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The manufacturer's resource for dietary supplements & healthy foods and beverages

September 2018
Vol. 21, No. 7

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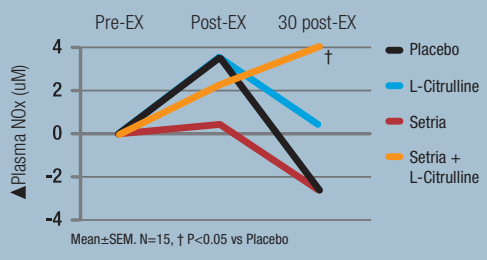


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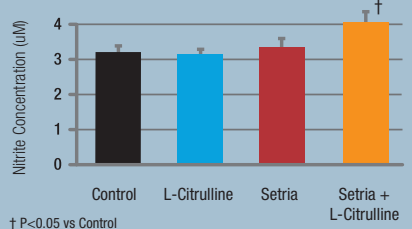


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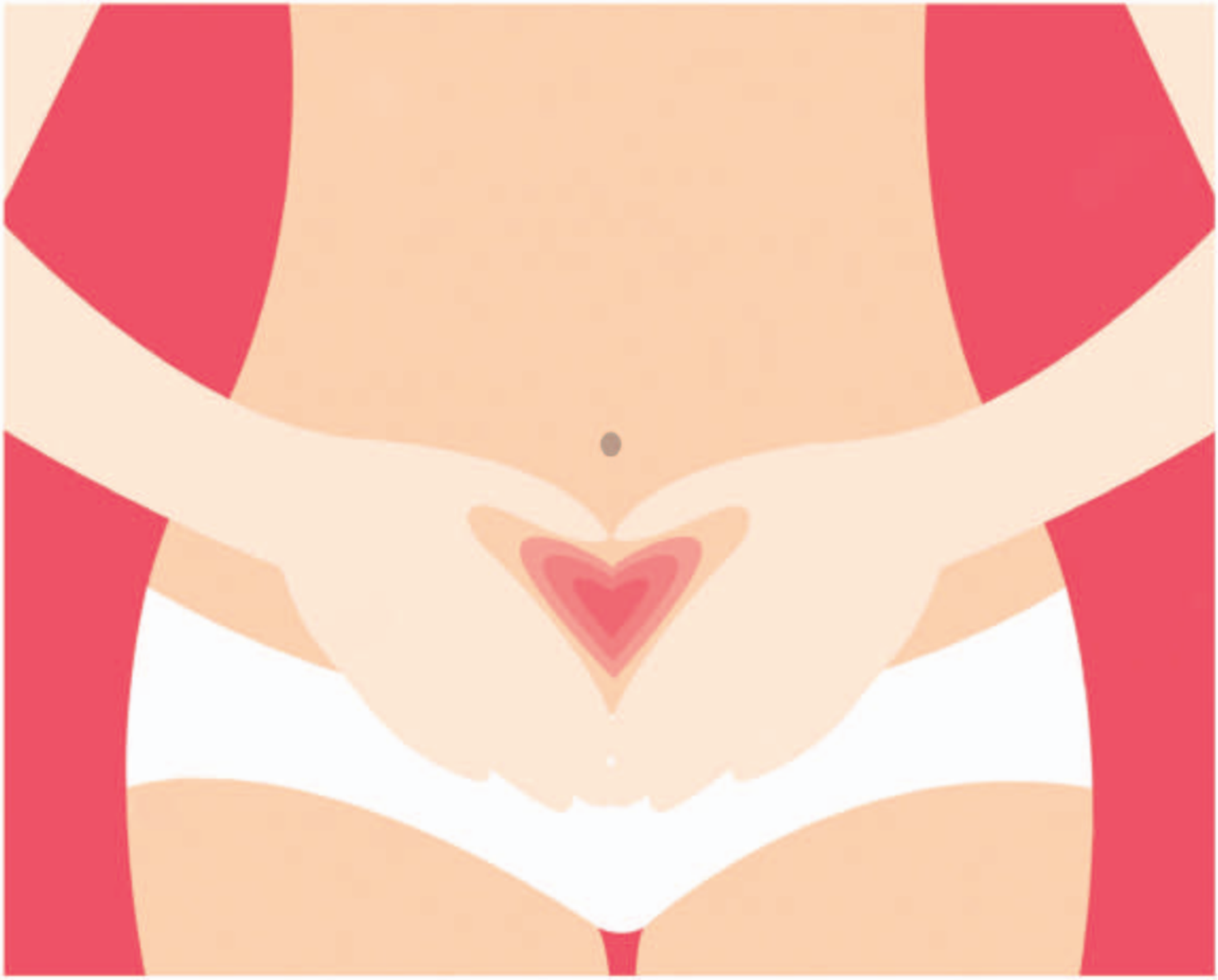


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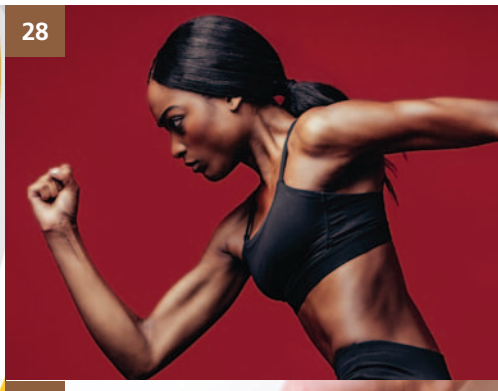



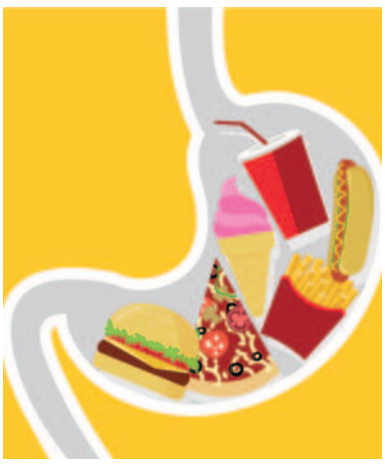

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# Misgivings over FDA Registry?

Would the dietary supplements market, including industry companies and FDA regulators, benefit if FDA were to create a mandatory finished-products registry for dietary supplements, much in the way that other industries, such as medical devices, must register their products with the agency?

On page 12, industry experts discuss the pros and cons of such a registry. For instance, one benefit of mandatory registry is that companies would be bound by law to participate, and FDA could go after companies that didn't. On the other hand, even as a federal registry boosted transparency, it would also give companies a whole new set of requirements to fulfill.

What kind of information should such a registry contain? Many of those I interviewed said it should be pretty basic: label information such as dosages, ingredients, manufacturer name and contact information, etc. (The same kind of information is captured in the voluntary, industry-led Supplement OWL registry that the Council for Responsible Nutrition, CRN, created last year.)

But some in the industry have misgivings of how FDA would use even basic data. They fear the agency could one day leverage that information to impose new regulations on industry. Some of their questions include: How much data would FDA demand? What kind of data would it require?

Some of those questions stem from a historic fear of many in the supplements industry that FDA will overstep its authority and over-regulate the industry. Attorney Scott Bass, a partner at law firm Sidley Austin LLP, whom I interviewed in July, said there is mistrust among those who believe that FDA has tried to suppress the supplements industry in the past. "What led to [the passage of the Dietary Supplement Health and Education Act of 1994] was the underlying premise that FDA abused its authority, which it did, and that they couldn't be trusted because they were constantly out to kill the industry. But that's history," he added, expressing his belief that those currently overseeing the Office of Dietary Supplements "are not against the dietary supplement industry."

If a federal registry were ever created, "I think [all of industry's concerns] would have to be worked out up front with assurances that FDA understood what the purpose of that registry was and would commit that it would live by those expectations," said Steve Mister, president and CEO of CRN. "There's this long history of tension between the industry and the agency that if the agency is allowed to regulate, will they go too far?"

There is, for instance, the question of what kind of system a federal registry would be. Would it simply be a notification-based system with no FDA judgment on whether a product is acceptable in the marketplace? Or, if a product were accepted in the registry, would that somehow imply that FDA tacitly or directly endorsed the product—or vice versa?

Mister used the analogy of a birth certificate to highlight the differences between those two scenarios. "I sort of look at it like the difference between a birth certificate and a driver's license," he said. "Everyone who is born gets a birth certificate. The government cannot deny you of your birth certificate. It's a legal document; if you're born, you get one. But with a driver's license, they can control and they can limit who gets a driver's license and who doesn't."

He continued, "And that's the distinction for us. As long as it's a registry, I think that the industry is fine with that and it does what we talked about. It gives FDA that window to see what the dietary supplement marketplace looks like. But if it starts to look more like a driver's license and they get to tell you whether or not you can be on the market or not, that sounds like premarket approval and that is something that the industry has *always* been very concerned about, FDA's potential ability to keep you off the market if they don't agree with your science or if they don't like your ingredient."

Michelle Zerbib, director of standards at New Hope Network (Boulder, CO), producer of the Natural Products Expo East and West trade shows, said another fear could be whether FDA would eventually start charging companies a lot of money to register their products, much like the agency does for medical devices in part to cover administrative costs. She noted that registration fees could be "pretty expensive," and that for medical devices, "it's a couple thousand dollars" per device.

It's debatable whether, in this current political climate, something as major and controversial as the creation of a federal product registry would see the light of day. Some of the momentum would have to come from the industry itself, Mister said.

"I think how quickly it moves really is going to depend on whether the industry looks at this and says this is something we want to do or not," he said.

**Jennifer Grebow**
Editor-in-Chief

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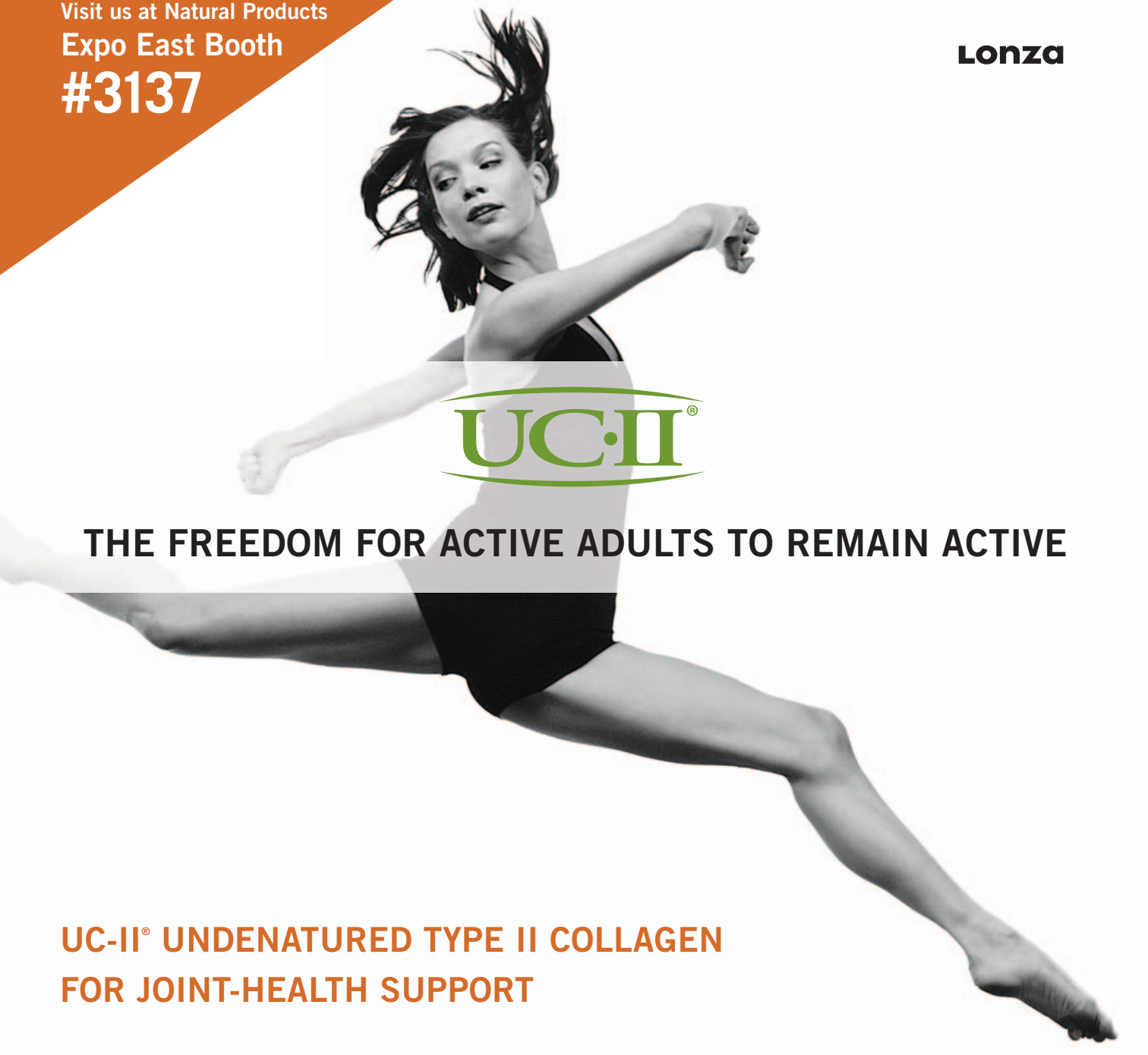

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# Do We Need Mandatory Product Registry?

If FDA had a comprehensive, mandatory, industry-wide database of every single dietary supplement product on the market, would such information help regulators as well as industry better police the dietary supplement market? Also, how could FDA create such a registry? These questions are being debated more often as the dietary supplement industry faces more public scrutiny and ongoing discussion about whether the existing regulatory framework for supplements is effective.

It also should be noted that a voluntary, industry-sponsored dietary supplement product registry was created just last year by industry association the Council for Responsible Nutrition (CRN; Washington, DC). In April 2017, CRN created a product registry called the Supplement OWL (Online Wellness Library). Participation is open to all industry members and is heavily encouraged. CRN says its goal is to build the Supplement OWL into the industry's comprehensive product registry that could also serve as a regulatory resource for FDA to draw on should the agency choose to do so. To date, the registry includes 10,000 product labels, with CRN aiming to double that number by next year, according to Steve Mister, CRN's president and CEO.

The Supplement OWL is a voluntary registry. It is not federally mandated; companies can opt in or out as they choose. One person *Nutritional Outlook* interviewed recently said he thinks that a mandatory product registry, maintained by FDA at the federal level, would be more effective than a voluntary registry in fulfilling the goal of making sure all products are included in the registry.

In July, *Nutritional Outlook* interviewed attorney Scott Bass. Bass helped draft the Dietary Supplement Health and Education Act statute of 1994 (DSHEA). Bass said that *not* having a mandatory registry critically limits FDA's ability to police the U.S. supplements market. His words: "[There is] no hope for effective fraud prevention unless government knows what is on the market."

Bass is adamant that a mandatory registry, not a voluntary registry, is needed: "A voluntary listing program is the right idea but by definition will only include the good players who want a clean market. The whole purpose of the listing is to identify those who are on the market and those who shouldn't be on the market, and a voluntary listing doesn't do that," he said.

Many of the sources *Nutritional Outlook* interviewed in August, a month after publishing the July interview with Scott Bass, said they support the overall suggestion for a registry, but not everyone agrees that it should be mandatory ( federally mandated and maintained by FDA); some feel it should be voluntary.

Attorney Jason Sapsin, JD, MPH, of counsel at Faegre Baker Daniels LLP (Boulder, CO), supports the general idea of a registry. He told *Nutritional Outlook*, "Consumers and retailers value transparency. A registry for dietary supplement products would demonstrate industry's commitment while also offering researchers, regulators, and healthcare providers valuable information about products available in the marketplace."

A comprehensive registry could even help industry enhance quality right down to its trade shows. Michelle Zerbib, director of standards at New Hope Network (Boulder, CO), producer of the Natural Products Expo East and West trade shows, told *Nutritional Outlook* that she and her colleagues would find a mandatory product registry beneficial as they work to maintain exhibitor standards and differentiate between good and bad players in the industry. "It would be so great, so helpful, to have a [registry] for what we do in the standards program at Natural Products Expo East and West," Zerbib said. (Disclosure: *Nutritional Outlook* and New Hope Network are both owned by Informa plc.)

CRN's Mister said he believes a comprehensive registry is important—hence, CRN's creation of the Supplement OWL with access available to FDA regulators. "If FDA doesn't know what the industry looks like, it's much harder for them to regulate," he said.

However, Mister said that a self-regulatory registry like the Supplement OWL, which CRN created with industry input, is preferable at this point in time "rather than having [a registry model] foisted upon us." Mister said that someday, perhaps, industry's registry could serve as a solid framework for a federal registry if FDA should ever be tasked with creating one. "One of the advantages of the Supplement OWL, and the fact that it's being created by the industry through our association, is that it gives us the opportunity to create a registry the way we want to so that if it did ever become mandatory, there is a very clear template for what it would look like," Mister said. "FDA would not have to start from scratch and potentially put things in there or put in requirements that we don't like." Mister said that CRN has not, however, discussed with FDA the notion of using the Supplement OWL as a template for a possible federal registry.

The biggest drawback to a voluntary registry is, of course, that participation is not legally enforceable, meaning there are no teeth to force a company to register.

Mister acknowledged that a voluntary registry might not capture all companies, but he said that CRN is trying to create some pretty strong "market-based incentives" to encourage companies to participate in the Supplement OWL—namely, by asking retailers to make participation in the Supplement OWL a requirement for the brands whose products they sell. "Hopefully, some retailers will very soon be announcing that you *must* be in the Supplement OWL if you want to be in their stores." Many of the industry's large dietary supplement companies are already participating in the Supplement OWL. Still, he said, "there will still be companies that won't."

Not everyone believes a registry is needed. "People have been talking about this kind of thing"—a federal registry—"for years, but

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it's a nothingburger. It's a big nothingburger," said Daniel Fabricant, PhD, president and CEO of the Natural Products Association (NPA; Washington, DC).

FDA already has the power to gather the same information that would be included in a registry, Fabricant said, and already gets that information in other ways. "FDA already gets labels. They get labels through certificate-of-free-sale applications (when you want to ship things to foreign countries) and they get them through cGMP [current Good Manufacturing Practices] inspections. So the notion that somehow if FDA had all the labels that it's a tighter-regulated market—FDA already has that information at their fingertips, or should."



Fabricant was director of FDA's Division of Dietary Supplement Programs in 2011-2014. "We certainly gathered labels when I was at the agency," he said. "We used them for preliminary [work] looking at things to see what was out there."

## The Power to Create a Registry

Thanks to the Supplement OWL, we've already seen how the industry can create its own product registry. But what would it take for FDA to create a mandatory registry? Does the agency currently have existing statutory power to mandate registration, or would doing so require new legislation? Industry opinions are mixed.

In July, Bass said he believes FDA "has the power under its current statutory mandate." As *Nutritional Outlook* reported: "When asked which parts of the Federal Food Drug and Cosmetic Act today would allow FDA to mandate listing, Bass points to two. First, he points to 21 *CFR* 402(f)(1)(A), which makes it illegal to market an adulterated dietary supplement. This provision, he says, could be interpreted as requiring FDA to know the full scope of products on the market… The second existing statute Bass points to is the FD&C Act's new dietary ingredient (NDI) regulation (Section 413(a)(2)). This regulation could be interpreted to mean that in order to establish and maintain an NDI process, FDA would need to know which companies need to file an NDI notification. 'And to be able to know who has to file, you need to have a listing,' Bass said."

New Hope's Zerbib said another existing route could be the FD&C Act's structure/function claims notification law that requires dietary supplement companies to notify FDA within 30 days of marketing a product if that product is making a structure/function claim.

"This current regulation is a great place for FDA to step in and get dietary supplement information," she said. "All a company would need to do is submit the label, and the label already has all the information" you would enter into a registry, including the list of ingredients, the statement of identity, and who the manufacturer is, she said. "So, the information would be there. Companies could simply submit to FDA [their label] with the claims they're going to make, and FDA could

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drop [that information] into a registry, no new regulation required."

Zerbib did, however, acknowledge that in this scenario, companies not making structure/function claims would not be required to submit a 30-day notification and thus would not submit labels, meaning this system might not capture every product on the market. But it could be a place to start.

Mister, on the other hand, said he does not believe FDA has existing authority to mandate registry. "The FDA probably *does not* have the authority under the current law to create a registry, and if they did try to do it by regulation or something like that, it would likely be challenged by someone in the industry, which would tie it up in litigation for years," he added. "So if it were going to be done, for expediency it would probably need to be done through legislation."

NPA's Fabricant said that although FDA "can grab labels on inspections" at present, if the agency wants to "mandate that people send them their labels, they would definitely need statutory authority for that."

He added that if the dietary supplement industry were held to a new mandatory registry requirement, it could "put another target [on the industry's] back." He explained that in the same way that California's Proposition 65 regulation has made companies more vulnerable to predatory lawsuits as well as to class action suits and lawsuits from states "that will sue off of consumer protections," a registry requirement could make dietary supplement companies more legally vulnerable. "You could set up an environment where someone goes, 'Whoops, FDA didn't get your labels on time,' so then states start suing you. That's crazy, and that will be exactly what will happen," he said.

A federal law would need to "preempt the states," he said. "Unless [a registry requirement were] done legislatively with some kind of preemption for the states, why would the industry even contemplate [the creation of a federal registry]? It's just adding to our burden, which is already pretty substantial."

## Anytime Soon?

How likely is mandatory registration to happen? In July, Bass said, "I don't think it's a dream far away. Let's just say there's a lot in motion now. This is not just some idea for five years from now."

Mister and Fabricant said they haven't heard of any developments regarding mandatory registry.

"As far as I know, there is nobody who has drafted legislation or shopped anything like that on Capitol Hill," Mister said. "As you know, even things that are not controversial in Washington take a long time to get through Congress."

Fabricant said he doesn't foresee anything happening "at least not this Congress, and likely not next Congress either. Nothing's happening legislatively to make this move along." N

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Interest in fermented products is invigorating the probiotics market.

**BY INNOVA MARKET INSIGHTS**

Despite ongoing interest in functional foods, probiotics—the ingredients that pioneered the functional food boom in the 1980s—now appear to have a much lower profile. According to Innova Market Insights data, less than 1% of global food and drinks launched in the 12 months ending in April 2018 were marketed as containing probiotics. (In the U.S., this figure was slightly higher, at nearly 2%.)

Dairy is the key application area globally. Just over 40% of launches featuring probiotics are in the dairy category, ahead of baby and toddler products at 24%, pet foods at 11%, and soft drinks at just over 10%. In the U.S., the picture is slightly different and more diverse, with dairy accounting for just under 36% of new probiotic launch activity, followed by pet foods at 22% and soft drinks at 18%.

Regulatory issues in some countries, such as uncertainty as to whether probiotic claims are allowed, have resulted in repositioning of many probiotic products away from probiotic claims, particularly in the dairy category. However, the recent rise in interest in fermentation in food and drink processing has brought a new lease of life to some areas of the market.

Yogurt is possibly the best-known fermented food and had already moved into public awareness with the rise of probiotic yogurt in the mid-1980s. Greater focus was paid to yogurt's health benefits, particularly with regards to digestive and immune health. In the 12 months ending April 2018, 22.5% of U.S. yogurt launches used a probiotic platform, and over 60% of the much smaller drinking yogurt/fermented beverages sub-category did the same.

In the U.S., Danone's Activia pioneered the mainstream market for probiotic yogurt in the mid-2000s and despite concerns over claims continues to focus on probiotic benefits. Their range has expanded to encompass fruit, fruit-on-the-bottom, light, Greek, fiber, and lactose-free varieties, as well as a number of dairy drinks, all with a focus on digestive health. A recent launch in 2018 was Activia Probiotic Dailies, a dose-delivery format in line with sister brand DanActive's DanActive Dailies, marketed on an immune support platform.


**Lifeway's Kefir Cup "has the thick, creamy texture of your favorite Greek yogurt with up to twice as many probiotics."**

## The Rise of Kefir

A revamp and repositioning of other related spoonable and drinkable cultured dairy options followed, including crème fraiche, smetana, skyr, ayran, lassi, and kefir. Kefir has been one of the key growth areas in fermented beverages in recent years. It originated in the Caucasus Mountains and was consumed most commonly in Eastern Europe, Southwest Asia, and Russia.

The U.S. pioneered the kefir market in the west and brought value-added options in resealable plastic bottles to the mainstream market, allowing more direct competition with other dairy and non-dairy beverages. Kefir is strongly promoted on its health benefits, and all U.S. launches recorded by Innova Market Insights in the 12 months ending April 2018 used some kind of health positioning. The kefir market's initial emphasis was its probiotic claims, but there is now also rising activity in low-fat and reduced-sugar claims, while organic and lactose-free varieties are also increasingly common.

While health remains a key focus, kefir launches have also taken on a wider range of other on-trend themes, including more exotic flavors, regional recipes, and even non-dairy options.

Lifeway Foods was a key kefir pioneer in the U.S., and it now has a wide range of kefir products, including organic and non-organic options, protein varieties, Greek-style formulations, and probiotic shots. Recent additions include a Kefir Cup spoonable product in Strawberry Rosehip and Granola varieties, as well as a Plantiful Plant-Based Probiotic Drink range in Vanilla, Mango, Reishi Chocolate, and Maca Coconut varieties.

## Kombucha Gains Ground

Key probiotic categories outside of the dairy category include sauces and seasonings,

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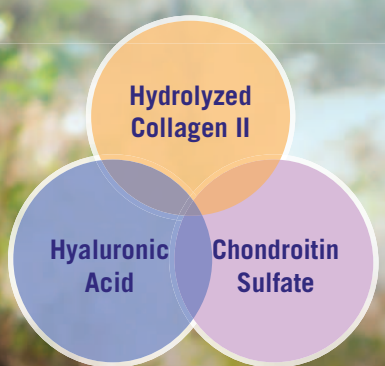


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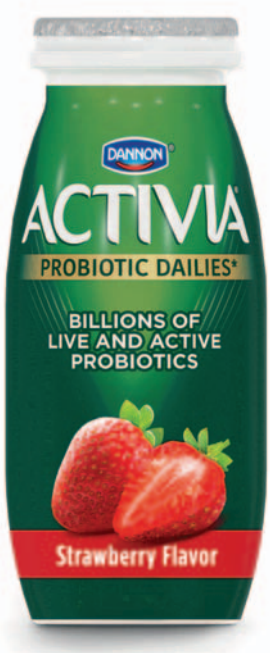
bakery and beverages, pickled products (such as natural sauerkraut and kimchi), sourdough bread, and kombucha drinks.

Kombucha, the ancient, fermented, lightly effervescent black or green tea drinks from China, traditionally contained multiple species of yeast and bacteria, along with organic acids, active enzymes, amino acids, and polyphenols produced by these microbes. These drinks have been available in other countries outside of Asia for some years; however, with rising interest in functional beverages and fermented products, they have moved out of the specialty sector into the mainstream.




**Dannon's Activia Dailies Probiotic Drink are a "quick, easy, and tasty way to enjoy your daily probiotics."**

A review of recent product activity in the U.S. indicates the increasing range of flavors and ingredients used as the kombucha market has developed. The 2018 introductions include Better Booch Morning Glory and Golden Pear premium kombucha teas in cans, and Bambucha Chef Crafted Kombuchas in a range of exotic flavors, including Orange Blossom, Thai Ginger, Blueberry Tart, Hibiscus Rose, and Mango Masala.

Nearly 95% of global launches are positioned on a health platform, with clean labeling and digestive health key areas of interest. Over 85% of launches carry a clean-label positioning of some kind (natural, organic, no additives/preservatives, GMO-free), while digestive health and/or probiotic claims featured on 65% of introductions.

## Probiotic Opportunities

There is clearly still interest in the use of probiotic cultures for health, primarily for yogurts and fermented beverages, as well as in supplements. With a wider focus on fermentation, which is seen as a natural and authentic process, new product development and heightened consumer awareness are combining to bring a raft of more traditional products back to the fore.

The market for probiotic foods and drinks has struggled in some parts of the world, particularly Europe and North America, with health claim regulation issues. The fermented foods route could present a new way forward for this type of product, particularly when the natural and authentic image of fermentation as a traditional food processing method can also be used to a brand's advantage. N

*Innova Market Insights is your source for new-product data. The Innova Database (www.innovadatabase.com) is the product of choice for the whole product-development team, offering excellent product pictures, search possibilities, and analysis. See what food manufacturers are doing around the world: track trends, competitors, ingredients, and flavors. In today's fast-moving environment, this is a resource you cannot afford to be without.*

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# GUT CHECK

## Emerging trends in the digestive enzymes market

**BY MIKE STRAUS**

Digestive health is a growing market with ample opportunities for manufacturer and brand expansion. Take digestive enzyme supplements. Data provided to *Nutritional Outlook* by Innova Market Insights (Arnhem, Netherlands) show an 8.6% compound annual growth rate (CAGR) in the number of digestive enzyme products launched from 2013 to 2017. While sports nutrition products remain the top market category for digestive enzymes, accounting for 82% of all product launches, Innova's data show that digestive enzymes are branching off into more categories. For instance, soft drink product launches containing digestive enzymes grew by 78% to account for 4.5% of new food and beverage product launches, according to Innova. Dairy products featuring enzymes, while still a minor trend, also saw significant growth, increasing by 57% to account for 2.7% of product launches, Innova says.

New product launches like these aren't the only market growth indicators for supplementary enzymes. Analysts and researchers are also predicting an increase in overall market valuation. According to Credence Research, the global digestive enzymes market, which had an estimated valuation of $845.8 million in 2016, is expected to see a 6.9% CAGR for the next seven years, growing to $1.58 billion by 2025.[1]

As the digestive enzyme market continues to grow and more SKUs enter the category, experts say several key trends are starting to emerge. Here are just a few of the ways the digestive enzymes space is evolving.

### Enzymes Gain Popularity in High-Protein Formulations

Protein supplements and high-protein products were once the domain of bodybuilders and professional athletes, but now, mainstream consumers are adopting protein as a daily supplement to their diet. With an expected CAGR of 6.3% from now until 2025, according to Grand View Research, the global protein supplement market is gaining new consumers such as women who do strength training and older consumers who want to maintain an active lifestyle.[2]

Tod Burgess, vice president of sales at Deerland Enzymes (Kennesaw, GA), says digestive enzymes are ideal for use in high-protein products due to their ability to break down large proteins into usable amino acids.

Says Burgess: "As an increasing number of people are taking whey protein to obtain more desirable lean muscle mass, enzymes like our branded and patented ProHydrolase become more critical. To be effective, protein must be broken down into a smaller particle size within about 90 minutes of consumption. Whey proteins are often too large to be effectively assimilated, leaving large peptides that can cause discomfort in some consumers."

Mike Smith, vice president of Specialty Enzymes (Chino, CA), agrees, noting that enzymes are particularly useful in formulating high-protein meal replacement shakes. "Typically, adults can only digest about 2 oz of protein at a time. But athletes

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## DIGESTIVE ENZYMES AND...BRAIN HEALTH?

Scientists have long theorized that phenomena in the brain also has an impact on the digestive system. According to Jay Pasricha, MD, director of the Johns Hopkins Center for Neurogastroenterology (Baltimore, MD), however, the gut-brain connection may also work in the opposite direction.

Pasricha says research now indicates that poor gastrointestinal health may contribute to mood changes by acting on the central nervous system. It is for this reason, he says, that gastroenterologists sometimes prescribe antidepressants to patients with irritable bowel syndrome. Furthermore, Pasricha hypothesizes that phenomena in the digestive system may affect cognition and memory—an area that he says is fertile ground for further study.[4] While further research is needed, the nature of the gut-brain connection means digestive enzymes may find an easy foothold in the brain health market.

and bodybuilders need to consume more in order to reduce catabolism of muscle tissue. Protease enzymes increase digestion of protein and improve absorption of the resulting amino acids, which improves the nutritional value of meal replacement shakes," he explains.

The broader adoption of protein-rich supplements and increasing consumer awareness around protein will allow proteolytics brands to gain market share as a mainstream consumer product. As the protein supplement market continues to grow, expect protein products to incorporate additional proteolytic enzymes like pepsin and trypsin in new formulations.

## PRODUCT BLENDS: PROBIOTICS AND MORE

In the early days, single-ingredient products were traditionally been more popular than blends in the enzyme market, with the earliest digestive enzyme supplement consisting of a single enzyme: amylase.[5] Now, however, manufacturer innovation and market demand for more versatile solutions are giving rise to a class of combination enzyme products that incorporate additional ingredients. Brands have already introduced combination enzyme-herb and enzyme-vitamin blends that incorporate ingredients like marshmallow root *(Althaea officinalis),* elm bark *(Ulmus fulva),* and vitamin B12 in their formulations.

Specialty Enzymes' Mike Smith says that one of the most popular emerging combination products is the enzyme-probiotic complex, a class of multi-enzyme supplements that includes multiple probiotic strains. As innovation in product blends continues, combination products will likely diversify.

### Plant-Based Enzymes See Substantial Growth

Smith says that while enzymes sourced from animals previously dominated the market, the trend has reversed, and today, plant-based and microbial enzymes are the norm. Animal-sourced enzymes fell out of favor among large consumer groups due to religious and lifestyle choices, he says, which is why manufacturers and brands have turned to plant-based enzymes instead.

"We're seeing a lot of growth in plant-sourced enzymes, like bromelain extracted from the pineapple stem, as well as microbial-sourced enzymes produced through fermentation," he says. "These enzymes are suitable for vegetarians and they're both kosher and halal-certified, which means almost anyone can take them."

Lifestyle factors and growth of the vegan market in general are two significant drivers behind the growth in plant enzymes. Burgess points to another, more formulation-based consideration that is fueling the plant-based enzyme submarket. Says Burgess: "Plant cell walls contain cellulose, which is very difficult for humans to digest because we don't produce the enzyme cellulase. Vegans in particular need to supplement with dietary enzymes in order to ensure they obtain all the nutritional benefits of fresh produce."

Furthermore, plant-sourced enzymes present some significant advantages over animal-sourced enzymes when formulating an enzyme-based product. Shaheen Majeed, president of Sabinsa Worldwide (East Windsor, NJ), says that plant-sourced enzymes don't require enteric or protective coating to survive exposure to gastric acid in the stomach. This survivability allows plant-sourced enzymes to maintain activity further along in the digestive tract relative to animal-sourced enzymes.

"Animal-based enzymes work better at a lower body temperature and a neutral-to-alkaline pH range," Majeed notes. "But plant-based enzymes and their microbe-based counterparts are very active at higher temperatures and in acidic environments."

### Lifestyle Habits Give Enzymes an Upward Boost

Digestive health is a rapidly growing market, one that is driven by the busy lifestyles of those who consume digestive enzyme products. Data gathered by Grand View Research shows that consumer demand for digestive enzyme supplements is the result of a significant increase in the consumption of packaged food, which, in turn, is the result of a growing population of workers who regularly clock overtime hours and whose schedules do not allow for proper meals.[3] Burgess agrees, noting that an unprecedented rise in the number of supplements and pharmaceuticals targeting digestive distress reflects a generational shift in lifestyle and eating habits.

"Lifestyles are hectic, and people don't take the time to eat as slowly or as nutritiously as past generations did," Burgess explains. "Eating quickly—and not drinking enough water during meals—puts pressure on the digestive system. Make this a continued habit and add in life stress, and it can create more instances of acid reflux, cramping, constipation, diarrhea, and flatulence. That's why we're seeing so many digestive health products advertised on television compared to a generation ago."

Majeed says that while lifestyle and dietary habits are generally the culprits behind all manner of digestive distress, consumer awareness around digestive health is growing. This new awareness, in turn, is generating demand in the digestive enzyme market.

"Lifestyle and dietary changes can cause any number of discomforts, but the digestive system is most affected," Majeed says. "The National Digestive Diseases Information Clearinghouse says that 60 to 70 million people are affected by digestive health–related conditions. As consumers have recently become more aware of the impact of a healthy digestive system on their overall health, they are exploring options to support digestive health."

### Enzymes for Pet Health: Demand Drives Formulation Improvements

The pet health market is a rapidly growing market opportunity for supplement brands, with enzymes offering easy inroads for brands that have traditionally focused on human consumers. Burgess says that digestive enzyme supplements are useful for pets with sensitive stomachs or digestive problems, as well as pets that are transitioning to a new type of food. He also notes the importance of enzymes for keeping older pets healthy as they age, as aging pets tend to lose their

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ability to produce endogenous enzymes over time. Burgess says that the same changes currently underway in the human protein supplement market are also taking place in the pet protein market, noting that "we're seeing an emphasis on increased quantities and higher-quality protein in pet foods and pet supplements. Deerland's protease enzyme blend, which is formulated to maximize protein digestion, has been of particular interest to companies developing pet supplements."

Smith notes that canine supplements will drive the majority of digestive enzyme market growth in the pet health arena. Dogs are well known for their tendency to eat anything and everything, he says, which makes supplement delivery practical and straightforward. In contrast, other animal markets are showing resistance to digestive enzymes. "The pet health digestive market is very strong for dogs, but not so much for cats or horses. Cats aren't terribly cooperative, and horses have a much more complex digestive system that presents challenges," he says.

Majeed says growth in the pet health market is driven by the heavily processed pet foods that maintain market supremacy. These pet foods originate from low-quality sources and contain a high concentration of preservatives, he says, which creates stress on pets' digestive systems.

"Just like human beings, pets are living longer," Majeed says, "and they're facing age-related health issues just like human beings. Consumers consider their pets to be extended family members and are concerned for their pets' well being. That's why researchers estimate that annual spending on pet supplements is over USD$1.8 billion."

## Beyond Digestion: Enzymes for Immune Support, Joint Health, and More

Enzymes have long featured prominently in the digestive health arena, but now, experts say enzyme products are entering new domains and featuring in formulations for all manner of wellness concerns. Majeed points to joint health, immune health, mental health, sports nutrition, and weight management as five key areas where enzymes are gaining ground.

"Undigested food material is likely to accumulate in the intestine, where it creates the right conditions for pathogenic microbial growth," he says. "This leads to a weakened immune system. Clearly, digestive enzymes have a major role in immune health."

Smith notes that an emerging trend involves featuring enzymes in condition-specific products. Dipeptidyl peptidase IV blends, for instance, are often marketed as supplements for consumers with gluten sensitivities. "These products can help individuals with gluten sensitivity while also protecting against hidden gluten in some processed foods," Smith says.

Mental health is another new arena where digestive enzymes are expected to become popular. Burgess says that as awareness of the gut-brain connection grows, there will emerge new opportunities for digestive enzyme products to expand into the mental health market: "Unfortunately, people of all ages are experiencing heightened stress, which often triggers nervous tension symptoms like anxiety and gut discomfort. It's very true that 'we are what we eat.'"

## Bright Future

With consumers gaining awareness about the importance of digestive health, the digestive enzyme arena is expected to diversify, with the high-protein, vegan, pet health, and convenience markets presenting new opportunities for savvy brands. The enzyme brands that succeed in this evolving market will be those that can pivot and offer more specialized products for each of these verticals. N

### NATURAL, NON-GMO ARE KEY MARKETING CLAIMS

Deerland Enzymes' Tod Burgess says consumers are developing a preference for non-GMO and naturally sourced products, a preference to which enzyme manufacturers should cater. "Consumers understand 'non-GMO' to mean 'pure', 'as nature intended', and 'not augmented by synthetic means,'" he says. "Consumers also link purity with safety, and they believe consuming non-GMO products means their bodies don't have to process unnatural elements."

Burgess stresses that consumers' desire to consume naturally sourced non-GMO products isn't a trend; rather, he says it is a "tectonic shift" in lifestyle management.

***Mike Straus** is a freelance writer living in Kelowna, Canada. He has written for publications including Canadian Chiropractor Magazine, Massage Therapy Canada, and Iconic Concierge Vancouver.*

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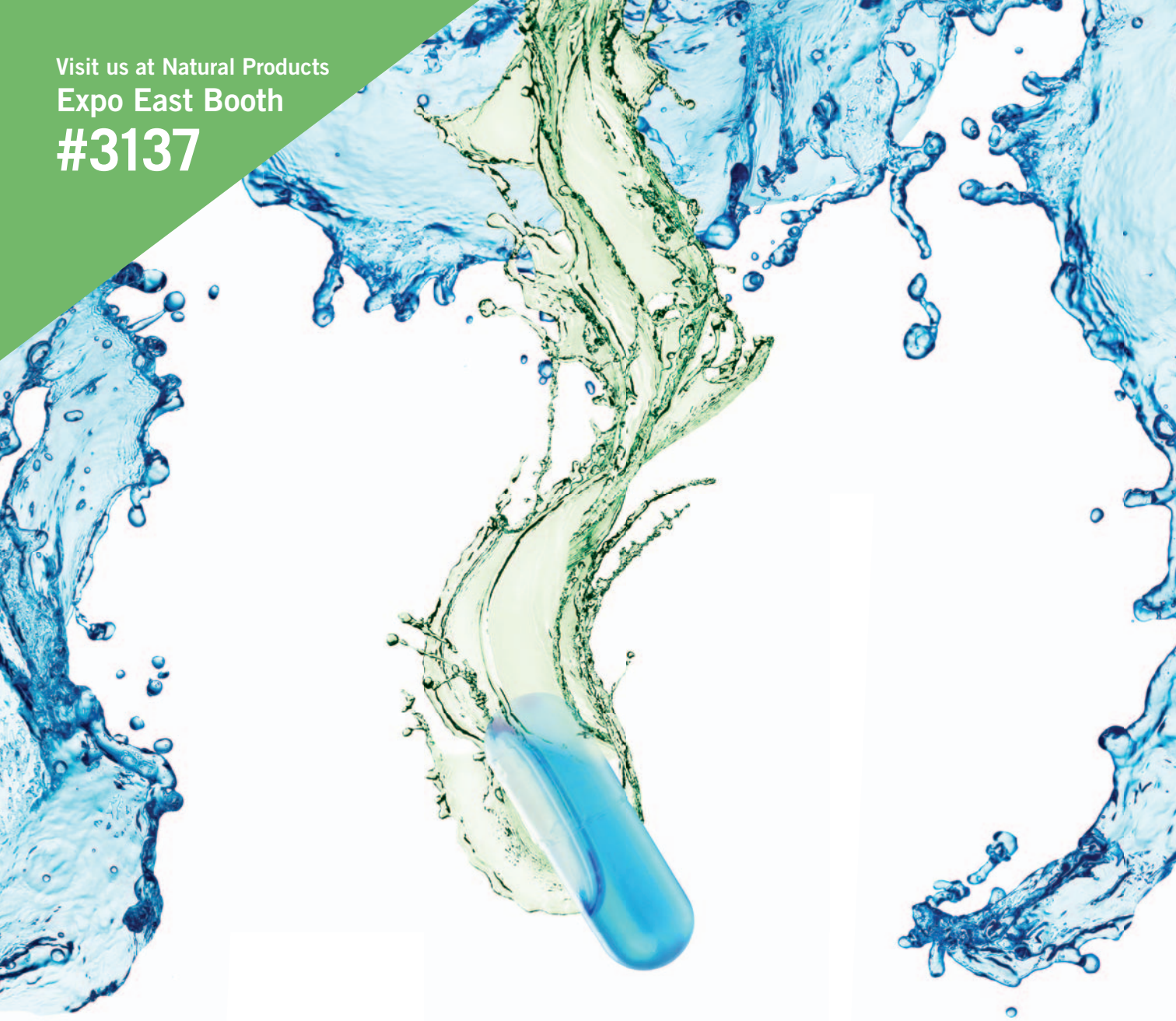

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# Girl's Got GAME

## Formulating for women's sports nutrition needs

BY KIMBERLY J. DECKER

When President Richard Nixon signed Title IX into law in 1972, just one in 27 girls participated in high school sports; 40 years after the landmark statute put an end to discrimination on the basis of sex in federally funded education programs, that proportion had risen to about two in five, according to the Women's Sports Foundation.[1] In those same four decades, women's participation in college athletics vaulted more than 600%.

Add to that the strides that female athletes have made in Olympic competition, World Cup soccer, and traditionally male-dominated pursuits like body building and basketball and the conclusion is clear: The days when "You play like a girl!" were an insult are over. After all, who *wouldn't* want to play like Serena Williams, or swim like Katie Ledecky?

But while women's sports have come a long way, women's sports nutrition still seems stuck in a pre-Title IX era wherein not nearly as much effort goes into understanding, let alone formulating for, the unique needs of athletic or even just active women as goes into doing so for men.

All of which suggests that it's time for some affirmative action in the dietary supplement and functional foods space. As Bruce Brown, president, Natreon Inc. (New Brunswick, NJ), says, "As more women find opportunities to embrace a healthy lifestyle in everything from fitness routines to the foods they eat, sports nutrition brands will respond by investing in innovative ingredients with targeted benefits, rather than solely focusing on male-centered formulations."

### Good Sports

High-profile female athletes are only the tip of a spear launching women of all ages, sizes, and interests into active lifestyles that place as much emphasis on wellbeing as on winning competitions or losing weight. This movement isn't so much about staying skinny or being first across the finish line; rather, the goal is to feel better, in body and mind.

Notes Nina Hughes-Likins, global marketing director, Prinova USA (Hanover Park, IL), "Women are realizing that working out isn't just a component of a fleeting fad diet, but actually benefits them mentally and physically. Strength is empowering: it produces visible results and fosters a more consistent fitness regimen."

Elyse N. Lovett, MBA, MS, marketing manager, Kyowa Hakko USA (New York City),

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*Sports and exercise nutrition research has historically focused on healthy males aged 18 to 35.*

agrees. "We've entered the age where 'strong is the new skinny'—where women all over the world are looking at Olympians and strong, fit influencer moms as role models when it comes to body image." The upshot: Statista research[2] found that, on average, 17.8% of the domestic female population engaged in sports or exercise *every day* in 2017, compared to 15.6% two years prior.

## Fitness Fuel

It should come as no surprise that all those bodies in motion generate growing demand for sports nutrition products designed to fuel their next fitness session—or reward the one just completed. And the fact that this market is entirely female signals a turning point for the entire category.

Carolina Ordonez, senior consumer health analyst, Euromonitor International (Chicago), sees it as a broadening. "Historically, female bodybuilders and athletes were the ones more interested in sports nutrition. But with sports nutrition's consumer base expanding, more women are following fitness trends and looking for sports nutrition products that can support their fitness goals."

To Emily Pankow Fritz, PhD, technical services manager, active wellness platform, human nutrition & health division, Kemin (Des Moines, IA), it's all of a piece with the changes reshaping the category. "Ten to 15 years ago, sports nutrition products were exclusively used by bodybuilders and professional athletes. Now, the category is sold in mass merchandisers, welcomes a wider range of consumers, uses more creative formats, and has broader claims aimed at overall health and wellness. Overall, the definition has expanded to be more inclusive and active, and provides a broader definition for consumers to identify with," she says.

## Vive la Difference

And female consumers are identifying, in droves. But whether they realize it or not, their identity *as females* plays a fundamental role not only in determining which sports nutrition products best suit their needs, but how their bodies respond to sport in the first place.

"Women's bodies are biologically and physiologically different from males'," Hughes-Likins says, noting that the former carry 6%-11% more body fat than the latter, "likely due to estrogen, as it suppresses fat oxidation, making it more difficult for women to lose fat." Women also metabolize some nutrients differently than do men, resulting in higher requirements for iron, calcium, vitamin D, and folate, to name a few.

Adds Sandy Chien, PhD, vice president of innovative products, Horn (La Mirada, CA), "Women also have lower sweating rates than men, mostly due to a lower metabolic rate and smaller body mass. And women have to deal with the rise and fall of estrogen and progesterone, which affects energy and water retention, as well as physical performance."

Indeed, it's this ebb and flow of reproductive hormones—including luteinizing hormone and follicle stimulating hormone—that accounts for what Pankow Fritz calls "the most obvious differences" between men's and women's metabolic profiles and optimal energy intakes.

Consider pregnancy and lactation, which pose "unique nutritional needs outside the context of activity level," Pankow Fritz continues. "Increases in recommended energy and micronutrient requirements during pregnancy and lactation are focused on optimizing fetal development and preventing nutrient deficiencies; the demands of physical activity add another layer of complexity, and sports nutrition supplementation adds yet another."

## How Little We Know

Of course, not all active women are pregnant or lactating, but even among healthy adult females who aren't, "the demands of exercise impact energy, micronutrient and mineral needs depending on the exercise volume and intensity, and on dietary intake," Pankow Fritz reiterates. The catch: "There are currently no official nutrient dietary recommendations based on exercise volume and activity level that are specific to gender."

"Some of the broader conclusions about the nutritional needs of active females are inferences or culminations of understanding about the physiological differences between males and females, and how the context of exercise might affect nutritional needs," Pankow Fritz explains. And though these conclusions give us an idea of why men's and women's needs differ, "they don't provide us with evidence of how these differences might affect sports performance, or how they can be addressed with supplementation." This underscores the need for more research.

Alas, a 2017 study[3] published in the *European Journal of Sport Science* found that among the more than 6 million participants tracked in the 1,382 sports and exercise medicine research papers that the researchers analyzed, only 39% were female.

Sports and exercise nutrition research has historically focused on healthy males aged 18 to 35, perhaps because "some researchers believe that conducting clinical research on females requires extra steps, and that the results could be swayed by the complexity of the menstrual cycle," Hughes-Likins says. And the need to administer pregnancy tests to potential subjects adds to already weighty research costs. Nevertheless, says

Hughes-Likins, "Claims based on clinical research performed on men may not be applicable to women."

That said, the situation may be headed for a turnaround. Although precious little research has investigated sports nutrition supplements or dietary interventions specific to females, Pankow Fritz says, "this is where ongoing efforts to close the gap are focused: researchers are making attempts to include both women and men in clinical trials so that we can substantiate efficacy in both genders."

## What Women Want (from Sports Nutrition)

Until they do, sports nutrition marketers don't have much concrete information to go on when formulating for women's sports nutrition needs. In the absence of targeted nutritional strategies, they may find themselves leaning more toward targeted concepts. And that requires asking active women not what they *need*, but what they *want*.

"Many women are looking for products that enhance their workouts holistically by reducing stress, increasing restful sleep, or providing lean muscle building rather than bulk," says Brown. "Furthermore, natural and non-GMO ingredients continue to gain momentum."

Ordonez points to a rough consensus among experts that as go Millennial women, so goes the gender in general. "After discussing this topic with sports nutrition players," she says, "we all agree that Millennial moms are becoming a very important target in sports nutrition." Female Millennials spend two times more on self-care than Boomers, she notes, adding, "This female consumer is very educated and looks for sports nutrition products that represent her values: transparency, organic, non-GMO, plant based, few natural ingredients, local sources, vegan or vegetarian, and so on." Credibility matters, too, and brands that have it include Truvani and Clean Machine, Ordonez says.

But a product needs more than progressive bona fides to succeed with active women. It also needs to produce a palpable effect. "Females love products that make them feel good—they love to 'feel' something," Lovett says. "While improving their outer image is important, their inner 'feeling' is just as important. So, I think products that can enhance their active nutrition performance while making them feel great will be key drivers for the category."

And do us a favor: make women's sports nutrition products easy to use, and to behold. As Chien says, "Women prefer delivery systems with easy use, such as sachets and drinks instead of powders. They also prefer vibrant, bright colors with simple, clean packaging and messaging compared to the color black marketed to men."

## Make Your Ingredients Count

So, looks do count. But ingredients count more. And even in the absence of conclusive science on women's sports nutrition needs, "Companies that offer innovative ingredients backed by clinical research are filling the gap" in products directed toward women, Brown says.

Of course, protein ingredients are as popular with active females as with everyone else, and James Komorowski, chief science officer, Nutrition 21 (Purchase, NY), says that athletic women "increasingly look for quicker ways to incorporate more protein into their diets for sustained energy and satiety and to help them achieve their health goals. This has shifted the protein market over the last decade away from a concentrated focus on sports nutrition consumers toward a wider focus on consumers interested in improving consumption to help improve general health."

Collagen protein in particular is attracting attention, and as Aouatef Bellamine, PhD, senior scientific manager, consumer health & nutrition, Lonza Nutrition & Health (Basel, Switzerland), points out, it has special relevance for female athletes. "As young women tend to be more prone to ankle injuries," Bellamine explains, "they may need appropriate joint-support supplementation." Her company's UC-II undenatured type II collagen from chicken sternum cartilage offers formulators a "natural, effective option for women's sports nutrition products" with plenty of science supporting its role in joint health, she says.

Komorowski adds that active women might appreciate his company's Velositol blend of amylopectin and chromium, which studies show helps the body mobilize the branched-chain amino acids (BCAAs) in dietary protein to accelerate muscle protein synthesis (MPS)—"key to enhanced muscle growth and quicker muscle recovery," he says. "This is relevant for active and athletic women who want to amplify the effect of protein or BCAAs on muscle growth. And because less protein is needed to boost MPS, it's also relevant to those who want more impact from their protein with fewer calories."

Another "focal point" for female active nutrition involves increasing energy, enhancing mental focus, and heightening cognitive function, Komorowski continues. "Nootropic supplements have been on the rise and are geared toward improving focus, mental acuity, and energy. Consumers looking for products with a nootropic effect are growing more interested in 'naturally' boosting energy and focus without caffeine, jitters, or a crash." Nutrition 21's Nitrosigine ingredient combines the amino acid arginine with silicon, stabilizing the blend with inositol, a carbocyclic sugar sometimes referred to as vitamin B8. Clinical results indicate that it improves processing speed and executive function and increases energy levels without changing heart rate or blood pressure.

Not quite a vitamin and not quite an amino acid, L-carnitine is perennially popular with the gym crowd who prize it for its purported fat-burning and performance-boosting properties. But because Lonza's Carnipure brand of the ingredient "is flexible and adaptable for the sports nutrition market," Bellamine says, "it lends itself to the growing requirements of active and athletic women. Studies show it provides significant recovery benefits by reducing tissue damage, muscle soreness, and injury after exercise. It's also been proven to help improve cardiovascular health by enhancing endothelial function through increase blood flow."

Also a boon to fitness recovery is curcumin *(Curcuma longa)*, "which has a myriad of health benefits including anti-inflammation and delayed-onset muscle soreness prevention," says Mariko Hill, product developer at Gencor Nutrients Inc. (Anaheim, CA). Gencor and its partner Pharmako Biotechnologies (New South Wales, Australia) offer formulators Hydrocurc, a cold-water-dispersible curcumin ingredient with 90% loading that functions in effervescent, capsule, and powder formats. "Its application in effervescent tablets with its natural orange color


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## DO WOMEN "BULK UP" WITH WHEY PROTEIN SUPPLEMENTS?

Protein supplementation is touted for increasing muscle mass and strength in men, but one common question when it comes to women is whether protein supplementation will lead to excessive female hypertrophy ("bulkiness.") Purdue University researchers conducted a meta-analysis addressing this question, now published in *Nutrition Reviews*.[1] According to the researchers, this is the first systematic review and meta-analysis to examine the impact of whey protein supplementation on female body composition when factoring in the effects of calorie restriction and resistance training.

Researchers included data from randomized controlled trials conducted in women who supplemented with whey protein compared to control subjects not supplementing with whey protein. Within each overall group (supplementation and control), researchers classified subjects into the following subgroups: 1) subjects restricting calories via dietary changes, 2) subjects engaged in resistance training, 3) subjects combining calorie restriction and resistance training, and 4) subjects who neither restricted calories nor resistance trained.

The meta-analysis included 488 female participants aged 20-64, and spanned whey protein supplement dosages ranging from 6 g/day to 48 g/day. Whey supplements included those containing whey protein concentrates, isolates, and hydrolysates, but no other protein types (such as casein).

The researchers analyzed changes in whole-body composition, including body mass, lean mass, and fat mass, with or without calorie restriction or resistance training. Overall, researchers found that compared to those not supplementing with whey protein, whey protein subjects overall saw positive, but modest, changes in lean mass and no significant changes in fat mass.

Their subgroup analysis found that among whey protein subjects: 1) the "most robust positive change" in lean mass happened in subjects restricting calories only (but not resistance training), 2) there was no difference in body composition in subjects resistance training only (but not cutting calories), and 3) there was decreased fat mass but no effects on lean or body mass in subjects neither resistance training nor cutting calories. In addition, researchers said there was not enough data to come to a conclusion on the effects in groups both restricting calories and resistance training.

What does this all mean? According to researchers, whey protein caused only modest increases in lean mass, and without influencing fat mass or total body mass, regardless of whether subjects restricted calories or resistance trained. When whey protein supplementation was combined with calorie restriction (such as during a weight-loss program), the increases in lean body mass were more pronounced.

Again, any increase in lean mass was moderate only, leading the researchers to conclude that "[t]his moderate increase in lean mass over time (0.37 kg) represents <1% of the total lean mass of study participants and therefore does not support the public perception that [whey protein] causes excessive hypertrophy or 'bulkiness' in adult women."

The researchers wrote: "In summary, findings from this systematic review and meta-analysis indicate that [whey protein] supplementation improves body composition in adult women by modestly increasing lean mass without influencing changes in fat mass."

In addition, they added, "Whey protein may be more beneficial for improving body composition when included as part of a weight-loss program. Although more research is needed to specifically assess the effects in varying states of energy sufficiency and exercise training, the overall findings support consumption of [whey protein] in women seeking to modestly improve body composition."

This study was funded by the U.S. Whey Protein Research Consortium, an industry-funded research and education group whose partners include dairy cooperatives, dairy associations, dairy processors, and multinational companies.

The researchers noted that "females are underrepresented in this line of research," with most studies examining whey protein's effects performed in male-only populations. In general, they pointed out, "there is a paucity of protein supplementation research in women."

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and flavor is perfect for the category, as its ability to form stable dispersions in water reflects the ease of use in a sports or on-the-go setting," Hill says.

The more that formulators turn to ingredients like this and others, the better able they'll be to create sports nutrition products that "serve female consumers more effectively than they have in the past," Hill says. "The focus on women's sports and active nutrition will have a significant impact on the sports nutrition space. As consumer awareness of health and wellness increases, female consumers will soon gravitate toward this trend to incorporate a healthier lifestyle." N

*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.*

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# BEARING FRUIT

## Nutritional supplements for couples trying to conceive

**BY MAUREEN KINGSLEY**

The United States Department of Health and Human Services' Office on Women reports CDC findings that about 10% of American women of childbearing age have difficulty becoming or staying pregnant. CDC defines infertility as the condition of not being able to achieve pregnancy within one year of trying, or within six months of trying for women older than 35. Nationwide, infertility affects about 6.1 million women between the ages of 15 and 44.

CDC also notes that about one-third of infertility cases are caused by medical problems in women, and another one-third are caused by medical problems in men. The final third are a combination of female and male reproductive issues and unknown causes.

The market for dietary supplements that support reproductive health in women—and also in men—is established and substantial. Additionally, CDC lists poor nutrition as one of a number of factors contributing to fertility problems, making the argument for supplementation that much stronger.

### Nutrition and Fertility: Recent Findings

In April of this year, a review of the current body of scientific literature studying the relationship between diet and human fertility was published in *American Journal of Obstetrics and Gynecology* by two Harvard professors, Audrey Gaskins, ScD, and Jorge Chavarro.[1] The authors identified some clear patterns:

1. Intake of supplemental folic acid, particularly at doses higher than those recommended for preventing neural-tube defects in babies, has been "consistently related to lower frequency of infertility, lower risk of pregnancy loss, and greater success in infertility treatment."
2. Antioxidant supplementation may be beneficial for promoting fertility in the male partner of a woman undergoing infertility treatment.
3. Long-chain omega-3 fatty acids appear to improve female fertility.
4. Adherence to a healthy diet "favoring seafood, poultry, whole grains, fruits, and vegetables is related to better fertility in women and better semen quality in men."

Additionally this year, in July, *British Journal of Nutrition* published a study by Keewan Kim et al. whose findings suggest that low manganese, selenium, and sodium levels increased the risk of sporadic anovulation (no egg release, and therefore, no conception) in women.[2] Additionally, low levels of magnesium were found to be associated with lower testosterone levels, while very low levels of potassium were associated with higher testosterone levels. (For the study, 259 women

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aged 18 to 44 were recruited; the women kept food diaries and had blood drawn and tested by the researchers throughout their menstrual cycles.) Taken all together, the findings of this particular study appear to recommend that women seeking to conceive adhere to the recommended daily allowances of these elements to support regular ovulation.

Successful, competitive supplement brands are staying alert to these recent scientific discoveries, formulating products that provide ample amounts of folic acid/folate in combination with other ingredients, such as minerals, antioxidants, omega-3 fatty acids, and herbs.

## A Pre-Prenatal Vitamin

One particularly well-known and successful fertility supplement line is Fairhaven Health's FertilAid, which includes a FertilAid for Women product and a FertilAid for Men. The women's version is essentially a prenatal supplement containing 600 mcg of folic acid (150% RDA), plus the B vitamins, vitamin D3, vitamin C, vitamin A, vitamin E, minerals, and a blend of herbs intended to both support fertility and maintain a healthy pregnancy. The herbal blend features selections to "stimulate and balance hormones that control ovulation," according to the company, including chaste tree berry extract and red clover extract. (For more on herbs and botanicals for fertility, see the sidebar above.)

The men's product contains large concentrations of antioxidants and minerals, and its formulation is supported by clinical trial data presented at the American Society of Andrology's Annual Proceedings in 2009.[3] The randomized, double-blind study was undertaken through 2006 over three months, to determine the effects of FertilAid on men with "abnormal sperm parameters" as defined by the World Health Organization. The researchers noted statistically significant improvements in sperm motility (an indicator of male fertility) for subjects using the dietary supplement, and also suggested that the use of FertilAid for Men may improve sperm count.

In line with findings that omega-3 fatty acid intake is associated with better fertility, Fairhaven's FH Pro Omega-3 contains "clinical-grade EPA and DHA," according to company literature. "In women, EPA and DHA are believed to help regulate hormones, reduce inflammation, promote cervical mucus production, and reduce blood clotting, all of which is beneficial for fertility," the literature reads. "EPA and DHA are also believed to be important for helping to prevent miscarriages and preterm labor and for brain and eye development in the fetus. In men, low intake of omega-3 fats has been associated with poor sperm production and quality."

Fairhaven also offers a product aimed singularly at improving cervical-mucus quality (another indicator of fertility) and a newer FertileDetox product containing herbs, amino acids, botanicals, and probiotics for the purpose of "promoting the efficient elimination of environmental toxins from the body" by "supporting the body's own detoxification and cleansing systems": the liver and the intestines.

Another brand adhering closely to the latest science is Daily Wellness Co., seller of the supplements FertilityBlend for Women and FertilityBlend for Men. The women's formula contains a blend of folic acid, letter vitamins, magnesium, zinc, selenium, and iron, as well as the amino acid L-arginine plus green tea extract and chaste berry extract. The formula "significantly improves ovulation health and hormonal balance," says Daily Wellness Co. president Denny Kwock. He cites a double-blind, placebo-controlled study published in 2006 in *Clinical and Experimental Obstetrics & Gynecology* that he says showed the FertilityBlend women's supplement improved the success rate of couples trying to conceive by three times over placebo.[4]

The men's FertilityBlend formula contains vitamins C, E, B6, and B12, plus folate, zinc, and selenium. The supplement also includes the amino acid L-carnitine, plus green tea extract and dong quai extract, for improved sperm quality.

## Improving on the Already Proven Folic Acid

Folic acid is an established star in the trying-to-conceive and prenatal supplement industry. As reported by *Nutritional Outlook* this summer, a recent small study of 30 couples with histories of infertility or miscarriage found that a full 26 of those 30

### HERBAL INGREDIENTS FOR A COMPLEMENTARY APPROACH TO INFERTILITY

Brien Quirk, director of R&D at Draco Natural Products (San Jose, CA), points to a handful of herbs and botanicals used in traditional Chinese medicine to combat infertility. "We have some great recommendations for both female and male infertility," he says. "For women, in traditional Chinese medicine, dodder seed *(Cuscuta chinensis)* is the most commonly recommended single herb by clinical practitioners, while the multiherbal formula most recommended is dang-gui-sha-yao-san. That formula consists mainly of blood-moving herbs, such as dong quai, lovage root, white peony root, poria, *Atractylodis macrocephala* root, and *Alisma* rhizome. These address blood stasis, a major cause of female infertility."

Another formula Quirk cites is Rehmannia 8, which he says "can address polycystic ovarian disease [PCOS], a major cause of female infertility due to excess body weight and metabolic syndrome."

In men, celery and red ginseng are backed by some studies showing they improve sperm quantity and quality, Quirk says. Herbs that increase sperm production or enhance their health and motility, he adds, include *Cuscuta chinensis* seed, goji berries, fupenzi or Chinese raspberry fruit, schisandra berry, plantaginis seed, Chinese yam, Chinese foxglove root or prepared radix rehmanniae, *Rosa laevigata* fruit, and glossy privet berry.

Quirk cites a number of scientific papers in support of traditional Chinese herbs and botanicals marketed for fertility, including one from the journal *Complementary Therapies in Medicine* in which the authors write, "Our review suggests that management of female infertility with Chinese Herbal Medicine can improve pregnancy rates 2-fold within a 4-month period compared with Western Medical fertility drug therapy or IVF."[5]

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*Savvy supplement brands aren't just following the science of nutrition and fertility; they're creating whole trying-to-conceive programs that combine technology with supplemental nutrition.*

were able to conceive after consuming a novel folate ingredient called Quatrefolic (a 5-MTHF glucosamine salt manufactured by Gnosis S.p.A.; Desio, Italy) for four months. The ingredient is a biologically active form of folate (the naturally occurring form of folic acid) "that does not need to be converted by the body via the folate enzymatic pathway that includes the enzyme methylenetetrahydrofolate reductase (MTHFR), which shows common polymorphisms of around 40% in the world population," according to a number of studies cited by Gnosis. In other words, those persons in whom MTHFR is mutated may not metabolize supplemental folic acid efficiently, in which case, the Quatrefolic ingredient may be a better alternative.

Gnosis also points to studies indicating that folate levels measured in semen have been associated with sperm count and health. "Folate supplementation had a beneficial effect on spermatogenesis, possibly by increasing cellular cohesion within the seminiferous epithelium, thus preventing abnormal release of immature germ cells into the lumen," Gnosis literature and spokesperson Lorena Carboni assert. "Over the years, a large number of genetic studies focusing on the association between genetic MTHFR polymorphism and male infertility have been carried out with different meta-analyses published. High levels of homocysteine in subjects with MTHFR polymorphism have been associated with low sperm quality," Gnosis reports. "Notable, different meta-analyses correlated the polymorphism with risk of male infertility," according to the company, suggesting that men wishing to conceive may also benefit from supplementation with the Quatrefolic ingredient.

## Fertility? There's an App for That

Savvy supplement brands aren't just following the science of nutrition and fertility; they're creating whole trying-to-conceive programs that combine technology with supplemental nutrition. One of these is Fruitful Way, a company that offers an app to help users "optimize [their] chances of getting pregnant" via a fertility assessment, an ovulation cycle tracker, a menstrual period calendar, personalized health and lifestyle recommendations, and a nutritional-supplement dosage reminder and tracker. The company's related supplements include Fruitful Couple (for women and men), featuring omega-3 fatty acids; Fruitful for Her, with folic acid, the B vitamins, and vitamins E, A, and D; and Fruitful for Him, made with the antioxidants L-carnitine, vitamin E, and selenium.

Udi Alroy, Fruitful Way's CEO and co-founder, tells *Nutritional Outlook* that his company's app is "focused on a personalized solution based on the proprietary fertility algorithm developed by Fruitful Way to accommodate [users'] lifestyles and relationship management, reduce stress, and formulate the best nutrition solution on the new-family level."

He adds, "Our technology enables us to connect the couples on a daily basis, assisting in the trying-to-conceive process, synchronizing the fertility window for both, and optimizing his and her physical condition. The Fruitful Way personalized supplements are science-based with the intention to improve… conditions toward conceiving."

Another brand combining fertility supplements with tech is Thorne Research, which sells a direct-to-consumer fertility test for just under $400 and provides results and recommendations to the user's desktop computer or mobile device. The test kit includes materials for at-home blood and saliva collection, and samples are subsequently mailed back by the user. Those samples are tested, and Thorne research sends a digital summary of results and recommendations within three to five days. Biomarkers tested include hormone levels (estradiol, progesterone, testosterone, follicle-stimulating hormone, luteinizing hormone, thyroid-stimulating hormone, triiodothyronine, free T4, cortisol), levels of the sex-hormone-binding globulin protein, levels of thyroid peroxidase antibodies, and levels of DHEA. The personalized plan provided by Thorne is based on test results and includes supplement recommendations; Thorne's fertility-related supplements include its Basic Prenatal, recommended for women trying to conceive in addition to those who are already pregnant or lactating. It features L-5-MTHF (glucosamine salt), vitamin B12, antioxidants, and minerals. The company also sells a Super EPA omega-3 fatty acid supplement. N

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# Magnesium Strong

Magnesium is an essential mineral for muscle function and performance.

**BY IRFAN QURESHI, ND**

Magnesium is a mineral that is a crucial cofactor for over 300 enzymes, playing a core role in the structure and function of the human body. Magnesium's broad-reaching importance extends to areas including energy production, the synthesis of DNA and proteins, structural roles in bone and cells, facilitating cellular signaling, and nerve function.[1] With its breadth of reach and influence over human physiology, it's not surprising that magnesium is a critical mineral for muscle function.

Magnesium influences muscle performance by participating in energy metabolism and maintenance of muscle contraction and relaxation. Research further shows that magnesium deficiency can lead to a disruption of neuromuscular function—and that high levels of physical activity increase the body's demand for magnesium. Further studies in individuals on a strength training program have found that suboptimal magnesium status leads to decreased endurance, while higher magnesium intake in aerobic exercise is associated with a requirement for less oxygen and improved cardiorespiratory fitness.[2]

Although maintaining optimal levels of magnesium is essential for all, athletes and others who are physically active may have increased requirements for magnesium. Similarly, those with sarcopenia as well as those experiencing other muscular issues related to the aging process may also need higher intakes of magnesium. However, according to USDA data, almost half of all individuals have magnesium intake levels below the Estimated Average Requirements (EAR) for this nutrient. Strikingly, for adults aged 71 and over, this percentage rises to two-thirds of the population.[3] The Recommended Dietary Allowance (RDA) for magnesium ranges from 400 to 420 mg per day for males aged 14 to over 70. For women, the RDA for those aged 14 to over 70 ranges between 310 and 320 mg per day.

In addition to nearly 60% of adults falling short of these guidelines, reviews suggest that magnesium consumption in most athletes falls well below amounts that are considered adequate.[4] As magnesium is an electrolyte, strenuous exercise causes a significant amount to be lost through urine and sweat. This can increase magnesium requirements by 10%-20%.[5]

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*Magnesium influences muscle performance by participating in energy metabolism and maintenance of muscle contraction and relaxation.*

## Magnesium and Muscle Function

A recent review coauthored by Mario Barbagallo and Ligia Dominguez from the University of Palermo (Palermo, Italy) outlines several important ways in which magnesium impacts muscle function and performance.[6] As physical exertion depletes magnesium and leads to increased oxidative stress, higher levels of reactive oxygen species, or free radicals, are generated. These free radicals may contribute to the development of muscle fatigue. Magnesium has antioxidant effects that can confer protection to muscle tissue.

Additionally, magnesium plays a fundamental role in mitochondrial energy production. Over one-third of total cellular magnesium is found in the mitochondria and is present complexed together with adenosine triphosphate (ATP) and as a component of membranes. Magnesium is, therefore, critical for basic mitochondrial functions, including the production of ATP, and confers a protective role to skeletal muscle mitochondria.

Furthermore, inflammation is a critical factor in reduced muscle performance. Poor magnesium status is known to exacerbate the inflammatory state and leads to increased circulating levels of pro-inflammatory markers. Magnesium intake, on the other hand, has repeatedly been found to reduce systemic inflammation, including significant reductions in the cytokine IL-6 and C-reactive protein (CRP) levels, two markers of inflammation.

Magnesium may also influence muscle function and exercise performance in another important way. Hsuan-Ying Chen and colleagues from Providence University in Taichung, Taiwan, found that administering magnesium to animals prior to a treadmill exercise led to increased glucose availability in muscle and brain tissue while increasing the clearance of lactate from muscle.[7] This central role of magnesium in glucose utilization and metabolism is critical for shuttling glucose to where it's needed in the body during exertion.

## Benefits of Optimal Intake across Demographics

Alisa Welch and colleagues from the University of East Anglia (Norwich, UK) recently conducted two relevant studies evaluating the significance of magnesium intake for muscle health across broad spectrums of the population.

In one study, the researchers analyzed data from a cohort of 156,575 men and women aged 39-72 to assess the impact of dietary levels of magnesium on skeletal muscle and bone health parameters.[8] They found that higher dietary intakes of magnesium were positively associated with greater grip strength, skeletal muscle mass, and bone mineral density in both men and women. In men over the age of 60, the relevance of higher magnesium intake as it relates to grip strength was even more exaggerated compared with younger men, emphasizing the importance of ensuring optimal magnesium consumption in this group. Furthermore, when the researchers analyzed the benefits of greater magnesium intake across this population versus the annual losses of bone mineral density and skeletal muscle with age, they concluded that the findings were of clinical significance in terms of higher magnesium intake stemming these decreases over time. Dietary levels of magnesium may, therefore, have relevance for prevention of sarcopenia, frailty, falls, and fractures.

In a second study, Welch and colleagues analyzed cross-sectional data from 2,570 women aged 18 to 79 years to determine the effect that dietary magnesium intake has on age-related skeletal muscle loss, power, and chronic low-grade inflammation.[9] They found that higher dietary magnesium intake was significantly positively associated with skeletal muscle mass ( fat-free mass as a percentage of body weight), leg explosive power (a measure of the force and velocity of muscle contraction of the quadriceps), and circulating levels of the inflammation marker CRP. Quite remarkably, the difference in leg explosive power was shown to be more than 24% greater in those women with the highest versus lowest magnesium intake. In terms of inflammation, the differences in CRP concentrations is significant as magnesium may play a greater role in skeletal muscle conservation in older women via attenuating the production and effect of inflammatory cytokines.

Moreover, an analysis from the Maastricht Sarcopenia Study in the Netherlands compared nutrient intakes in 227 older adults (aged 65 or older) and found that individuals with sarcopenia had significant nutritional differences in five nutrients compared to those without sarcopenia.[10] Sarcopenic individuals had a 10%-18% lower intake of omega-3 fatty acids, vitamin B6, folic acid, vitamin E, and magnesium, with the difference in magnesium intake approaching 12% between the groups.

These data taken together substantiate the critical importance of ensuring optimal magnesium intake for skeletal muscle health through the lifespan.

## Magnesium Supplementation and Physical Performance

Clinical trials involving magnesium supplementation for improving athletic performance and muscle function have yielded mixed results; however, some recent studies point to positive benefits in professional and recreational athletes, as well as the elderly.

In one recent study conducted by Córdova Martínez Alfredo and colleagues from the University of Valladolid (Soria, Spain), researchers investigated the effects

*Continued on page 44*

## IS MAGNESIUM AWARENESS GROWING IN ACTIVE NUTRITION?

Evidence continues to build showing magnesium is crucial for muscle function, but are supplement shoppers getting the message? *Nutritional Outlook* interviewed one industry expert, Stephen Ashmead, MS, MBA, senior fellow for Balham Corp., Albion Minerals (Layton, UT), about how well consumers understand the link between magnesium and active nutrition and sports nutrition.

***Nutritional Outlook:*** **How aware are today's sports nutrition customers about the role of magnesium in muscle function and performance?**

Ashmead: While scientific evidence continually emphasizes the importance of proper magnesium intake, and despite the fact that consumers have access to more information about magnesium than ever before, research consistently shows that people aren't getting the recommended amounts in their diet. According to the National Health and Nutrition Examination Survey (NHANES) 1999-2000, researchers found 68% of Americans consumed less than the recommended minimum daily intake (400 mg) of magnesium.

However, there is greater and growing awareness within the sports nutrition market of the many roles of magnesium. The lines between athletes and "lifestyle users" have blurred, and active nutrition is an important segment of the sports nutrition market. With growing interest in leading active lifestyles and increased participation in sports and fitness activities, the demands within this market are evolving. Both athletes and active-lifestyle consumers want supplements that help support specific goals for energy, endurance, performance, weight loss, muscle comfort, and overall wellness.

We are seeing tremendous growth for magnesium in this sector. Magnesium sales will continue to grow as more consumers recognize the benefit of adequate magnesium in their diets and lifestyles. They will use it to prevent deficiencies due to diets or other issues, and to support physiological function and their active lifestyles.

**Can you highlight the importance of magnesium to athletic performance?**

Magnesium is the catalyst or cofactor in many of the oxidative phosphorylation reactions, converting sugars into glycogen and ultimately ATP (adenosine triphosphate) needed for refueling in preparation for future exercise or athletic performance. Sports performance and exercise require a high supply of the energy produced by magnesium-sparked reactions.

As we exercise, the body burns through our glycogen stores. The longer and the more intense the exercise, the more glycogen we burn. Fast glycogen recovery or refueling is most important in athletes who train multiple times per day or participate in back-to-back events. In these individuals, a proper refueling strategy is essential, otherwise they put themselves at risk for poor performance and even injury.

Minerals play important roles in counteracting the impact that exercise performance can have on the body. Magnesium and zinc play important roles in fighting against oxidative stress and reducing inflammation, thereby reducing muscle damage. Magnesium is involved in a multitude of processes that impact muscle function, including oxygen uptake, electrolyte balance, and energy production. Proper magnesium intake can enhance exercise performance.

**What kind of inroad has magnesium made in the sports nutrition market? Can you comment on the volume of sports nutrition products you see now incorporating magnesium?**

According to the *Nutrition Business Journal,* magnesium supplements had almost 9% in sales growth in 2017. In fact, it is predicted that by next year, magnesium sales will overtake calcium as the single largest mineral sold in the market. Some of this growth can certainly be attributed to growing interest from the sports nutrition market, which is also growing steadily. Euromonitor reports that sports nutrition sales grew from US $7.3 billion in 2011 to $13.6 billion in 2017, and is expected to continue growing at nearly 8% CAGR by 2021.

**What kind of synergistic benefits does magnesium have with other commonly used sports nutrition ingredients? Are you seeing those combinations featured in the end-product market today?**

When formulating sports nutrition products, it is also important to consider the cognitive aspects, along with the physical benefits of the ingredients. Nootropics are gaining substantial interest in sports nutrition. Minerals such as iron, zinc, and magnesium play important roles in achieving optimal physical and cognitive sports performance, and are considered to have nootropic characteristics.

For example, magnesium is crucial in ATP synthesis. ATP is the primary energy source for mitochondria in every cell, including those in the brain. ATP must be bound to magnesium in order to be activated. Magnesium combined with B vitamins can help maximize the energy potential. Magnesium joined to creatine has shown to increase work output over individual components and is present in many powder formulations in the market today.* As cognition and active lifestyles gain more awareness, magnesium and beneficial combinations with other nutrients will become more important.

**How well does magnesium formulate into the many types of sports nutrition products on the market?**

Magnesium has traditionally been supplemented as tablets and capsules, and can still be used in that way. However, magnesium lends itself well in the many sports nutrition applications, including sports drinks, powders, bars, "shots," and gummies. Selecting the right form of magnesium for the application is important based upon delivery mechanism, other ingredients, and organoleptic properties.

** Editor's note: Balchem/Albion supplies a magnesium creatine chelate ingredient called Creatine MagnaPower.*

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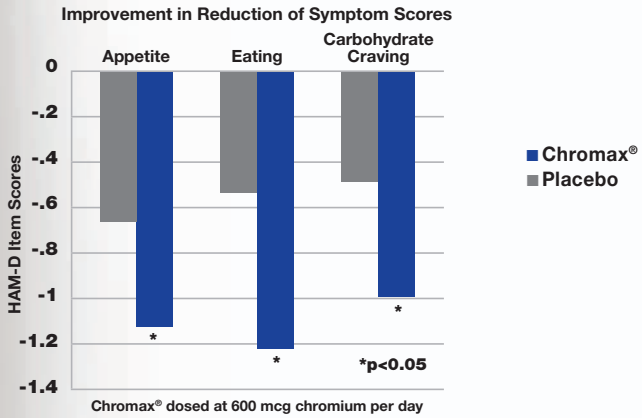


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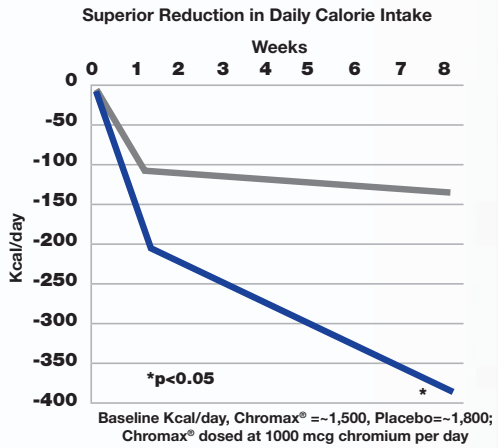


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† In subjects with atypical depression and high carbohydrate cravings. ** In healthy, overweight, adult women with carbohydrate cravings.

 **1.** Data on file 2017, Nutrition 21, LLC. **2.** Kaats *et al., Current Therapeutic Research* 1998. **3.** Docherty *et al., Journal of Psychiatric Practice* 2005; 11(5):302-14. **4.** Anton *et al., Diabetes Technology & Therapeutics* 2008; 10(5):405-12. DRA1176102317

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Continued from page 41

of magnesium supplementation on muscle damage in male professional basketball players.[11] Twelve elite basketball players who were members of a team were asked to supplement with 400 mg magnesium daily in the form of magnesium lactate during the entire basketball season (approximately 32 weeks). Blood samples assessing parameters of muscle damage were taken throughout the season at eight-week intervals. As a comparison, twelve college age students who played recreational basketball and competed in minor university leagues were used as a control group to assess baseline parameters. This group was not supplemented with magnesium.

Serum magnesium levels did not differ significantly at baseline between the professional players and the recreational players serving as controls. Over the course of the study, serum magnesium levels registered a decrease at the third timepoint with respect to the first and second timepoints; however, these levels recovered and were significantly higher at the fourth timepoint versus the third. Additionally, there was no significant increase in the parameters of muscle damage versus baseline levels in the professional athletes, indicating a protective effect on muscle tissue associated with magnesium supplementation.

In general, with exertion levels seen in these athletes, a rise in these markers of muscle damage is expected. The parameters assessed included myoglobin, lactate dehydrogenase, aldolase, serum urea, and total proteins, along with the liver enzymes ALT and AST. Overall, this small study supported the use of magnesium supplementation in elite athletes for preventing the normal drop seen in serum magnesium with intense physical activity as well as mitigating an increase in biochemical markers of muscle damage during the basketball season.

Another study aimed to assess the effect of magnesium on muscle fatigue. Conducted by researchers at the University of Mazandaran (Babolsar, Iran), the randomized controlled trial looked at the benefits of magnesium supplementation on muscular fatigue following intense anaerobic exercise.[12]

In this pilot study, 16 physically active male college-aged volunteers who exercised regularly for at least 30 minutes four days per week for the prior three months were randomly divided into a placebo groulp or a supplementation group. The subjects were asked to supplement with 350 mg of magnesium sulfate or placebo nightly before dinner for fourteen days. They underwent the Wingate test at the beginning of the trial period and again at the end. The Wingate test is a stationary bicycle test of exhausting physical anaerobic activity. It involves 30 seconds of maximal exertion (pedaling as fast as possible) following a five-minute warmup session.

*As the majority of the adult population in the U.S. fails to meet basic RDA levels, improving magnesium intake is essential.*

Blood was drawn both prior to and after the test. The muscular activity of the right leg (three main muscle groups) was assessed by an electromyography (EMG) device. While in the placebo group a decline was noted in mean power frequency (an indicator of muscular motor unit fatigue) between pre-test and post-test numbers, magnesium supplementation led to significant increases in these values post-test, suggesting an increase in the ability of muscle fibers of the leg to continue to fire. Magnesium supplementation led to reduced muscular fatigue and enhanced performance on the Wingate test, while no significant changes were noted with placebo. The results of the study suggest that magnesium supplementation benefits muscle function during anaerobic exercise performance.

Earlier, Nicola Veronese from the University of Padova (Padova, Italy) led a study looking at the ability of magnesium to impact physical performance in healthy elderly individuals involved in a weekly exercise program.[13]

In the 12-week randomized controlled study, 139 women (average age of 71) were allocated to either a magnesium group (300 mg/day as magnesium oxide) or a control group (no intervention). The primary outcome assessed during the study at baseline and week 12 was a change in the Short Physical Performance Battery (SPPB), which consists of three objective physical function tests: 4-meter gait speed, repeated chair stands, and standing balance in increasingly challenging positions. Secondary outcomes included changes in peak torque isometric and isokinetic strength of the lower limbs and handgrip strength.

Baseline SPPB scores were similar between the supplement group and control group; however, at 12 weeks, magnesium supplementation led to significant improvements in total SPPB scores, chair stand times and 4-meter walking speeds. No significant changes were seen in the secondary measures of muscle strength. Overall, the authors concluded that 12 weeks of supplementation with magnesium improved physical performance in healthy elderly women and noted that those with magnesium intake lower than the recommended daily allowance saw the greatest benefits.

## Benefits for All

Magnesium's importance in muscle health and physical performance in individuals of all ages can't be overemphasized. Its necessity for skeletal muscle function is indispensable.

As the majority of the adult population in the U.S. fails to meet basic RDA levels, improving magnesium intake is essential. In athletes, the influence of magnesium in improving athletic performance combined with the potential increased needs in those who are physically active necessitates a second look to ensure adequate intake in this group of individuals. After taking a closer look at improving dietary intake, a simple cost-effective approach would be to supplement with this mineral in at-risk populations. This could lead to better performance in athletes, better physical fitness with age, and better overall musculoskeletal health throughout life. N

***Irfan Qureshi, ND,*** *is executive director, research and regulatory affairs for Healthy Directions.*

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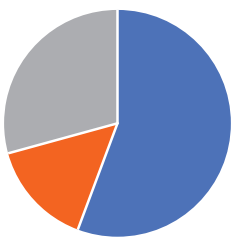

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- Increase in TeloYear Age™
- TeloYear Age™ Remained the Same

| Average TeloYear Age™ Decrease | |
|---|---|
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| B | -8.52 |
| P-value | 7.42E-01 |

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# SYNERGY SELLS

## Innovative formulations and a widening consumer base are redefining the joint health category.

**BY MELISSA KVIDAHL**

Though SPINS reports that sales of supplements targeted for joint health were down about 10% overall during the 52 weeks ending June 17, 2018, the news isn't all bad. In fact, in the natural channel, sales are up, to the tune of 6.6%. And if you ask Jaume Reguant, director of Spain-based Bioiberica Health Care Business Unit, increased growth is on the horizon as the population continues to age and, simultaneously, up the amount of physical activity in their daily lives.

"The joint health market is thriving as an increasingly aging as well as active population looks towards natural solutions to support their range of motion, fluidity, and flexibility," agrees Samantha Ford, business development director at AIDP (City of Industry, CA). "People are simply living longer and recognize the importance of taking care of their bones and joints for the sake of quality of life into their later years."

Also driving sales is the fact that younger consumers are taking joint health supplements, says Deanne Dolnick, science director at TR Nutritionals (Alpharetta, GA). Younger consumers are doing so not only because they're generally a group that's open to taking supplements, but also because they've gravitated towards group workouts like CrossFit and Spartan challenges, the intensity of which can put stress on the joints.

One ingredient on many supplement consumers' minds is collagen. New research coming out of Lonza Health & Nutrition (Basel, Switzerland) and recently published in *Osteoarthritis and Cartilage* supports the use of Lonza's UC-II undenatured type II collagen in supporting joint health across different age groups.[1]

The aim of the study was to determine the ability of the ingredient to prevent excessive articular cartilage deterioration in a rat model with osteoarthritis. The results found that immediate treatment with UC-II preserved the weight-bearing capacity of the limb with deteriorated articular cartilage. Taking a small daily dose also helped preserve the integrity of the cancellous bone at tibial metaphysis, and limited further damage to the articular cartilage. "As such, the study demonstrates that a clinically relevant daily dose of the UC-II brand, when applied immediately after injury, can improve the mechanical function of the injured knee—preventing excessive deterioration of the articular cartilage," says senior marketing manager Juliana Erickson.

But collagen isn't the only game in town. "Virtually everybody suffers from some sort of joint discomfort and it's not the type of ailment where the consumer runs to the doctor," Dolnick explains. "And because joint problems are either ongoing or intermittent, most people do not want to take NSAIDs for an unspecified period of time or even for a week or two, so they turn to supplements."

### Trends to Watch

A number of trends are driving sales across the joint health market.

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*"People are simply living longer and recognize the importance of taking care of their bones and joints for the sake of quality of life into their later years," says Samantha Ford of AIDP.*

First is an increased interest in alternative delivery formats. "Consumers don't want to take yet another pill or capsule, but rather a convenient supplement—in a food, drink, or powder format—that can easily be part of their daily routine," says Ford.

If you ask Erickson, younger consumers with busier schedules look for alternative formats like shots, bars, ready-to-drink beverages, and gummies, which help "pave the way for increased supplement usage in the joint health category."

The challenge, according to TR Nutritionals' Dolnick, is that many manufacturers need extracts that are water soluble, which aren't always easy to find. And, even if they do find it, it's usually "not too tasty," she says, especially in the case of turmeric, a hot joint health ingredient for which Dolnick says her company receives quote requests daily.

Another trend is consumer demand for transparency, which is driving sales and interest in vegan and vegetarian joint health ingredients and supplements. "In the information age, with so much false information and hype, consumers are increasingly becoming more skeptical about the ingredients in the products they consume and are demanding more transparency from manufacturers," explains Suhail Ishaq, president of BioCell Technology LLC (Irvine, CA), supplier of branded ingredient BioCell Collagen. "Everything from the source, quality, purity, non-GMO, and clinical substantiation are all factors that consumers consider in their purchasing behavior."

And, according to Silvia Pisoni, marketing manager at Gnosis S.p.A. (Desio, Italy), this desire for transparency and quality is translating into demands for ethical and non-animal-based ingredients. The company's vegetarian chondroitin sulfate, Mythocondro, gained U.S. GRAS status in the U.S. and Novel Food Approval in the beginning of 2018. "Non-animal origin claims are recognized as added value," Pisoni says.

Pending publication is new research that supports the effects of Mythocondro at 600 mg per day, Pisoni says. The randomized, double-blind, placebo-controlled study was carried out in 60 individuals over the course of 12 weeks. Researchers evaluated pain intensity at motion and rest using the Visual Analog Scale; knee function as assessed by the WOMAC Index; and knee pain, health-related quality of life, and inflammation markers in plasma at baseline, four weeks, and 12 weeks. "All endpoint results show a statistically significant modification of the parameters with impressive results related to the decrease in the WOMAC Index and the Tegner Lysholm Knee Scoring," says Lorena Carboni, product support specialist, Gnosis. Mythocondro can be used at a daily dosage of 600 mg, and offers a once-a-day alternative to larger chondroitin sulfate pills that need to be taken twice a day, the company says.

Pycnogenol, a French maritime pine bark extract from Switzerland-based Horphag Research, was the subject of a recent study published 2017 in the journal *Nutrients*[2], which showed that the polyphenols from Pycnogenol are distributed directly into the synovial fluid of patients with osteoarthritis.

The double-blind study examined 33 individuals diagnosed with severe osteoarthritis, and who were scheduled for knee replacements. Participants were supplemented with 200 mg of Pycnogenol daily over the course of three weeks leading up to their surgeries. Synovial fluid samples were collected during surgery to detect and measure the presence of polyphenols.

Results from the synovial fluid samples show that the polyphenols found in Pycnogenol, including taxifolin, ferulic acid, and catechin, were distributed throughout the synovial fluid in the Pycnogenol-tested group. Taxifolin and ferulic acid were not detected in control group serum samples. "This research further supports previous studies examining Pycnogenol's benefits for joint health, including the ability to reduce inflammatory mediators COX-2 and 5-LOX which helps alleviate discomfort," says Sebastien Bornet, vice president of global sales and marketing, Horphag Research.

Because many ingredients in the bone and joint health market are animal-derived, finding ethical and equally effective alternatives to appeal to clean label and vegan consumers has been an ongoing challenge and category driver. AIDP recently launched Phytodroitin, a 100% plant-origin alternative to chondroitin. According to Ford, the ingredient mimics the structure and function of animal-based chondroitin and is Vegan Society registered.

Finally, combination supplements are resonating with consumers in the joint health space. "Any of the popular combinations of nutrients designed for the bone or joint categories usually have a synergistic effect on each other," says Steve Holtby, president and CEO of Soft Gel Technologies Inc. (Los Angeles), "or often target the functionality of that category through different pathways to support the overall health of that system."

Some suppliers and formulators are meeting this trend by targeting systemic inflammation with ingredients like turmeric. Others are creating proprietary blends, as in the case of Valensa (Eustis, FL). "Formulations that attack joint issues from multiple pathways provide a better product overall and better differentiation for our brand partners," says Valensa senior vice president of global sales and marketing Doug Lynch. "In short, one physiological mechanism equals a better claim; multiple mechanisms equal a better consumer response."

Valensa's flagship joint formulation, FlexPro MD, received its 18th patent in 2018. Its FlexPro ES formulations capitalize on the synergy trend by offering egg membrane alongside astaxanthin. "Our FlexPro line works on synergies of multiple mechanisms to support your joints," Lynch adds. "Ultimately, FlexPro brings anti-inflammatory

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benefits to the joints themselves, and our use of phospholipids in the formulation—coming from krill oil or vegetarian sources—unlocks the antioxidant benefits of astaxanthin."

In support of synergistic formulas, Bergstrom Nutrition (Vancouver, WA) recently published a study demonstrating that adding 500 mg of MSM to glucosamine and chondroitin doubles the benefits of the latter ingredients[3]. And while Bergstrom's OptiMSM ingredient is beneficial as a standalone ingredient, this study makes the case that OptiMSM also delivers synergistic effects when formulated with other ingredients, says vice president of sales and marketing Tim Hammond.

Bioiberica plans to launch a new combination ingredient for joint and mobility in 2019, called Mobilee, the company says. It will blend hyaluronic acid with polysaccharides and collagen for joint function and muscle strength. According to Bioiberica's Reguant, this ingredient responds to the market trend that has evolved the joint health market to encompass bone and muscle health for overall mobility support.

At Lonza Consumer Health & Nutrition, DuoCap capsule-in-capsule technology can help "overcome complex formulation challenges by allowing manufacturers to incorporate traditionally incompatible ingredients together in one single dosage form," says Erickson, which addresses "diverse health needs from bone and joint health to cardiovascular and weight management."

Going forward, supplements that target athletic consumers will find favor, too, says Valensa's Lynch, as will those that step outside the box on delivery and offer vegetarian or vegan labels. Reguant agrees: "Convenient dosage and intake, effective and safe ingredients from natural origin, a reliable producer—that's what consumers are asking for."

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***Melissa Kvidahl** is a freelance journalist and copywriter specializing in the health and wellness industry.*

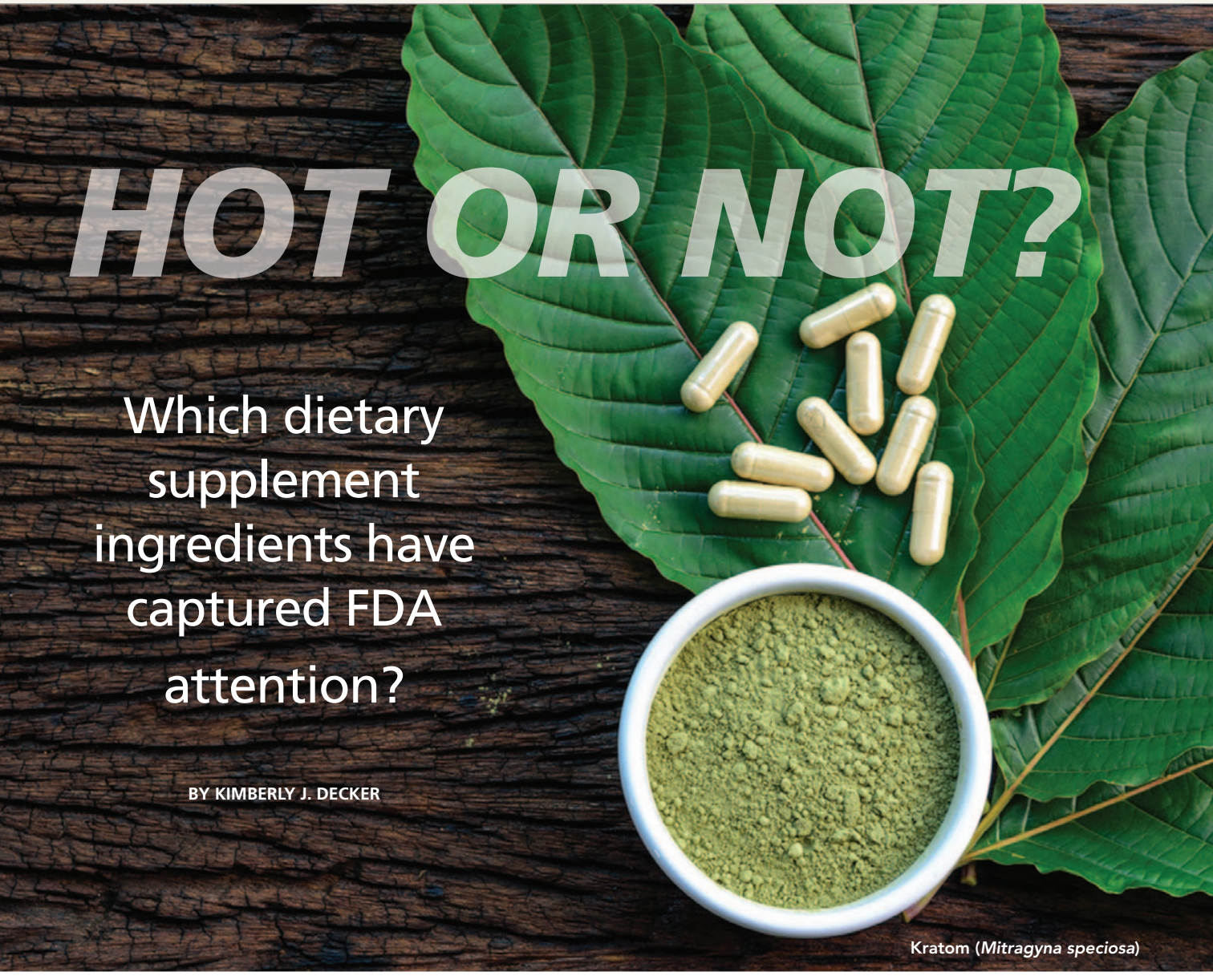
# QUALITY CONTROL:

## Playing the Long Game

# HOT OR NOT?

## Which dietary supplement ingredients have captured FDA attention?

BY KIMBERLY J. DECKER



Kratom (*Mitragyna speciosa*)

Close observers of the dietary supplement industry have their pick of metaphors for describing the sector's regulatory state-of-play: a jungle, a minefield, a game of whack-a-mole (or gotcha, if you happen to be one of the moles getting whacked). But given the current administration's inclination toward relaxed regulating, is FDA as ready, able, and willing as ever to take action against supplement ingredients that arouse its suspicion?

As far as attorney Justin J. Prochnow, shareholder, Greenberg Traurig LLP (Denver), can tell, FDA's eagerness doesn't always translate into escalated enforcement. "FDA continues to take action against companies selling products with ingredients it believes to be dangerous," Prochnow concedes. "But I don't really believe it's gotten any more heated than before."

### Reactionary Agency

Why not? Chalk it up to the downstream effects of starving the bureaucratic beast. Years of funding and personnel cuts have turned FDA into what Prochnow calls "a pretty reactionary agency" that focuses on ingredients mainly *after* they capture public—and congressional—attention.

Case in point: In 2010, FDA took action against "the Four Lokos of the world"—namely, Charge Beverages Corp. (Portland, OR), New Century Brewing Co., LLC (Boston), United Brands Company Inc. (Los Angeles), and Phusion Projects LLC (Chicago), maker of Four Loko—for marketing caffeinated alcoholic beverages, "but only after college kids started going to the hospital and congressional representatives started raising issues," Prochnow says.

"Then about four or five years ago," he continues, "there was a focus on caffeine in energy drinks and supplements—again when Congress raised issues. And about a year or two ago, FDA sent out warning letters about picamilon"—a nootropic synthesized from niacin and gamma-aminobutyric acid—"after Missouri Senator Claire McCaskill raised issues."

So with FDA's enforcement seemingly contingent upon the volume of congressional

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outcry, it's no wonder some brands "continue to push the envelope," says Prochnow, "selling products with the next alternative to ingredients that FDA's already questioned."

## Functional Foods the New Frontier

The trend has been especially evident in the functional food and beverage space, where a blurring of the boundary with supplements may encourage some brands to pursue ingredients that are common in the latter—activated charcoal, algae, and "medicinal" mushrooms like chaga, reishi, and cordyceps, Prochnow notes—but that aren't generally recognized as safe (GRAS) for use in foods and beverages.

Yet despite this, "It's a very rare occasion when FDA actually asks for GRAS confirmation from a brand owner," Prochnow says. "This cues many companies to push the envelope and include ingredients for which there's no previous evidence of GRAS. The result is more products on the market with questionable ingredients, leading more companies to think it's okay to use those ingredients."

## Grey Areas

To be fair, it isn't always clear which ingredients companies can conclusively consider "okay."

In the case of dietary supplements, a permissible ingredient must meet the definition of a "dietary ingredient" as spelled out in the Federal Food, Drug and Cosmetic Act—that is, it must be "a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances."

But some synthetic herbal and botanical extracts that would otherwise appear to meet these standards have caught FDA's attention "because they were never actually constituents of the original plant," Prochnow explains. And he's noticed "some difference of opinion" among experts as to whether processing can turn a previously established dietary ingredient into a new dietary ingredient (NDI) for which FDA would require safety notification from the manufacturer before it could appear in a product.

For example, while bitter orange extract is an established dietary ingredient, a bitter orange extract that a manufacturer standardizes to 30% p-synephrine qualifies as an NDI because the amount of p-synephrine that occurs naturally in bitter orange is only about 6%, Prochnow says. "So the view of whether an ingredient requires an NDI notification or not may depend on whose view it is: FDA's or the private brand owner's." (FDA released a revised NDI draft guidance in 2016, and though it falls short of settling all outstanding questions, it at least keeps the conversation going.)

## Clear Boundaries

"I would say the number-one thing FDA could do to make the line clearer is actually to take action and enforce issues like GRAS, or whether an ingredient is a dietary ingredient or not," Prochnow concludes. "As mentioned, FDA's regulation is somewhat sporadic and more reactionary than proactive. But tighter enforcement of GRAS and dietary ingredient requirements would result in a clearer demarcation between permissible and impermissible ingredients."

Adds Sylvia Laman, managing toxicologist for dietary supplements, NSF International (Ann Arbor, MI), "Supplement brands should feel encouraged to reach out directly to FDA when they're unsure about the regulatory status of a dietary ingredient. In addition, brands should collaborate with companies or individuals dedicated to substantiating the legal status and, more importantly, mitigating the risk associated with all ingredients used in product formulations."

## The Mouse Is Winning

For now, FDA's hamstrung posture gives the mouse an advantage in this perennial cat-and-mouse chase. "The agency has limited resources and must therefore prioritize acting on consumer safety," Prochnow says. "Thus, ingredients that might not technically be GRAS are unlikely to be challenged unless safety concerns are raised."

Paradoxically, brands are as likely to face a challenge these days from commercial retailers like Whole Foods or Target—"both of whom are more vigilant than FDA about ensuring that ingredients are legally permissible," Prochnow says—as they are from FDA proper.

So with uncertainty the only certainty, we asked the experts which ingredients have caught not just retailers' and regulators' eyes, but their own.

## Cannabidiol (CBD)


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FDA doesn't yet permit the food, beverage, or (some argue) dietary supplement use of cannabidiol (CBD), a non-intoxicating cannabinoid constituent of cannabis with proven therapeutic value. So far, their decision is based on what's going on in the pharmaceutical world.

Yes, marijuana remains on the DEA's list of Schedule 1 drugs; and yes, CBD's association with that much-maligned plant continues to cloud its reputation. But FDA's beef with CBD stems less from the agency's reefer madness than from an investigational new drug (IND) application that GW Pharmaceuticals (Cambridge, UK) filed for a CBD isolate in 2006. And as Greenberg Traurig's Prochnow explains, "If an ingredient was investigated as a new drug prior to being used in a supplement, food, or beverage, it's then precluded from being used in those products." (In June, FDA went full steam and approved GW Pharma's Epidiolex CBD drug, the first drug the agency has approved for those with a rare form of epilepsy called Dravet syndrome.)

Prochnow emphasizes that this IND-based prohibition differs from "an express law" prohibiting CBD's use—as would be the case with, say, a targeted regulation prohibiting the use of ephedrine alkaloids in supplements. "With CBD, it's FDA's *opinion and interpretation* of the law that precludes use," Prochnow says. "But many in industry disagree with FDA and are prepared to challenge it."

And how. Following the Epidiolex approval as a new drug, and while the agency maintains its position that CBD is not a permissible ingredient, agency personnel have confirmed that FDA "must prioritize enforcement activities with a likely focus on products making express disease-treatment claims—as for, say, cancer or epilepsy," Prochnow says.

The upshot: FDA has issued roughly 20 warning letters to companies selling products that contain CBD, but in each letter it's the companies' explicit disease claims that FDA takes exception to. "They're less likely to take action against companies making either structure-function claims or no claims at all," Prochnow notes.

In any case, opponents are running out of reasons to justify CBD's continued prohibition. "As more information comes out, it seems it'll be harder for FDA to keep CBD off shelves," Prochnow predicts. "Obviously, the age-old view of marijuana and cannabis as 'dangerous drugs' is continuing to evolve as more states legalize it."

Still, he counsels companies to "proceed with some caution." With FDA telegraphing its focus on disease claims, he suggests that companies pressing the issue pay careful attention to labeling and advertising efforts.

"This is probably the most changing area of regulation and enforcement in the FDA spectrum," Prochnow says. "Weekly, if not daily, we see new announcements about congressional bills being passed. FDA regulation—the status quo now—will likely not be the status quo at year's end."

## Kratom

If you haven't heard of kratom, you haven't been paying attention. After all, says John E. Villafranco, partner, Kelley Drye & Warren LLP (Washington, DC), "It's all over the news."

Known botanically as *Mitragyna speciosa* Korth., kratom is a tropical plant in the coffee family native to Southeast Asia with a long history of medicinal use for its purported stimulant effects at low doses and sedative ones at high. Advocates praise it as a pain killer, diarrhea medicine, recreational drug, and even treatment for opioid addiction.

Yet, says Villafranco, "Kratom has a very loyal and vocal following, as well as powerful adversaries." As evidence of the latter, FDA issued warning letters in May to three kratom marketers responsible for a total of 68 products—Front Range Kratom (Aurora, CO), Kratom Spot (Irvine, CA), and Revibe Inc. (Kansas City, MO)—alleging their illegal sales of unapproved kratom-containing drug products with unproven claims to treat cancer and opioid addiction and withdrawal, relieve pain, lower blood pressure, and reduce neural damage from stroke.

And as with CBD, FDA's chief complaint is with the drug claims—"not kratom's capacity as a dietary ingredient," Villafranco says. "Kratom marketers are making very strong claims related to cancer, diabetes, blood pressure, chronic pain, improved immune response,

stroke treatment, neurological disease treatment, and mood enhancement," he says. Such claims lie outside the structure-function realm that law permits for dietary supplements.

Complicating things further is kratom's presence in the opioid treatment space, which Villafranco calls "a lightning rod, considering the extent of this country's opioid epidemic." Because FDA considers kratom an opioid analogue, the agency believes it may actually *contribute* to opioid addiction rather than help curb it, Villafranco adds.

Six states have already banned kratom, and it wouldn't surprise Villafranco "to see that list grow in future months." But don't discount the substance's "fiercely loyal following," he argues. "Industry groups estimate there being 3 to 5 million kratom users nationwide, and they're organized. Just last week, the Kratom Community Grassroots, a nonprofit advocacy organization, led a week of advocacy on Capitol Hill. They appear to have a head of steam and aren't shying away from a fight. So we shall see."

Is FDA's concern justified? "Hard to say until we've seen the science," Villafranco concludes. "Certainly, a lot of consumers swear by kratom products. But their endorsement isn't enough. Government agencies need to evaluate the substantiation. So do marketers considering taking a kratom product to market. They'll need to rely on competent and reliable scientific evidence to make health claims. And they'll need to comply with the law if they insist on making drug claims."

## Caffeine

Demonstrating a flair for understatement, Prochnow describes caffeine's regulatory history as "very interesting." He can say that again.

While the compound occurs naturally in everything from coffee and chocolate to kola nut extract, when added to a cola-type beverage as an ingredient, caffeine falls under the strictures of the Federal Food, Drug and Cosmetic Act. And per that act, caffeine in amounts not exceeding 0.02% (200 ppm) is considered generally recognized as safe (GRAS).

"This doesn't mean you *can't* use it in other products," Prochnow notes, "but it must be established as GRAS through the GRAS self-affirmation process to go into use legally." And that's precisely what a number of companies have done.

But within the past few years, concerns have surfaced in Congress questioning caffeine's presence in applications ranging well beyond the usual territory of coffee, tea and, as Prochnow calls it, "soda pop." And though detractors initially set their sights on all caffeinated products, their efforts eventually shifted to those marketed toward children, with calls to limit levels, implement warnings, and impose other restraints in tow.

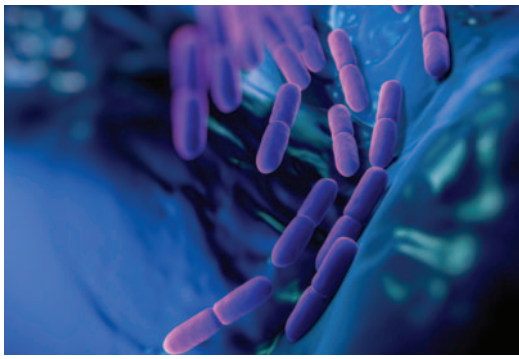
But congressional and media attention notwithstanding, "FDA has essentially come out and stated that caffeine in amounts around 400 mg or less per day is not unsafe for healthy adults," Prochnow says. Prioritizing safety over scare tactics, the agency targeted caffeine in alcoholic beverages as non-GRAS (see above re: Four Loko), and more recently took action against makers of highly concentrated forms of caffeine powder, citing safety concerns.

Ultimately, though, FDA's greater interest was in stemming the potential proliferation of caffeinated products across categories, including snacks, syrups—"even foods like waffles," Prochnow says—with the theory being that consumers would have a harder time keeping track of their daily intake if the compound were coming at them from all directions.

As for whether the concerns have merit, Prochnow believes that those related to alcohol, children, and high concentrations do. "Otherwise," though, "at some point, we have to let people regulate themselves."

## Probiotics

Probiotics have been such a supplement success story that, on one hand, it's almost



unimaginable that they'd be the subject of regulatory skepticism.

But on the other, it might be precisely their success that has watchdogs looking more closely at these "good gut bugs," and at how marketers are formulating with them and disclosing information about them.

Notes NSF's Laman, "From a certifier's perspective, labeling and safety substantiation for products formulated with probiotics may be inconsistent from brand to brand."

But absent direction on how best to evaluate the acceptability of probiotic dietary ingredients, she says, "supplement brands may consider it a pass to create their own standard. This could lead to probiotics being used in supplement formulations with potentially inadequate substantiation that they're legal dietary ingredients, or that the strains are reasonably expected to be safe at the recommended daily dose."

So trade associations and regulators worldwide are reaching the consensus that probiotic ingredients "should be labeled," Laman says, "and that risk associated with exposure should be mitigated at the strain level." Meanwhile, industry and certifiers continue to work with regulators "toward clear guidance on probiotics in an effort to relieve the confusion that supplement brands are experiencing."

## SARMs

Because the desire to grow fitter and stronger with a minimal input of effort is likely universal—and maybe even inevitable—there will always be a market for products that contain ingredients like SARMs (selective androgen receptor modulators).

But while these steroid-like compounds are no stranger to performance-enhancing products, they're also associated with such safety concerns as liver damage and

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increased risk for heart attack and stroke. And as far as FDA is concerned, they're unapproved drugs, which is why the agency issued warning letters late last year to Infantry Labs LLC (O'Fallon, MO), IronMagLabs (Henderson, NV), and Panther Sports Nutrition (Garfield, NJ) for distributing products containing SARMs.

Now Senators Orrin Hatch (R-UT) and Sheldon Whitehouse (D-RI) have introduced legislation that would not only place SARMs under the Drug Enforcement Administration's purview per the 2014 Designer Anabolic Steroids Control Act to cover SARMs, but would add SARMs to the list of Schedule III drugs and prohibit their illegal import, export, manufacture, and distribution.

While an analysis on Govtrack.us gives the bipartisan SARMs Control Act of 2018 a 3% chance of being enacted, the legislation has no dearth of support from within the supplement industry. In the wake of the act's introduction in April, leaders of organizations including the American Herbal Products Association (Silver Spring MD), the Consumer Healthcare Products Association (Washington, DC), the Council for Responsible Nutrition (Washington, DC), the United Natural Products Alliance (Washington, DC), and the U.S. Anti-Doping Agency (Colorado Springs, CO) released a joint statement directed at the bill's sponsors pledging "to work with you and all of Congress to deliver a strong bill to the President."

*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.*

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# RECALL READINESS

How ERP systems help companies mitigate risk and vet their recall preparedness.

**BY DANIEL ERICKSON, PROCESSPRO**

*Recall* is a word that no one in the manufacturing industry wants to hear. In addition, the negative attention that social media can circulate adds another dimension of fear over a recall incident. Disparaging tweets, unfavorable Facebook posts, or poor online reviews can project undesirable information about your products and company out of your control, producing long-lasting effects brought on by loss of trust and/or tarnishing the company's brand well into the future.

Unfortunately, recalls are not uncommon. FDA issued over 9,000 product recalls in 2017.[1] In fact, the Centers for Disease Control and Prevention estimate that one in six Americans get sick each year from foodborne illnesses.[2]

Mitigating the effects of a recall or preventing recalls from happening in the first place is essential. Being prepared is critical, and it's imperative your manufacturing company has an effective recall management plan and solution in place to identify and reduce unnecessary risks in your organization.

## Recalls Defined

Product recalls involve retrieving a batch or entire production run of an end product, usually involving a lot or many lots of the product or raw materials used to create the end product. Recalls are most common due to a defect or safety concern, including due to undeclared ingredients or allergens, inadequate plant safety, mislabeled products, cross-contamination, or lack of temperature control. The procedures involved in executing a recall are tedious, thorough, and involve oversight by the FDA.

Your company needs to be proactive rather than reactive in addressing safety concerns. It's important to ensure unsafe products are removed from store shelves and reported per regulatory standards in a timely manner.

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## Recall Costs

Recalls happen to even the most conscientious of companies; yet, it is how a company responds to a recall that makes a difference in mitigating negative blowback. Failure to handle a recall effectively has serious consequences both financially and legally. Being unprepared leaves your company open to risks and potential litigation, including the inability to recall a product, untimely recall handling, or lack of compliance with governmental regulations, all causing potentially devastating consequences.

Even with the most comprehensive recall management plan, both direct and indirect costs can occur. Direct expenses include laboratory testing, production stoppage, overtime pay, legal penalties, class action lawsuits, managing the return and disposal of affected products, and post-recall marketing efforts to lessen the negative effect on your company's reputation. Indirect monetary effects include erosion of customer confidence, stock price instability, and loss of brand loyalty and future sales—all costing your company in unquantifiable ways that will require damage control.

## Consumer Attentiveness

Consumer are increasingly growing aware—and concerned—about safety in the food supply chain. Health demands from the public further highlight the need for recall preparedness to meet supplier, retailer, and regulatory expectations.

Pressure to meet these rising expectations has become a focus of companies as they strive to foster transparency throughout their manufacturing operations. Consumers are oftentimes the driving force behind increased governmental regulations as their knowledge prompts legislative change regarding the quality, safety, and health benefits of products consumed. Today's increasing connectivity of consumers makes them a voice to be heard by all manufacturers.

## Recall Prep: As Easy as 1, 2, 3

To institute a successful recall, three steps must be taken to mitigate risk and plan for the possibility.

**1. Utilize Effective Tools**

Ensure that you have a documented, FSMA compliant Food Safety Plan. A recall procedure should include integral components such as an appointed and properly certified coordinator, traceability procedures, contact information for regulatory agencies and legal counsel, sample notification letters for media and retailers, and access to a current list of customer purchase history. A chain of command should also be designated to establish protocols and accountability for implementation of the plan.

An industry-specific ERP (enterprise resource planning) software solution is a vital tool in recall preparedness and effective management. ERP can assist with helping to prevent and execute a product recall. A real-time, integrated software with full forward and backward lot traceability and allergens tracking saves time and eliminates errors caused by manual methods and disparate systems, providing timely identification and location of possible contaminants.

An ERP system can help you achieve end-to-end traceability, maintaining a comprehensive record that tracks ingredients and products throughout the supply chain using barcode scanning, linking product and lot information to batch tickets, shipping documents, and labels. Certificates of analysis (CofAs) and quality-control tests can be generated to bolster preventative measures in production, ensuring product consistency.

ERP functionality supports current Good Manufacturing Practices (cGMPs) and FDA requirements and industry regulations with the ability to manage and retain detailed inventory information, allowing raw materials and finished projects to be located quickly within the first maximum 24-hour time period of a product recall.

**2. Develop a Communication Plan**

The value of communication is often overlooked, but its impact on recall preparedness is immense. Failure to address proper communication channels can have devastating consequences, worsening the impact of a product recall on your brand and reputation.

Establishing a sound and comprehensive communication plan that details recall efforts to all stakeholders and that involves ways to test the plan's effectiveness and resolve any communication issues through practice is key. Once in place, a plan can help to drive the recall process and deliver consistent and timely company messages to the appropriate individuals. These elements should be included in the communication plan:

- Identification of stakeholders affected by a recall, both internal and external
- Clearly defined communication methods and updated contact information
- Detailed responsibilities for each communication team member
- Key messages that address disposal procedures, risks, and concerns
- Press release templates and other communication channel templates
- Document procedures for notifying regulatory bodies

Having a communication plan in place prior to a product recall allows for the efficient and effective sharing of critical information to necessary individuals. An ERP solution retains contact information of stakeholders and regulatory bodies and detailed data records, including purchase orders, bills of lading, CofAs, and shipping information to easily identify affected outlets and consumers.

**3. Perform Mock Recalls**

The importance of mock recalls cannot be stressed enough. The adage "practice makes perfect" is truly applicable in this setting. Even though regulatory requirements do not require a company to conduct mock recalls, they're a crucial component of your company's preparedness plan and should be considered a best practice for process manufacturers. With an integrated ERP system at the helm to guide the mock recall process, you're able to test and refine plans regarding recall procedures.

Simulated exercises test recall procedures, the goal being the ability to locate 100% of designated products within the assigned timeframe and notify interested parties. Employees also have the opportunity to familiarize themselves with procedures and responsibilities within the plan.

While a successful simulation involves being able to locate all contaminated products and notify clients, vendors, and government

agencies quickly, ideally the goal is to identify trouble spots to improve the plan. Conducting a mock recall identifies issues, mistakes, and deficiencies of the plan and allows your company to refine the key personnel, processes, and the communication plan. Multiple mock recall simulations may be necessary to solidify procedures. Your organization should develop a schedule for regular performance of mock recalls to evaluate the recall plan's effectiveness.

## Recall Ready

An industry-specific ERP solution supports the following for recall preparedness:

- Full forward and backward lot traceability
- Allergen tracking
- In-process quality-control testing
- Historical data recordkeeping, including batch tickets, bills of lading, CofAs, and shipping documents
- Easy identification of possible contaminated products and batch tickets
- Real-time location of raw materials and finished goods
- Mock recall practices

With the time, money, and effort you've expended to bring your company's products to market, it's important to make sure a recall doesn't destroy your efforts. Implementing proactive measures and crafting a well managed response plan prevents recalls and saves lives while allowing your brand to continue to thrive. With effective tools, a detailed communication plan, and utilization of mock recalls, you'll have a well-thought-out, well-executed plan to succeed and remain competitive in the marketplace in the event of a product recall. N

*Daniel Erickson has been with ProcessPro since 1999. As ProcessPro product strategy manager, Erickson focuses on driving overall market success by ensuring products meet both current and future market demands. His diverse experience with the customer base within the food, beverage, nutraceutical, personal care, pharmaceutical, cannabis, and chemical industries within ProcessPro provides a strong foundation for his position.*

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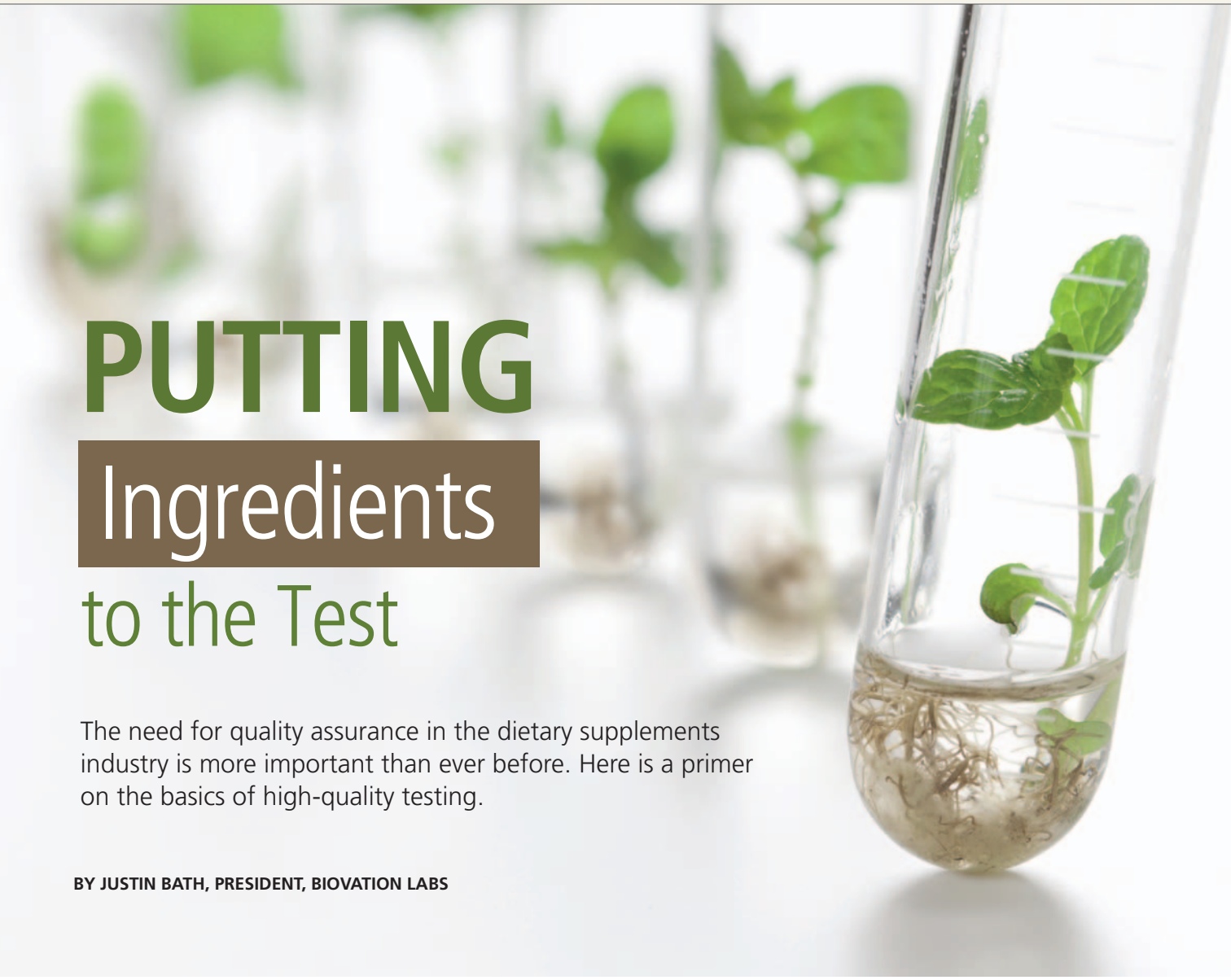

# PUTTING Ingredients to the Test

The need for quality assurance in the dietary supplements industry is more important than ever before. Here is a primer on the basics of high-quality testing.

**BY JUSTIN BATH, PRESIDENT, BIOVATION LABS**

*Test*. The word itself can raise blood pressure and bring back unbidden memories of unprepared students awaiting the scores of their high school chemistry exams. Out in the "real" world, particularly in the natural products industry, the word *test* means something completely different. It means trust; it means quality; and above all, it means safety.

Nutraceutical and dietary supplement makers are responsible for manufacturing the highest-quality products possible. As more companies recognize the need for heightened quality assurance, there has been a widespread shift wherein more firms are choosing to partner with contract manufacturers who can help handle and manage the manufacturing and testing of high-quality products.

Partnering with contract manufacturers brings several benefits, not least of which is that these companies are, or should be, familiar with the proper processes and procedures required to comply with the regulations governing these products. Such compliance should be second nature to them.

## Good Manufacturing Practices

As part of its dietary supplement current good manufacturing practices (cGMPs; 21 *CFR* 111), the U.S. Food and Drug Administration (FDA) says that to ensure the quality of the finished product, manufacturers are responsible for establishing specifications for identity, purity, strength, and composition related to components of dietary supplements (21 *CFR* 111.70). They are also responsible for establishing limits for the types of contamination that may adulterate or lead to adulteration of the finished batch of the dietary supplement.

These cGMPs are designed to prevent the inclusion of the wrong ingredient, the addition of too much or too little of an ingredient, the possibility of contamination, and the improper packaging and labeling of a product. The manufacturer must then ensure that the tests and examinations they use to determine whether these specifications are met are based on appropriate, scientifically valid methods. (21 *CFR* 111.75)

## Defining *Test*

What is interesting is that these cGMPs do not dictate which specific tests and examinations

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a company should use to substantiate that established specifications are met, only requiring that test methods be appropriate ( fit for purpose) and scientifically valid. Perhaps unsurprisingly, because margins can be thin and competition fierce, some manufacturers, even contract manufacturers, take half-measures or skip critical tests in an effort to save money.

## What to Test for

For those responsible companies seeking high-quality, fit-for-purpose test methods, the following are examples of what is involved when testing for identity, purity, strength, and composition.

## Identity

Identity testing means testing to make sure the raw material in hand is what it's claimed to be. The way to test for identity is to compare a sample of the raw material against a reference standard of that raw material. This is often accomplished by using Fourier-transform infrared spectroscopy (FTIR).

FTIR is used to make a qualitative match. A beam comprising many frequencies of light at once is shined at the sample. FTIR measures how much of that beam is absorbed by the sample. Next, the beam is modified to contain a different combination of frequencies, yielding a second data point. This process is repeated several times to infer what the absorption is at each wavelength.

This process compares the sample's test results with the test results from a reference standard. The reference standard can either be an internally provided standard or be obtained from an outside, independent standard provider, such as the United States Pharmacopeia (USP). The USP standardizes many types of raw material samples, which manufacturers can use to verify the identity of the sample raw materials they have.

Other tests that can satisfy the Dietary Supplement cGMP identity-verification requirements include:

- HPLC (high-performance liquid chromatography)
- TLC (thin-layer chromatography)
- NIR (near-infrared spectroscopy)
- Organoleptic testing
- ELISA (enzyme-linked immunosorbent assay)
- SNIF-NMR (site-specific natural isotope fractionation–nuclear magnetic resonance)
- IRMS (isotope ratio mass spectrometry)
- Wet-chemistry methods

## Purity

If a contaminated product makes its way into consumers' hands, a number of problems can arise, some potentially harmless and some potentially deadly. When the contamination could cause a product to result in harm if consumed, the product is deemed adulterated. According to the Dietary Supplement Health Education Act (DSHEA) of 1994, adulteration of a dietary supplement occurs when:

- A product presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or even if no conditions of use are suggested or recommended in the labeling but when the consumer uses the product under ordinary conditions of use
- Contains a new dietary ingredient (NDI) for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury
- Regulators declare that a product poses an imminent hazard to public health or safety
- The product is or contains a dietary ingredient that renders it adulterated

Purity tests look for contamination to ensure there are no microcontaminations or metals. These include tests for yeast, mold, chloroform, salmonella, *E. coli,* and heavy metals.

Full-panel tests for microorganisms like *E. coli,* yeasts, molds, etc., are well advised. Tests can be carried out to determine a total number of organisms on a surface, device, or instrument, or in a product. A surface is swabbed to collect bacteria. The collected material is measured (counted) against a standard. A count lower than the standard indicates no danger; a count higher than the standard indicates the opposite. Tests include, but are not limited to, sterility, general microbiology, and bioburden testing.

For heavy-metal testing, one method used is inductively coupled plasma mass spectrometry, or ICP-MS. This is an analytical technique used for elemental determinations. It is performed by ionizing a sample with inductively coupled plasma and then using a mass spectrometer to separate and quantify those ions.

## Strength

Testing for strength is testing to determine how much of the active ingredient is present in a particular dosage. Testing for strength is performed by HPLC. HPLC measures how much of an active ingredient is present.

## Composition

Each component of a dietary supplement needs to be verified to ensure what is listed on the label matches what's in the bottle. There are two categories of supplement component: 1) dietary ingredients, and 2) non-dietary ingredients.

DSHEA defines the five categories of substances that qualify as dietary ingredients: a vitamin; mineral; herb or other botanical; amino acid; or a dietary substance used to supplement the diet to increase the total dietary intake of a nutrient; as well as a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. Non-dietary ingredients, on the other hand, include ingredients like fillers, artificial colors, sweeteners, flavors, or binders.

Testing requirements for dietary and non-dietary ingredients are different. Non-dietary ingredient suppliers must be validated and approved by a manufacturer. Dietary ingredients are generally tested in a qualified laboratory to ensure they meet standards and specifications.

## Testing Processes

It is important to note that cGMPs require testing at the beginning and at the end of manufacturing, as well as in-process. Also, while contract manufacturers should be following the testing protocols listed above, nutritional supplement brand owners are ultimately responsible for confirming that products produced under its label conform to FDA's requirements. The brand owner can be held responsible for selling non-conforming and/or adulterated prod-

uct, so it is important that companies choose a contract manufacturer carefully.

Understanding the requirements as outlined in 21 *CFR* Part 111 is essential for anyone producing a nutritional supplement. Choosing the right manufacturer is an important part of the process, and all brands should ensure they are properly educated on the FDA requirements. Below is a list of some of the most basic testing requirements a brand should understand when producing nutritional supplements. (Note: this list is not intended to be all-inclusive.)

- Raw material validation and testing (purity, potency, strength, and composition)
- Production testing to ensure all equipment is clean and properly calibrated
- In-line checks at regular intervals to confirm lots and batches are being produced to specification
- Finished-goods validation and testing (purity, potency, strength, and composition)

Finally, it is important for a brand to ensure that its chosen manufacturer follow all cGMP processes before releasing finished goods. Understanding and auditing how products are released at multiple stages in the manufacturing process will help any brand provide the highest-quality product possible.

## The Future of Testing

Just like in high school, more tests are on the way. For instance, NSF International recently launched an independent testing protocol and verification program for raw botanical ingredients used in the dietary supplement industry. This protocol not only utilizes advanced DNA authentication of the target species, the testing program also screens for contamination, including common adulterants, toxic adulterants, allergens, and fillers.

Moving forward, tests such as DNA sequencing with real-time (qualitative) polymerase chain reaction testing (PCR) will help to continue to propel individual products as well as the entire industry towards greater levels of safety and quality. N

***Justin Bath*** *is president of Biovation Labs, a contract manufacturing, formulation, private label, and supplier company serving the natural products industry. The company works within the life science space, manufacturing products for supplement and nutraceutical companies worldwide. Its new 104,000-sq-ft corporate headquarters houses a state-of-the-art, high-capacity manufacturing facility serving the needs of both large and early-stage companies. Biovation Labs follows cGMP standards. For more information, visit www.biovationlabs.com.*

# PLANNING for Quality

## How a Quality by Design model can benefit the dietary supplements industry at large

**BY JENNIFER GREBOW, EDITOR-IN-CHIEF**

Quality by Design (QbD) is a quality-assurance model centered on preemptively building in QA controls from beginning to end. QbD has captured the interest and following of global industries, including automotive and pharmaceutical, as well as the attention of regulators worldwide.

Christen Davis, director of quality, Lonza Consumer Health & Nutrition (Greenwood, SC), recently talked to *Nutritional Outlook* about how Lonza Consumer Health & Nutrition has implemented QbD, what it entails, and how this model can benefit all dietary supplement manufacturers.

***Nutritional Outlook:*** **As a capsules supplier, Lonza Consumer Health & Nutrition sources the ingredients required to produce its capsules and also, through capsule filling, often has an extended view of the ingredients filling a capsule. In this scenario, how does a QbD model fit in?**

***Davis:*** An integrated supply chain is the foundation of quality. Each unit contributing to the product—internally and externally—must be unified and aligned on product and testing expectations. They partner together to improve performance.

The cornerstone of a QbD model is to clearly define expectations with partners—and then require that they are met. For ingredients, Lonza CH&N searches out raw material suppliers who understand the regulatory guidelines for safety and efficacy. Manufacturers should do the same. We want to know we are receiving what we ordered, and so should any supplement manufacturer. One way to ensure this is to outline contractually enforceable purchase specification standards based on worldwide regulations and guidelines. Some of the key standards are:

- Identity: Is the ingredient actually what the supplier says it is?
- Strict purity criteria
- Impurity limits to include contaminants, elements, and solvents
- Viral safety guarantees for animal-derived ingredients (in our case, bovine for capsules)
- Biological safeguards as it relates to GMOs
- Controlled use or absence of allergens

The clearly defined standards can be applied to each and every supplier. The supplier should not be used unless it can meet these specifications with very little variation. This can weed out any bad apples and ensure consistency of product for a manufacturer.

**What kind of quality assurance challenges has your company observed in the market?**

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*Davis:* In a QbD operation, all divisions are integrated and all are functioning at the top of their games. But challenges will and do arise. Here are some examples of what we have seen and heard—and our thoughts on solutions.

**Capsule filling:** When customers run their own capsule-filling operation, higher levels of defects can surface, ranging from ingredient leakage to cracked capsules. This can slow down filling speed and reduce yield, leading to waste and downtime. These issues can be solved with a QbD approach to matching the capsule-filling machine with the right capsule for the specific density and dosage amount for the ingredient.

**Audit readiness:** Unplanned audits can be tense. But an unexpected visit from a regulatory agency can be anticipated and "planned" for if a company sets up an Internal Audit Program (IAP). The IAP is a self-policing system that ensures cGMP requirements are met at every step. The IAP is a list of items checked and reviewed on a regular schedule. The checklist helps identify what is working and what is not working and needs to be corrected immediately. It also signals what could potentially go wrong, spurring preventive action to minimize corrective action. Red flags can be raised by the trends that emerge in regular periodic reports from internal tracking of the records kept by various divisions. When all departments and supporting operations are on constant lookout for issues as they arise, quality can be reinforced daily and a culture of "readiness" for audits can be cultivated.

**Laboratory and manufacturing operations:** Cleanliness and organization is imperative to ensuring a succinct quality program. When labs or operations are not using organized techniques, it only leads to more questions.

**How can your company's Certified Vendor Program serve as a model for enhancing quality and legal compliance? Can you describe some of the most important steps in such a program?**

*Davis:* Lonza CH&N follows several key steps in the verification of a supplier from any region of the globe to assure the supplier meets our stringent cGMP screening that the material supplied is safe, pure, and effective. It includes:

- Creating a purchasing specification based on a validated method and assuring the supplier can meet it

*"The cornerstone of a Quality by Design model is to clearly define expectations with partners—and then require that they are met," says Christen Davis, Lonza Consumer Health & Nutrition.*

- Thorough review of all documentation and descriptions of manufacturing processes
- Obtaining certifications from third parties like NSF cGMP, ISO 9001-2015, etc.
- Obtaining three consecutive lots of materials to test against the purchasing specification
- Performing onsite audits

All our vendors must go through the same level of scrutiny and meet the same standards as part of FDA guidelines.

As already stated, Lonza CH&N insists on security of capsule raw material. Our Supplier Selection and Qualification Program guarantees that our hard capsules meet the highest standards for quality, traceability, and integrity. This core five-phase program requires critical key raw materials suppliers to undergo an intensive, year-long selection and qualification process to make sure they meet the most stringent regulatory and industry standards that exist anywhere in the world. Here are the five components:

- **Preliminary investigation:** reviews the supplier's quality system, state of manufacturing technology, and scope of products and services offered and determines the supplier's performance metrics in details
- **Manufacturing-suitability evaluation:** assess the crucial issue of whether the supplier's raw materials is compatible with Lonza CH&N's manufacturing processes and protocols
- **Production trial:** use of supplier's raw material in large-scale, high-volume production trials at various Lonza CH&N sites to confirm both finished capsule quality and manufacturing efficiency performance levels
- **Onsite audit:** full traceability exercise and quality system check to ensure compliance with applicable and Lonza CH&N standards
- **Acceptance contract:** formalizes the technical and commercial requirements and expectations, including both initial scale-up support and ongoing quality

Once suppliers are selected and qualified, we consistently monitor them to ensure ongoing quality. The evaluation process assures supply chain traceability and finished capsules that comply with the highest standards. The management involves constant testing and regular in-depth onsite audits.

**How do these insights and quality-control best practices benefit the customers that work with the company?**

*Davis:* Lonza has created white papers about its CVP and other quality initiatives. These have been shared directly with customers at trade shows and face-

*The investment in a quality system can save a business money as well as yield dividends for reputation and business growth in the long run.*

to-face meetings. In addition, they are available for review on our website and through online trade publication exposures. We also offer to directly pass on our knowledge to our manufacturing customers by showing them how to integrate processes from a QbD model to their operations where appropriate. We partner with them to establish processes that will help them to become more self-sufficient and successful. Our Quality Engineering Services (QES) can collaborate with them through the entire manufacturing process, from receiving raw materials to supplement applications and production to improving capsule-filling productivity to bolster profits.

As a more specific example, we can conduct an audit of a manufacturer to assist them in setting up a regulatory foundation for their operation. We also embrace customer audits and visits to our facilities to educate and openly show them our quality processes to better understand them so they can more easily adapt them to their own businesses. On-site visits help us both keep ahead of the latest regulations and be "audit prepared" at all times.

Finally, through spearheading and hosting an annual Quality Summit, Lonza has stepped onto the national podium as a quality torchbearer and industry educator. At the events, we share our practices in presentations and Q&A panel discussions. We also bring together quality industry leaders to voice their opinions and fresh thinking about how to assure quality, adapt to regulatory challenges, manage risk, and develop best practices. The August 2017 summit hosted 80 quality professionals from North America at our Greenwood, SC, manufacturing headquarters for the Americas. In October 2018, Lonza will host another Quality Summit in Greenwood.

**Why is it important for everyone in the supply chain, from the ingredient suppliers to the dosage provider to the contract manufacturer and the marketers themselves, to have a solid quality-control process and to consider implementing a QbD model?**

*Davis:* First and foremost, because this is how to best serve the consumer. If all suppliers are in sync with quality-control processes, specs, and criteria, products can not only meet consumer expectations but work to exceed them. A brand can cultivate a reputation for going far beyond Acceptable Quality Levels and race far ahead of their competition. Consumers will catch on and keep spending for top-notch products that are known to be safe and effective.

Integrated quality controls throughout the entire supply chain allow a manufacturer to be "audit prepared" at all times. This is very good for business. Knowing their products would comply to regulations with flying colors, a manufacturer and brand can remain consistently competitive because their products can be released to markets confidently and quickly, without worries of shutdowns or recalls due to consumer complaints or unplanned visits from regulatory bodies.

A solid quality-control process is more economical. Sure, there are upfront time and monetary expenditures to set up processes and certify vendors plus ongoing outlays for upkeep and monitoring. But consider how expensive it can be without such controls. There can be costs for defects of products already released, product waste, unproductive labor, and excessive testing, as examples.

From this vantage point, the investment in a quality system can save a business money as well as yield dividends for reputation and business growth in the long run. N

## Saffron Extract Improves Depression and Anxiety in Teenagers

Results from a new study indicate that saffron *(Crocus sativus* L.*)* may help reduce depression and anxiety symptoms in teenage children. The first-of-its-kind study found that supplementation with Affron, a branded saffron extract from biotechnology firm Pharmactive Biotech Products (Madrid), improved feelings of separation anxiety, social phobia, and depression in young people.

The randomized, double-blind, placebo-controlled study[1] included 68 young people between the ages of 12 and 16 with mild-to-moderate anxiety or depressive symptoms. According to data from the World Health Organization, the study authors write, psychiatric disorders including anxiety and depression are among the leading causes of disability in young people, with as much as 15%-20% of the youth population experiencing an anxiety or depressive disorder before the age of 18. Saffron, they add, has been shown to be effective in reducing feelings of depression and anxiety in adults with mild-to-moderate depression. However, saffron for depression and anxiety had not yet been studied in a youth population prior to publication of the current study, they said.

The researchers divided participants into two groups. One group received 14 mg Affron, while another group received the same dosage of a placebo. Both groups were instructed to take one tablet of either Affron or the placebo twice daily for a total of eight weeks. In order to determine what effects supplementation with Affron had on parameters of anxiety and depression, participants completed a 47-item questionnaire called the Revised Child Anxiety and Depression Scale (RCADS). RCADS includes subscales on separation anxiety, social phobia, general anxiety, panic, obsessions and compulsions, and depression. Subjects' parents also completed the parent-report version of RCADS; those results served as the secondary outcome measure.

The group supplemented with Affron reported improvements in overall internalizing symptoms, separation anxiety, social phobia, and depression, compared with the placebo group. Parental reports of improvement in the subjects' mental health were inconsistent. The researchers thus concluded that "administration of a standardized saffron extract (Affron) for eight weeks improved anxiety and depressive symptoms in youth with mild-to-moderate symptoms, at least from the perspective of the adolescent." Affron was also found to be safe and well-tolerated.

The study authors write that while the results are encouraging, the self-reporting nature of this study represents a limitation. Pharmactive Biotech Products funded the study.

1. Lopresti AL et al., "Affron, a standardized extract from saffron *(Crocus sativus* L.*)* for treatment of youth anxiety and depressive symptoms: a randomized, double-blind, placebo-controlled study," *Journal of Affective Disorders*. Published online February 26, 2018.

## Can Astaxanthin Give Sun Protection to Human Skin?

Could the red carotenoid astaxanthin, which makes crabs and other animals red, one day be found in sun-protection products? Algatech Ltd. (Kibbutz Ketura, Israel) is a manufacturer of natural astaxanthin from microalgae. Recently, FujiFilm (Kanagawa, Japan) conducted a research study on Algatech's astaxanthin ingredient, which is featured in FujiFilm's branded supplement, Astots. The FujiFilm researchers sought to examine what happens to humans when their skin is exposed to UV light after oral consumption of astaxanthin. Results of their study[1] are now published in the journal *Nutrients*.

Twenty-three subjects were assigned to a 4-mg supplement of astaxanthin or placebo daily for nine weeks. Their skin was irradiated at the beginning of the study and after nine weeks of daily astaxanthin intake to see if any skin changes would be detected.

According to the researchers, astaxanthin intake was associated with a higher minimal erythema dose (MED), meaning the amount of UV exposure required to visibly redden the skin. This effect was linked to a reduction in epidermal water loss. A subjective visual and touch assessment of non-irradiated skin yielded higher scores following astaxanthin.

While the skin parameter improvements are believed to result from astaxanthin intake, the company claims that its patented dispersant technology may have also been an important factor. The company says its technology has been shown to improve astaxanthin absorption in the body.

This latest study banks on previous animal and cell studies, as well as a cosmetic trial on women,[2] that have found astaxanthin may have sun-protecting effects. A weakness of this latest study, however, is that outside dietary astaxanthin intake was not monitored. The study took place in Japan, where astaxanthin-rich crab, shrimp, salmon, and salmon roe are common foods. Had these researchers measured blood and/or skin levels of astaxanthin in each study participant, they believe their study design would have been even stronger.

Astaxanthin is believed to protect the skin from UV damage by acting as an antioxidant that can reach the epidermis. The nutrient seems to protect itself from UV damage, too, since it's best grown commercially in extremely sunny environments. Still, the precise mechanisms by which astaxanthin may function against UV light in humans and plants are yet to be fully understood.

Algatech Ltd. supplied its AstaPure astaxanthin to Fujifilm for this study. Its astaxanthin is sourced from the microalgae *Haematococcus pluvialis,* which Algatech grows in the Arava desert of Israel where sun is always plentiful. N

1. Kaoki I et al. "The protective role of astaxanthin for UV-induced skin deterioration in healthy people—a randomized, double-blind, placebo-controlled trial." *Nutrients*. Published online ahead of print June 25, 2018.
2. Akira S et al. "Effects of the intake of astaxanthin on the reduction of skin darkling induced by UV irradiation in adult women." *Pharmacometrics*, vol. 80, no. 1–2 (March 7, 2011): 7–11

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# GOT **BLUE?**

## Why blue is the Holy Grail of natural colors in beverages

**BY JENNIFER GREBOW, EDITOR-IN-CHIEF**

Social media has spurred changes good and bad—among them, an obsession with photographing food. Today, it's not enough for food to taste good; it has to *look* really good. But sometimes, making food look good is hard. Take ready-to-drink (RTD) beverages. Drink makers are always searching for vibrant, arresting colors to catch consumer attention, whether via Instagram or on a market shelf. These same manufacturers, however, have also been tasked with using natural colors in place of artificial colors—and natural colors sometimes just don't stand up to the look and performance of artificial colors, especially in a drink matrix.

"To be successful in beverage applications, natural colors need to be able to withstand pasteurization temperatures as well as be heat and light stable at the desired pH," explains Cori Satkowski, lead product development technologist for supplier California Natural Color (Fresno, CA).

Natural blue is often considered the Holy Grail of the beverage industry. One of the few natural blue sources today, spirulina extract *(Arthrospira platensis),* was FDA-approved as a color additive in 2013, but spirulina still struggles in acidic beverages and under high-heat processing. While blue is one of the most requested natural colors for beverages, "the industry is looking for a natural replacement to [FD&C] Blue No. 1 and No. 2 that can overcome the acidic pH in beverage applications," Satkowski says.

In acidic beverages, the color of spirulina extract "may fade rapidly or precipitate," says Winston Boyd, PhD, technical director at Gold Coast Ingredients (Commerce, CA). Spirulina extract "functions best at a pH between 4 and 8, and it still must be protected from heat and light," he explains.

"In low-water-activity, fat-based systems, spirulina is great. As soon as you add water or heat, not so good," seconded David Rigg, director of global food marketing for Sensient Colors LLC (St. Louis), at this summer's Institute of Food Technologists' Annual Meeting & Food Expo (IFT) in Chicago.

These obstacles don't just limit natural blue. "Any shades that use blue have been challenging for the industry for a while—so, purples, greens, browns, which do use blue as a primary color, are a bit of a challenge," said Mukul Juneja, vice president, marketing, for Archer Daniels Midland's Wild Flavors and Specialty Ingredients division (São Paulo), at the IFT show.

Given spirulina's sensitivities in beverages, color suppliers have explored other sources. One of them is a tropical plant called huito *(Genipa americana).* Huito is said to be more stable in acidic pH and less sensitive to heat and light compared to spirulina. Wild Flavors and Specialty Ingredients offers huito sourced from the Amazon region of Peru as a blue colorant. Juneja called it "the only natural blue that's acid and heat stable."

Huito yields a different shade of blue than spirulina, which Juneja said his company also supplies. "It's not the same blue shade," Juneja said. "Spirulina is going to be a traditional, brighter blue, and huito tends to be more grayish, kind of a navy shade or a shale blue." By using both spirulina and huito, he added, Wild Flavors can achieve "a great range of different blue shades, and those blue shades then allow us to do all sorts of different purples and greens and browns."

As a color, huito is used more as a fruit juice than an extract and thus does not require an FDA color additive petition, companies say—a process that can take "anywhere from five to 10 years," Juneja said. When asked whether one can get the same color intensity from a fruit juice as opposed to an extract, Juneja said, "It just depends on the strength of the color you're looking for. Sometimes the juice is not strong enough, so then you may need an extract."

At the IFT show, Sensient's Rigg said his company has a "novel," proprietary natural blue source that isn't huito and that is stable, especially in less-acidic drinks. Rigg called the source "a unique anthocyanin."

Its color is actually a purple that appears blueish depending on the pH range, he said. "It's our source that we've discovered that provides a wonderful purple—really deep grape—in the low-pH range, and it's blue at the higher [less acidic] pH ranges. It's a beautiful blue, more like a Blue No. 2. It's more of a denim blue at higher pH ranges, but in the low-pH range, it will be a deep, beautiful purple."

As for blue for more acidic beverages, "Today, there's still a gap for that," Rigg added. "It's something we continue to look for."

Color suppliers continue to search for sources that make business sense. "I would say shade, stability, and cost are the areas we're exploring," Juneja said, noting that some natural color sources may not be practical if they are too expensive. "You'll see more innovation in those three areas, and sometimes it's also about modifying what you already have," he added.

Are we likely to find other natural sources for the color blue in the future? When asked if there are a lot of untapped potential natural color sources in general, Juneja said, "Oh, yeah, there are tons of them. I mean, if you think about colors in nature, most fruits and vegetables have unique shades. So there are a lot of sources we have not tapped yet." Maybe that's something to chase away formulators' blues. N

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