and protection with antioxidants and other beneficial ingredients. Why? Because many consumers prefer not thinking of themselves as "elderly."

Less than 0.1% of the global food and drink launches Innova Market Insights recorded in the 12 months ending October 2012 were positioned specifically on an antiaging or "aging well" platform. By contrast, ten times that number, or over 1%, were marketed as high in antioxidants.

The antiaging category is highly fragmented, with products focusing on a broad and diverse range of ingredients and general benefits. Although key antiaging concerns include cognitive function, eye health, bone and joint health, and more general categories of immune health and heart health, companies are increasingly targeting these areas with everyday foodstuffs instead of creating "antiaging" products specifically advertising these benefits.

Products and Ingredients

What types of products and ingredients have healthy-aging benefits? "Superfruit" juices such as pomegranate, cranberry, and goji, for starters. Demand for these juices is rising strongly alongside demand for other functional drinks that imply specific health benefits. Demand for products that straddle the boundary between mainstream food and drinks and dietary supplements, such as supplement-style drinks and chews, is also growing.

Other active ingredients used in the aging-well category include antioxidant vitamins, omega-3 fatty acids, coenzyme Q10, and glucosamine.

Relatively high-profile ingredients just starting to appear in mainstream food products include resveratrol, a powerful antioxidant claimed to help prevent the free radical damage that can lead to premature aging of cells. Resveratrol has been linked to benefits for cardiovascular health and anti-inflammatory processes, as well as antiaging properties that help promote youthful energy and appearance. While the ingredient is relatively well established in the dietary supplements market, it is starting to appear more regularly as a component of U.S. beverage and confectionery launches. Launches in 2012 included Genesis Today's juice drink Pomegranate & Berries with Resveratrol and the first resveratrol-fortified chewing gum, Cheiron's Heart Strong Gum, which claims to have 40 times more resveratrol than a glass of red wine.

In the United States, another example of a beverage offering antiaging benefits is Activate. Its vitamins and nutrients are housed in a cap on top of the drink bottle, and they pour into the liquid only when the consumer opens the product. The Activate line includes Defy Blueberry Pom and Beauty Exotic Berry, which contain powerful ingredients such as vitamins A, C, and E; tea polyphenols; and epigallocatechin-3-gallate (better known as EGCG).

Carotenoids—particularly lutein and zeaxanthin—are linked with eye health and the protection of eyes against age-related macular degeneration (AMD). But their use hasn't moved much outside of supplements. There are some exceptions: in some supplement-style health drinks, for instance, carotenoids have appeared in combination with other nutrients. Genesis Today's Goji 100 drink, for example, claims to help improve mood, memory, vision, and overall health with naturally occurring, high levels of polysaccharides and antioxidants such as zeaxanthin and lutein. The company also offers Goji Vitamin Chews with similar purported benefits.

Activate's Defy Blueberry Pom

The Future

When asked why antiaging shows promise for continued growth, Activate Drinks vice president of marketing Jesse Merrill says, "Consumers are starting to think about the aging process at a much earlier age and are taking measure to maintain their health and appearance as early as in their 20s. A beautiful and healthy appearance is a hot topic that's highlighted in popular culture, and consumers are much more aware that what you put in your body affects your health, appearance, and overall well-being....Consumers are being proactive in seeking products that meet these needs." N

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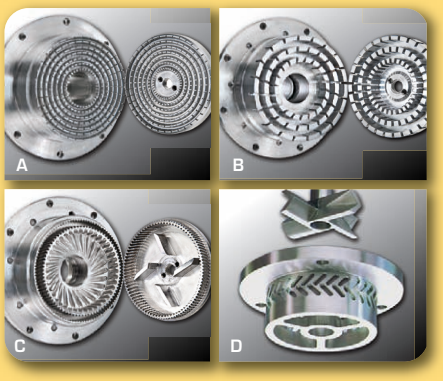

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Safeguarding Energy Drinks

To survive scrutiny and ensure a healthy future, energy drinks must court the responsible consumer. This requires formulating wisely.

BY KIMBERLY J. DECKER

With U.S. energy drink sales slated to more than double in 2013, potentially raking in as much as $19.7 billion in revenue, according to Datamonitor figures, you'd expect manufacturers' hands to be full—*with celebratory glasses of bubbly.* But maintaining a grip on those Champagne flutes could get tricky, as industry leaders' palms break into a sweat over a spate of illnesses and even deaths linked to the popular drinks.

Since 2009, FDA has received hundreds of safety incident filings, with as many as 90 linked to one liquid energy product alone: 5-Hour Energy, distributed by Living Essentials (Farmington Hills, MI). The incidents cited range from convulsions and heart attacks to a case of spontaneous abortion, according to *The New York Times,* and they've brought a flood of negative attention to the category from government agencies, watchdog groups, and anxious consumers.

The ink spilled on energy drinks could fill a superstore beverage section, and the heated discussion that's followed has compelled lawmakers to petition FDA to increase its oversight of the category. Most vocal among the Washington critics are Senators Richard Durbin (D-IL) and Richard Blumenthal (D-CT). In October 2012, they sent a letter to Margaret Hamburg, FDA commissioner, noting in particular their concerns about marketing practices that target youth, lax regulations regarding caffeine, and the ambiguous boundary separating energy beverages from supplements.

Of course, whether energy beverages *are* in fact beverages and not just supplements administered by straw is a question lawyers will litigate long after a new product has seized Capitol Hill's notice. But on the fundamental question of safety, it's important to remember that a link between an adverse health event and energy beverage consumption does not necessarily a causal relationship make.

Indeed, FDA has yet to move aggressively on energy beverages because it doesn't believe it has sufficient evidence to do so. Nevertheless, the agency plans to work with outside groups, including the Institute of Medicine, to "strengthen our understanding" of the products, with a focus on "such matters as the vulnerability of certain populations to stimulants and the incidence and consequences of excessive consumption of 'energy drinks,' especially by young people," Michele Mital, FDA's acting associate commissioner for legislation, wrote in a response to Senator Durbin.

In the meantime, energy drink manufacturers must operate in a tentative regulatory environment. But that doesn't mean they can't make changes to improve the reputation of their products and, perhaps more crucially, their potential to maintain a clean safety record. Clearly, the place to start is an ingredient review.

Caffeine in the Crosshairs

Which ingredient to start with? With the one ingredient most decisive in establishing energy drinks' success—and the one most liable for the current controversy: caffeine. From South America to Arabia, today and throughout history, millions have relied on caffeine for mental stimulation and physical acuity.

How caffeine provides these benefits is well-trod territory. Researchers have determined that it attaches to receptors that normally bind the neurotransmitter adenosine. Adenosine's job is to signal the central nervous system (CNS)—via those receptors—that it's time to slow things down and go to sleep. But if adenosine can't communicate with the CNS because its receptors are already binding caffeine, the "get to bed" message remains unheard and the body stays awake.

Further, caffeine may be one of the world's most widely used "performance-enhancing

drugs," sparing muscle glycogen by shunting the body toward metabolism of fat for energy, and also possibly lowering the threshold for neuronal activation and making it easier to recruit muscles into exercise, thus tricking the brain into thinking a workout isn't as hard as it really is.

Menacing headlines notwithstanding, the case for the safety of caffeine itself, when used responsibly, is largely settled. "Studies on the safety of caffeine in the form of coffee are abundant," says Jeff Wuagneux, CEO, RFI Ingredients (Blauvelt, NY), "and people have been consuming caffeine from natural sources for centuries without serious safety issues."

Tea, chocolate, guarana fruit, yerba mate, the aforementioned coffee: All claim caffeine as a naturally occurring constituent, and none has raised serious safety concerns when consumed in reasonable amounts. (The LD50, or median lethal dose required to kill half the members of a test group, for caffeine is widely accepted as 150 to 200 mg per kilogram of body mass—or, says Wuagneux, "roughly 80 to 100 cups of coffee for an average adult." Even a java addict would admit: That's hardly a reasonable amount.)

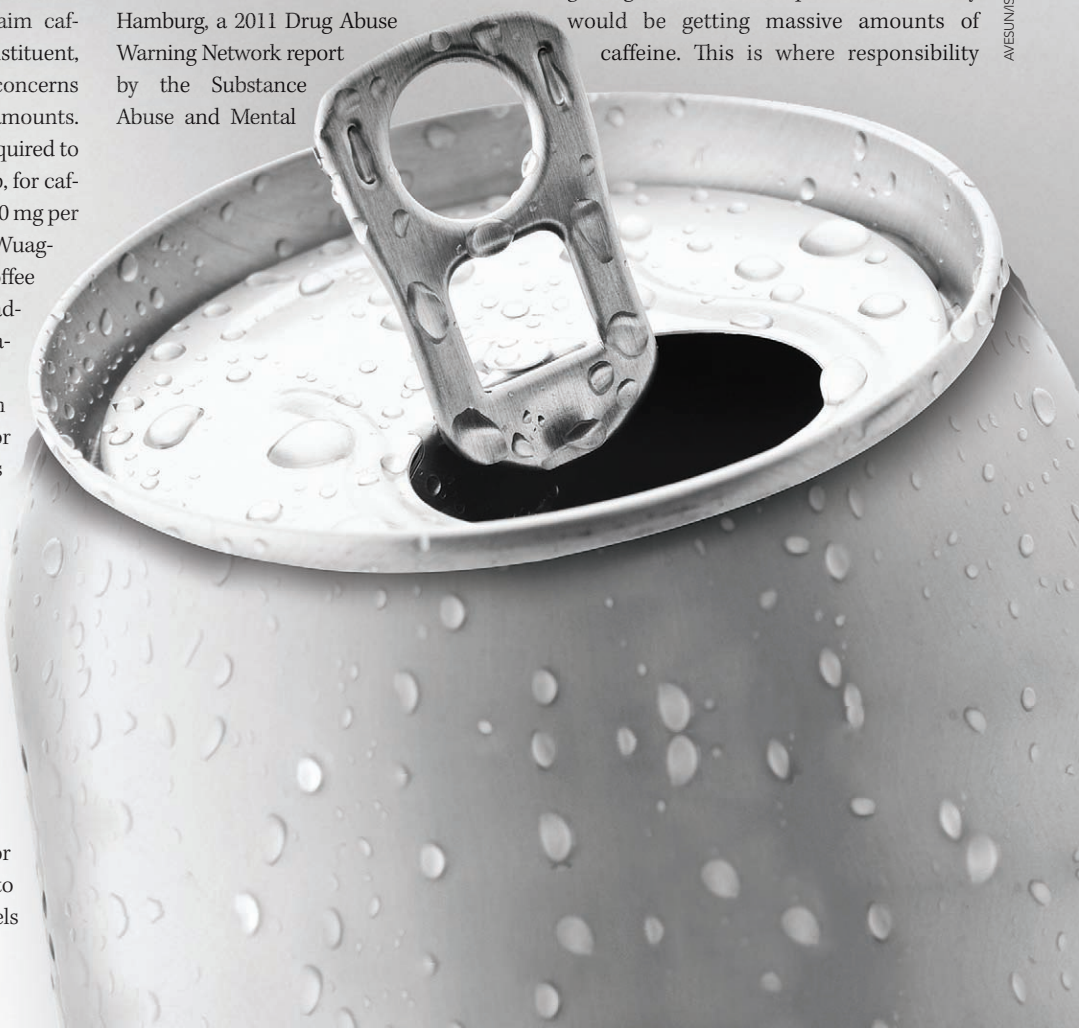
Beverages have historically been a convenient delivery medium for caffeine, and for good reason. As Nichole De Block, marketing director, Nutraceuticals International Group (Paramus, NJ), says, "Many people depend on caffeine to start their day. It boosts energy and causes you to feel more alert and awake. These effects seem to wear off after a couple of hours, so consumers look for energy drinks that provide them with the extra 'oomph' to get them through their day."

What they don't look for—or shouldn't—are drinks that pack into a single shot or can caffeine levels far in excess of what's safe. As De Block observes, "Scientific and public concern has developed due to the increasing numbers of energy drinks entering the market with caffeine concentrations well above those of mainstream energy drinks, which contain, on average, 10 mg per oz." Combine this with many consumers' predilection for drinking several energy beverages in one fell swoop and the "adverse events" that FDA has logged start making regrettable sense.

For the record, FDA currently limits the amount of caffeine in soft drinks to 0.02% or less of the product—roughly 71 mg caffeine per 12-oz soda. However, as Senator Durbin noted in his letter to Commissioner Hamburg, a 2011 Drug Abuse Warning Network report by the Substance Abuse and Mental Health Services Administration (SAMHSA) found energy drink caffeine levels ranging from 80 to 500 mg per serving—considerably higher than the 0.02% ceiling for soft drinks.

Steven Kessler, a cofounder of Steaz, (Doylsetown, PA), a producer of energy beverages and shots, believes that "serving size is an important aspect of the energy drink sector," and that "the responsibility falls on the company to accurately designate serving sizes." Realistically designating them helps, too.

"It certainly could send the wrong message," Kessler points out, "if a company labeled its 20-oz can as one serving. Consumers would obviously think they were getting a reasonable portion, but they would be getting massive amounts of caffeine. This is where responsibility



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comes in." For example, one 2.5-oz Steaz energy shot equals one serving and delivers 150 mg of caffeine, Kessler says; one serving of the company's energy drink weighs in at 8 oz, but even at 12 oz, a full can still contains a sensible 100 mg of caffeine.

And consumers can read these levels right on the product package, as Steaz chairman Jay Garnett says the company has always disclosed caffeine content voluntarily. Meanwhile, although U.S. regulations require that companies list added caffeine in the ingredient statement, "the actual amount of caffeine—or any other ingredient, for that matter—does not need to be listed on the label, leaving consumers uninformed in regard to the amount they are consuming," De Block says.

Organizations like the Center for Science in the Public Interest (CSPI; Washington, DC) have long advocated mandatory disclosure of added—not naturally occurring—caffeine contents, and the current energy beverage controversy may aid their efforts. That would please De Block, who supports such labeling, too, even if energy beverage ingredients are part of a proprietary blend. "I think all consumers should be aware not only of what ingredients they are ingesting but of *how much* they are ingesting," she says. "We have a right to know how much of something is in a product." (For more on the issue of caffeine labeling, turn to page 10.)

ENERGY DRINKS IN THE NEWS

April 3, 2012
Senator Durbin Writes FDA

Senator Richard Durbin (D–IL) writes to FDA asking the agency to "take regulatory action and to address the rising health concerns around energy drinks."

May 23, 2012
FDA Warning Letter to Rockstar

The agency says Rockstar's product is considered a conventional beverage—not a dietary supplement, as labeled—and thus is adulterated for containing unapproved food additive *Ginkgo biloba*.

August 28, 2012
NY Attorney General Subpoenas Energy Drink Firms

Reuters reports that New York's Attorney General requested information from three makers of energy drinks: PepsiCo, maker of AMP Energy; Monster Beverage Corp.; and Living Essentials LLC, maker of 5-Hour Energy. The companies were asked to provide documents related to their products and marketing.

September 2, 2012
EFSA Calls for Data on Energy Drink Consumption

The European Food Safety Authority (EFSA) calls for data on the consumption of energy drinks by specific consumer groups.

September 11, 2012
Senators Durbin, Blumenthal Write FDA

Senators Durbin and Richard Blumenthal (D–CT) write to FDA asking the agency to respond to "concerns regarding the interaction of ingredients in energy drinks and the effect that the caffeine in energy drinks has on children and adolescents."

October 17, 2012
Wrongful Death Suit Filed Against Monster Brand

The parents of 14-year-old Anais Fournier file suit against the Monster energy drink brand, claiming that her death was due to a "toxic" amount of caffeine and other stimulants as the result of consuming two 24-oz Monster energy drinks within 24 hours. The suit says Monster failed to warn consumers of the product's risk of adverse health effects.

October 26, 2012
Senators Durbin, Blumenthal Write FDA Again

Senators Durbin and Blumenthal write to FDA again, this time asking the agency "to quickly identify and recommend remedies for weaknesses and loopholes in current law that are exploited by energy drink manufacturers in order to avoid oversight."

Kessler agrees, seeing only upsides to his company's dose disclosure policy. "First of all, it shows transparency to the consumer," he says. "Secondly, if levels of ingredients like caffeine are reasonable, it proves responsibility to the consumer. Lastly, an informed consumer is a more loyal, trusting consumer."

A Natural Evolution

And that's just the kind of consumer—loyal, trusting, *responsible*—that energy beverage manufacturers would be wise to court. Not only are such consumers less likely to overindulge during an all-night arm-wrestling match at the Sig Tau house; they'll also help extend the category beyond its traditional base.

As De Block explains, "Athletes initially were the primary consumers of energy drinks, but as the market grew and expanded, athletes were no longer the primary target. Today, the majority of energy drinks are targeted at teenagers and young adults 18 to 34 years old, due to this generation's on-the-go lifestyle and receptiveness to advertisements for these types of products."

The youth demographic has been good to the category, but it has its limits. As Wuagneux says, "The youthful consumer wants to stay up late and get that immediate spike in energy, while the older consumer wants longer-lasting but less-intense energy and the ability to sleep. They also would like ingredients that keep them focused. The older consumer likely does not want addictive ingredients, and they usually want less sugar for fewer calories." In other words, they may be as thirsty for energy as the frat-house crowd; they'd simply rather that energy come in a natural form and a more conservative dose.

Steaz's Kessler has seen this shift firsthand. His company's typical consumers are "health-conscious individuals who want extra energy and focus, but with the added benefits of all-natural, organic superfruits and caffeine." Meeting their demands, he says, "reassures consumers that what they're fueling their bodies with came from all-natural sources. Therefore, they're not just keeping their bodies safe, but are doing something good for them, too. This will ultimately attract a wider base of consumers who are interested in living naturally."

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ENERGY DRINKS IN THE NEWS *(CONTINUED)*

November 16, 2012
FDA Posts AERs for Popular Energy Drinks

FDA's Center for Food Safety and Applied Nutrition (CFSAN) publishes two files detailing adverse event reports (AERs) for energy drinks, including Red Bull, Monster, 5-Hour Energy, and Rockstar. Consumption of Red Bull was connected to 21 AERs filed between January 1, 2004, and October 23, 2012. During the same time frame, 5-Hour Energy was linked to 92 AERs, Monster to 40 AERs, and Rockstar to 13 AERs. In the reports, Red Bull is characterized as a conventional food, whereas the other three brands are characterized as dietary supplements. Under current law, mandatory reporting of AERs is required for dietary supplements, but not conventional food. FDA says the reports only reflect information provided and do not represent a cause and effect.

November 21, 2012
FDA Responds to Senators, Says Agency Will Take Action as Needed

Responding to the September and October letters from Senators Blumenthal and Durbin, FDA says it will continue to review the safety of energy drinks and will take action as needed regarding the caffeine content of energy drinks and label disclosures/warnings.

November 30, 2012
Congressman Markey Asks the FTC to Investigate Drinks Targeting Children

Representative Ed Markey (D–MA) asks the FTC to investigate energy drinks that target children. "Along with caffeine, energy drinks typically contain other ingredients such as high levels of certain B vitamins, taurine, and other amino acids that may have additional stimulating impacts on the body. The additive impacts and safety of these and other stimulative ingredients in energy drinks have not been determined," he writes.

Of course, that assumes we can all agree on what *natural* really means. And in the case of energy ingredients, that's a tall order. Outside of inputs like flavors and colors, FDA is largely mum on the term's meaning, while USDA limits its opinion to the matter of natural meat and poultry. Thus, industry has filled in the blank with a working definition that encompasses "ingredients that are not synthesized or highly processed," Wuagneux says. So according to this loose definition, "Artificial FD&C colors are often used in energy beverages, but are not natural," he continues. "A sweetener like highly processed high-fructose corn syrup is not natural, even though it is naturally derived. Aspartame is not natural, but stevia extract is. And anhydrous caffeine is not natural, but extracts of caffeine-containing herbs are."

This appears to check out with consumer opinion, too. As Steaz's Garnett says, "We've found that the natural ingredients consumers love are guarana berries, green tea, and rainforest-grown yerba mate." Studies apparently show that "these superfruits give a boost without the crash, and fuel bodies in a more natural way," he adds.

The safety of caffeine itself—when used responsibly—is settled.

His company feels comfortable using yerba mate as a natural source of caffeine because of its long history of safe use by South American cultures, and because of the scientific research supporting it. Going by the botanical name *Ilex paraguariensis,* the plant contains the purine alkaloids caffeine, theobromine, and theophylline, Garnett says, and its safety record is strong enough for FDA to designate it GRAS, or Generally Recognized as Safe. In fact, he continues, "Evidence suggests that use of yerba mate in energy beverages is not only safe, but provides numerous health benefits, including vitamins, minerals, amino acids, and antioxidants."

While the company combines yerba mate with açaí, guarana, and other natural ingredients, "there isn't anything chemically that happens to 'synergize'" them, Garnett says. "However, the combination of all three helps to provide a balanced, sustained energy boost." And as for levels, low to moderate amounts prove effective. Brewed and consumed like tea—as is common practice in South America—yerba mate can contain as much as 85 mg of caffeine per serving, or close to a cup of coffee. Mixed with other caffeine sources like green tea and guarana, he says, it "will create practical and safe levels of caffeine in beverages of any size, depending on the amount used."

Also taking a cue from South America, De Block's company offers a natural, plant-derived caffeine ingredient called chá de bugre. "Chá de bugre is brewed in large drums at times of festival in Brazil, and the people consume it to sustain their energy through the night," she explains. Energy beverage manufacturers use the ingredient as a safe, all-natural stimulant that De Block says carries none of the "negative side effects commonly associated with stimulants like caffeine or ephedra."

"It is known to contain naturally occurring caffeine, potassium, allantoin, and allantoic acid," she says of the plant. And while De Block says that the latter two compounds may account for chá de bugre's traditional use in wound healing—as well as its purported fat-burning properties—research hints that the combination of caffeine and plant sterols is what gives it its safe, mild energy. De Block's company works with a Brazilian manufacturer to produce an exclusive 10:1 concentration of the ingredient that it notes should not be confused with the low-grade leaf powder commonly exported from Brazil.

Beyond Caffeine

Also, remember: caffeine isn't the only game when it comes to energizing our bodies or our beverages. Wuagneux's company offers a product called Chocamine cocoa extract that provides a natural, caffeine-free source of theobromine, the main methylxanthine in cocoa.

Theobromine, Wuagneux explains, is "similar to caffeine, with a few important differences." For one, a 2011 study published in the *Handbook of Experimental Pharmacology* (Smit HJ), found that it yields a milder stimulating effect, producing energy without caffeine's characteristic jitters. And because it

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has a longer half-life than caffeine—according to both the Smit paper and a 1996 study in the *European Journal of Clinical Pharmacology* (Mumford, GK)—it provides a more sustained dose of energy. Also like caffeine, theobromine inhibits adenosine receptors; however, it binds the A_{2A} receptors associated with caffeine's addictive qualities much more weakly, suggesting that it may be less habit forming.

The branded, self-affirmed GRAS ingredient is made from *Theobroma cacao*—a.k.a. chocolate—and "patented as a specific composition of cocoa and its key phytochemicals," Wuagneux says. "This type of product will have appeal among older consumers because it is not simply 'more caffeine.' It's also a very experiential ingredient. Much of the population actually feels something when they eat dark chocolate, whether it's improved energy, enhanced ability to focus, or improvement in mood and well being."

At use levels of 500 to 1,000 mg per serving, it could make a valuable addition to energy shakes and smoothies.

Then there's D-ribose, the naturally occurring stereoisomer of the monosaccharide ribose. Ribose is the backbone of adenosine triphosphate (ATP), "the source for all cellular energy," according to Tom VonderBrink, president, Bioenergy Life Sciences Inc. (Minneapolis). "Ribose is the starting point and the rate-limiting compound in the synthesis of these fundamental cellular compounds, and the availability of ribose determines the rate at which they can be made by our cells and tissues."

VonderBrink's company produces Bioenergy Ribose, a branded ingredient identical to the ribose in our cells but produced using natural bacterial fermentation. It's not a stimulant, he notes, "and it does not produce the ebbs and flows to energy levels experienced with stimulant-based products." He says it merely regulates the body's natural energy synthesis process, helping

ENERGY DRINKS IN THE NEWS *(CONTINUED)*

December 2012
Consumer Reports Tests Caffeine Label Claims

Consumer Reports analyzes 27 top-selling energy drinks and shots and finds that a handful contain more than 20% the level of caffeine listed on their labels. It also says the caffeine levels per serving ranged from 6 to 242 mg. Only 16 of 27 products listed specific amounts of caffeine. (Energy drinks are not required to list caffeine content levels.)

December 6, 2012
Senators Say FDA to Address Concerns

Senators Blumenthal and Durbin report that, following their meeting with FDA, the agency appears to be "moving forward in a number of areas to protect vulnerable populations against high levels of caffeine in energy drinks." During the meeting, they urged FDA to convene an expert panel on caffeine and stimulant consumption by early 2013.

December 19, 2012
JAMA Publishes Energy Drinks Page

The Journal of the American Medical Association (JAMA) publishes an online information page on energy drinks, listing the caffeine content of leading brands and health risks associated with energy drinks.

January 1, 2013
New York Times Questions Energy Drinks

New York Times columnist Barry Meier kicks off the new year with his latest story on energy drinks, titled "Energy Drinks Promise Edge, but Experts Say Proof Is Scant."

January 7, 2013
Researchers Say Energy Supplements at Military Bases Mislabeled

Researchers from NSF International, Harvard Medical School, and the Uniformed Services University report that dietary supplements widely available on military bases may be mislabeled for caffeine content. Their study is published in *JAMA International Medicine*.

January 10, 2013
DAWN Report Says Energy Drink–Related Emergency Room Visits Double

The Substance Abuse and Mental Health Services Administration (SAMHSA; a U.S. government agency) releases an updated Drug Abuse Warning Network (DAWN) report. Calling energy drink consumption "a rising health problem" due to excessive caffeine intake, the agency reports that the number of emergency department visits related to energy drinks doubled from 10,068 visits in 2007 to 20,738 visits in 2011. SAMHSA says the majority of visits involved either adverse reactions due to misuse or combination with pharmaceutical drugs (27%), alcohol (13%), and illicit drugs (10%).

January 11, 2013
Morgan Stanley Says Energy Drink Sales Down in Convenience Stores

According to *BevNet*, Morgan Stanley cites slowing sales of energy drinks in convenience stores: "It appears that the recent slide in sales growth may be directly tied to the sustained deluge of controversy and criticism in recent months surrounding energy drinks."

January 14–16, 2013
ABA Counters DAWN Report

The American Beverage Association slams the January 10 DAWN report, calling it "more sensational than substantive." ABA says the report does not adequately account for the health status of individuals; whether they had consumed other caffeinated products; or the specific effects of alcohol, illegal substances, or pharmaceuticals involved. It adds that the report's purpose "is intended to monitor drug-related emergency department visits, not the alleged effects of consuming non-alcoholic beverages."

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reduce energy loss during stress and "minimizing any physiological consequences of a supply-versus-demand energy mismatch," he explains.

VonderBrink points to more than 100 studies vouching for the ingredient's benefits. "Clinical studies continue to show that supplementing with Bioenergy Ribose can significantly improve exercise tolerance during intermediate and strenuous bouts of exercise, shorten recovery time, reduce cramping and soreness, and reduce fatigue in people suffering from energy depletion," he says. With over 30 issued or pending patents and the distinction of being the only ribose to receive a no-questions letter from FDA along with its GRAS affirmation, the product, VonderBrink says, "helps the body create and maintain energy naturally, and appeals to a broad range of consumers."

Another supplier, Beneo (Manheim, Germany), says its functional carbohydrate isomaltulose Palatinose, derived from sugar beet, provides a more prolonged type of energy. Beneo says this is because Palatinose provides energy over a longer period of time in the form of glucose, the essential energy source for mental and physical performance. Thanks to a steady release of glucose, blood glucose and insulin levels are said to remain consistent, avoiding the "crash" which consumers may associate with more traditional forms of energy drinks. Thus, says Beneo, drinks using Palatinose are able to provide a combination of carbohydrate energy and increased alertness.

Supplier Cargill (Minneapolis) takes a different approach. This January, the company reported on a study published in *Nutritional Neuroscience* on sucromalt, a slowly digestible carbohydrate. Researchers said sucromalt may better maintain feelings of mental and physical energy compared to glucose. (Cargill markets its Xtend sucromalt brand, calling it a source of "steadier" energy delivery that doesn't cause blood glucose spikes because it is slowly digestible.)

Cargill said this could give consumers more ingredient options. "Despite the growth of super-caffeinated products, it is clear that a growing sector of the population wants more options," said Xtend line manager Deborah Schulz.

And at the 2012 Health Ingredients Europe trade show, supplier Naturex (Avignon, France) unveiled what it called a new, healthier energy drink concept—Lift, a fruit-flavored carbonated drink formulated with ginger and ginseng. Both botanicals are associated with energy boosting and are part of Naturex's NAT healthy range of botanical extracts. (NAT also includes other energy-boosting ingredients like maca, rhodiola, guarana, yerba mate, and rosehip.)

"The global energy drink market was worth a massive €26.5 billion a year in 2011, according to research by Zenith International. But there are still large numbers of people who are not currently engaging with the energy drinks market because they feel they can't identify with existing brands and don't like the chemical-sounding ingredients found in many energy drinks," said Antoine Dauby, marketing director.

He continued, "Our new Lift concept addresses these barriers to purchase directly by creating an alternative to traditional energy drinks, using only natural ingredients that will appeal to female consumers and more mature demographic groups. We believe Lift will act as a platform to inspire beverage companies to create innovative energy drink brands that score more highly on naturalness and healthiness than current energy drinks, thereby attracting new consumers to the category."

More than Just Energy

But energy alone may not broaden the base for the energy beverage category. Marketers can include ingredients for cognitive health, memory, focus, performance, and mood enhancement, too.

"Even if products do contain caffeine, companies may instead choose to emphasize the product's other attributes besides just the rush of energy it provides," says Justin Prochnow, attorney and shareholder at Greenberg Traurig LLP (Denver).

De Block says formulators might consider including saffron, which contains crocetin and crocin, two compounds that, according to the University of Pittsburgh Medical Center, may improve memory and cognitive processing. "Memory and cognitive decline are common disorders in the elderly," De Block says, "and saffron is a relatively mild intervention that may be effective." Her company's Saffr'Activ is a branded, all-natural extract of the red stigmas of the *Crocus sativus,* or saffron, plant. "It is used as a natural approach to reducing the feelings of stress, anxiety, and oxidant stress—especially in athletes—and also for cognitive function for good mental health."

For its part, Steaz adds 400 µg of folic acid to its energy beverages for the vitamin's health

ENERGY DRINKS IN THE NEWS *(CONTINUED)*

January 16, 2013
JAMA Releases More Reports

JAMA publishes two more reports on energy drinks, titled "Risks of Energy Drinks Mixed with Alcohol" and "Energy Drinks and Caffeine-Related Adverse Effects."

January 16, 2013
Red Bull Sees Class Action

The lawsuit calls Red Bull's marketing and labeling misleading, questioning claims of "enduring performance" or that Red Bull is a superior source of energy.

January 17, 2013
Lawmakers Question Marketing

Representative Markey and Senators Durbin and Blumenthal send letters to 14 energy drink companies—including Red Bull, Pepsi Co., and Monster—asking companies to "explain their rationale for marketing their energy drinks and to provide data about their ingredients and claims in marketing campaigns." One of the questions asked is whether marketers consider their products to be dietary supplements or conventional food/beverages.

January 17, 2013
France Rejects Energy Drink Tax

According to *Agra Informa,* the French Constitutional Council rejected a proposed tax on energy drinks. The tax was originally proposed with the hope of reducing energy drink consumption based on concerns of consumption with alcohol.

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[1]Natural Marketing Institute, Supplement/OTC/Rx Database (SORD) Overview, November 2011

benefits, "including preventing certain birth defects if consumed prior to conception; prevention of colon, cervical, esophageal, stomach, and pancreatic cancer; and aiding in protection from cell damage and healthy development of cells," Kessler says. The beverages also contain vitamin B_{12}, which can help reduce fatigue and lethargy, regulate the nervous system, maintain healthy digestion, protect against cancers, and build healthy skin, hair, and nails, he adds.

But whatever ingredients you use, Wuagneux counsels caution. "In the current regulatory environment," he says, be mindful of the claims you make. Energy beverages can't "treat" illnesses or reverse aging, and it's best not to make promises that a product can't keep—especially considering that Representative Edward J. Markey, of Massachusetts, has asked the FTC to investigate energy beverage marketing claims.

It's also important to remember that just because an ingredient is natural doesn't mean it's safe. "Again," Kessler says, "it goes back to transparency, responsibility, and reasonability on the part of the manufacturer. For example, caffeine could come from all-natural sources, but if the portion size is massive, it may not be safe."

He, and others, think that the industry can regulate itself—if it looks at the long term. "At the end of the day," he says, "consumer health, well being, and safety are the most important aspects of this business; the goal of energy drink companies should be to satisfy those three aspects in addition to enriching the lives of consumers." We'll drink to that.

Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area, where she enjoys eating food as much as she does writing about it. Contact her at kim@decker.net.

FOOD CHEMICALS CODEX REVISES CAFFEINE STANDARDS

As reported in January, the U.S. Pharmacopeial Convention (USP) has put forth a revised *Food Chemicals Codex (FCC)* monograph for caffeine. (The *FCC* is a compendium of food ingredient quality standards.) The new monograph includes a "more discriminating" liquid chromatography test for measuring the identity and quantity of caffeine content.

USP says the new analytical method is based on an equivalent method recently published in the caffeine monograph of the USP 35–NF 30, which is USP's compendia for pharmaceutical and excipient standards. USP is now calling for public comment on the proposed caffeine standard. The deadline to comment is March 31, 2013.

In a press release, USP stated, "With the potential for closer regulatory scrutiny of products high in caffeine content following alleged adverse events and consumer group petitions, companies will need to be confi dent that they know with greater precision what they are incorporating into their products—and in what quantity."

USP's senior director of food standards, Markus Lipp, told *Nutritional Outlook* that the monograph update is part of USP's continual, routine process of ensuring standards reflect the latest technology. "We did receive specific feedback from some of our international *FCC* users that the current method in the monograph was not specific and unique enough for caffeine and could be disturbed by other components," he says.

Are monographs eventually needed for botanical ingredients that naturally contain caffeine, such as guarana or yerba mate? "The complexity of quality standards for plant-derived ingredients such as guarana and yerba mate that are comprised of many different chemical compounds is even higher than for a rather well-defined chemical such as caffeine," says Lipp.

CANADA MOVES FORWARD WITH CAFFEINE LIMITS FOR ENERGY DRINKS

Health Canada is now offi cially regulating caffeine levels in energy drinks, according to a December 31, 2012, report from the *Toronto Star.* Canada's public health agency released a proposal for caffeine limitations in October 2011, followed by official guidance in March 2012. The transition period for companies to reformulate their energy drinks and update their marketing language is over.

Single-serving energy drinks are now restricted to no more than 180 mg of caffeine (100 mg per 250 ml of liquid), a limit that the *Toronto Star* says forced 28 products to undergo reformulation. Assuming all details of the initial proposal went through, nutrition facts panels are also required of energy drinks, as well as warning labels, including "Do not mix with alcohol" and "Not recommended for children, pregnant or breastfeeding women, and individuals sensitive to caffeine."

In January, *Nutritional Outlook* learned from Canadian regulatory specialist Dicentra Inc. (Toronto) that Health Canada intends to grant five-year Temporary Marketing Authorizations (TMAs) to companies marketing caffeinated energy drinks, instead of original plans for two-year TMAs. (For more on Canada's TMA process, turn to page 20.) Dicentra quality and compliance director William Morkel says the five-year TMAs will allow related marketers to do business with minimal market disruption. Marketers could also use the extra time to develop data on purchasing habits—as required by TMAs—since Health Canada hasn't offered much guidance in terms of protocol for collecting relevant data.

Energy shots are controversially absent from the new caffeine limitation regulations because they are still regulated as Natural Health Products (NHPs). "I know that a lot of companies in the industry are trying to challenge the NHP directorate because sometimes they'll have a product line that [includes both] a shot format and a bigger bottle format, and they don't want one regulated as a food and one as an NHP," says Morkel. "They just want to have a standard approach to their product line. But the NHP directorate is being adamant in saying, 'No. Shots are NHPs, and anything bigger is a food.'"

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10 to Bet On in 2013

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BY NUTRITIONAL OUTLOOK STAFF

Zero-Calorie Natural Sweeteners

Last year's regulatory approval for stevia *(Stevia rebaudiana)* in Canada, South Africa, and Indonesia grew stevia's global footprint. This year, two more major markets—Thailand and India—may get approval. "Recent and pending approvals represent the potential access to over 1.6 billion new consumers around the world," says Jason Hecker, vice president, global marketing and innovation, PureCircle Ltd. (Oak Brook, IL). "By the end of 2012, over 1000 stevia-sweetened products were launched globally."

Over the next year, drinks and tabletop sweeteners will continue to lead, but we will also see more breakfast cereals, snacks, desserts such as ice cream, confectionery products, and jams and jellies with stevia, adds Maria Teresa Scardigli, executive director of the International Stevia Council (Brussels).

Monk fruit *(Siraitia grosvenorii)* is also gaining. "After 15 years of development work ahead of the curve, it is incredibly satisfying and exciting to see monk fruit as a sweetener now coming into commercial reality," says Chris Tower, president, Layn USA (Newport Beach, CA).

Two major tabletop launches in 2012, Nectresse by Splenda maker McNeil Nutritionals and Monk Fruit In The Raw by Cumberland Packaging, herald more to come from the monk fruit market—and indeed for natural sweeteners overall. "We have...high expectations for Monk Fruit In The Raw, as the pace of retailer acceptances has been faster than anticipated," says Cumberland's Sara Slivon. Also, she says, sales of Stevia In The Raw recently surpassed sales of Sugar In The Raw.

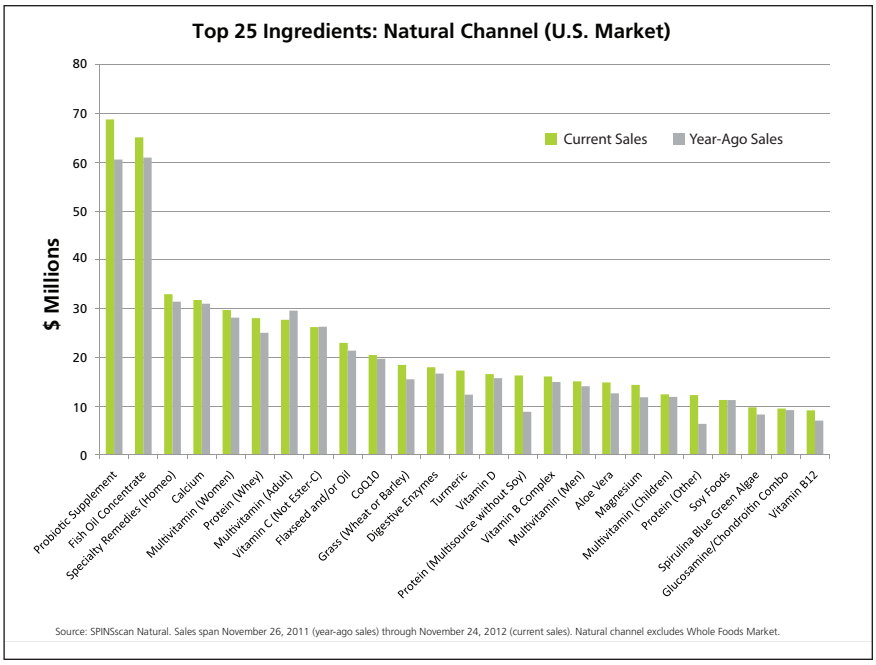
"We see [monk fruit] as complementing, not cannibalizing, stevia's demand and popularity with consumers," Tower says. He points out that, when paired with stevia in formulation, monk fruit provides "slighter up-front sweetness" and a longer-lasting, better aftertaste. "This balances out those opposite, related characteristics of stevia," he says.

Saffron

Saffron *(Crocus sativus L.)* is the world's most expensive spice. A single saffron crocus bears only three stigmas from which the spice is extracted, and each flower must be handpicked. For all its labor intensiveness, there must be something more to saffron than its use for flavor and color.

Published research over the last several years at least suggests this much, with saffron studies showing potential benefit for stress, depression, Alzheimer's, and even sexual health. Long-term studies on adults have found saffron to be equally effective as antidepressants, and a 2012 study found saffron improved erectile dysfunction associated with fluoxetine (Prozac). Another 2012 study found saffron to improved fluoxetine-related female sexual dysfunction. The standard dose for saffron is 30 mg daily, yet a 2011 study found the mere odor of saffron (even when undetected) could lower stress hormones more than placebo.

How exactly saffron might improve these and other health areas is still up for debate, but it likely has to do with saffron's main antioxidant compounds: crocin and crocetin. It's this antioxidant potential that motivates ongoing saffron studies in other areas, such as eye health. Iran, the world's lead harvester



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of saffron, is largely responsible for contemporary saffron research. Ingredient suppliers are also paying attention, such as Nutraceuticals International Group (Paramus, NJ), with its branded Saffr'Active ingredient.

Krill Oil

Krill's share of the omega-3 market is still small—but no other source is growing market share as quickly. "While traditional sources of omega-3s limp along at 5%–6% growth, krill is growing in the high double-digits. It grew 43% last year in the natural channel and 70% in the food/drug/mass channel," says Becky Wright, communications and marketing manager, Aker BioMarine Antarctic US (Issaquah, WA).

"We think 2013 will show what the category is capable of," adds Even Remøy, sales and marketing director for Olympic Seafood, a Norwegian company whose Rimfrost Krill division last year became the newest comer to the ingredients sector.

Although krill still comes in at only about 6%–8% consumer awareness compared to omega-3s overall, says Wright, prominent launches are helping. Schiff Nutrition's MegaRed is working it in the mass market, and in the natural channel, omega-3 brand Barlean's is just now coming to market with its new Wild & Whole Krill Oil with Aker's Superba ingredient. "Krill is just another no-brainer line extension for us. It provides better absorption and efficient delivery in the form of phospholipids, and great sustainability," says Andreas Koch,

Canola Oil

If it weren't for FDA approving canola oil for infant formula last fall, this fat probably wouldn't make our list. FDA's nod gives formula makers another oil to work with, and this one might just be viewed as a "premium" fat for infants.

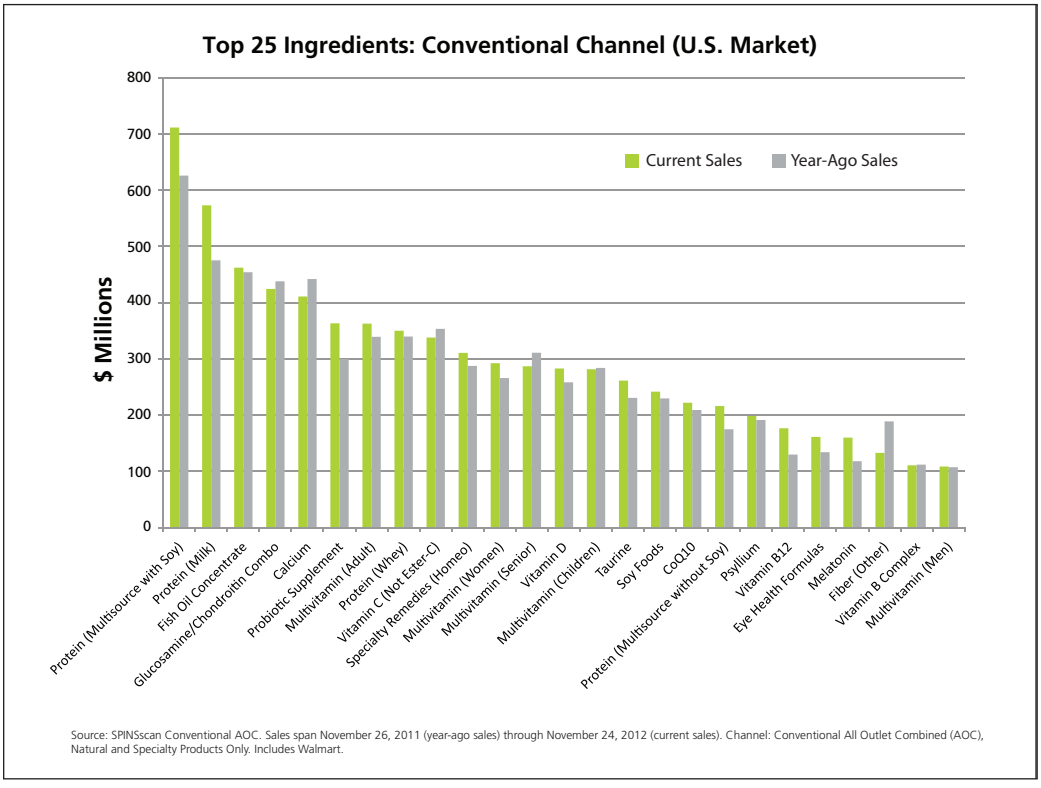
Canola oil is produced from the crushing of the canola plant, a relative of rapeseed *(Brassica napus, Brassica rapa,* or *Brassica juncea)* standardized for low erucic acid and glucosinolate levels. Based on December 2012 prices, canola oil is slightly more expensive than soybean oil, but its healthier fat profile might justify its price. Canola oil has more of the requisite omega-3 alpha-linolenic acid (ALA) than any other commonly consumed oil, and less saturated fat, too. The ingredient also holds a lower ratio of omega-6 alpha-lipoic acid (LA) to omega-3 ALA.

Babies aside, canola oil is increasingly used in healthy snacks, and high-oleic canola oil is providing better stability in all applications.

Flax

Because flax *(Linum usitatissimum)* is one of the most popular plant sources of omega-3s, expect sales to remain steady for this ingredient. Or look at the recent science and picture an even brighter future.

Aside from its rich reserves of select nutrients like fiber, protein, and omega-3 ALA, something else appears to be brewing in flax that could give the ingredient a bump in heart health sales. Recent trials using flaxseed or flax oil consistently show significant



Source: SPINSscan Conventional AOC. Sales span November 26, 2011 (year-ago sales) through November 24, 2012 (current sales). Channel: Conventional All Outlet Combined (AOC), Natural and Specialty Products Only. Includes Walmart.

reductions in total cholesterol, LDL cholesterol, triglycerides, and maybe even fasting glucose levels (a plus for diabetics).

Still, none of these recent studies have garnered as much attention as Flax-PAD, a 2012 placebo-controlled trial on 110 adults with PAD (peripheral arterial disease). After six months of consuming baked goods with 30 g of milled flaxseed daily, subjects saw what lead researcher Delfin Rodriguez, PhD, deemed "the largest decrease in blood pressure ever shown by any dietary intervention." Rodriguez said such reductions could likely result in a 50% lower risk of stroke and a 30% lower risk of heart attack.

Flax continues to find its way into baked goods, but not just for flax's nutrition. A recent bakery study found flax (as a flour) could replace up to 12% of wheat flour in cookies without affecting their structure.

The high risk of spoilage that still comes with flax products might be on its way out, as flaxseed supplier Glanbia Nutritionals (Fitchburg, WI) just launched a flax heat treatment process, MicroSure Plus, which the company says uses a "5-log kill process" equating to 99.999% pathogen destruction. Flax formulated with MicroSure Plus should offer a shelf life of at least two years.

B Vitamins

Business is up for Bs, which offer many benefits. Sam Wright IV, CEO of The Wright Group (Crowley, LA), lists just a few: pantethine and niacin for healthy cholesterol; pyridoxine, B_{12}, and folic acid for reducing homocysteine

levels; folic acid for preventing fetal neural tube defects; riboflavin for depression; biotin for skin health; pyridoxine and B_{12} for colorectal cancer; B_{12} and pyridoxine for brain function.

B vitamins—particularly thiamine and B_{12}—are popular in energy drinks these days as consumers look for healthy energy-boosters. "We also see rising use of biotin and panthenol in beauty drinks," Wright says.

Other companies dealing in B agree that business is on the up. Dave Dobkin, operations manager for B_{12} lollipop marketer Revitapop, attributes the rise to recent articles highlighting B_{12}'s role in memory function. Kyowa Hakko USA (New York City) says increased sales of its Pantesin B_5 are driven by recent studies like one showing reductions in total cholesterol by 6 mg/dl and LDL by 4 mg/dl, at a 600 mg/day dose. And leading B_3 supplier Lonza (Basel, Switzerland) plans to open a new B_3 manufacturing facility in China, citing high demand.

"Another spur to growth is the fact that some very expensive products like B_{12} and biotin have come down in price in recent years, opening up new opportunities," Wright says.

Aloe

Wishful thinking has some suppliers hoping that aloe *(Aloe vera* or *Aloe barbadensis* Miller) is the next coconut water. A noticeable uptick in aloe beverage brands is as good an indication as any, not to mention aloe's global recognition for beverages and topicals. Research on aloe is still admittedly lacking, but there are bright spots in the areas of cholesterol reduction, fasting glucose reduction, oral health, and wound healing.

Aloe quality and compliance standards are also a new focus. At the 2012 International Aloe Science Council's aloe summit, presentations revealed concern about aloe products having little to no aloe in them. The American Herbal Pharmacopeia addressed this issue with its November 2012 release of an AHP monograph for *Aloe vera* leaf juice and *Aloe vera* inner leaf juice.

Pomegranate

The pomegranate *(Punica granatum)* story is full of new science, including positive trials on blood pressure and inflammation, and several ongoing POM Wonderful (Los Angeles) trials on prostate health. Verdure Sciences (Noblesville, IN) even discovered new compounds in the pomegranate flower: punicatannins A and B.

"Punicatannins contain a very rare functional moiety that has only been found in one other plant species on the planet," says Verdure technical director Blake Ebersole. "Punicatannins have antidiabetic activity, which could be related to this moiety. The discovery of new chemistry in natural products such as this one is often used as a foundation to not only develop new drug treatments, but also supplements with new activities."

Curcumin

Promising research continues to drive sales of curcumin *(Curcuma longa)*, whose antioxidant and anti-inflammatory properties address some of today's biggest health concerns—arthritis, neurodegenerative disorders and Alzheimer's disease, cancer, heart health, diabetes, and gastrointestinal health. Research is also exploring effects on prostate and skin health and wound healing. Metabolic syndrome is also mentioned more frequently, given curcumin's links with inflammation, diabetes, and cardiovascular support.

N. Kalyanam, PhD, president, research and development, for Sabinsa (East Windsor, NJ), says the firm's Curcumin C3 Complex was recently shown to lower triglycerides in obese patients. And Verdure Sciences says that a very recent animal study by University of California–Los Angeles researchers showed that a low dose of the company's Longvida curcumin reversed some of the cognitive impairments caused by tau protein tangles.

"Curcumin may be the most therapeutic herb in modern use, and it is important to make sure that the forms used are pure, absorbable, and clinically studied," says Terry Lemerond, president and founder of curcumin marketer EuroPharma.

Protein Rich

Globally, protein-rich products are hot. In the United States, the number of high-protein product launches is three times higher than anywhere else in the world, according to a new report from Mintel.

Consumers are looking for more protein, agrees Vikki Nicholson, senior vice president, global marketing, U.S. Dairy Export Council. She cites The NPD Group's *Functional Foods and Beverages* (August 2012) report, which says that 56% of U.S. adults and 59% of U.S. teens rank adding more protein to their diet as very or somewhat important.

The drive to create high-protein food and beverage options is especially high in snacks, fortified drinks, and spoonable yogurts. "In the last 10 to 15 years, proteins have mainly been marketed in the form of supplements. But there is increasing demand for convenient ways to consume protein," says UK dairy protein supplier Volac in its January report forecasting overall company growth in 2013.

Protein suppliers are innovating. Archer Daniels Midland (Decatur, IL) has made great strides with its Clarisoy line of soluble soy proteins. Clarisoy 100 works in low-pH drinks like fruit juices while remaining transparent, and Clarisoy 150 is very stable—and heat stable—for neutral pH beverages.

Last fall, whey protein specialist Arla Foods Ingredients (Viby J, Denmark) introduced Lacprodan DI-7017, a "new generation" pure whey protein concentrate that is stable in ultra-high temperature (UHT) formulations at neutral pH. The firm says this is a market first because whey protein is otherwise notoriously difficult to incorporate in the UHT processes used to make clinical nutrition beverages with a long shelf life. As a result, prior to Lacprodan DI-7017, manufacturers have had to fall back on alternative proteins such as casein.

"We are moving away from seeing whey protein as a basic commodity and instead we are developing differentiated ingredients that offer added value," says Jack Egelund Madsen, business development manager. N

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Inulin Fiber: A Manufacturer's Dream

Why inulin is popping up on ingredient labels everywhere

By Robby Gardner, Associate Editor

Fortifying with fiber can be a speculative business decision. Which fiber source is best? And for what application? There isn't one clear answer, but it's safe to say that inulin makes a strong case for almost any product. So here's what we know about this soluble fiber and how it can fit your business plans.

Best Sources of Inulin

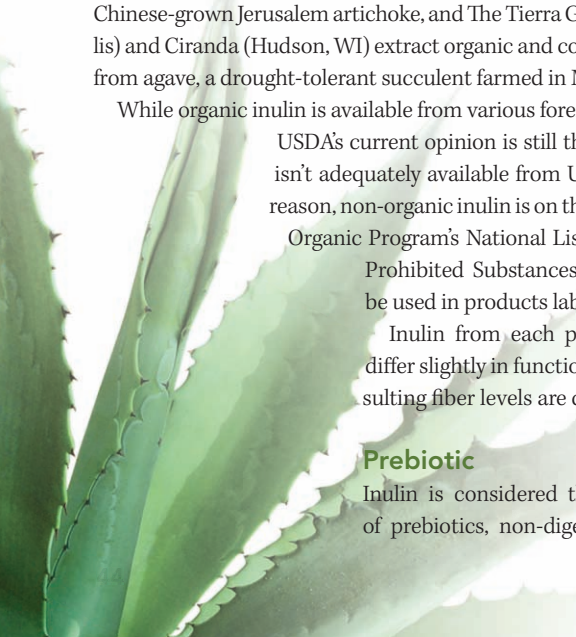
Inulin can be found in many plants—from onions to bananas—but chicory root is, by and large, the leading commercial source of food-grade inulin. Traditionally farmed in Belgium, the Netherlands, and France, the chicory root is plucked, chopped, and extracted of inulin by a water process. Major inulin suppliers, like Beneo-Orafti (Morris Plains, NJ) and Cargill (Minneapolis), procure inulin from these countries. Beneo also sources from the Southern Hemisphere to bolster its supply.

Other inulin-rich plants are clean-processed in similar fashion to chicory root. Fenchem USA (Chino, CA) supplies organic inulin from Chinese-grown Jerusalem artichoke, and The Tierra Group (Minneapolis) and Ciranda (Hudson, WI) extract organic and conventional inulin from agave, a drought-tolerant succulent farmed in Mexico.

While organic inulin is available from various foreign countries, the USDA's current opinion is still that organic inulin isn't adequately available from U.S. crops; for this reason, non-organic inulin is on the USDA National Organic Program's National List of Allowed and Prohibited Substances, meaning it can be used in products labeled organic.

Inulin from each plant source may differ slightly in functionality, but the resulting fiber levels are quite the same.

Pictured above: Jerusalem artichoke.
Pictured below left: agave.



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Prebiotic

Inulin is considered the most studied of prebiotics, non-digestible food substances that pass through the stomach and small intestine fully intact before they are fermented by beneficial bacteria in the colon. This fermentation cleans up the colon by stimulating growth of this good bacteria and inhibiting growth of less-desired inhabitants. Both activities benefit digestive health.

Extensive *in vitro* and animal trials—even human intervention trials—offer evidence that inulin has this prebiotic effect. The optimal dosage for a minimum prebiotic effect is presumed to be 5 g daily.

As industry and academia remain vigilant in learning more about the role prebiotics have on human health, manufacturers are already eager to market fiber as a prebiotic.

"Our customer feedback indicates that this is what manufacturers are looking to point out on their packaging," says Oliver de Bats, Fenchem account manager for the United States and Latin America. "Every company is looking for an edge, and because of all of the focus on probiotics, interest is moving towards pre- and probiotics for a complete marketing package." This, de Bats explains, will leave consumers seeing fiber in a whole new light.

So far, FDA hasn't authorized a health claim for inulin and digestive health, but other claims may be permissible, if substantiated. Cargill regulatory senior scientist Kristen Dammann, PhD, says that U.S.

ANCIENT GRAINS

Ancient grains are very much en vogue, but grains like barley, amaranth, quinoa, and chia don't have to be consumed in the same old fashion. FutureCeuticals Inc. (Momence, IL), a sister company of Van Drunen Farms, is a big reason why.

Back in 2001, FutureCeuticals collaborated with the USDA on a patented manufacturing technology, later coined "TRIM," that would allow grains to suspend in liquid. TRIM technology made fiber's heart-healthy beta-glucans (for which Canada, the EU, and FDA have a heart health claim) more convenient to formulate with and consume. Now, with newfound interest in ancient grains, FutureCeuticals is seeing a spike in business for its BarleyTrim barley beta-glucans and other grain products.

"Using a high-shear process and jet cooking—with no chemicals whatsoever—our process simply ruptures the cell walls of the material and makes beta-glucans much more available to go into solution," says company general manager John Hunter. "Consequentially, the materials become very hydrophilic, and, when mixed with milk, juice, or water, become smooth and creamy."

Therein lies the benefit: formulation-friendly, hydrophilic grains that, as far as Hunter knows, are not possible with other grain products. Potential applications include ready-to-mix powders, soups, juices, and even functional water. "You really can't normally make a soup using oat bran or barley bran," he says. "You would have to put it through our TRIM process to create a material that, when mixed with water or any other liquid, would have a linear viscosity—the more bran you add, the thicker and creamier the solution gets."

Beyond improved mouthfeel, the story of complex carbohydrates is increasingly reaching new audiences. Unlike simple sugars, grain carbohydrates' slow-burning nature can offer sustained energy for competitive and casual athletes and can modulate absorption of glucose for diabetics. FutureCeuticals says it is seeing sports products increasingly formulated with complex carbs in combination with protein for sustained energy. BarleyTrim has garnered interest for healthy glucose management applications, especially since it is supported by a USDA-led clinical study indicating that the product can improve glucose and insulin response in insulin-resistant subjects.

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inulin products often run structure/function claims such as "Inulin is a prebiotic fiber that helps promote digestive health by stimulating the normal, beneficial bacteria in the digestive tract."

Calcium Absorption

As inulin's digestive health benefits remain to be fully interpreted, many experts believe inulin has already made a strong case for its effect on mineral absorption. A number of human and animal trials show compelling evidence that this fiber promotes calcium absorption.

"The vast majority of this research is historically on adolescents and postmenopausal women," says Deborah Schulz, product manager for Cargill Health & Nutrition. "Our opinion is that if more studies were done on the normal population, you'd probably see the same effect: enhanced calcium absorption."

Higher calcium absorption could benefit many populations, including those with celiac disease, who are notoriously prone to calcium deficiency.

Gluten-Free Baking

Beyond its prebiotic effect and calcium absorption qualities, inulin could very well please celiacs in other ways. Gluten-free breads represent an area of the food sector in much need of work. Nutritionally speaking, these breads usually consist of refined flours and starches that are likely low in fiber. Inulin, with its soluble fiber, can be of service here.

Another challenge with gluten-free breads is improving their acceptance with consumers. Extrapolating from the chemical makeup of inulin, Beneo president and general manager Joseph O'Neill says that inulin should also be capable of improving the look and feel

of these products. "Because inulin has a lot of residual sugars in it, this should contribute a browning reaction to make gluten-free products look similar to whole-wheat products," says O'Neill. "This is just one way we see inulin complementing the gluten-free areas when you take out wheat gluten and wheat fibers."

It so happens that a team of Brazilian researchers just reached the O'Neill's conclusion in a state-sponsored study. Writing in the journal *Food & Function* in January 2013, researchers from Universidade Federal de São Paolo formulated gluten-free bread with Synergy1—a Beneo inulin product—and compared it to a control gluten-free bread. Compared to the control, the inulin-fortified bread yielded better volume, softer crumb, and darker crust and crumb. A tasting panel confirmed improvements in appearance, color, texture, and overall preference.

Because of some loss of inulin during the baking process, the researchers needed to add 12% inulin to the bread recipe in order to yield 4 g of inulin per serving.

Fat and Sugar Substitute

Inulin's impact on food product design extends even further, with potential fat and sugar replacement.

Longer-chain inulin has a curious ability to enhance viscosity and mouthfeel in food products. The advantage here is potential uses of inulin for developing low-fat products, even without the use of gums or other hydrocolloids. A host of trials on creamy-type products has found inulin fruitful in this crusade, and in cases where gelling is desired, some inulins can encourage this characteristic, too.

Inulin's residual sugar can provide an extra edge for sweetening, too—not necessarily because inulin offers lots of sweetening, but because it can act as the bulking agent lost when sugar is replaced with stevia or another high-intensity sweetener. And because inulin is an indigestible carbohydrate, it has a negligible effect on blood sugar response after eating. The same can't be said for digestible carbohydrates.

Because inulin is an indigestible carbohydrate, it has a negligible effect on blood sugar response after eating.

There's no telling how much this little fiber might benefit manufacturers and consumers. But the next frontier is widely believed to be...weight management. N

SATIETY

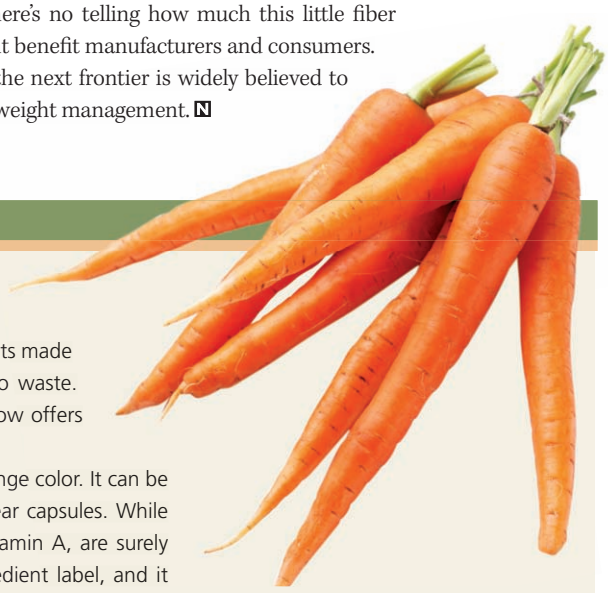
For most fibers, proving that eating them can induce a feeling of fullness is still only exploratory. But Danisco (Copenhagen) is making a case for its Litesse polydextrose. The soluble fiber has been tested for things like prebiotic effects and cholesterol support, but two late studies have the company optimistic about a potential effect on satiety. In one of them, published in the journal *Appetite,* a mid-morning snack formulated with Litesse boosted satiety and lowered energy intake over control. Previously, researchers at Oxford Brooks University observed 10% less energy intake when subjects consumed Litesse in a fruit smoothie one hour before lunch. A new, higher-in-fiber liquid version of Litesse is now available for markets in Asia.

CARROT FIBER

Normally, carrot juice makers throw out their leftover pomace; but with carrots made of 80% fiber, BI Nutraceuticals (Long Beach, CA) saw a resource going to waste. Thanks to a partnership with carrot farms in California, BI Nutraceuticals now offers carrot fiber.

Carrot fiber offers a slightly sweet carrot flavor, mild aroma, and light-orange color. It can be added to foods, beverages, and tablets, and it might look wonderful in clear capsules. While carrot fiber is only standardized for fiber, other phytonutrients, such as vitamin A, are surely present to some extent. The vegetable source will look great on any ingredient label, and it doesn't take much processing to get this final ingredient.

"We wash it to remove some excess sugars, and then we dry it, sterilize it, and mill to whatever size and texture our customers request," says BI food technologist Alison Raban. BI can sell both organic and conventional carrot fiber. These fibers complement BI's apple fiber, better intended for sweet applications and produced in much the same way as carrot fiber.



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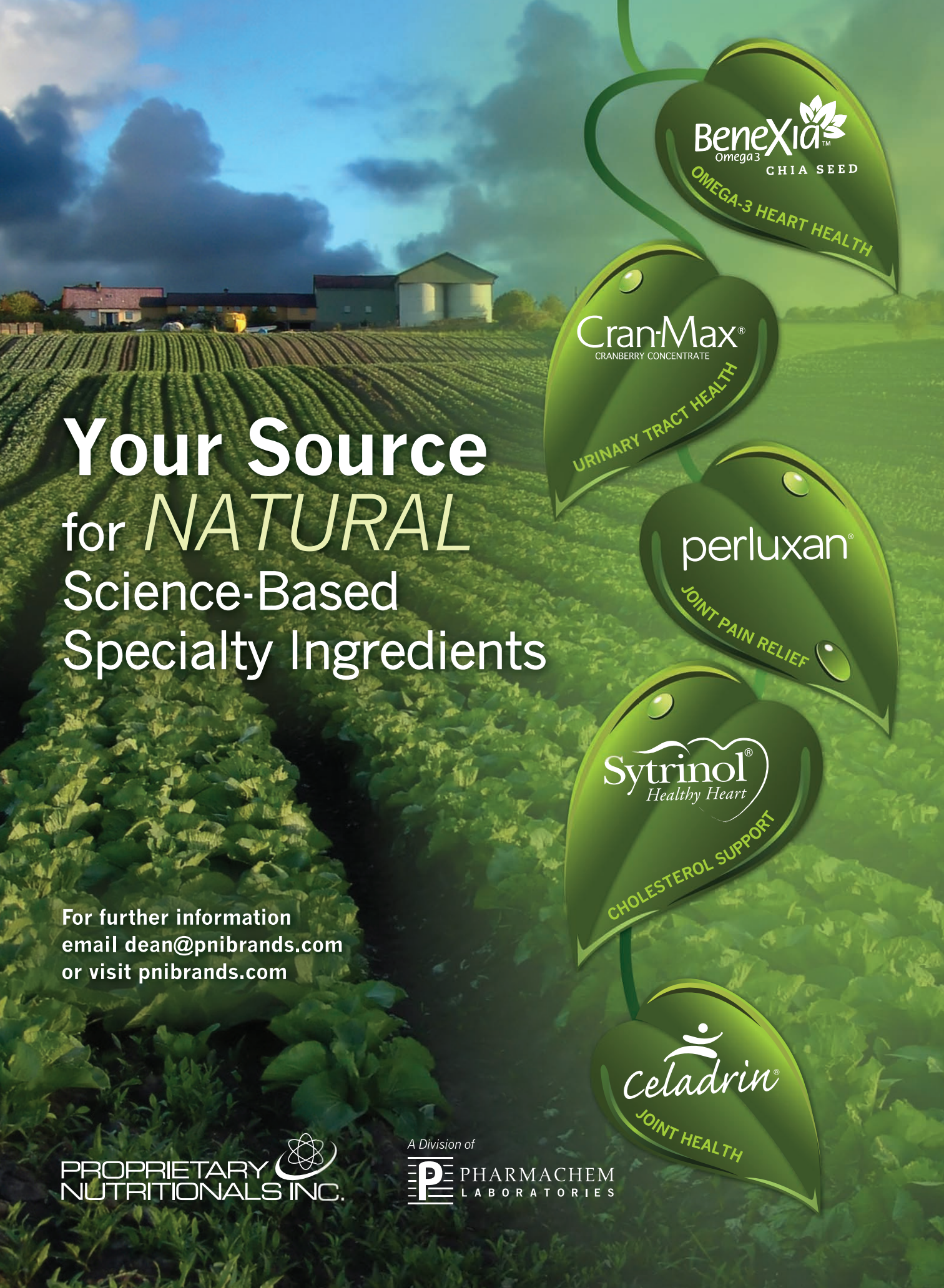

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Beating High Blood Pressure with Polyphenols

Polyphenolic compounds like those found in dark chocolate and coffee offer protection.

BY IRFAN QURESHI

Cardiovascular disease is a major healthcare burden for the United States. Estimates of total prevalence in the U.S. adult population top 83 million—that's more than 1 in 3 adults. According to the American Heart Association's (AHA) Heart Disease and Stroke 2013 Statistical Update, total direct medical costs related to care for cardiovascular diseases are projected to exceed $1.48 trillion annually by the year 2030. Commonly recognized risk factors for cardiovascular disease include obesity, cholesterol and lipid imbalances, diabetes, and compromised blood sugar metabolism.

Another major risk factor for cardiovascular disease is elevated blood pressure.

The concept of elevated blood pressure as a risk factor for cardiovascular disease gained recognition decades ago, when a 30-year follow-up analysis of data *(Hypertension*, 1989*)* from over 5000 adults in the Framingham Heart Study revealed that blood pressure levels are a strong predictor for the development of coronary heart disease, congestive heart failure, stroke, and transient ischemic attacks. These associations are further illustrated by AHA estimates that hypertensive blood pressure readings greater than 140/90 mmHg are linked to 77% of first stroke cases, 69% of first heart attacks, and 74% of congestive heart failures.[1]

AHA estimates that nearly 78 million Americans are hypertensive, defined as a blood pressure of >140/90 mmHg. (Normal blood pressure readings are considered to be below 120/80 mmHg.) A review of data from the National Health and Nutrition Examination Survey (NHANES) 1999–2000 estimates that the *worldwide* prevalence of prehypertension—defined as blood pressure readings in the range of 120–139/80–89 mmHg—is 31%.

The important thing to remember, however, is that blood pressure is *modifiable* through healthy diet, lifestyle choices, and nutritional intervention—before more drastic alternatives need to be considered.

Flavanols in dark chocolate, and chlorogenic acids in green coffee, show significant promise for enhancing cardiovascular function.

Polyphenols and Vascular Health

Polyphenolic compounds from plants have demonstrated significant benefits to the cardiovascular system. While these compounds are likely to have multiple mechanisms of action for cardiovascular health, one mechanism may be to promote the natural ability of the endothelial lining of blood vessels to relax.

Polyphenols also seem to promote beneficial antioxidant effects in blood vessels by enhancing plasma antioxidant levels, decreasing free radicals and their byproducts, and attenuating damage due to oxidative stress. These compounds also influence the activity of endothelial Nitric Oxide Synthase (eNOS), an enzyme that supports healthy nitric oxide (NO) synthesis and availability to the endothelial lining of blood vessels. The availability of sufficient NO in blood vessels is critical to supporting optimal vascular tone by reducing contraction of the blood vessels and inhibiting platelet aggregation for healthier blood flow.

Research on polyphenol-rich foods and food extracts has found some can induce clinical benefits for cardiovascular health and related risk factors, including lowering elevated blood pressure. Two of the most promising foods are dark chocolate and coffee, especially green (unroasted) coffee beans. Flavanols in dark chocolate, and chlorogenic acids in green coffee, show significant promise for enhancing cardiovascular function and exerting protective effects.

Green Coffee and Chlorogenic Acids

Chlorogenic acids are powerful antioxidants found abundantly in green coffee beans but also in many other plants. The term encompasses a number of compounds, including three major subclasses: caffeoylquinic acid, feruloylquinic acid, and dicaffeoylquinic acid. A regular cup of coffee contains between 70 mg and 300 mg of these polyphenols.

A review article by Youyou Zhao and colleagues *(Hypertension Research,* 2011*)* from the Nestlé Research Center in Beijing highlights the mechanisms by which chlorogenic acids

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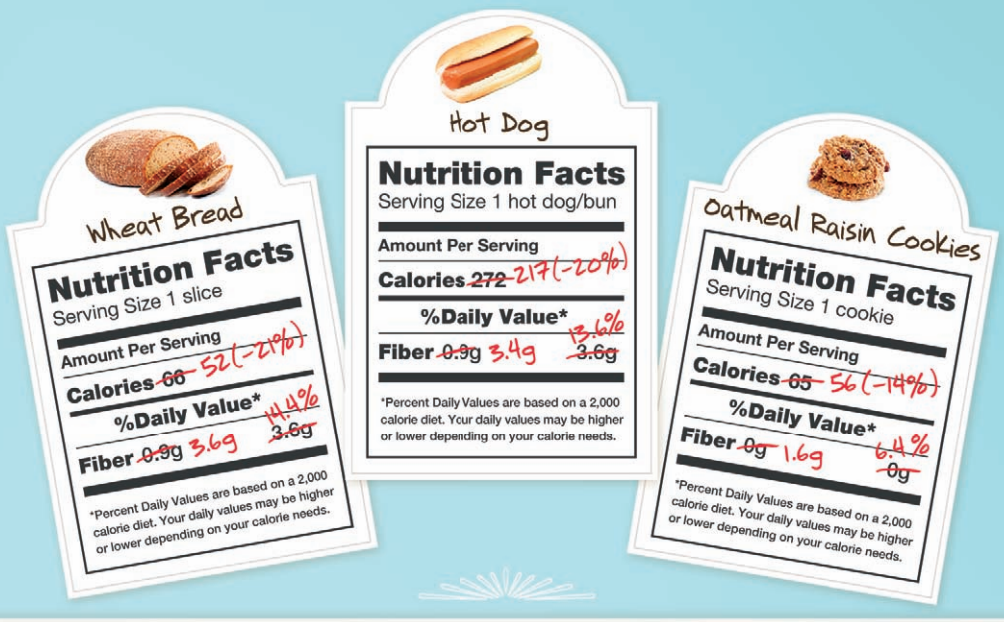

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exhibit antihypertensive effects. It also summarizes the pertinent animal and human studies demonstrating blood pressure lowering as an endpoint. According to Zhao, chlorogenic acids influence blood pressure by several mechanisms: 1) direct free radical scavenging activity; 2) inhibition of enzymes, thereby reducing free radical production; 3) stimulation of NO production; 4) inhibition of angiotensin-converting enzyme (ACE) in the plasma and tissues; and 5) anti-inflammatory effects.

While several animal studies show impressive effects on blood pressure with acute and long-term dosing of green coffee extracts, clinical studies are now confirming similar benefits in humans. In a randomized, double-blind, placebo-controlled trial *(Hypertension Research,* 2005*)* conducted by Kao Corp. in Tokyo, 117 patients with mild hypertension were assigned to placebo or a daily 180-ml beverage containing 46, 93, or 185 mg of a hot water–extracted green coffee standardized to 54% total chlorogenic acids. After 28 days, blood pressure levels dropped in a dose-dependent manner, with the highest-dose green coffee group showing average reductions of 5.6 mmHg in systolic pressure and 3.9 mmHg in diastolic blood pressure.

In another trial *(Clinical and Experimental Hypertension,* 2006*),* conducted by Takuya Watanabe and colleagues in Tokyo, 40 Japanese patients with mild hypertension consumed placebo or 480 mg of a green coffee extract daily (standardized to 140 mg of chlorogenic acids each day). The subjects consumed the green coffee extract in a mixture of fruit and vegetable juice for 12 weeks. At four weeks, average blood pressure reductions in the treatment group were 8 mmHg and 7 mmHg in systolic and diastolic values, respectively. At 12 weeks, average reductions were 10 mmHg and 7 mmHg, respectively.

Green coffee beans should be unroasted because the roasting process otherwise results in the production of hydroxyhydroquinone (HHQ), a compound that seems to antagonize the antihypertensive effect of chlorogenic acids. In animal studies, coffee extract with HHQ has failed to lower blood pressure. When HHQ-free coffee extract was administered instead, the development of hypertension was significantly reduced. Human studies have yielded similar effects.

Flavanols and Dark Chocolate

Flavanols are phenolic compounds present in a variety of foods, and they include catechins and epicatechins. Recent investigations suggest that these substances promote cardiovascular health by enhancing blood flow, with studies showing improved endothelial function and blood circulation throughout the body.

An estimated 10% of cocoa powder's weight is made up of flavonoids, and finished chocolate is considered to be a most concentrated source of the flavanols catechin and epicatechin. A unique attribute of cocoa flavanols is that they exist as long polymers, whereas catechins found in many other foods are shorter-chain molecules. The long-chain structural properties confer strong free radical scavenging and antioxidant benefits.

Clinical studies on cocoa flavanol intake reveal blood pressure benefits. A meta-

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BARRY CALLEBAUT GETS AN EU HEALTH CLAIM FOR COCOA FLAVANOLS AND BLOOD FLOW

KMAHELONA/ISTOCKPHOTO.COM

In July 2012, the European Food Safety Authority (EFSA; Parma, Italy) published its first positive opinion for a health claim linking cocoa flavanols and healthy blood flow. Cocoa manufacturer Barry Callebaut (Zurich, Switzerland) filed the claim.

Raw cocoa beans are highly concentrated with flavanols. When derived from cocoa, these flavanols have been linked to potential benefits for cognition and mood, cholesterol, blood pressure, and blood circulation. EFSA concluded that enough data is available to support a link between cocoa flavanol consumption and the maintenance of normal endothelium-dependent vasodilation. In fact, several studies suggest that consuming high amounts of cocoa flavanols can support healthy blood flow even in at-risk populations, such as smokers, overweight subjects, diabetics, and the elderly. Efficacy, however, appears to rely on very high amounts of cocoa flavanols.

Because traditional chocolate manufacturing relies on high-heat processing, which can destroy flavanols, companies like Barry Callebaut have focused their efforts on creating advanced processes that retain high amounts of flavanols in finished cocoa and chocolate ingredients. EFSA's opinion is based on findings with Barry Callebaut's ACTICOA process, which the company says preserves up to 80% of raw cocoa flavanols.

In order to obtain the claimed effect on healthy blood circulation, EFSA recommends daily consumption of 200 mg of cocoa flavanols (2.5 g of high-flavanol cocoa powder or 10 g of high-flavanol dark chocolate).

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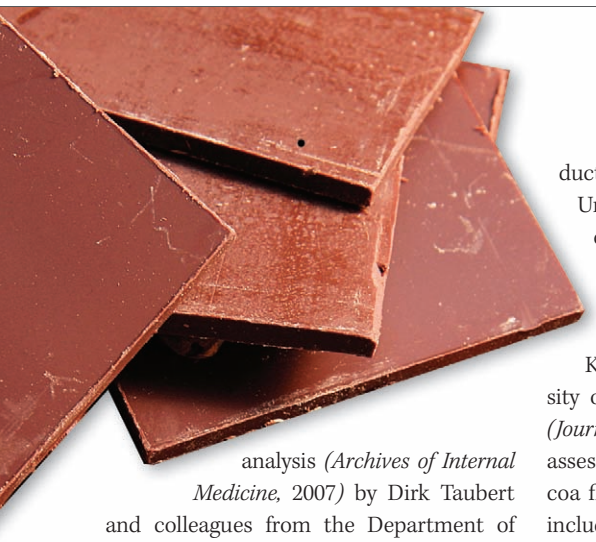

analysis *(Archives of Internal Medicine,* 2007*)* by Dirk Taubert and colleagues from the Department of Pharmacology at the University Hospital of Cologne in Germany covered five randomized trials in which cocoa products were administered for seven days or more. It found statistically significant average decreases in systolic and diastolic blood pressure levels of 4.7 mmHg and 2.8 mmHg, respectively, in a total of 173 subjects across all studies.

In another meta-analysis *(The American Journal of Clinical Nutrition,* 2008*),* conducted by Lee Hooper's group from the University of East Anglia in Norwich, UK, chocolate intake was associated with reduced systolic and diastolic blood pressure by an average of 5.88 and 3.30 mmHg, respectively.

Kade Davison's group from the University of South Australia undertook a study *(Journal of Human Hypertension,* 2010*)* to assess the effects of differing doses of cocoa flavanols on blood pressure. The study included 32 men and 20 postmenopausal women with untreated mild hypertension (blood pressure greater than 130/85 and less than 160/100 mmHg). Participants were divided into four groups and instructed to consume a daily cocoa beverage, for six weeks, containing 33, 372, 712, or 1052 mg of cocoa flavanols. In only the group consuming the highest dose of cocoa flavanols, significant reductions were seen in mean arterial blood pressure as well as 24-hour measurements of systolic blood pressure (average reduction of 5.3 mmHg) and diastolic blood pressure (average reduction of 3 mmHg).

Verawati Sudarma and colleagues from the University of Indonesia in Jakarta conducted a randomized study *(Acta Medica Indonesiana,* 2011*)* in 32 prehypertensive subjects. For 15 days, half of subjects consumed 30 g/day of dark chocolate (flavanol rich) while the other half consumed 25 g/day of white chocolate (flavanol poor). Both groups received dietary counseling in addition to their interventions. Serum levels of NO were assessed at baseline and after 15 days, and they were significantly higher in the group consuming dark chocolate. Blood pressure levels decreased in both groups, but significant improvements were seen in systolic blood pressure levels for the dark chocolate group versus the white chocolate group, with average systolic pressure readings of 120.64 mmHg

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in the dark chocolate group versus 131.19 mmHg in the white chocolate group. Diastolic readings were also lower in the dark chocolate versus white chocolate group, yet these changes didn't reach statistical significance.

Lastly, a study conducted in Jordan and led by Saafan A. Al-Safi *(Current Drug Delivery,* 2011*)* looked at the relationship between weekly mean intake of dark chocolate and cardiovascular parameters in 14,310 adults. Study participants self-reported their weekly dark chocolate intake and were divided into three groups: mild intake (1–2 bars/week), moderate intake (3–4 bars/week), and high intake (>4 bars/week). Blood pressure readings revealed significantly lower values for subjects reporting the highest consumption of dark chocolate. Blood pressure reductions also appeared linked to increased dark chocolate intake regardless of age or family history of hypertension.

It's likely that the long-term intake of cocoa flavanols can encourage healthy blood pressure and can significantly impact other aspects of cardiovascular health by improving the function of the endothelium and promoting healthy NO levels. These benefits are likely to extend to other areas as well, including support for brain health by enhancing neural microcirculation and the flow of nutrients to critical tissues. Being selective in choosing healthier chocolate preparations over those with excessive sugar and other additives can go a long way in reaping the benefits of cocoa flavanols without the risks that may be associated with sugar and other additives. N

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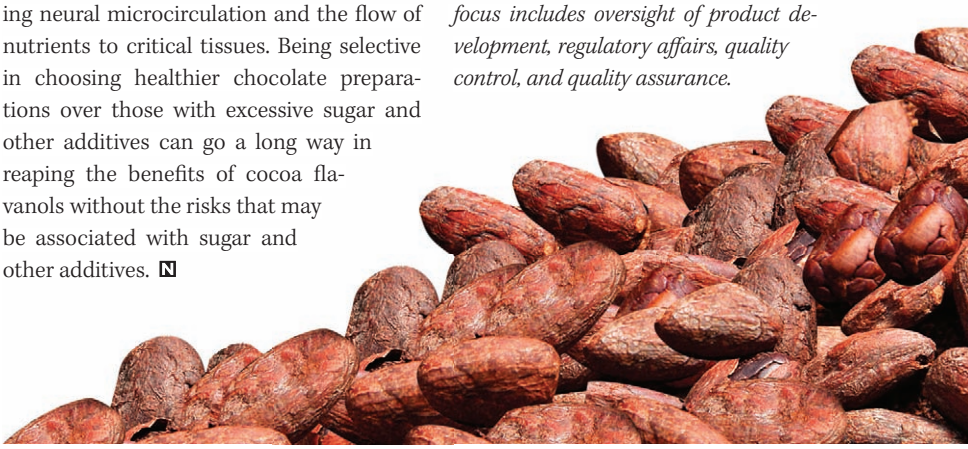
Irfan Qureshi, ND, *is chief regulatory officer for Vitamin Research Products LLC. His current focus includes oversight of product development, regulatory affairs, quality control, and quality assurance.*



RESEARCH FROM 2012: NUTRITIONAL INTERVENTIONS FOR BLOOD PRESSURE

*As previously reported by *Nutritional Outlook*

Cochrane Review on Cocoa Flavanols for Blood Pressure

Published online on August 15, 2012, a *Cochrane Review* on cocoa flavanols concluded that high consumption of these compounds can significantly reduce blood pressure.

Australian researchers conducted a meta-analysis on 20 clinical trials involving more than 800 adults—with and without hypertension—who consumed cocoa flavanols or a control for 2–18 weeks. Statistically significant reductions were found with flavanol-rich cocoa consumption for both diastolic (-2.2 mmHg) and systolic blood pressure (-2.8 mmHg) compared to consumption of zero flavanols.

How high of a dose was needed for efficacy? The researchers couldn't reach a consensus here, because the studies used a wide range of flavanols (from 30–1080 mg daily). The average amount used was 545.5 mg daily.

More work is needed to iron out how exactly cocoa flavanols can support healthy blood pressure, said the research team.

Heart Health Meta-Analysis on Chocolate and Cocoa

A meta-analysis on 42 studies published in March 2012 in *The American Journal of Clinical Nutrition* strengthened the case for consuming chocolate and cocoa for their heart-healthy compounds. Using data from studies on 18 weeks or less of chocolate, cocoa, or cocoa flavonoid consumption, researchers from Harvard Medical School and the UK's Norwich Medical School assessed the experiences of nearly 1300 participants.

Consumption of cocoa ingredients and compounds was linked to better insulin resistance and flow-mediated dilation (a key measurement of blood flow regulation), reduced diastolic and mean arterial blood pressure, and "marginally significant" effects on cholesterol.

Some factors improved regardless of dosage, but other factors only reached significance at certain levels of dosage.

"My takeaway message would be that if people like dark chocolate, then eating a little in place of other 'treat' foods is fine, and may be beneficial," said study author Lee Hooper in an interview with *Reuters*. "However, the evidence is not yet good enough to suggest that we should all be doing this."

Cranberry Juice Lowers Blood Pressure

Drinking cranberry juice may significantly lower blood pressure, according to a study presented at the American Heart Association's High Blood Pressure Research 2012 conference. One of several studies presented on food supplementation and blood pressure, this trial concerned subjects drinking a low-calorie cranberry juice beverage or placebo daily for eight weeks.

Blood pressure was calculated at baseline, midway through the study, and at the end of the study. Subjects who drank cranberry juice experienced significant reductions in both systolic blood pressure (from an average of 121 mmHg down to 118 mmHg) and diastolic blood pressure (from an average of 73 mmHg to 70 mmHg) from baseline to completion of the study. No changes were reported for the placebo group. Ocean Spray Cranberries (Lakeville-Middleboro, MA) funded the study.

ChromaDex Pterostilbene Lowers Blood Pressure in Human Clinical

In a first human clinical trial, ChromaDex's (Irvine, CA) pTeroPure pterostilbene ingredient significantly reduced blood pressure in humans. These results were also presented at the American Heart Association's High Blood Pressure Research 2012 event in September.

The patented pterostilbene is a nature-identical form of this antioxidant found in blueberries.

In double-blind, placebo-controlled fashion, researchers from the University of Mississippi assigned 80 adults to a high dose of pTeroPure (250 mg), a low dose of pTeroPure (50 mg), a low dose in combination with 100 mg of grape extract, or placebo.

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At the study's close, subjects in the high-dose pterostilbene group showed significantly greater reductions in blood pressure compared to the placebo group. Specifically, the group showed reductions of 7.9 mmHg in systolic blood pressure and 7.33 mmHg in diastolic blood pressure.

Blood Pressure–Lowering Potential of Protein

A Dutch study on 94 overweight adults supports the growing notion that ample dietary protein may alleviate hypertension. The study was published in April 2012 in *The American Journal of Clinical Nutrition.*

Researchers from the Top Institute of Food and Nutrition (Wageningen, the Netherlands) assigned 94 men and women to a protein (20 g of plant and animal protein) or maltodextrin supplement three times daily for four weeks. Diastolic and systolic blood pressure were evaluated periodically for patients, all of whom had elevated, but untreated, blood pressure. Blood pressure readings were evaluated as either office readings or daytime readings.

Compared to readings from the maltodextrin group, systolic blood pressure decreased by 4.9 mmHg (office) and 4.6 mmHg (daytime) in the protein group. Diastolic blood pressure dropped 2.7 mmHg for the protein group over maltodextrin group (office), and daytime readings did not differ between groups.

The results of this protein trial complement previous intervention studies linking protein intake and blood pressure. Agglomix (Tilburg, the Netherlands) provided protein and maltodextrin supplements for the study. N

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Full-Service Future

Companies rely on contract manufacturers to be their "one stop" saviors.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

These days, it seems, you can't be a contract manufacturer without offering a little extra somethin'. Today's contract manufacturers do it all, from ingredient sourcing, formulating, manufacturing, testing, and packaging to providing regulatory expertise, warehousing, and fulfillment. A handful of contract service providers shared their thoughts on what this business model means for the future.

Why do today's dietary supplement and healthy food/beverage companies need more services from contract service providers?

Steve Holtby, president and CEO, Soft Gel Technologies Inc. (Los Angeles): A lot of companies are struggling to comply with heightened FDA GMP requirements, which require a lot of resources—both time and money. A well-rounded contract manufacturer may be able to offer some services and knowledge as part of its customer service package, thereby freeing the marketer from having to outsource or hire internally.

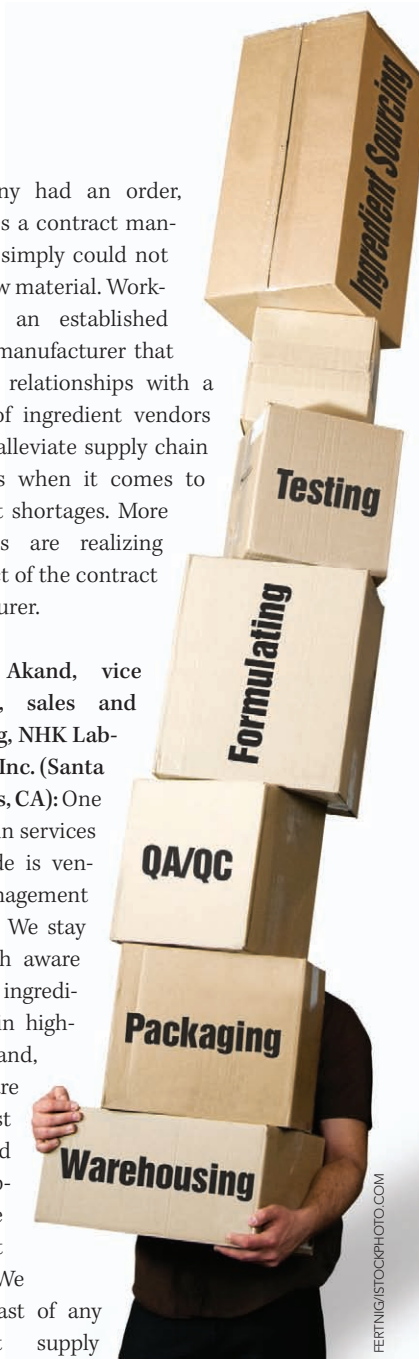
Global economic forces naturally also affect today's business climate. Many companies have to compete for an increasingly competitive market share, and they have to focus more on the marketing side of their business. Therefore, contract companies that are able to shoulder a lot of the technical load are attractive.

Jason Provenzano, president and founder, Nutricap Labs (Farmingdale, NY): It's cost-effective. Why work with multiple vendors to complete the manufacturing, packaging, labeling, and fulfillment of your product when one company can do it all for you under one roof? This also yields faster product turnaround times, which I'm sure all business owners would consider a benefit.

Tim Bray, vice president, Pharmachem Laboratories Inc. (Kearny, NJ): Say that your marketing group has come up with a product that it wants to introduce at the next trade show in nine months. It's up to you, as the general manager, to come up with a manufacturing plan. What are your options? The first decision: to produce the product in house, or go outside.

You could hunt down an equipment manufacturer. The challenge is that it would take a minimum of six months to get the equipment, and probably another month to set it up. Can you meet your timeline for production? Can you train your staff to run the equipment? Is it better to buy specific equipment to produce your product, or to invest in the promotion of your new product?

Eugene Ung, CEO, Best Formulations (City of Industry, CA): More often, customers are relying on their contract manufacturers for regulatory advice, formulation, research and product development, international product registration, ingredient trends, and supply chain solutions. Also, in the past few years, there appears to be more shortages of various raw materials, such as vitamin E, whey protein, and astaxanthin. Even if a company had an order, sometimes a contract manufacturer simply could not get the raw material. Working with an established contract manufacturer that has solid relationships with a number of ingredient vendors can help alleviate supply chain challenges when it comes to ingredient shortages. More companies are realizing this aspect of the contract manufacturer.



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Shabbir Akand, vice president, sales and marketing, NHK Laboratories Inc. (Santa Fe Springs, CA): One of the main services we provide is vendor management inventory. We stay very much aware of which ingredients are in highest demand, which are in shortest supply, and which supplies are the most volatile. We stay abreast of any ingredient supply

fluctuations that can affect lead time and cost. So if a customer has a standing order, and suddenly we get information that some ingredients are in short supply or that there is going to be a price increase, we can let the customer know early on and perhaps try to manage some inventory for the customer before the market even becomes limited in supply.

Provenzano: The role of a contract manufacturer has transitioned from simply creating the product and delivering it to the customer to becoming an extension of a company's marketing and operations departments. For example, we help our customers develop eye-catching product labels and printed marketing materials such as inserts, pamphlets, and brochures. We also offer customers order fulfillment and drop-shipping services so they don't have to stress about where to store their inventory, where it needs to be shipped, and if it reached its final destination.

Shaheen Majeed, marketing director, Sabinsa Corp. (East Windsor, NJ): For many marketing companies these days, their contract manufacturer has to be the "one stop" shop. Marketing companies once had the resources to shop around for various services, but with the lean economy of today, companies find one contract manufacturer and let that manufacturer deal with all the company's headaches, including printing labels, supplying bottles and caps, etc.

Thomas T. Tierney, CEO, VitaTech Nutritional Sciences Inc. (Tustin, CA): We've seen contract manufacturers become undeclared champions of marketers, especially in terms of all things regulatory. [It's] a smart development, as everyone—contract manufacturer and marketer alike—gets hurt when a mistake is made. Both the contract manufacturer and the marketer are linked to regulatory risk, despite what contracts may state. Smart marketers will only work with responsible manufacturing partners.

Demetrius Bledsoe, director of sales, National Enzyme Co. (Forsyth, MO): The role of the contract manufacturer has changed due to the fact that everyone is being held accountable even more for regulatory and GMP practices. The contract manufacturer has to be a good steward for the industry as well as for the consumer who will be receiving the finished goods.

Peter Holocher, director of business development, IFP Inc. (Faribault, MN): For new product launches, intense competition has driven a tremendous shift in thinking about how to efficiently and successfully collaborate with contract manufacturers. IFP is looked upon to assist clients with launching products more quickly, to test commercial viability of new concepts, and to identify tangible technological solutions to real business problems.

Majeed: In many cases, creating a successful product requires dialogue and working more closely together. Once we learn more of what the customer is looking for—their intended target market, their form of selling (multilevel marketing, online, retail)—our formulators can provide suggestions.

Ung: It's worth pointing out, though, that some customers are concerned about sharing proprietary information with a contract manufacturer, even with confidentiality agreements in place. But as the customer works with one contract manufacturer and feels more comfortable with that manufacturer, there can be a more open exchange of ideas that usually results in success for both parties.

What services does your company specialize in?

Holtby: We specialize in a soft gelatin capsule delivery system. We produce and market both branded products and turnkey custom formulations.

Provenzano: We primarily manufacture capsules, tablets, and powders for the sports nutrition industry. In addition to those products, we also have the ability to provide our customers with high-quality softgels, liquids, and lotions. Over the past year, we've seen a large amount of requests for effervescent tablets as well as 2-oz energy shots.

Ung: We are very well known for our softgel manufacturing capabilities, but we're gaining momentum in powder, tablet, and capsule manufacturing and packaging as well. We also manufacture teas, which is quite niche and very specialized.

Bray: In addition to our own product line, we have 13 contract manufacturing facilities, each with its own expertise in either spray drying, fluid-bed granulation, chilsonation, compaction, fermentation, micronization, and herbal extraction. Plus, we have extensive analytical help in our Totowa, NJ, quality facility.

Akand: We focus strictly on solid dosage forms: capsules; two-piece, hard-shell capsules; tablets (whether sustained released, chewable, or color coated); and powders.

Tierney: Our core competencies are in powder-denominated, oral dosage forms: tablets, two-piece hard capsules, and drink mixes. We are also acquiring more gelatin and liquid capabilities through acquisitions.

Bledsoe: We specialize in the contract manufacturing of dietary supplements, with an emphasis on enzymes. We provide product development, precision blending, bottling, tableting, encapsulation, convenience packaging, in-house labeling and graphics, and fulfillment center and regulatory assistance.

Majeed: Our services run the gamut of simple mixing, milling, and blending to large-scale granulation, tableting (single layer and bilayer), encapsulation, and coating of tablets. We began offering the mixing and blending operations to customers early on specifically because if they bought two or more ingredients from us, we could send them a blend of the items, saving them time and money for finished-goods manufacturing.

These days, as herbal ingredients—the large portion of Sabinsa's business—grows, so does the need for granulating some of these extracts to help them compress better. We have two large-scale 500 kg–capacity granulators that tackle some tough projects for customers. Our largest category we deal with in terms of finished-form products is joint health, primarily due to our proprietary Curcumin C3 Complex. Due to curcumin's pungent yellow/orange color, not many contract manufacturers want to entertain this ingredient in their facilities. We've handled tons of curcumin, both at our raw material facilities in India and at our contract manufacturing facility in Utah. Companies and individuals who have walked through these sites commend us on the cleanliness of the sites after handling such an ingredient. We're able to mix curcumin, mill it, granulate it, and compress and/or encapsulate it with ease.

Sam Kwon, president, Vesta Pharmaceuticals Inc. (Indianapolis): We focus on projects ranging from R&D and pilot batches to big commercial batches. Vesta specializes in blending, tableting, encapsulation, and packaging of dry dietary supplements. In particular, we specialize in formulations including nattokinase, vitamin K2 MK-7, and SAM-e.

Holocher: We [specialize] in the design, development, contract manufacturing, and packaging of powder products. We...allow our customers to develop products in the pilot plant, and we answer important questions around feasibility, cost, and timing. IFP is also very unique in that it has an innovation team solely focused on generating prototypes in various commercial stages.

Describe the type of formulating assistance today's marketers seek.

Holtby: Our company offers two types of products: stock formulations of popular ingredients and dosages, and custom formulations based on a customer's label claim. Although we require the basic formulation details from the customer for custom formulations, there is countless potential for variation within those formulas. That is where we can offer suggestions and advice, based on such things as market trends or ease of manufacture.

We feel it is our responsibility to inform the customer if we see possible issues with a formula. We often give suggestions or advice on improving a formulation, should the customer request our opinion. For instance, there are situations in which softgels are not an optimal format. In some cases, with softgels, there may be space limitations for the formula (the ability to include ample quantities of protein, for example) or interactions between raw materials (such as the effect of very low pH on a gelatin shell). Thus, it is important to consider both the physical and chemical properties of a formula. Since we have extensive experience developing formulations, we always try to work with

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our customers to help them understand the importance of choosing the appropriate delivery system.

However, we do have to keep in mind that a custom formulation is the customer's own and that the customer has often performed its own research when deciding how to create the formulation.

Ung: We have a mix of customers. Some have their formula all worked out and just need a contract manufacturer to produce it. Others have semiformulated products and they know which active ingredients they want, while some have us help them formulate from the ground up. After seeing a slowing of new product launches between 2008 to 2010, we have more recently seen an increase in new product development from our customers.

Bray: A qualified contract manufacturer will sit down with your staff to review your product specifications and to suggest the best equipment for running it. Its formulators will be available to review the specifications to ensure optimal product run. These are well-trained people who have worked under similar specifications, and they know their equipment, which will ensure a consistent product.

What packaging/labeling services do you offer?

Holtby: We offer to handle third-party packaging for our customers. Labels need to be supplied by the customer.

Provenzano: We offer a variety of packaging solutions, including bottles, jars, blister packs, stick packs, and sachets. We've also increased the size of our in-house graphic design team.

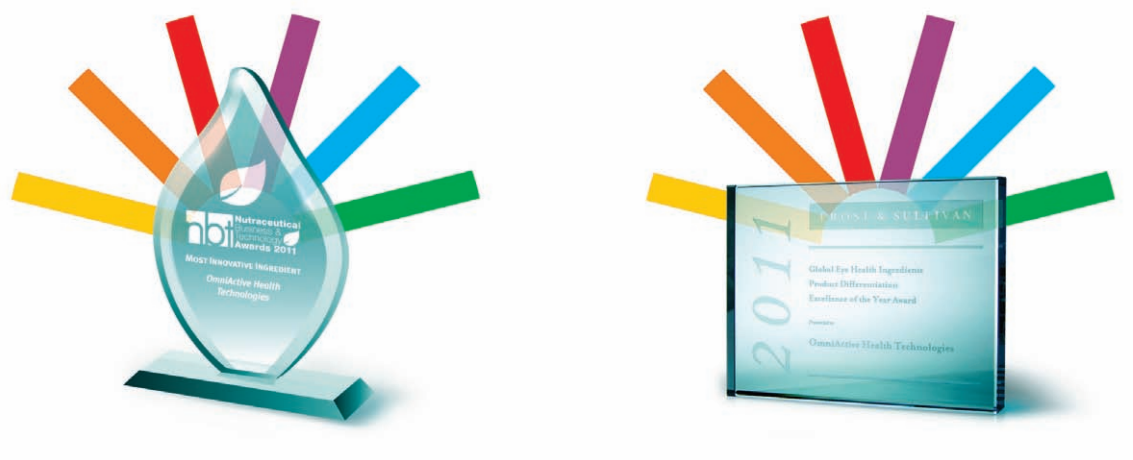
Holocher: [Our packaging] formats include stick packs, HDPE and PET jugs, fiber-form cans, and sachets.

Bray: If you need finished-product packaging, we can supply turnkey packaging of dry powders in fiber canisters or jars, processed in our Teterboro, NJ, facility. If liquid-fill products are needed, we can supply finished products through our facility in Salt Lake City, UT.

Kwon: We see increased demand for cold-form-foil blister packaging. This is an area we are actively expanding in.

Tierney: Demand for custom packaging services and prototyping is on the rise.

Ung: We expanded our bottling capacity last year in response to increased demand for bottling. We believe part of this increased demand is due to FDA regulations. Before, many companies simply purchased bulk pills from us and would do their own packaging. With the GMP regulations in place, however,



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some companies feel it is most cost-effective to have us package the product rather than invest in the cost of compliance for their own packaging operation.

Bledsoe: Our in-house labeling and graphics department allows customers to feel at ease when it comes to making sure their labels are compliant with regulatory changes and that products are delivered in a timely manner. We have also expanded our packaging capabilities to offer convenience packaging to our partners. This allows our partners to package some of their top-selling products in "to go" packaging.

Majeed: Manufacturers should spend a great deal of time on labeling because this is what regulatory bodies will see, assess, and take action on. Even if the marketing company has had its legal team make sure everything looks okay, it's worth sitting down with your contract manufacturer at the manufacturing site to review the labeling again. In some cases, the contract manufacturer can be held liable for labeling infractions, too, and therefore it's smart for a contract manufacturer to take precautions and check the labels it is putting on a bottle.

What do you offer for product testing?

Holtby: We not only perform standard analysis on finished softgels, such as micro- and active-ingredient testing, but we also do extensive testing on raw materials for identity, potency, and contaminants where applicable to assure ourselves and our customers that the ingredients we use are viable.

Bledsoe: Our partners are asking for more after-product testing due to FDA audits and increased regulatory requirements. We have partnered with Sora Laboratories LLC—a third-party ISO 9001:2008 certified, ISO 17025:2005 accredited testing facility—to assist our partners with the additional testing.

Majeed: Testing is one of the major in-house services Sabinsa offers, both pre- and post-product testing. What makes this nice is that the customer does not lose any production time, which they would if we had to ship outside for chemical, analytical, and biological tests.

Microbial testing can take several days just in terms of transit alone, but we're able to cut that time nearly in half by testing in house. Performing testing in house also helps us confirm and ensure our own production accuracy.

Are you involved with logistics?

Provenzano: We recently doubled the size of our on-site warehouse facility. We worked with NSF International to ensure it is GMP certified so our customers can rest assured their products are being stored in a safe and contaminant-free environment.

Bledsoe: We have created and spun off a separate entity that allows our partners to have their various products fulfilled and shipped to their customers based on individual ordering patterns.

"Microbial testing can take several days just in terms of transit alone, but we're able to cut that time nearly in half by testing in house."

Do you help source ingredients?

Provenzano: In the past, we kept roughly $6 million worth of raw materials in our inventory. Now that our business has exponentially increased, we keep around $8 million of ingredients on hand.

Ung: With the new GMPs, the contract manufacturer has to work with established raw material suppliers with good quality systems. Requirements for certificates of analysis and product testing have certainly changed for the better, and we work with reputable suppliers that can provide the documentation, traceability, and testing that we need. Suppliers must have open communications with their contract manufacturers.

What other services is your company focusing on?

Majeed: Stability studies. Sabinsa has in-house capabilities to run stability studies on final products at our Utah facility. In fact, we do this free of charge as part of our manufacturing cost when we quote customers. The U.S. marketplace especially prefers labels that state an expiration date, and thus stability data is a must for final products. By contrast, some other countries list only the "manufactured on" date and not a particular expiration date.

Stability testing can be daunting, though, and FDA details on stability dating are vague. Not all manufacturers handle stability dating, but other contract manufacturers, like Sabinsa, can do it in house. Others would have to send the work out, and depending on the complexity of the formula, this can be a costly part of the business project.

Akand: We have a lot of experience with international product registration. We maintain a large database of documents required to register products internationally.

Which third-party certifications do you have?

Holtby: We have GMP registration through NSF International's Dietary Supplements Certification program and the Natural Products Association and have held these certifications for many years prior to the emergence of the FDA GMPs. We have also gone an extra step and are certified through NSF's athletic banned substances program, also known as NSF Certified for Sport, which means that our products will not contain any ingredients that might be of concern to professional athletes with regard to drug testing.

The majority of our customers demand compliance with the current GMPs. In fact, some of our customers require us to under-

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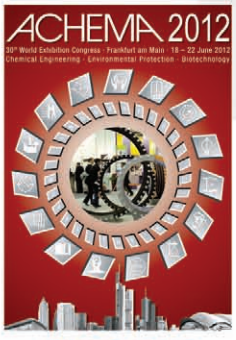

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go periodic internal and third-party audits to confirm GMP compliance. We've always been a proponent of GMP compliance, even before 21 *CFR* 111 went into effect for our company.

Provenzano: The first thing potential customers ask when they speak to our sales representatives is whether our laboratory is GMP certified by NSF International, which it is.

Over the past year, we've had many customers inquire about TGA certification as well. Although there is a lot of paperwork involved with TGA certification, having the ability to sell products in Australia can give a company a distinct advantage. Additionally, our on-site warehouse undergoes a thorough, two-day NSF audit to ensure it complies with GMP regulations.

Ung: We hold the following certifications: federal and California Drug License; NSF International GMP and NSF Certified for Sport; Natural Products Association GMP; organic certification through Oregon Tilth; halal certification through IFANCA; and kosher certification.

Companies do expect their contract manufacturers to have certain certifications—mostly GMP certifications through NPA or NSF. It will be interesting to see how dietary supplement companies look at NPA/NSF certifications as FDA continues its own audits and the industry as a whole becomes more compliant and better regulated.

Bledsoe: The demand for TGA certification and requirements for Australia has increased. We have been one of the pioneering companies in the whole process and have been of great assistance to our partners in this area.

NSF Certified for Sport has been another area of increased demand. Not only does our facility have this certification, but our various formulations hold this certification as well.

Majeed: Kosher and halal certification are requested most. Our primary customers go overseas for business and they are keen on these two certifications. Along with these, a state license for business operations and of course a GMP certificate are crucial.

Kwon: There does seem to be increased interest in halal and kosher certification. Vesta is GMP certified by the Natural Products Association. We use this as a marketing tool.

Bray: Several of our facilities have GMP certification monitored through NSF. We have organic certification through Oregon Tilth, OU kosher certification, as well as halal on product-by-product basis.

Akand: We have the following certifications: NPA GMP, NSF GMP, NSF ISO 9001:2008, QAI organic, kosher, and halal.

Our customers know that FDA's limited resources—time, money, and manpower—may prevent auditors from being able to visit manufacturing sites as often as they'd like to. Third-party certifications ensure customers that we are audited throughout the year. Sometimes, we are audited five or six times per year.

As a contract services provider, what are some of your biggest challenges these days?

Kwon: Turnaround time has dramatically increased as a result of the raw material and finished product lab testing the contract manufacturer must now perform. Many of our customers, however, have not adjusted to the longer required lead time when ordering products.

We are challenged to both educate our customers on the need to order sooner and to make our own processes more efficient.

Ung: Raw materials are the biggest challenge. From a quality and testing standpoint, some ingredient suppliers still have a learning curve regarding the testing requirements based on the new GMPs.

We should point out that many of the more established and reputable ingredient suppliers have certainly stepped up in communicating with contract manufacturers, getting their materials tested and providing the information we need.

The other challenge from a raw materials perspective is that supply of certain materials and pricing can change on what seems like a daily basis. Our industry goes through shortages of various materials every year, whether it be CoQ10, gelatin, cocoa, whey protein, vitamin E, astaxanthin, or certain fish oil concentrates. These shortages, coupled with price spikes with little to no notification, are significant issues for our industry.

Majeed: Also, we don't see enough customer inspections. Quite frankly, this alarms us because it's part of the GMPs to conduct these types of vendor/facility audits. Maybe it's due to a lack of knowledge in terms of auditing.

Marketers need to understand that the days of only auditing contract manufacturers through self-questionnaires are gone. While questionnaires are still around, they should be merely a formality prior to a physical audit.

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Probiotic drink brand KeVita offers KeVita Daily Cleanse, a beverage that combines lemon and cayenne and the company's proprietary blend of four strains of live probiotics—*Bacillus coagulans, Lactobacillus paracasei, Lactobacillus plantarum*, and *Lactobacillus rhamnosus*. The company calls the product "a healthy and convenient approach to cleansing" and a "low-calorie, low-glycemic interpretation of the classic Master Cleanse." The product, which aims to curb craving for snacks and sugary drinks, contains only 10 cal and 2 g of sugar per bottle and is sweetened with stevia rather than high-glycemic maple syrup.

Drinkable Yogurt

Grupo Gloria's new Pro Defensis drinkable yogurt for the Peruvian market combines probiotics and Biothera's (Eagan, MN) immune-health beta-glucan ingredient Wellmune WGP. The companies say this is the first yogurt to combine the systemic immune-health benefits of Wellmune WGP and the gut health benefits of probiotics. Each bottle contains 100 mg of Wellmune WGP.

Take CONTROL of Men's Health

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Six out of 10 men age 40+ experience mild to severe lower urinary tract symptoms*.

AssuriTEA™ Men's Health is a proprietary formula of catechins and theaflavins that provides safe and natural support for healthy urological function. Clinical research demonstrates AssuriTEA Men's Health helps improve lower urinary tract health as measured by AUA Symptom Score**. AssuriTEA Men's Health promotes prostate, bladder and urinary health.

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* Irwin DE, Milsom I, Hunskaar S et al. Population-based survey of urinary incontinence, overactive bladder and other lower urinary tract symptoms in five countries: results of the EPIC study. Eur Urol 2006; 50: 1306–15. LUTS defined using the 2002 ICS definitions.

** Study on Effectiveness of AssuriTEA Men's Health on Urologic Health at 1,000 mg

KEMIN INSPIRED MOLECULAR SOLUTIONS™

For Appetite Control

A *Garcinia cambogia* dietary supplement from supplements brand Genesis Today aims to support appetite suppression. The supplement features SuperCitrimax *Garcinia cambogia,* a standardized ingredient containing 60% hydroxycitric acid that has been shown to enhance thermogenesis and appetite suppression. It also contains ChromeMate, a highly absorbable, niacin-bound chromium complex that supports healthy blood sugar, cardiovascular function, and weight management. Both ingredients are from supplier InterHealth Nutraceuticals Inc. (Benicia, CA).

Reishi Extract Mushroom Complex

Unlike other Reishi mushroom extracts on the market, Life Extension says that its new Reishi Extract Mushroom Complex is both standardized for triterpenes and is more bioavailable. The product targets immune support. The firm adds that the advanced extraction technology it uses yields more bioavailable active compounds.

Energy-Boosting D-Ribose

Corvalen OPC—a natural D-ribose dietary supplement with added antioxidants—is the latest energy-enhancing supplement in Douglas Laboratories' Corvalen dietary supplements line for athletes as well as everyday consumers. D-ribose can help maintain energy, heart function, and healthy cardiac stroke volume during high-intensity exercise or everyday activities. Corvalen OPC marries the benefits of D-ribose and oligomeric proanthocyanidins (OPCs) in a pomegranate beverage. In addition to replenishing ATP, the formula helps neutralize free radicals. Its ORAC value is approximately 4,100 umole TE/serving, which the firm says is on par with six or seven full servings of fruits and veggies.

ELI_ASENOVA/ISTOCKPHOTO.COM

Tart Cherry Melatonin Absorbed

G Howatson et al., "Effect of tart cherry juice *(Prunus cerasus)* on melatonin levels and enhanced sleep quality," *European Journal of Nutrition*, vol. 51, no. 8 (December 2012): 909–916.

Tart cherries contain high levels of melatonin, a key compound in the human sleep-and-wake cycle, and research now confirms that this melatonin is absorbed by humans.

The scientific community has known about the melatonin content of tart cherries for some time. In 2001, researchers even identified a melatonin content in Montmorency variety cherries six times higher than that in Balaton cherries. Still, a PubMed search yields scant evidence that tart cherry supports *human* melatonin levels or sleep factors—until now.

In an admittedly low-powered trial, researchers assigned 20 adult subjects to 30 ml of tart cherry juice concentrate or placebo daily for one week. They analyzed participant sleep quality and measured urine samples for 6-sulfatoxymelatonin, an active melatonin metabolite found in the human body. As hypothesized, total melatonin increased in the cherry juice group and not the placebo group. Cherry juice consumption also significantly increased time spent in bed, total sleep time, and sleep efficiency as measured by ActiWatch software.

First Human Study on Korean Red Ginseng and Gallstones

JK Lee et al., "Effect of Korean red ginseng as an adjuvant to bile acids in medical dissolution therapy for gallstones: a prospective, randomized, controlled, double-blind pilot trial," *Food & Function*, vol. 4, no. 1 (January 19, 2013): 116–120.

Early research on Korean red ginseng *(P. ginseng)* suggests that the botanical might reduce the burden of gallstones in animals. Now, researchers from Dongguk University in Korea have completed what they believe is the first trial on Korean red ginseng and gallstone disease in humans.

Gallstones are hard, rock-like deposits that can form in the gallbladder and cause, among other symptoms, sharp pain. An estimated 10%–15% of the world population has gallstone disease, but not everyone experiences its symptoms.

Researchers recruited 28 subjects to supplement with Korean red ginseng (7.5 g in three daily doses) or placebo daily for 24 weeks. All subjects had confirmed gallstone disease and were instructed to stay on their daily prescription bile acids (500 mg of chenodeoxycholic acid and 500 mg of ursodeoxycholic acid). Ginseng was associated with less overall stone burden—the total volume of the five largest gallstones—than placebo. But not to a level that was statistically significant. The researchers acknowledge several limiting factors in this first-of-its-kind study: short duration, few subjects, and low dosage.

"As this was the first human study about the combination with bile acids as far as we know, safety was of the utmost importance, and we chose one of the lowest doses (7.5 g per day) used in published trials with Korean red ginseng in humans for various diseases," wrote the lead researcher.

No adverse reactions were observed in either group, so the ginseng is at least deemed safe for long-term use.

Black Tea's Blood Pressure Effect May Take Time

JM Hodgson et al., "Short-term effects of polyphenol-rich black tea on blood pressure in men and women," *Food & Function*, vol. 4, no. 1 (January 19, 2013): 111–115.

Historical research supports the consumption of black tea for blood pressure support. In one six-month trial on 95 adults drinking black tea or placebo, tea drinkers experienced lower systolic and diastolic blood pressure. However, a new study by the same team of researchers suggests that *short-term* black tea consumption isn't enough to do the job.

Researchers from the University of Western Australia assigned 111 men and women to three cups of black tea for four weeks daily or placebo. At the end of this intervention, on a single occasion, subjects then consumed three cups of powdered black tea solids (containing 429 mg of polyphenols) or a control beverage matched for flavor and caffeine. Blood pressure and heart rate readings taken at four weeks and after the second intervention revealed no significant changes for blood pressure in either group and mixed results for heart rate changes.

In light of the results and those of a previous study, the researchers concluded that blood pressure benefits observed with black tea are "unlikely to be due to short-term changes." N

RESEARCH BUZZ

Branded Hydroxytyrosol Shows Record ORAC Value

Certified Nutraceuticals Inc. (Murrieta, CA) reports that its Olea25 hydroxytyrosol ingredient has the highest ORAC value of any plant extract tested to date.

Hydroxytyrosol is a phytochemical found in olives and olive oil.

Brunswick Laboratories (Southborough, MA) confirmed the ingredient's ORAC value at a record 68,756 µmolTE/g (6,876,600 µmolTE/100 g) across all five predominant free radical species found in the body. That score, says Certified Nutraceuticals, puts Olea25 at an ORAC value 15 times higher than green tea.

The use of ORAC testing to determine antioxidant capacity of plants has received criticism of late, primarily due to companies misrepresenting data and overrelying on this single test. But the assay still holds value in identifying antioxidant capacity *in vitro*.

Hydroxytyrosol is backed by an EU health claim for protection of low-density lipoprotein particles from oxidative damage.

EFSA Says Aspartame Isn't Toxic

EFSA has reconfirmed the safety of aspartame in a draft scientific opinion requested by the European Commission.

Aspartame is approximately 200 times as sweet as table sugar, but limited animal research shows potential toxicity due to phenylalanine, one of aspartame's breakdown products. High levels of phenylalanine can be toxic, and a rare disorder called phenylketonuria (PKU) can result in dangerously high phenylalanine levels in humans. For this reason, all EU products containing aspartame must be labeled "Contains a source of phenylalanine."

Based on an extensive review of previously published data, "[Aspartame and its breakdown products] pose no toxicity concern for consumers at current levels of exposure," says EFSA. "The current Acceptable Daily Intake (ADI) is considered to be safe for the general population and consumer exposure to aspartame is below this ADI." Aspartame's ADI is 40 mg/kg of body weight daily.

Expect a final scientific opinion in May 2013. N

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Nutritional OUTLOOK

Source: BPA Worldwide, June 2012.

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Benefits of Fermented Ingredients

Fermenting food can improve nutrient absorption, among other benefits. RFI Ingredients has launched a line of fermented ingredients—cereal grasses, vegetables, fruits, spices, and seeds—under the name FermaPro. The company can ferment a range of dry ingredients with health-promoting bacterial or yeast cultures. *RFI Ingredients (Blauvelt, NY), 800/962-7663, www.rfiingredients.com.*

Probiotic Drink Cap

Shelf-stable, non-refrigerated probiotic beverages are now possible, thanks to a partnership between probiotic ingredient supplier Chr. Hansen and bottle cap innovator Fresh Beverages International (Dublin). Thanks to a bottle cap that releases active ingredients right before drinking, Chr. Hansen's probiotic strain *Bifidobacterium* BB-12 can now be served in shelf-stable beverages. *Chr. Hansen (Hoersholm, Denmark), +45 45 74 74 74, www.chr-hansen.com.*

DHA Omega-3 Line

GCI Nutrients' new DHA-3 Sure omega-3 fatty acid line includes a 35% oil, an oil powder, and a water-soluble version. The microalgae-derived ingredients are vegetarian. DHA-3 Sure Water-Soluble is transparent and suited for beverages, smoothies, and other liquid applications. All DHA-3 Sure ingredients are also rich in omega-6 fatty acid docosapentaenoic acid (DPA), by about 16%. The company says this DPA level is high compared to the approximately 7% DPA found in fish oil. *GCI Nutrients (Foster City, CA), 650/697-4700, www.gcinutrients.com.*

Green Coffee Extract

A GMO-free green coffee extract standardized to 50% chlorogenic acid content is the newest ingredient from NP Nutra. In addition to chlorogenic acid's antioxidant benefits, green coffee offers possible benefits for weight management, although the mechanism of action has not been fully elucidated. NP Nutra says a small, 22-week human study linked the ingredient with significant reductions in body weight, body mass index, and percent body fat. Its green coffee extract is a light, yellow-brown powder that is 100% water soluble and used in supplements and other functional products. *NP Nutra (Gardena, CA), 310/694-3031, www.npnutra.com.* N

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49	International Fiber Corp.	www.ifcfiber.com	888/698-1936
42	Jiaherb Inc.	www.jiaherb.com	973/439-6869
51	Jost Chemical Co.	www.jostchemical.com	314/428-4300
67	Kemin Health LC	www.kemin.com	800/777-8307
52–53	National Enzyme Co.	www.nationalenzyme.com	800/825-8545
74	NHK Laboratories	www.nhklabs.com	866/645-5227
68	Nutraceuticals International Group	www.nutraintlgroup.com	800/651-2587
61	OmniActive Health Technologies	www.omniactives.com	866/588-3629
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11, 15, 31, 47, 70–71	Pharmachem Laboratories Inc.	www.pharmachemlabs.com	800/526-0609
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Gum Gifts

Today's gum market gives everyone new opportunities.

BY ROBBY GARDNER, ASSOCIATE EDITOR

Manufacturers around the world depend on gums and hydrocolloids, whether for improving yogurt mouthfeel or binding granola clusters. But as the market grows for these humble plant substances, so too does the need for increased performance.

So what's new in the gum market?

Gums + Fiber

The high price of some gums can be a necessary burden for formulators—that is, unless they realize the benefits of combining gums with citrus fiber. As part of a continuing effort to lower customer costs, Gum Technology Corp. (Tucson, AZ) now offers Hydro-Fi, a line of gum and citrus fiber combinations that joins the textural and stabilizing ability of gums with the moisture-management qualities of citrus fiber. The resulting solutions can lower the need for pricey gums while improving the functional synergies of finished products.

"We saw the benefits of using citrus fiber as a moisture-binding agent," says Josh Brooks, Gum Tech vice president of sales. "Its unique properties allow for freeze-thaw stability and staling reduction, because it prevents water from migrating or separating out."

In-house research at Gum Tech suggests a wealth of potential Hydro-Fi applications, including: better cling in sauces and dressings; better yield and texture of ground meat; reduced-egg cake applications; and reduced fat and crystal size in ice cream. Adding *fiber* to an ingredient list isn't a bad move either.

Crumbs at the Bottom of the Bag?

Despite their deliciousness, crumbs at the bottom of a snack bag are the result of an *adherence* issue. And when salt, seeds, spices, and other topical ingredients can't stay on snack foods, it can be a pricey waste of raw material; after all, topical inclusions are sometimes the most expensive ingredients in a formulation.

What, then, do manufacturers do to keep these ingredients in their rightful place?

They often use egg wash—which comes with a requisite allergy statement, contamination risks, and the need for refrigeration.

For egg-free adherence, try Add-Here CSA from TIC Gums (White Marsh, MD). It's a gum system that the company says will keep more inclusions on food, even with the same gloss of egg wash. Sprayable and easily dispersible, Add-Here CSA might just shorten production time. It can even seal burritos and fruit pockets!

Talking Gums

We now have an unofficial gum lexicon. Courtesy of TIC Gums, the "Texture Revolution" lexicon makes talking about gums easier than before, with enough descriptive words to get formulators saying exactly what it is they want from gums.

Consider a term like *crunchy*, says TIC Gums applications manager Michael Flemmens. "*Crunchy* can mean a million things, but there are also highly specific attributes, like *tooth pack*. If customers and developers can agree on the vocabulary, this might really short-circuit the development process."

The lexicon covers more than 100 useful words and is freely available online.

Flax

If gums aren't your thing, flax may be an alternative, thanks in large part to ingredient supplier Glanbia Nutritionals (Fitchburg, WI). The company's OptiSol 5000 range of flaxseed ingredients now includes OptiSol 5300, a guar gum replacer that Glanbia says can be cheaper than guar and other gum systems. It works at a lower inclusion rate than its predecessor, and it's high in fiber and protein.

Consider OptiSol 5300 for applications such as bakery mixes, gluten-free baked goods, breadings and batters, and more. N

XANTHAN GUM LITIGATION

First, guar gum prices rocketed because of oil fracking. But when gum supplier CP Kelco (Atlanta) filed for litigation last year with the U.S. Department of Commerce, it was because some xanthan gum prices were just *too low*.

Nutritional Outlook has learned from CP Kelco that Chinese and Austrian xanthan suppliers are exporting xanthan gum to the United States at prices so low that local suppliers can't compete. The Commerce Department first estimated that dumping margins—the amount by which a product is sold under normal value—were at 17.18% and 21.69–154.07% for Austrian and Chinese suppliers and producers, respectively. As of this writing, CP Kelco said that Commerce officials were enroute to China and Austria to verify those estimates. If any new data is uncovered, it will weigh into Commerce's final determination, which is scheduled for May 18, 2013, and likely to include tariffs on foreign xanthan.

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