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FDA's new dietary ingredient (NDI) draft guidance has raised plenty of rancor among the dietary supplements industry in its time. The agency's second stab at the guidance, the revision issued this August, was more warmly received than the first draft in 2011, but there are still many who fear the NDI guidelines will hurt the industry financially and in terms of growth.

Now, there is one more thing to fear.

On September 7, FDA shocked the industry when it published a Federal Register notice "tentatively" concluding that the ingredient vinpocetine is not a dietary ingredient (and therefore could be banned from dietary supplements). Vinpocetine, a synthetic ingredient produced from the alkaloid of the periwinkle plant (Vinca minor), does not meet the Federal Food, Drug, and Cosmetic Act's (FD&C Act) definition of a dietary ingredient for several reasons, FDA said: 1) the ingredient is not considered to be a vitamin, mineral, or amino acid, 2) because the ingredient is synthesized, it is not considered to be an herb or a botanical, nor a constituent, extract, or derivative of an herb or a botanical, 3) there are apparently no food uses of vinpocetine to indicate that the ingredient is intended to be a "dietary substance for use by man..." Oh, and there's one more thing, the agency said: it turns out that vinpocetine, before its debut as a dietary supplement ingredient, was authorized in 1981 for scientific investigation as a new drug, and according to the FD&C Act's investigational new drug (IND) rule, this nullifies vinpocetine's status as a dietary supplement ingredient.

There's just one catch, though: FDA itself already formally acknowledged vinpocetine as a dietary ingredient—five times. FDA acknowledged, without objection, no fewer than five separate vinpocetine NDI notifications that companies submitted over the years. The first notice was sent as far back as 1997.

Does the agency now have a right to object to vinpocetine's status as a dietary ingredient—in effect, reversing its previous five decisions? As the Natural Products Association (NPA; Washington, DC) pointed out, considering that FDA already reviewed vinpocetine's safety data in those five NDI notifications, "this means that vinpocetine has already undergone intense scrutiny five times over by the leading authority on food safety in the U.S."

"The agency," NPA said, "is looking to remove the ingredient via a rendering that they have been silent on for approximately 20 years regarding the ingredient's status."

FDA, of course, does have the right to reconsider the safety of an ingredient at any time should safety concerns arise, such as an uptick of adverse-event reports. But there hasn't been any such uptick for vinpocetine, NPA pointed out: "From the Federal Register notice, FDA does not appear to have any clear safety signal based on [serious-adverse-event reports] or other means."

So why is the agency reversing its stance on vinpocetine? One argument could be that the agency is now aligning its verdict with the stance the agency takes on synthetic botanical ingredients in the revised NDI draft guidance. The guidance flat-out states that synthetic botanicals are not considered dietary ingredients—a current pain point in the industry.

But there is also now understandable fear among industry that FDA could, at any time, revoke clearance for any ingredient, even if the ingredient already has acknowledged NDI status from FDA itself. That's definitely not what the supplements industry wants to hear right now, especially when some are suggesting that the end-cost to industry of submitting NDI notifications could be billions of dollars.

As for NPA, the association immediately sent comments on the vinpocetine matter to FDA's associate commissioner of policy, Leslie Kux, JD. But already the association is calling this vinpocetine turnaround by FDA "major" and "unprecedented."

"This is a form of double jeopardy," stated NPA's CEO and executive director Dan Fabricant, PhD, in the NPA press release. "To go through the regulatory gate a second time is akin to finishing a round of golf and winning, but then having to play a second round while someone charges at you while you hit each golf shot. This sets a very bad precedent and is no environment to conduct business in."

Jennifer Grebow
Editor-in-Chief
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Would FDA’s NDI Guidance Really Cost Industry Billions of Dollars?

It’s the million-dollar question—or maybe even the billion-dollar question—raised by FDAs revised new dietary ingredient (NDI) draft guidance: how much would it cost the dietary supplement industry to meet the requirements outlined in the draft guidance? In the weeks since the new draft guidance dropped on August 11, industry experts have proposed vastly different estimates for both the total number of NDI notifications (NDINs) industry would need to submit and the cost of each separate NDIN.

On the high end, the United Natural Products Alliance (UNPA; Salt Lake City) suggested a preliminary estimate of the total NDIN cost burden on industry could range from $2 billion to $6 billion. Those figures, which UNPA noted were a very early and tentative assessment, are based on a reading of the guidance that requires a separate notification be submitted for every manufacturing process change and every combination of different NDIs. If that turns out to be the case, it’s easy to imagine tens of thousands of instances when a separate NDIN would be necessary.

“It’s a spawning effect,” said Loren Israelsen, president of UNPA, in UNPA’s August 25 webinar on the new NDIN draft guidance. “If FDA really means this, then you will have a constantly generating set of new dietary supplement products that require notification.” And if the cost burden on industry really does extend into the billions of dollars, many companies may simply find it too expensive to submit the required NDINs, Israelsen cautioned, for fear of going bankrupt.

Other industry experts, however, foresee a less daunting future under the revised NDI draft guidance. Perhaps it’s only hundreds of new NDINs that will be necessary, instead of thousands, or maybe some NDINs can be submitted at relatively low cost. Much of the potential cost may also depend on what type of ingredient a firm is working with and how strongly its researched safety profile is already.

How Many New Notifications?

There’s at least one certainty in the new NDI draft guidance: FDA believes the supplements industry is currently underreporting NDIs.

“Over the past 20 years, we’ve received over 900 notifications. We have not yet reached 1000,” said Cara Welch, PhD, senior advisor at FDA’s Office of Dietary Supplements, during a September 7 NDI webinar hosted by the Council for Responsible Nutrition (CRN; Washington, DC). “Now, we don’t have all the information as to how many notifications should have been submitted that have not been submitted, but our impression is we should have received more than the 50 or so we receive a year.”

Though Welch declined to estimate whether it was closer to hundreds or thousands of NDINs that needed to be filed, she did note that there are tens of thousands of supplement products on the market. Not all require notifications, Welch said, but many do. And while she chose not to guess at the total number of new notifications that would be required under the revised draft guidance, Duffy MacKay, ND, CRN’s senior vice president of scientific and regulatory affairs, took a stab at the question.

“If I were to read the document literally and look at every manufacturing change considered both for old ingredients as well as new ingredients, I would hedge a bet that there are thousands of finished products that would require a notification,” MacKay said. Going one step further, UNPA arrived at its preliminary cost estimate by figuring in tens of thousands of new NDINs.

But other industry leaders, including Dan Fabricant, CEO and executive director of the Natural Products Association (NPA; Washington, DC), said estimates based on such high NDIN numbers are just “fearmongering tactics.” He noted that the addition of a “master file” provision in the latest draft guidance, which allows ingredient firms to create a single NDIN for a broad range of product formulations, would enable fewer NDINs, especially with regard to ingredient combinations.

“You can’t say we got a master [file] list and then [say] the FDA is requiring a new submission for each independent NDI,” Fabricant told Nutritional Outlook. “It doesn’t work. There’s clearly a way that you can do a cube submission if you build [an NDIN] that covers a broad range of combinations and amounts of ingredients.”

Michael McGuffin, president of the American Herbal Products Association (AHPA; Silver Spring, MD), also pushed back against the idea that thousands or tens of thousands of new NDINs would be necessary, even if that’s what the guidance may seem to imply as currently written.

“I don’t believe we’re going to actually see that every dietary supplement that contains an NDI is going to be subjected to a
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notification if we can continue to focus on where the assurance of safety to the public is needed, a clear reading of the law, and some guidance on how to put your notification together so that it does have a broad application against broad conditions of use,” McGuffin told Nutritional Outlook.

How Much Will Each NDIN Cost?
Aside from the sheer number of new NDINs proposed under the revised draft guidance, the question of how much each NDIN costs is just as important in arriving at an overall cost estimate.

During NPA’s August 17 webcast on the NDI guidance, Corey Hilmas, MD, PhD, NPA’s senior vice president of scientific and regulatory affairs, shared NPA’s estimate that a single NDIN may cost up to $500,000. That’s based on the estimate that a toxicology study may cost $178,000–$328,000, on top of an estimated $162,500 in consultant fees and other added costs.

“Those are real costs,” NPA’s Fabricant told Nutritional Outlook. “Those are costs we got from quotes from contractors, research organizations, and the labs themselves that do the animal testing and those sorts of things.”

However, not all outstanding NDINs will require such large fees, AHPA’s McGuffin suggested. For ingredients that already have much of the supporting research work completed, it could be a fraction of that cost. McGuffin said he has spoken with companies that paid less than $25,000 for their NDINs, and in at least one case, less than $10,000.

“We’re not going to have to do a [toxicology] study except for truly novel new ingredients,” McGuffin said. “We’re going to have to do some work, but this isn’t intended to be a ‘start over, assume it might be poison’ approach for ingredients that are reasonably expected to be safe at the beginning of the review. I’m not saying we can ignore it and staple a bunch of pieces of paper together, but this idea that it’s going to cost billions, that’s in a worst-case scenario.”

Part of a given ingredient’s NDIN cost calculation may also depend on what category it falls in. Some ingredient types, such as synthetic botanicals or probiotics, may require considerably more work than other ingredients.

Clearly, industry cost estimates stemming from the NDI draft guidance are all over the map. As they prepare their public comments, several trade associations have already announced plans to call on FDA to conduct its own economic cost-burden analysis.


U.S. Herbal Supplement Sales Climb 7.5% in 2015
U.S. sales of herbal dietary supplements posted a 12th straight year of consecutive growth in 2015, increasing by 7.5% last year to reach a total of $6.92 billion, according to a new report published in the American Botanical Council’s (ABC; Austin, TX) journal HerbalGram. This marks the second highest year-over-year growth rate for U.S. herbal supplement sales in more than a decade, ABC notes.

The annual HerbalGram report, which is based on supplement sales statistics provided by Nutrition Business Journal and market researchers SPINS and IRI, finds that mainstream retail sales of herbal supplements increased by 1.5% in 2015 to reach a total of $943 million. As in years past, herbal supplement sales in the natural channel (excluding Whole Foods Market) grew at a faster rate than in mainstream retailers—rising by 4% in 2015 to post a total of $365 million.

The fact that U.S. herbal supplement sales continued to climb at a rate more or less in line with previous years (7.5% in 2015 compared to 6.8% in 2014 and 7.9% in 2013) is especially noteworthy in light of the negative publicity that dogged the herbal supplements industry for much of last year. Last year saw New York Attorney General (NYAG) Eric T. Schneiderman’s months-long investigation into allegedly mislabeled herbal supplements, which spawned numerous negative headlines about the category despite many experts criticizing the methodology of Schneiderman’s investigation. But judging from the sales figures in the new HerbalGram report, it doesn’t appear consumers were discouraged by the bad press.

“Herb supplement sales continue to grow to record levels, evidence that much of the public considers herbs to be an essential component of a healthy lifestyle,” says Mark Blumenthal, founder and executive director of ABC.

Mainstream Channel
Among mainstream retailers, including mass market, grocery, drug, military commissary, convenience, and club stores, horehound (Marrubium vulgare) was the top-selling herbal dietary supplement for the third year in a row. The ingredient, commonly used for relief from upper respiratory symptoms, was the top-selling ingredient of a healthy lifestyle,” says Mark Blumenthal, founder and executive director of ABC.

In 2015, U.S. herbal supplement sales saw the second highest year-over-year growth rate in more than a decade.
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posted 2015 sales of nearly $115 million in mainstream outlets. It was followed by the next bestsellers: cranberry (Vaccinium macrocarpon), echinacea (Echinacea spp.), Garcinia cambogia (Garcinia gummi-gutta), and green tea (Camellia sinensis).

Propelled by a surge of interest in anti-inflammatory ingredients, boswellia (Boswellia serrata) and turmeric (Curcuma longa) both posted some of the highest mainstream sales increases, with boswellia in particular having a “remarkable year in 2015” with its 673.6% sales increase over 2014, the HerbalGram report points out.

It’s also interesting that many of the ingredients that took center stage in the NYAG’s February 2015 investigation, such as echinacea, garlic (Allium sativum), ginseng (Panax spp.), ginkgo (Ginkgo biloba), St. John’s wort (Hypericum perforatum), saw palmetto (Serenoa repens), and valerian (Valeriana officinalis), all experienced sales changes of less than 15% last year, with most continuing to see sales growth.

“Mainstream sales of many well-known herbal supplements, such as the seven originally targeted in the New York attorney general’s investigation that began in February 2015, remained fairly stable in 2015,” the report states.

Meanwhile, herbal ingredients that experienced significant percentage sales decreases in the mainstream channel last year included green coffee extract (Coffea arabica), isoflavones, rhodiola (Rhodiola spp.), and acai (Euterpe oleracea).

The top-10 selling herbal ingredients in the mainstream channel were:

1. Horehound (Marrubium vulgare)
2. Cranberry (Vaccinium macrocarpon)
3. Echinacea (Echinacea spp.)
4. Garcinia cambogia (Garcinia gummi-gutta)
5. Green tea (Camellia sinensis)
6. Black cohosh (Actaea racemosa)
7. Flax or flaxseed oil (Linum usitatissimum)
8. Ginger (Zingiber officinale)
9. Valerian (Valeriana officinalis)
10. Bioflavonoid complex

*View the HerbalGram article for a complete list of the top-40 mainstream-channel sellers.

Natural Channel
Turning to the natural channel, turmeric took the top selling spot on the sales chart for the third year in a row with more than $37 million in total sales. The popular Ayurvedic ingredient experienced 32.2% sales growth in 2015—second only to ashwagandha’s 2015 natural-channel growth rate of 40.9%.

“The popularity of turmeric and ashwagandha in the natural channel—as well as boswellia’s 674% sales increase in the mainstream channel—reflects a broader trend in herbal dietary supplements in 2015: increased consumer familiarity with and acceptance of Ayurvedic herbs,” the HerbalGram report explains.

Following turmeric in top sales were wheatgrass and/or barley grass, flaxseed and/or flax oil, Aloe vera, and elderberry (Sambucus nigra). The only herbal ingredients to experience significant percentage sales decreases in the natural channel last year were Garcinia cambogia and chia seed and/or chia oil (Salvia hispanica).

The top-10 selling herbal ingredients in the natural channel were:

1. Turmeric (Curcuma longa)
2. Wheatgrass and barley grass (Triticum aestivum and Hordeum vulgare, respectively)
3. Flaxseed (Linum usitatissimum) and/or flax oil
4. Aloe vera
5. Elderberry (Sambucus nigra)
6. Milk thistle (Silibum marianum)
7. Maca (Lepidium meyenii)
8. Echinacea (Echinacea spp.)
9. Saw palmetto (Serenoa repens)
10. Oregano (Origanum vulgare)

*View the HerbalGram article for a complete list of the top-40 natural-channel sellers.

In addition, U.S. direct-channel sales of herbal supplements increased by 7.2% in 2015 to hit a total of more than $3.36 billion—a slight increase over the year before.

It should be noted that the report covers only sales of herbal dietary supplements, while sales of most herbal teas, botanicals for cosmetics, and herbs sold as over-the-counter medicines were excluded.

Cheerios Protein Lawsuit Will Proceed

Despite its attempt to dismiss the case, General Mills will now have to face a class-action lawsuit that alleges it falsely marketed its Cheerios Protein breakfast cereal as a healthier, high-protein alternative to Cheerios, a federal judge ruled on August 10.

Last November, nonprofit consumer advocacy group the Center for Science in the Public Interest (CSPI; Washington DC) filed a lawsuit suggesting “Cheerios Protein has only a smidgen more protein per serving than Cheerios” and includes 17 times more sugar than original Cheerios. Cheerios Protein includes 7 grams of protein per serving compared to 3 grams for original Cheerios, but CSPI says the difference in actually negligible when you consider that the Cheerios Protein listed serving size is twice as big as it is for original Cheerios.

General Mills has not commented on the latest ruling, but when the lawsuit was first filed last year it said that Cheerios Protein is denser than Cheerios and actually offers 18% more protein by weight than original Cheerios.

In his August 10 decision, U.S. District Judge Thelton Henderson said he was “skeptical” the lawsuit would succeed, but ruled that consumers may pursue the claim that the product was misbranded and General Mills violated the Nutrition Labeling and Education Act, Reuters reported. [2]
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Ayurvedic medicine, with its deep, historical roots in India, is still relatively new to the U.S. market—but growing quickly. For those unfamiliar with Ayurveda, it is an ancient Indian system of holistic medicine that combines the use of plants and herbs as medicinal treatment and a variety of lifestyle practices, including for diet and exercise. As the market has grown, so have advertising claims around ingredients or products with ties to Ayurvedic medicine.

In the U.S., practices such as Ayurveda, Chinese medicine, and homeopathy are referred to as “complementary and alternative medicine,” or CAM. According to the U.S. National Center for Complementary and Integrative Health (NCCIH), “many Americans—more than 30% of adults and about 12% of children—use healthcare approaches developed outside of mainstream Western, or conventional, medicine.” In the U.S., NCCIH is the main federal agency charged with conducting scientific research on complementary and integrative health techniques.
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*Panahi Y, et al. Lipid-modifying effects of adjunctive therapy with curcuminoids-piperine combination in patients with metabolic syndrome: Results of a randomized controlled trial. Complement Ther Med (2014), Mashhad University of Medical Sciences

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FDA Clarifies Regulations for CAM Products

FDA has noted the rise of Ayurveda in the U.S. In particular, the agency says, as the market proliferates, there is increased confusion over how the Federal Food, Drug, and Cosmetic Act (FD&C Act, which governs food, drugs, and cosmetics), as well as the Public Health Service Act (PHS Act, the law that gives FDA the authority to quarantine products arriving from foreign countries), apply to the Ayurveda category. In 2006, the agency aimed to dispel some confusion by publishing draft guidance, “Draft Guidance for Industry: Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.”

FDA’s CAM guidance states that Ayurveda products may indeed be subject to the FD&C Act as well as the PHS Act. Some CAM therapies or practices would fall under the scope of biological products under the PHS Act, or food, drug, or cosmetics (such as dietary supplements) under the FD&C Act.

As such, CAM products are not exempt from FD&C Act or PHS Act regulations. As FDA’s guidance explains, “This means, for example, if a person decides to produce and sell raw vegetable juice for use in juice therapy to promote optimal health, that product is a food subject to the requirements for foods in the [FD&C] Act and FDA regulations, including the hazard analysis and critical control point (HACCP) system requirements for juices in 21 CFR part 120. If the juice therapy is intended for use as part of a disease treatment regimen instead of for the general wellness, the vegetable juice would also be subject to regulation as a drug under the [FD&C] Act.”

In short, FDA stressed, the agency applies the same statutory definitions to CAM products that it applies to conventional products.

What kind of enforcement actions has FDA taken against CAM products? The “Alternative Medicine Fraud” page on FDA’s website lists several warning letters the agency issued regarding CAM products relating to a variety of issues—most commonly, disease-treatment claims on products that are not approved drugs. Since the page was last updated in 2010, there have been additional warning letters, safety alerts, and import alerts posted.

In addition, in early 2015, FDA held a workshop to discuss the regulatory framework governing homeopathic products. Homeopathic products, which target holistic medicine, must meet the regulations of an FDA Compliance Policy Guide. While this guide does not require homeopathic products to have premarket approval, it does set forth a formal definition for homeopathic products as well as outline packaging and labeling guidelines. To date, no other FDA changes to the regulatory framework for CAM products have been announced.

FCC Increasingly Scrutinizing Substantiation

Following FDA’s homeopathic workshop, the FTC held its own workshop on homeopathic products in August 2015. The FTC’s primary interest in homeopathic products is to prevent unfair or deceptive advertising practices. Just as it has for other categories, the FTC has taken a primary interest in ensuring marketing claims are backed by adequate substantiation. The FTC also announced in late September that the agency will be issuing guidance relating to homeopathic products and claims as a follow-up to its 2015 workshop.

The FTC’s currently available guidance, “Dietary Supplements: An Advertising Guide for Industry,” speaks to “traditional use” claims, suggesting that marketers of traditional-use products look closely at how consumers perceive advertising claims and the degree of supporting evidence such claims require. The guidance also points out that it is important to avoid inferences that such products have been evaluated for efficacy if that is not the case. Also, the Guidance notes, “[as] consumer awareness of and experience with ‘traditional use’ supplements evolve, the extent and type of qualification necessary is also likely to change.”

The FTC also cautioned traditional-use products from making disease claims, noting that “an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit.” The agency said it would “closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.”

Historically, the FTC has not been very active in enforcing against “traditional use” claims; however, given recent FTC enforcement trends of looking closely at product and claims substantiation, it is foreseeable that the agency may take a conservative view of whether a claim based in traditional use can be properly substantiated. Companies marketing in this space will want to be sure to consider the forthcoming new guidance and the full body of available substantiation to determine whether the FTC’s “competent and reliable scientific evidence” standard can be met.

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Snack Pack

Top trends like paleo and gluten-free continue driving the healthy-snacks market.

BY INNOVA MARKET INSIGHTS

The first word that comes to mind when snacking on impulse may not be healthy, but that hasn’t stopped snack makers from providing better-for-you options just the same. The snacks market as defined by Innova Market Insights encompasses a wide range of categories, including traditional savory or salty snacks, snack nuts, and seeds, as well as meat snacks, popcorn, fruit-based snacks, finger foods, and hors d’oeuvres.

Healthy Claims

More than 43% of global snack launches and 70% of U.S. snack launches Innova Market Insights recorded between May 2015 and May 2016 featured a health claim of some kind. These claims varied from “passive”—low-calorie, whole-grain, natural, etc.—to “active or functional,” such as vitamin and mineral fortified, added fiber, as well as claims of specific health benefits, such as for heart health or energy/alertness.

Of all passive health claims, clean-label and “free from” product claims were used most, particularly in the United States where prevalence is highest. “Natural,” “no additives/preservatives,” and/or organic claims featured on 28% of global launches and up to 48% of launches in the United States.

In the neighborhood of “free from” claims, non-GMO claims were especially popular in the United States. While nearly 7.7% of global snack launches featured a non-GMO claim, well over a quarter of those in the U.S. featured a non-GMO claim, up from merely 17% of launches two years prior.

Paleo Promise

Interest in natural products and a back-to-basics approach has led to more activity in paleo products (products associated with the so-called Paleo Diet and its focus on eating lean meat, nuts, fruits, and vegetables, as our Stone Age ancestors did).

Although paleo snacks only account for a still-modest 13% of snack introductions, use of the word paleo in launch activity has surged in recent years, with snacks as one of its top three product categories. More recently, the paleo sector has begun branching out beyond nuts and fruit mixes, as well as seed mixes, to encompass savory/salty snacks such as vegetable chips and grain-based crackers, as well as meat snacks.

Gluten-Free

Gluten-free claims are still going strong. During May 2015–May 2016, gluten-free claims were used in nearly 17% of global snack launches and in over 44% of U.S. launches. The gluten-free Paleo snack brand Caveman Foods’ new Caveman Chicken Bites usher in what the company calls the “evolution” of traditional jerky. Produced in tender, bite-sized pieces that are easier to eat than traditional jerky, the Bites “are a great source of on-the-go protein, delivering 10 g of lean protein and only 70 calories per serving,” the firm says, adding that they are lower in sodium and sugar than traditional beef jerky as well. Sold in three flavors, the products feature all-natural chicken and other paleo-inspired ingredients and are certified by the Paleo Foundation.
Getting your flavors to go with the flow is easy with MALTRIN® maltodextrins. Your spray-dried product performance will be enhanced with its unmatched flowability, quick dispersibility, high solubility, low hygroscopicity, neutral flavor and easy drying. Contact GPC today.
trend may be easier for snack makers to address simply because many basic snack ingredients—potatoes, corn, soy, and nuts—are naturally gluten-free.

Still, manufacturers are taking advantage of a wide range of other ingredients that can also replace wheat and other cereals, including lentils, beans, cassava, rice, nuts, and sweet potatoes, plus other traditional and on-trend vegetables like beetroot, kale, and sea vegetables.

High Protein
The snacks market is not immune to the high-protein trend overtaking the general food and drinks sector particularly in the United States. Just under 15% of total U.S. snack foods launches Innovia Market Insights tracked in May 2015–May 2016 used “added protein,” “high in protein,” or “source of protein” claims. Sub-categories like meat snacks inherently benefit from high-protein claims and have taken the opportunity to leverage these claims more widely; for instance, more than 50% of U.S. meat-snack launches featured a protein claim.

Bars
Another type of snack with strong growth due to its healthy positioning is the cereal or granola bar. Despite concerns over how healthy some of these bars actually are, manufacturers are nonetheless emphasizing their healthier attributes. Over 80% of global cereal bar launches and up to 94% of U.S. cereal bar launches Innovia Market Insights tracked in May 2015–May 2016 embraced healthy marketing. Clean-label concerns are big in granola bars, with nearly 53% of U.S. cereal bar launches positioned on a natural, additive-/preservative-free, and/or organic platform.

In the U.S. bar market, gluten-free claims were used on over 63% of bar launches—even more frequently than natural, additive-/preservative-free, and organic claims. Nearly 47% of U.S. bar introductions featured protein claims. And approximately one-fifth of U.S. performance-bar launches featured a sports/recovery or energy/alertness positioning.

Healthy and Delicious
All of this healthfulness aside, consumers still seek indulgence and good flavors. These consumers are clamoring for great-tasting, easily accessible products and new and improved snack formats optimizing taste, novelty, portability, and convenience. As the snacks market grows increasingly diverse and competitive, brands must evolve and cater to these shifting consumer preferences.

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Fuel for the Fire

Research is pushing lesser-known ingredients to the forefront of sports nutrition.

BY ROBBY GARDNER AND NUTRITIONAL OUTLOOK STAFF
A considerable market exists for nourishing trained and untrained athletes. According to market researcher Euromonitor International, the biggest sports nutrition markets today are in North America (currently with a $7.6 billion value), followed by Western Europe, Asia Pacific, and Eastern Europe.

Dietary supplements are still in highest demand for sports nutrition. Sophisticated ingredients that go into supplements are oftentimes more viable in a bulk powder or capsule than in complicated environments, such as bars, juices, and other food-friendly consumables. Ahead are some up-and-coming ingredients in the sports nutrition world.

**HMB**
The importance of leucine in sports nutrition cannot be understated. As an essential amino acid, leucine is necessary for protein synthesis, the growth and repair of muscle tissues, and numerous other biological functions. All of this gives reason for us to consume leucine frequently, which is why leucine is often incorporated into protein powders and other sports supplements. What consumers may not realize, however, is that a metabolite of leucine may be worth supplementing with, too.

Leucine’s conversion into the metabolite β-hydroxy β-methylbutyrate (HMB) is critical for completing biological functions. Unfortunately, recent studies suggest that the conversion of leucine to HMB can decline with age in both humans and other animals, potentially leading to lean mass and strength loss in adults of all ages.1,2

Already, numerous reports link HMB use to enhanced workout recovery, especially after high-intensity exercise.3,4 The ingredient may be useful for seasoned athletes pushing their training programs to higher intensities, as well as untrained sports consumers just starting an exercise program.

Research continues on HMB supplementation alone and in combination with other sports nutrients such as creatine and whey protein.5,6 Although HMB supplier Metabolic Technologies Inc. (Ames, IA) says that sports nutrition is HMB’s primary market, the company also adds that there is growing awareness around HMB for addressing sarcopenia and maintaining muscle mass later in life. For this reason, HMB should gain interest from older consumers as well.

**A-GPC**
Although casual consumers may not be familiar with a substance called α-glyceril phosphoryl choline (A-GPC), its utility relates to a better-known nutrient: choline. A-GPC comes into play by increasing free choline in the bloodstream, according to recent data.7

The benefits of increasing the production of acetylcholine via A-GPC supplements appear to be both physical and mental. In recent exercise studies, A-GPC use was associated with improvements in strength and power (broadly categorized by one researcher as “explosive performance”), as well as improvements in mood and cognitive function comparable to the effects of caffeine.8,9 In response to such findings, Chemi Nutra LLC (Austin, TX), a global supplier of AlphaSize A-GPC, recently filed a patent application for replacing, displacing, and/or augmenting caffeine with AlphaSize.

A-GPC is available in powder form and, at least in the case of AlphaSize, can also be used in beverages because it’s completely water-soluble. While young men make up A-GPC’s primary purchasing group, Chemi Nutra says that “vitality” and well-being marketing are creating opportunities to appeal to older consumers who aren’t necessarily the sporting types.

**Probiotics**
Probiotics are gaining attention in the sports world. New study results10 shared by probiotics firm Ganeden (Cleveland) suggest that the Ganeden BC30 (Bacillus coagulans GBI-30, 6086) strain may be an effective partner to casein protein for delivering certain sports-related benefits. Compared to casein protein...
alone, the combination of Ganeden BC30 (1 billion CFU) and casein protein was found to be more effective at significantly reducing indices of muscle damage and soreness.

Researchers assessed the effect of the probiotic and protein combination in 29 recreationally trained men. “Ganeden BC30 with just 20 grams of protein was able to protect the muscle from damage as shown by perceptual measures and blood work, resulting in improvement in five protein utilization endpoints: decreased recovery time, decreased soreness, reduced swelling, increased power, and decreased blood kinase,” Ganeden explained. The probiotics-and-casein group was also able to maintain athletic performance in subsequent exercises; by contrast, the casein-only participants experienced a significant reduction in athletic performance following the damaging exercise bout.

In fact, research on the potential effects of probiotic supplementation on inflammation—specifically, inflammation induced by strenuous exercise—is still limited; however, probiotics supplier Probiotical S.p.A. (Novara, Italy) and its distributor partner Pharmachem Laboratories (Kearny, NJ) are adding to the information bank with the results of a new, 21-day, double-blind, randomized, placebo-controlled crossover trial highlighted at the SupplySide West trade show in October and submitted for publication.

Researchers examined the effect of supplemented probiotics on inflammation and muscle performance in 16 healthy, resistance-trained men between the ages of 21- and 29-years-old following a muscle-damaging exercise. For three weeks daily, the subjects consumed either a placebo or a probiotic blend containing 5 billion live cells of *Streptococcus thermophilus* FP4 and 5 billion live cells of *Bifidobacterium breve* BR03. The probiotics were also microencapsulated using Probiotical’s patented Microbac coating in order to protect the probiotics from damage, while also enhancing colonization. Following supplementation, subjects performed a muscle-damaging exercise involving the elbow flexors. Prior to and for several days after the start of the study, researchers measured both subsequent performance of the elbow flexors as well as levels of the inflammation marker interleukin-6 (IL-6). The subjects then underwent a 21-day washout period before switching to the alternate protocol.

The probiotic group saw several benefits from supplementation, researchers said. Anti-inflammatory benefits were observed as soon as 30 minutes post-exercise, with a “very likely anti-inflammatory effect” noted 24 hours following exercise. Compared to placebo, the probiotic also helped lessen reductions in performance during each subsequent exercise. “Further study is warranted to determine if the attenuation observed herein may result in the ability to train more...
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frequently or at higher intensity, thereby enhancing performance to a greater extent,” the researchers said.

Alexis Collins, Director of Scientific Affairs, Pharmachem Laboratories, notes the need for continued research on probiotics in the realm of sports in general. “As with most health outcomes, the role of the gut has been largely ignored until the last decade. New research is showing encouraging data for probiotic use in athletes, but these results need to continue to be confirmed by larger clinical trials,” she says. “Specific areas of interest are support for immune health (strenuous exercise can stress the immune system), protein absorption (probiotics as nutrition optimizers), and inflammation (we know that certain probiotics can reduce inflammation, which is key to improving exercise performance).”

She concludes, “We are sure there are still probiotic sport nutrition benefits that remain undiscovered, and it will be interesting to see which strains show the greatest impact in each category.”

**Amaranth Extract**

In response to the growing popularity for beets in sports, DolCas Biotech LLC (Landing, NJ) just introduced an amaranth extract with similar benefits to those of beets.

Like beets, amaranth (or red spinach) is rich in nitrates, which is a big reason why some athletes consume beets for sports performance. The conversion of nitrates to usable nitrates and nitric oxide in the body has been posited to have a beneficial effect on muscle function and exercise.12

But DolCas goes a step further with its Oxystorm amaranth extract by not only supplying nitrates in a bioavailable form13, but also guaranteeing their content. The extract is standardized for 9% nitrates and 13% potassium in every dose, which contrasts the inevitable variability that will come with buying beets and their derivatives (juices and powders) in grocery stores.

Oxystorm is free of oxalates, compounds that are present in beet products and that may be harmful if they over-accumulate in the body. Researchers completed an exercise study on the extract earlier this year and found that the ingredient’s use was associated with improved ventilatory threshold in recreationally trained athletes.14 Full results of the study will be published in the future, alongside results of a vascular phase of the same study. Oxystorm distributors include PLT Health Solutions (Morristown, NJ).

**French Oak Extract**

Horphag Research (Hoboken, NJ) recently shared study results15 for its new Robuvit French oak-wood (*Quercus robur*) extract launched in the United States this past summer. The data suggest the ingredient may improve triathlon performance, endurance, and recovery in athletes aged 30–40.

The study involved 54 amateur athletes, half of whom consumed 300 mg of Robuvit daily for two weeks. Following two weeks of triathlon training and Robuvit supplementation in the experimental group, researchers found that subjects supplementing with Robuvit experienced greater improvements in swimming and biking time than the control group, as well as a greater decrease in average running time. Overall, total triathlon time improved by -10.56% in the Robuvit group, compared to -3.41% in the control group. “The -10.56% shorter total triathlon time was considered as very good improvement, considering that for this type of athletes, being almost at the top of their form, it is difficult to improve even further without severe training,” researchers noted.

Fred Pescatore, MD, nutraceutical consultant for Horphag Research, says that Robuvit “cuts down on the chemical processes that impede your top performance,” such as oxidative stress.

“For many, the muscle soreness that can linger days afterward is what keeps them out of their gym and off their routine,” Pescatore says. “Robuvit greatly reduces the length and severity of this, empowering you to keep training and keep pushing through.”

**Resveratrol**

A good portion of recent resveratrol studies have focused on prospects in sports and exercise. Although not all of these studies have yielded positive outcomes16,17, plenty have. Resveratrol supplier Sabinsa (East Windsor, NJ) is especially delighted with recent study outcomes relating to improved mitochondrial performance in response to low-intensity exercise, and cerebral blood flow increases with resveratrol and piperine.18,19

In the 16-subject, low-intensity-exercise study18, healthy young adults with a mean age of 20 consumed either a placebo or 500 mg of Sabinsa’s resveratrol plus 10 mg of its BioPerine piperine for four weeks. All participants completed submaximal endurance training of the wrist flexor muscles of the nondominant arm per week. Based on near-infrared spectroscopy to assess skeletal muscle mitochondrial capacity, researchers found that participants in the resveratrol plus-BioPerine group experienced a 40% increase in mitochondrial capacity of the trained arm at the study’s conclusion compared to baseline. The placebo group, on the other hand, experienced an increase of 10%—a significant difference between the two groups.

The study authors also noted that much of the previous research on resveratrol has been conducted on high-intensity exercise, but this study is unique in assessing the effects of resveratrol supplementation on low-intensity exercise, which could help
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the ingredient draw in people of all athletic levels.

**Ashwagandha**
The root of the Ayurvedic plant ashwagandha is receiving increased scientific interest. In just the last two years, studies have associated consumption of ashwagandha supplements with improvements in muscle strength and recovery, cardiorespiratory endurance, and, most recently, chronic stress. These results complement previously available data suggesting that ashwagandha can have positive influences on both mind and body.

Much of the existing ashwagandha research has been conducted with KSM-66, a standardized ashwagandha extract from supplier Ixoreal Biomed Inc. (Los Angeles). The company says that several more clinical studies are in the works investigating similar health factors but in different populations.

Ashwagandha is sold as a standalone dietary supplement, but it’s also incorporated into broader sports nutrition formulas, too, such as post-workout ones. Its neutral flavor allows for a wide range of uses in dietary supplements, functional foods, and beverages.

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**PROTEIN AND SPORTS WEBCAST**


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**Botanicals for Sport**

Highly standardized products aside, plenty of simple plant ingredients have shown potential in sports and exercise settings. Tart cherry, in particular, continues to make news because of its demonstrated potential to reduce exercise recovery time, muscle damage, and oxidative stress after exercise. The ingredient is available seasonally in supermarkets, but Anderson Global Group LLC (Irvine, CA) makes it available year-round with its research-backed CherryPure powder and juice concentrates.

Other domestic fruits offer some exercise benefit. Draco Natural Products (San Jose, CA) says blackberry and apple are particularly rich in epicatechin. In a recent human study, epicatechin demonstrated potential to inhibit myostatin (a compound that inhibits muscle growth) and increase muscle strength. Also, Draco says, in an endurance test, grape juice consumption was linked to increased time to exhaustion in runners.

For more exotic approaches, Ecuadorian Rainforest suggests manufacturers consider astragalus among other foreign botanicals such as green coffee bean. This Asian root is believed to support the immune system and be useful against fatigue, as demonstrated in at least two independent studies.

Robby Gardner is the former associate editor of *Nutritional Outlook* magazine.
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Name That Brand

Google Trends confirms that consumer understanding of branched-chain amino acids is more advanced than ever before.

BY MELISSA DELLABARTOLOMEA, NUTRASCIENCE LABS

Thanks to the Internet, we can gain a better understanding of almost anything these days. Market trends are no exception, including those in the world of sports nutrition.

In the sports market, one acronym currently ranks above the rest: BCAA. Short for branched-chain amino acids, these uniquely structured amino acids have worked their way—one powder product at a time—into the sports nutrition spotlight. With the help of Google (and, more specifically, Google Trends), we can gain some valuable insight into consumer interest in BCAAs and predict what may be next for these exceptional amino acids.

**Recognizing the Larger Trend**

Google Trends (www.google.com/trends) is a search platform that allows users to see how certain Internet search terms are trending. Through Google Trends, for instance, we can discover that turmeric is a “rising star” (as Google calls it), sitting among some of the most-searched food words in 2016. Even though BCAA isn’t at the level of a “rising star,” Google Trends still reveals that interest in the term is high—and growing.

Taking a look at the past decade, even though interest in the term BCAA did start to climb by mid-2008, according to Google’s “Interest over Time” report, the surge in interest over the last five years has been nothing less than tremendous. From August 2011 through August 2016, interest in the search terms BCAAs and branched-chain amino acids grew at an average rate of 22% each year. What’s more, this quantifiable (not to mention impressive) surge in interest has shown no sign of slowing as we work our way into 2017.

**Digging Deeper with Related Queries**

Perhaps even more useful than data on a certain single term (e.g., BCAA), Google Trends also provides insight on search queries for terms related to the primary search term (such as best BCAA or BCAA for women).
Among those related queries, users can view the top "rising" related queries (those that have seen the most significant increase in search volume).

If we review the last 12 years’ worth of search queries related to BCAAs, an interesting trend starts to emerge. To simplify things, let’s break the last 12 years into three windows, with each window covering a four-year span.

January 2004–January 2008: Google’s query data is relatively scarce over this time frame, which shouldn’t come as much of a surprise given the fact that from 2004 through mid-2008, user interest in BCAAs was at its lowest recorded (barely breaking double-digit interest). The search terms recorded as “rising” and “breakout” were nothing if not basic and included the simple queries branched-chain amino acid and BCAA.

January 2008 – January 2012: The number of related queries increased significantly during this time. Google was able to provide data on more than 20 related queries, and they included more specific phrases and questions about BCAAs, including BCAA benefits, best BCAA supplement, and BCAA side effects.

January 2012–January 2016: In the final leg, the nature of consumer interest in BCAAs appears to have shifted. Search terms consisted almost exclusively of terms and phrases related to branded BCAA products. While the questions and phrases concerning the BCAA basics are still some of the top related queries, almost all of the “rising” and “breakout” queries are brand-or product-specific.

Why did this shift in behavior happen? It’s simple. As demand and interest in BCAAs increased, so did the willingness of users, supplement takers, and supplement industry insiders to learn about BCAAs. As consumer awareness of BCAAs and their benefits reached the “common knowledge” levels of today, it follows that the nature of the conversation has shifted from “What are they, and how do they work?” to “Of all the different BCAA products out there, which one is best suited to meet my unique needs?”

What’s Next for BCAAs?
If current trends hold, BCAAs will maintain their place in the sports supplement spotlight into 2017 and well after. It looks as though the mindset of the BCAA market going forward will continue to be an increasingly product-centric one.

With the help of the Internet, social media, and digital media, consumers will likely spend more time seeking to understand the differences between BCAA brands, formulations, and delivery methods. For brand owners and manufacturers, this means finding more new and acceptable methods for distinguishing their BCAA products from the thousands of others that are currently on the market.

Almost all of the “rising” and “breakout” BCAA queries today are brand- or product-specific.

Melissa DellaBartolomea is a content marketing specialist and writer for NutraScience Labs (Farmingdale, NY), a subsidiary of Twinlab Consolidation Corp.
Cool It

Can dietary supplements help manage the widespread effects of heightened inflammation?

BY KIMBERLY J. DECKER

When the movie “Concussion” hit theaters, it made an impact (and some enemies in the NFL) for revealing the damage that years of gridiron rough-and-tumble can inflict on players’ brains, their relationships, their lives. But while most viewers saw the film as a dramatized exposé of the dangers of contact sport, Harry B. Rice, PhD, vice president, regulatory and scientific affairs for the Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City), viewed its message through a different lens.

“Consider the handful of football players mentioned in the movie,” he says. “Mike Webster, Terry Long, Justin Strzelczyk, Andre Waters, Junior Seau: they committed suicide due to chronic traumatic encephalopathy, or CTE, a progressive degenerative disease found in people who have had a severe blow or blows to the head.” So even as their stories laid bare the tragedy of repeated head injury, they underscored the mechanism that renders those injuries so tragic over the long term: inflammation.

As Rice explains, “Neuroinflammatory processes apparently progress after the initial head injury and worsen with time.” Research now shows that inflammation from such injuries can instigate a number of chronic, debilitating conditions, not least of which are traumatic brain injury, Parkinson’s disease, Alzheimer’s disease, and—yep—CTE.

But that’s only the start. Studies link chronic inflammation to osteoarthritis, allergies, heart disease, diabetes—even some cancers. And while football players can look to rules changes for protection, evidence suggests that supplements can do the same for the rest of us. As Linda Doyle, senior vice president, global marketing, OmniActive Health Technologies (Morristown, NJ), says, “What’s exciting is that we have a better understanding of the relationship between inflammation and disease, the mechanisms involved, and the science on natural ingredients that can help.”

Inflammation Nation

If “Concussion” placed head injuries squarely on the public’s radar, the inflammation underlying them “has covered only half its journey” toward widespread relevance, says Shaheen Majeed, marketing manager, Sabinsa (East Windsor, NJ). Yet thanks to coverage (not to mention advertisements) on websites, blogs, social media, television, and the big screen, inflammation’s profile is growing. The upshot, says Majeed, is that more consumers “now take measures to prevent and manage inflammation with the intent of avoiding the chronic disorders” that it triggers.

Doyle sees a similar trend. Consumers have traditionally associated inflammation mostly with joint health, she notes, but the continued effort to call attention to inflammation’s broader consequences has left mainstream shoppers “increasingly aware of the relationship between inflammation and disease.”

When Good Inflammation Goes Bad

Of course, that relationship isn’t all black and white, as inflammation isn’t universally bad. There’s a reason our immune systems mount vigorous inflammatory responses when conditions warrant: such responses keep us alive, putting a defensive ring around pathogens, toxins, and garden-variety dead and damaged cells. Notes Rice, “My perception is that most people think inflammation is a dangerous thing, but inflammation is necessary for the body to heal itself after injury, or to protect itself against bacteria and viruses.”

Yet if healthy inflammation is a body’s best friend, inflammation cranked into overdrive is more trouble than it’s worth. One need look no further than the inflammatory components of, say, meningitis or inflammatory
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Inflammation

bowel disease (IBD) to understand that just as “an absence of inflammation would be deadly,” as Rice puts it, “the presence of inflammation can be deadly, too.”

**Warning Signs**

If nothing else, inflammation is unpleasant, with pain, heat, redness, and swelling all cardinal signs of its acute presence. But at the molecular level, clinicians and researchers monitor more sophisticated markers to determine whether or not inflammation has gone dangerously chronic. Cyclooxygenases (COX), tumor necrosis factor alpha (TNF-α), prostaglandin E2 (PGE2), thromboxane A2 (TXA2), leukotriene B4 (LTB4), C-reactive protein (CRP), monocyte chemoattractant protein-1 (MCP-1), matrix metalloproteinases (MMPs), and interleukins (IL)-1, IL-6, and IL-8 all “give us a detailed perspective of the grade or extent of inflammation,” Majeed says.

Once that grade and extent reach a breaking point, chronic diseases ranging from metabolic syndrome and rheumatoid arthritis to pulmonary disorders and depression surface.

**Botanical Benefits**

“As an aging population confronts these diseases, the increasing demand for dietary supplements targeting inflammation is understandable,” says Eric Anderson, senior vice president, global sales and marketing, NattoPharma USA Inc. (Metuchen, NJ), North American subsidiary of NattoPharma ASA (Oslo, Norway).

Thanks to research into the mechanics of inflammation, the means by which supplements target inflammation are increasingly understandable, too. “Broadly speaking,” Doyle explains, “supplements help reduce inflammation by interacting with biochemical and messenger pathways that regulate—or dysregulate—inflammation.”

In vitro and in vivo human clinical studies bear this out, with results indicating that plant-sourced bioactives may “prevent and manage a host of inflammatory-related conditions,” Majeed notes. He points to clinical evaluations of such natural supplements as curcuminoids, ginger extract, and boswellia extract, to name a few, that find a “significant role” for these ingredients in managing inflammation-associated conditions.

Take boswellia. A product of the same plant that gives us Indian frankincense (Boswellia serrata), boswellia extract is rich in boswellic acids, the pentacyclic triterpenes that are its active components. “The anti-inflammatory property of boswellic acid is...
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Curcumin's anti-inflammatory effect is attributed to its suppression of NF-kB, a protein complex that controls DNA transcription, cytokine production, and cellular survival. Due to its unique ability to block two pro-inflammatory enzymes: 5-lipoxygenase and human leukocyte elastase," Majeed says. "This mechanism is much like conventional non-steroidal anti-inflammatory drugs, or NSAIDs," but without side effects like stomach irritation and ulceration.

His company produces a powdered extract sold as Boswellin that’s standardized to contain β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid, and acetyl-11-keto-β-boswellic acid. In a 48-subject, double-blind, randomized, parallel-group, placebo-controlled internal company study investigating the extract’s effect on arthritis symptoms, researchers found a statistically significant reduction in clinical symptoms—pain, stiffness, physical function—in the treatment group as compared to the placebo, Majeed says. Improved scores on the WOMAC osteoarthritis index and visual-analog pain scale (VAS), plus longer distances covered in six-minute walk tests, “further confirm” the extract’s utility, he concludes.

**Ancient Traditions**

Majeed notes that India’s Ayurvedic medical tradition has long deployed botanicals like boswella against arthritis and related inflammatory conditions. Another tool in its arsenal is ginger extract (Zingiber officinale) and the gingerols that are its major bioactive compounds. While ginger extract’s use as an anti-inflammatory “has been well documented throughout history,” Majeed says, “we now know that its mechanism of regulating inflammation is to inhibit prostaglandin biosynthesis,” specifically of COX-1 and COX-2. “Ginger additionally suppresses the immune system’s production of pro-inflammatory cytokines and chemokines,” he adds, “reducing disease severity in patients with inflammatory conditions such as rheumatoid arthritis [RA].”

As far as managing the more commonly experienced osteoarthritis (OA) goes, Majeed cites a 2005 double-blind, randomized, placebo-controlled study that compared the effects of ginger extract against the NSAID ibuprofen and a placebo in 120 outpatients with moderate to severe arthritis pain. After one month of treatment, VAS scores and reports of regressive pain after rising were significantly lower in both the ginger and ibuprofen groups than in those taking the placebo—indicating not only that ginger extract helps manage arthritis pain, but that it does so as effectively as ibuprofen.

Another staple of Ayurvedic medicine—and another botanical in the anti-inflammatory armamentarium—is turmeric extract (Curcuma longa) and its constituent curcuminoid actives. As Majeed explains, curcumin’s anti-inflammatory effect is attributed to its suppression of NF-kappaB (NF-kB), a protein complex that controls DNA transcription, cytokine production, and cellular survival. “Through this suppression,” he says, “curcuminoids reduce pain and inflammation.”

Daily supplementation with Sabinsa’s Curcumin C3 Complex—standardized to contain no less than 95% curcuminoids and to be particularly rich in curcumin, demethoxycurcumin, and bisdemethoxycurcumin—was the subject of a six-week, double-blind, placebo-controlled study whose 40 participants had mild to moderate osteoarthritis of the knee. The curcumin complex proved “effective in alleviating pain associated with OA, as evaluated by significant reduction in WOMAC scores,” Majeed notes, “especially with respect to significant improvement in pain and physical-function scores.” Researchers similarly observed a reduction in VAS and Lequesne’s pain functional index scores, and a significant reduction in patient painkiller dependence.

While the results of such studies aren’t exactly common knowledge, Doyle notes that “consumers are well aware of the benefits of supplementing with curcuminoids.” Her company, OmniActive, may claim some credit for putting it on the map, as it’s undertaken “an exhaustive amount of preclinical work, including nutrigenomics; enzyme assays; *in vitro*, dose testing, interaction, and safety studies; and a battery of toxicological studies to characterize metabolic targets and cellular uptake” of the curcumin, she says.

For example, OmniActive presented findings at Experimental Biology this year demonstrating the influence of its branded CurcuWin extract on endothelial dysfunction, a key indicator of heart disease. It also presented a patent on the product detailing a “landmark” animal study that shows the ingredient’s implications for brain and mood health. "Our robust clinical program is exploring more novel uses for the product," she adds, "including heart health, cognitive function, diabetes, and exercise performance, to name a few."

And because bioavailability "has been an area of focus," Doyle says, her company uses what it calls its UltraSol delivery system to increase the extract’s solubility and bioavailability, dispersing the curcumin into a powder purified to 95% curcuminoids and blending it with a water-soluble carrier, food-grade excipients, and antioxidants to protect its...
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methods found absorption 46 times greater
compared to standard curcumin and signifi-
cantly greater than that achieved with other
enhanced forms, she says.

Friendly Fats
Botanicals like curcumin are promising, but
they’re not the only effective anti-inflamma-
tory supplements in town. Indeed, a full ac-
counting of the range of supplements that
address inflammation exceeds the scope of
this article. But among the more extensively
studied are the long-chain polyunsaturated
omega-3 fatty acids (PUFAs) eicosapentaenoic
acid (EPA) and docosahexaenoic acid (DHA).

GOED’s Rice believes EPA and DHA stand
out thanks to their “long history of safe use
coupled with an impressive portfolio of re-
search results supporting their anti-inflam-
matory benefits.” Consider what goes on in
Alzheimer’s disease. “There are many hy-
potheses about its causes,” Rice says, “and the
inflammatory theory is one of them. If true,
keeping acute inflammation from progress-
ing to chronic inflammation with EPA and
DHA could very well result in maintaining
cognitive health throughout life.”

There’s also “high-quality research” dem-
onstrating an EPA/DHA benefit with regard
to rheumatoid arthritis, such as a 2015 study3
showing that “individuals with rheumatoid

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A Novel Path to Cardiovascular Health

NattoPharma’s Anderson notes that one nutrient heretofore associated mainly with maintaining calcium balance in bones and blood vessels is now garnering attention for fighting inflammation. That nutrient is vitamin K2, or menaquinone, and while this “is an early area of research” for the vitamin, Anderson says, “the results thus far are promising.”

For instance, by testing and confirming that the longer-chain menaquinone-7 form of vitamin K2 helps modulate certain immune and inflammatory biomarkers, a study published this year in the Journal of Medicinal Food successfully demonstrates yet another path by which the vitamin supports cardiovascular health.

It sounds like a roundabout conclusion, but as the study’s authors note, cardiovascular disease “is not only considered a disorder of lipid accumulation, but also a disease characterized by low-grade inflammation of the endothelial cells and an inappropriate healing response of the vascular lining.” That prompted the researchers to investigate the ability of high-purity natural vitamin K2 (98.4% MK-7 from NattoPharma) to inhibit gene expression and production of pro-inflammatory markers in human monocyte-derived macrophages (hMDMs) from two sources (hMDMs and THP-1).

Sure enough, MK-7 did show a dose-dependent inhibition of the in vitro gene expression and production of inflammatory markers TNF-α, IL-1α, and IL-1β in healthy hMDMs. “In view of these encouraging findings on the anti-inflammatory properties of MK-7,” the researchers write, “we plan to test additional biomarkers of immune and inflammatory response in this form of vitamin K2 in vivo.” In so doing, they hope...
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Inflammation to tease out vitamin K’s anti-inflammatory mechanism and establish potential biomarker targets for the clinical testing of MK-7 in cardiovascular health and other chronic conditions. And if similar effects emerge in vivo, they added, “It will be very beneficial for people who need to be on anti-inflammatory treatment.”

Inflammatory Statements
Despite the promise of these natural interventions, supplement marketers will need to be very careful in communicating their effects to consumers. “Key here is that anti-inflammatory supplements ‘reduce’ inflammation,” Doyle says. “They don’t stop it. So supporting healthy inflammation is an important aspect of supplements.”

Just ask FDA, which regards inflammation-related health claims as drug claims unless they’re crafted specifically as structure/function statements referring to the process of modulating the normal inflammatory response. In other words, Doyle says, “Claims must be made for ‘normal functioning,’ and disease endpoints must not be involved in claims or studies that support compliant health claims.”

Even so, “Consumers, for the most part, are more interested in products that address specific needs,” she says. That means that statements like “supports heart health” or “supports joint health” carry more weight than “supports healthy inflammation.” But as consumers grow savvier about the inflammation-disease relationship, Doyle insists, “They will pay more attention to inflammation as part of a lifestyle and supplement regimen to mitigate its effects.” And we’ll all be better off as a result.

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6. Pan MH et al., “Inhibition of TNF-α, IL-1α, and IL-1β by pretreatment of human monocyte-derived macrophages with menaquinone-7 and cell activation with TLR agonists in vitro,” Journal of Medicinal Food. Published online May 20, 2016.

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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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By now, the notion that glucosamine and chondroitin sulfate sales are declining, or at least leveling off, should not come as a big surprise. After all, some market researchers (not all) have reported net losses for these joint-health giants for a few years now. Although glucosamine and chondroitin still make up the whopping majority of the market, consumer concerns over issues like adulteration, reports of some poor-quality products, allergies related to shellfish sources, plus the not-so-natural state of some highly processed ingredients have all contributed to diminishing sales—in spite of the fact that there is modern data suggesting that these ingredients may alleviate conditions such as osteoarthritis.

Some of those lost dollars are now being taken up both by other familiar joint-health ingredients and lesser-known alternatives (like botanicals). There are many options, and research is expanding around these ingredients.

**Vegetarian Alternatives**

If there’s one bright spot for glucosamine and chondroitin right now, it may just be vegetarian versions of these ingredients. These options not only open channels to vegetarian consumers; they also eliminate any animal-source concerns, such as shellfish allergies.

Gnosis S.p.A. (Desio, Italy), for instance, is stepping into the chondroitin sulfate arena with its latest ingredient, Mythocondro, launched at this year’s SupplySide West trade show. Produced through a non-animal fermentation process, Mythocondro is said to be structurally and functionally similar to traditional chondroitin sulfate. Because cow, pig, chicken, and fish species can all be used as raw material for chondroitin sulfate, Gnosis product-support specialist Lorena Carboni says it’s possible that products may include a blend of all of these sources. According to Carboni, the result may be “a chondroitin sulfate final product [with] mixed characteristics and not-well-defined activities.” By providing a traceable and consistent product, she adds, Mythocondro can avoid product-of-origin and adulteration questions that plague the modern chondroitin sulfate market.

Chondroitin isn’t the only ingredient going vegetarian; multiple ingredient suppliers offer glucosamine ingredients created from plant sources using fermentation and fungal processes. Some of the most famous of these ingredients are Cargill’s (Minneapolis) Regenasure ingredient, TSI USA’s (Missoula, MT) GlucosaGreen and its brand new GlucosaGreenDF, and Ethical Naturals’ (San Anselmo, CA) GreenGrown glucosamine. Although these ingredients have been on the market for years, suppliers like Cargill say they are now seeing renewed interest in them, from both new and existing joint-health product manufacturers, some of whom may have once been formulating with animal sources.
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Collagen

Collagen sales continue to impress with an estimated 123% sales boost over the last year, according to SPINS data. These building blocks of connective tissue are well studied, and, in some cases, they’re found with innate glycosaminoglycans and other useful compounds.

Not all collagen is the same, however. BioCell Technology LLC (Newport Beach, CA), for instance, supplies a collagen composition of type II collagen, hyaluronic acid, and chondroitin sulfate. BioCell has already completed significant amounts of joint-health research on this ingredient, BioCell Collagen. Recent clinical-trial findings indicate that, by supporting joint health, the ingredient may lead to improvement not only in daily activities but also functional recovery from exercise.1,6

Rousselot (Son, Netherlands), on the other hand, offers a collagen peptide, Peptan, based on type I collagen. When put to the test earlier this year, Peptan generated more cartilage and protein synthesis in animal subjects, while also significantly reducing joint-related inflammation markers.7

Type I and type II collagen aren’t the only collagen types making news. Thanks to a patented processing method, Certified Nutraceuticals’ (Murrieta, CA) KollaGen IVX ingredient, derived from eggshell membrane, contains significant levels of type I collagen, but also type V and type X collagen. While these obscure collagens are found in extremely lower amounts, they are believed to play important roles in the regeneration of type I collagen and the protection of tissues. The company also offers another joint-health product, TendoGuard, that combines types I, II, V, and X with glycosaminoglycans, plus hyaluronic acid and chondroitin sulfate.

As the research piles up on collagen ingredients and joint health, companies are actively seeking global health claims to back their collagen ingredients.

Gelita (Sergeant Bluff, IA) filed for European health claims relating to its Fortigel gelatin peptides back in July 2015, but then EFSA announced new guidelines for health claims in January 2016. The new guidelines included new recommendations for scientific substantiation, leading Gelita to withdraw its original applications. The company told Nutritional Outlook that it is already working on new studies and intends to refile its applications to meet the new recommendations.

Collagen ingredients can be derived from a variety of animal byproducts, including cartilage from cattle, pig, fish, and chicken. Eggshell membrane is another such byproduct. Byproducts enable companies to reuse materials that otherwise would be discarded, and by doing so, create an appealing sustainability story.

Together with its manufacturing partner ESM Technologies, ingredient distributor Starch Nutrition (St. Charles, MO), which markets the NEM brand of eggshell membrane, says the NEM business has already diverted over 11,000 million tons of raw, broken eggshells from landfills to the ingredient supply.

MSM

As a naturally occurring sulfur compound in plants, methylsulfonylmethane (MSM) continues to gain the backing of positive clinical results in studies testing MSMs use alone or in combination with other ingredients intended for joint health.

In recent trials, MSM combined with ingredients like boswellic acid, chondroitin sulfate, curcumin, collagen, hyaluronic acid, and numerous other ingredients appeared to relieve pain and improve functionality in various joint-related disorders.8,9,10

While noting that MSM is highly effective on its own, “many of our customers use it in combination with other ingredients,” says Tim Hammond, vice president of sales and marketing at Bergstrom Nutrition (Vancouver, WA), purveyor of the OptiMSM brand. Hammond adds that additional areas of interest for MSM include uses in post-workout recovery. Already, positive studies are starting to emerge in this area.

Turmeric

A host of botanical ingredients have also shown therapeutic promise for joint health.

The botanical superstar turmeric (Curcuma longa) is probably one of the most famous in this area. Latest sales numbers out of the American Botanical Council’s HerbalGram journal indicate that in 2015 alone, turmeric sales grew 32.2% in the natural channel. According to another market report from SPINS, turmeric sales in U.S. health channels increased 156% in the past year.

As turmeric suppliers fight for their share of the joint-health space, one supplier, Sabinsa (East Windsor, NJ), believes its unique approach to turmeric and joint health is best for yielding results. For nearly a decade now, the company has promoted the ingredient turmeric in Arthriblend-SR, a sustained-release combination of curcumin (a primary bioactive in turmeric), boswellic acid, glucosamine, and piperine. Each component of Arthriblend-SR has been evaluated in its own right for joint health, and each works through a different mechanism of action.

Arthriblend-SR’s unique delivery system ensures sustained release of the actives over an eight-hour period. This can be reassuring when one considers the relatively short

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half-life of curcumin and boswellic acids in the body. Put simply, by extending release, Arthriblend-SR gives these active ingredients a better chance of efficacy, Sabinsa suggests.

Clinical improvements seen with Arthriblend-SR include reduced use of painkillers and improvements in musculoskeletal movement and WOMAC scores.

Research also continues to support curcumin’s potential role in alleviating joint-health problems on its own.11,12

Chebulic Myrobalan
Throughout South Asia, the Ayurvedic plant chebulic myrobalan (Terminalia chebula) is regarded for its fruit’s healing properties—so much so that it is sometimes referred to in Tibet as “King of Medicine.”13 Seeing a financial opportunity in this, Natreon (New Brunswick, NJ) recently introduced AyuFlex, an aqueous extract of chebulic myrobalan that can be sold as a dietary supplement.

Earlier this year, researchers reported clinical improvements in stiffness and WOMAC scores, along with a decreased need for painkillers, when AyuFlex supplementation was compared with placebo supplementation in osteoarthritis subjects after 12 weeks.14 Results of an additional study, this time on joint mobility in overweight subjects, were revealed at this year’s SupplySide West show but were not available at press time.

Horsetail
Although it may come as a surprise to some of us, horsetail (Equisetum arvense) was a big earner in joint-health supplements last year, according to SPINS data. The species of rush plant pulled in an 18% increase in industry sales. Horsetail supplier Draco Natural Products (San Jose, CA) confirms the success, having seen its own recent increase in horsetail powder sales and turnover of inventory.

Clinical research on horsetail consumption is still lacking, but some studies suggest that horsetail may be a useful supplement for bone nutrients and pain relief.15,16 Horsetail is believed to be a bioavailable source of silicon. Silicon performs an important role in connective tissues, such as cartilage and bone.

A considerable body of research exists for silicon. And the horsetail supply is ripe, too. Draco Natural Products, for instance, can and does source horsetail powder from virtually every province in China.

Robby Gardner is the former associate editor of Nutritional Outlook magazine.

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1. SPINS recorded a $23.8 million loss in cross-channel aggregate U.S. sales for glucosamine–chondroitin combination products in the 52 weeks ending July 10, 2016, and a $14 million loss for solo glucosamine supplements.
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5. HL Lopez et al., “Evaluation of the effects of BioCell Collagen, a novel cartilage extract, on connective tissue support and functional recovery from exercise,” Integrative Medicine, vol. 14, no. 3 (June 2015): 30–38


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Because zinc is such an important part of human biochemistry, any deficiency in zinc can have dire consequences, including stunted growth and development, immune dysfunction, and metabolic imbalances. We’ve seen the consequences of zinc deficiency in underdeveloped countries where food is scarce and socioeconomic status is low. In 2004, zinc deficiency in these populations was linked to over 450,000 deaths in children under the age of five.2

But even marginal or subclinical levels of zinc can be detrimental, as seen in populations that require increased zinc stores, such as pregnant woman and growing adolescents.3 Finally, several chronic health conditions may exacerbate the need for zinc, including bowel diseases, liver and kidney diseases, and diabetes.1

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a whopping 17% of the population. What’s perhaps even more surprising is the level of zinc deficiency in developed countries. In the United States, 35%–45% of adults aged 60 and older have zinc intakes below the recommended dietary allowance (RDA).

Why aren’t we getting enough zinc in the diet alone? It’s simple. The foods we eat today are relatively low in zinc (as well as other vitamins and minerals). This makes zinc deficiency a public health issue. From a dietary perspective, we need to place more emphasis on eating nutrition-rich foods. Failing that, we can also turn to dietary supplements to help fill in nutritional gaps.

There is some good news, however: more consumers are interested in supplementing with zinc these days. According to recent SPINS data, U.S. sales of zinc supplements (in which zinc was the primary ingredient) grew 20% between July 2015 and July 2016, from $18 million to $21.6 million. Nearly half of those sales ($10.3 million) came from the immune-health market. In fact, within the cold and flu category, sales of products with zinc as a primary ingredient grew 8% between July 2015 and July 2016.

Zinc sales are also growing across delivery systems. According to SPINS, sales of zinc caplets grew the most during that time frame, followed by capsules, soft gels, liquids, tablets, and lozenges, respectively, with only chewables showing a decline.

Why is the importance of zinc now resonating more strongly with dietary supplement users? Perhaps those users have been following the promising research on zinc, not only for immune health but for other important aspects such as metabolic health, growth, and development. Here are just a few recent studies driving home the necessity of this crucial mineral.

**Immune Health**

Immune health is the health condition most often linked with zinc. Researchers continue to investigate the association between zinc status and immune wellness. More studies are finding that zinc in fact has a tremendous influence on all areas of the immune system. Immune cells by nature are constantly renewed and reproduced. The two major arms of the immune system are the innate immune response and the adaptive immune response.

The **innate** response acts as a first line of defense involving polymorphonuclear leukocytes, macrophages, and natural killer cells. Zinc’s major role in this area is to support cell proliferation. Zinc shores up the function of all of these cells. Conversely, a zinc deficiency reduces these cells’ ability to function.

T cells form the core of the **adaptive** immune response. Zinc supports both the production and function of T cells and the overall balance of T cell subsets, helping to modulate the adaptive immune response.

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anti-inflammatory cytokines. For all these reasons, zinc has a substantial impact on the body’s immune defenses.

In a current review paper, Martina Maywald and Lothar Rink of RWTH Aachen University Hospital (Aachen, Germany) argue that elderly populations need to supplement with zinc to support their immune health. Marginal zinc deficiency is common in this population. The researchers stress that even a marginal deficiency results in substantial dysregulation in adaptive immune function in seniors, leading to an increased production of pro-inflammatory cytokines and disturbances in the balance between cell-mediated and humoral immunity. Supplementing with oral zinc can help normalize zinc levels and restore important functions of the immune system in elderly individuals, the researchers say.

In a recent study on zinc supplementation in seniors, 58% of nursing home residents tested were found to have low serum zinc concentration (<70 mcg/dl). Led by Junaidah Barnett and colleagues from the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University (Boston, MA), the researchers then performed a double-blind, placebo-controlled trial to explore the immune-health benefits of supplementing with 30 mg of zinc per day for three months. Subjects supplementing with zinc were found to have significantly enhanced T-cell function thanks to an increase in T-cell proliferation, all in support of better overall immune function.

What’s more, in yet another recent study on zinc and immune function, Thai researchers from Chulalongkorn University (Bangkok) assessed the benefits of supplementing with 30 mg of zinc daily for eight weeks in individuals with type 2 diabetes and metabolic syndrome. Because this patient population is considered immune-suppressed and at higher risk of developing infections and cancer, researchers were impressed to find that daily zinc supplementation led to improved function of monocytes (white blood cells crucial to the immune response).

**Metabolic Health and Diabetes**

One indicator that zinc is important to metabolic health is the fact that the pancreas contains the body’s second-highest store of zinc, after the prostate. Recent research on zinc’s role in metabolic health has revealed some novel findings, including the fact that zinc plays an important part in supporting the function of insulin.

Zinc is involved in a number of functions related to insulin. It performs as an insulin “mimetic” (mirroring the role of insulin), helping to support signal transduction via insulin receptors, influencing insulin storage and secretion, and directing insulin distribution in tissues and organelles. Zinc also supports insulin-mediated glucose transport in muscle, fat, and liver tissue, thus influencing glycemic control.

In order to explore zinc status in individuals with diabetes, Judith Jansen and colleagues from RWTH Aachen University recruited 75 individuals with either type 1 or type 2 diabetes. The researchers then matched the subjects (by sex and age) with 75 non-diabetic individuals who served as controls. After measuring subjects’ serum zinc levels, researchers found that diabetics were significantly zinc deficient. Similar trends were found in intracellular zinc concentrations compared to controls.

A more recent trial led by Fatemeh Foroozanfar of Kashan University of Medical Sciences (Kashan, Iran) evaluated the effect of zinc supplementation on metabolic markers
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in women with polycystic ovarian syndrome (PCOS). In the eight-week randomized, double-blind, placebo-controlled study, 52 women aged 18–40 with PCOS supplemented with 220 mg of zinc sulfate (50 mg elemental zinc) or a placebo daily. Blood tests were performed at baseline and after eight weeks to assess changes in blood sugar control, insulin, and lipid concentrations.

Subjects taking zinc had significantly reduced fasting plasma glucose and serum insulin levels compared to the placebo group; the placebo group displayed slight increases in both parameters. In addition, markers of insulin resistance, serum triglycerides, and very-low-density lipoprotein (VLDL) cholesterol were all significantly lower in zinc-treated women. Assessment of pancreatic beta-cell function also revealed significant improvements versus placebo, indicating the potential benefits of zinc supplementation for supporting metabolic parameters related to blood sugar management.

The results of these and other studies suggest that zinc is not only essential for metabolic health and function, but that, pending the results of further research, supplementing with this mineral may have significant therapeutic benefits for impaired blood sugar control.

Growth and Development

Zinc is also an essential nutrient for growth and development. Research indicates that inadequate zinc status increases the risk of pregnancy complications. Unfortunately, pregnant women generally do not get enough zinc.

Even mild zinc depletion in expecting mothers has been associated with growth retardation in the uterus. Furthermore, zinc is essential for bone growth and development. It interacts with several hormones involved in bone metabolism. In bone tissue, zinc concentrations are quite high compared to zinc stores in several other tissues, making it an essential component of bone matrix. Zinc has also been found to enhance the effects of vitamin D on bone health by enhancing the stimulation of DNA synthesis in bone cells.

Several recent investigations reveal the beneficial effects of zinc on various aspects of growth and development. In a recent double-blind, randomized controlled trial, Samia Nossier and colleagues from Alexandria University (Alexandria, Egypt) investigated the impact of zinc supplementation in healthy pregnant women with low serum levels of zinc. In the trial, 675 pregnant women aged 20–45 were randomized into one of three supplementation groups: 1) supplementation with 30 mg of zinc (as zinc sulfate), 2) supplementation with 30 mg of zinc plus vitamins, or 3) supplementation with a lactose placebo. Subjects supplemented daily, from the time of study recruitment to one week post-delivery (the follow-up period).

The zinc supplements in both zinc groups were equally effective, and superior to placebo in reducing second- and third-trimester complications as well as the occurrence of stillbirth and preterm delivery. The occurrence of neonatal infections also significantly decreased with zinc supplementation, supporting the benefits of zinc supplementation for both mother and developing fetus.

An interesting study led by Paige Berger from the University of Georgia (Athens, Georgia) assessed the potential usefulness of zinc for bone development in adolescent girls. Adolescence is a time of rapid growth and, as such, the authors sought to determine the impact of zinc on markers of bone turnover in 147 girls aged 9–11.

The girls were randomized to supplement with zinc (9 mg/day) or a placebo for four weeks. At the end of the study, zinc supplementation, compared to placebo, significantly enhanced serum levels of an important marker of bone turnover known as procollagen type 1 amino-terminal propeptide (PINP). The increase in this marker indicates zinc’s ability to enhance bone formation in young, adolescent girls and suggests that zinc plays a crucial part in improving childhood bone strength.

Another recent study, published in August 2016, looked at zinc’s effects on growth. Conducted by Sanguansak Rerksuppaphol and colleagues from the Department of Pediatrics at Srinakharinwirot University (Nakorn Nayok, Thailand), the study evaluated the benefits of zinc supplementation, along with a multivitamin, in children.

In the randomized, controlled trial, 140 children aged 4–13 were asked to supplement with either a placebo or with 20 mg of zinc (as zinc bisglycinate) plus a multivitamin. Subjects took these protocols five days per week for six months.
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The primary endpoint of the study was to assess a change in height. In the groups supplementing with zinc, subjects grew significantly more compared to the placebo group (a mean gain of 4.9 cm versus a mean gain of 3.6 cm, respectively), indicating the positive effect of zinc in combination with multivitamins in growing children.

**Zinc’s Time to Shine?**

As a mineral intimately involved in so many biological processes, from birth onwards, zinc is an indispensable nutrient for life. Given that such a large swath of the global population is at risk for stark zinc deficiency, and that several populations such as seniors, pregnant women, and children have a greater need for this essential mineral, it’s important to ensure a sufficient intake of zinc through diet and supplementation. The wide-ranging roles zinc plays in areas as diverse as immune health, growth and development, and numerous metabolic functions make zinc a critical nutrient for achieving optimal health throughout the human lifespan.  

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

**References**


Digestive-Health Market

The digestive-health market is thriving. Experts explain why probiotics and low-FODMAP diets are growing their slice of the pie.

BY KIMBERLY J. DECKER

Digestive health is one of the most successful dietary supplement categories today. Whether it’s gluten avoidance or probiotic usage, discussions of gastrointestinal (GI) health aren’t just trending on talk shows and wellness blogs; they’re fueling an entire category of functional foods, beverages, and ingredients that promise smoother gastrointestinal sailing.

As Julian Mellentin, director, New Nutrition Business (London), wrote last year in another publication, “It’s often overlooked how much consumers’ interest in good digestive health powers many other trends.”

Product developers who do overlook interest in digestive health do so at their peril. For digestive health, Mellentin wrote, “is a benefit with wide appeal.”

Modern Tendencies
How wide of an appeal? Marissa Gilbert, health and wellness analyst, Mintel, notes that two-thirds of adults have experienced some species of gastrointestinal issue, “indicating a strong consumer base for the digestive-health market,” she says. And a dive into her company’s Global New Products Database (GNPD) reveals that as many as 16% of worldwide functional claims made between 2013 and 2015 spoke to digestion. As far as the global market value of the category goes, market researcher Euromonitor International pegged it at an impressive $70 billion in 2015 alone.

Such robust interest won’t surprise any of those who know gastro grief up close and personally. For, says Melissa DeVincenzo, chief marketing officer, TrueSelf Foods (Waccabuc, NY), “The pain and discomfort that come with gastrointestinal discomfort can wreak havoc on consumers’ quality of life.” Making matters worse, she adds, “Triggers associated with gastrointestinal discomfort can be difficult to identify, and treatment options limited.”

Factors like everyday stress; the postmodern tilt toward highly processed, fiber-poor diets; and the incontrovertible fact that none
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of us is getting any younger all compound the problem. The result: digestive health will be a concern going forward. As Euromonitor’s 2015 “Digestive Remedies in the US” report stated, “These modern tendencies have significantly increased the frequency of acute digestive ailments, such as indigestion, bloating, nausea, and diarrhoea.”

**Digestive Health = Whole Health**

Fortunately for the afflicted, digestive distress is now worthy of “dialogue.” Once not fit for polite company, gut health has become easier to discuss, and that deepening discussion has made consumers more comfortable as contributors. Notes Megan DeStefano, probiotics marketing, DuPont Nutrition & Health (Madison, WI), “Consumers have always been bothered with digestive issues. But this more-public discussion has removed the taboo associated with it. Now consumers are less reluctant to share information with others who have similar issues.”

They’re less reluctant to share information with their clinicians, too, and the entire medical community—not just GI specialists—are realizing, along with the rest of us, that without digestive health, whole-body health is out of reach. As DeStefano says, “We’re seeing mounting evidence that healthcare professionals and consumers alike understand that good gut health can have benefits beyond the belly.”

That’s evidence that Mike Bush, president, Ganeden Biotech (Cleveland), and executive board president of the International Probiotics Association, knows well. “Maintaining a healthy gut is unbelievably important, as the digestive system is ground zero for many of the body’s vital functions,” he says. “We know the role the gut plays in breaking down nutrients, but there’s growing evidence of a link between gut health and the proper function of the immune system, reduction in inflammatory processes, mood regulation, and metabolic processes.”

**Feed Me**

The more consumers learn about this gut-body connection, the more they value products that optimize the functioning of both. Further, though digestive-health supplements have long been mainstays of the sector, smart money now gravitates toward functional foods and beverages as naturally promoting healthy digestion.

The logic is elementary: If we know that some foods and drinks exacerbate digestive distress, it follows that “a chief solution can largely be attained through dietary management,” Gilbert says. What’s more, the food-first strategy fits with how health-aware consumers care for themselves today. Says Bush, “The beauty of functional foods is that consumers are able to get the desired health benefits from foods and beverages that they already enjoy, without taking another pill.”

**Bugging Out**

Among the first foods and beverages to develop a following for their digestive benefits were fermented yogurts and dairy beverages rife with probiotic bacteria—the OGs of gut-health ingredients. As Bush points out, “While health fads have come and gone, the probiotic category appears to have serious stamina.”

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He’s not kidding. Mintel’s “Digestive Health - US - July 2015” report found probiotics and prebiotics accounted for 69.4% of the digestive-health market in natural supermarkets that year. And in a consumer survey that Bush’s own company recently conducted, 40%–54% of respondents said they’d be willing to pay more for a food or beverage containing good gut bugs, while a notable 70% of them expressed a preference for consuming those probiotics in foods or drinks rather than via supplements. No wonder Ganeden’s partners launched more than 60 new probiotic SKUs during March 2016’s Natural Products Expo West trade show, Bush says—“more than double last year.”

Yet if consumers are hungry—and thirsty—for probiotic products, that doesn’t mean they’ll shell out for options that promise more than they deliver. The upshot: ingredients with scientific track records stand the best chance of success, DeStefano notes that “strong clinical studies” validate the ability of patients with scientific track records stand the best chance of success. DeStefano notes that “strong clinical studies” validate the ability of her company’s probiotic strains Bifidobacterium lactis HN019, Lactobacillus acidophilus NCFM, and Lactobacillus paracasei LPC-37 to support both digestive and immune health. Multiple studies also support the company’s strain combination of NCFM + Bifidobacterium lactis Bi-07, she continues, noting that the probiotic tag team “is being added to new digestive-health products all the time.”

Bush touts the research behind his company’s probiotic strain, too. GanedenBC30 (Bacillus coagulans GBI-30, 6086) not only has 20-plus peer-reviewed clinical studies backing it, he says, but “survives ten times more effectively than yogurt cultures.” That hardiness suits it for use in product environments that would prove too much for standard probiotic strains to tolerate—environments like Brad’s Crunchy Kale, Kale Chi, and Broccoli Poppers snacks; and Little Duck Organics’ Tiny Gummies range of fruit and vegetable snacks; and Little Duck Organics’ Tiny Gummies range of fruit and vegetable snacks—all of which contain the branded probiotic ingredient. “The launches,” Bush says, “demonstrate the endless opportunities for probiotics to expand into new functional-food categories, including children’s products and healthy snacks.”

Sara Cahill, consultant, client insights, IRI Worldwide, believes that “in a society where people are looking to take charge of their digestive issues,” probiotic products “will only continue to see more traction in the marketplace as consumers gain more knowledge and try—and remain satisfied—with the benefits of ‘good’ bacteria.”

As it stands, however, there’s still plenty of space in the room for marketers. IRI’s own All Outlet panel data reveal that fewer than 13% of households currently purchase probiotics. That hints at what she calls “a huge opportunity for educating consumers on the benefits of these products.”

**Filling the FODMAP Gap**

If probiotic products ever realize their full potential, they’ll have both healthy consumers as well as the digestively distressed to thank. By contrast, foods designed to fit into a low-FODMAP diet rely on a much narrower slice of the public for their success.

FODMAP stands for “fermentable oligo-, di-, mono-saccharides, and polyols,” and it emerged as the guiding principle behind an entire way of eating because evidence suggests that limiting consumption of these poorly absorbed carbohydrates may ease symptoms in those suffering from irritable bowel syndrome and other functional gastrointestinal disorders. As TrueSelf Foods’ DeVincenzo notes, “Gastroenterologists, nutrition scientists, and dieticians have identified that symptoms of digestive discomfort associated with gastrointestinal discomfort are relieved when the intake of FODMAPs is restricted.”

Alas, the modern Western diet abounds in FODMAPs, including lactose, sorbitol, xylitol, mannitol, and other sugar alcohols; short-chain fructans found even in healthful foods like beans, nuts, whole grains, and vegetables; and the fructose and other non-glucose monosaccharides present in high-fructose corn syrup, honey, and fruits like watermelon and apples. With these carbs so ever-present, people trying to avoid them could be forgiven for losing hope.

But as the need for low-FODMAP foods has grown, product developers—many who live with that need themselves—are launching products to fill the gap. Dr. Miechelle O’Brien, a practicing gastroenterologist and founder of TrueSelf Foods, is a case in point. “Day in and out,” she recalls, “I would listen to my patients as they told me about the difficulties of managing the pain and discomfort associated with their gastrointestinal disorders. And the treatment options I could offer were so limited.” Their tales inspired her to try low-FODMAP living alongside them—an experience that, for her, “confirmed the research.” According to O’Brien, her patients feel better within two to three weeks of starting a low-FODMAP diet, “allowing them to enjoy a higher quality of life.”

But given that implementing a low-FODMAP diet involves a multi-week routine of scrutinizing labels and constructing meal plans from a strict do/don’t ingredient list, the utility of simplifying, if nothing else, the snacking portion of that regimen occurred to O’Brien, and TrueSelf Foods was born. Launched this fall, the line began with snack bars, with expansion to follow. The bars are certified by the FODMAP Institute, DeVincenzo says, “meaning they’re compliant with a low-FODMAP diet.” The inaugural flavors of banana cinnamon, blueberry, lemon poppy, and pumpkin spice should give consumers sensory pleasure as well as gastrointestinal peace.

O’Brien certainly thinks they will. She believes that her company’s products “will bring greater convenience to those looking to implement a low-FODMAP diet, with certified products that consumers can purchase with confidence.” And when it comes to digestive health, confidence is just what consumers are looking for.

**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.

**References**

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ENZYMES All Around

Enzymes aren’t just about digestive health any more. Today’s enzyme market is flourishing, thanks to a widening reach into many condition-specific categories.

BY MELISSA KVIDAHL

Digestive enzyme sales are on a firmly upward trajectory. According to Euromonitor, the retail value of the digestive enzymes category in the United States rose from $77.2 million in 2011 to $86.8 million in 2016; by 2021, the market could grow to $96.5 million. Chris Penet, vice president of enzymes supplier Bio-Cat (Troy, VA), says growth “is being driven by consumers looking for natural alternatives, and also by increasing awareness and education of the consumer” about these ingredients.

One point in enzyme supplements’ favor is that they enjoy a uniquely widespread appeal, says Melony Fuller, director of marketing at National Enzyme Co. (Forsyth, MO). Enzymes aren’t just popular among the 55-and-older set, who are generally receptive to supplement use; they also enjoy popularity among Millennials, who Fuller says are “the group to watch” when it comes to enzymes. Why? “This group is well informed,” she says, “and actively looking for ways to improve their health and feel their best.”

Undoubtedly, much of the category’s growth comes from enzymes’ popularity in the area of digestive health. Enzyme marketers, however, are smart. They are making a concerted effort to extend the reach of enzymes with innovative, condition-specific blends targeting everything from sports nutrition to pet health. By building on enzymes’ roots in digestion to reach a wider swath of consumers, the opportunities for enzymes are truly limitless. Here’s a look at the top applications driving growth.

Digestion

Consumers are catching on to the fact that enzyme supplements can help them with their digestive woes, and digestive-health concerns remain the top reason consumers buy enzyme supplements.

Some come to the enzymes category having experienced a benefit from probiotics, a sector that’s benefitted from a large volume of positive press in recent years, says Maday Labrador, vice president of education at Enzymedica (Venice, FL). “Enzymes and probiotics are very different but complementary,” she says, and enzymes can take advantage of the fact that education-hungry probiotic
devotees are looking for additional gut support. These customers are more likely to be receptive to enzymes, Fuller says. “Since consumers are always on the prowl for the next ‘magic bullet,’ creating awareness of the importance of digestive enzymes in the body will undoubtedly be the next ‘aha’ moment for digestive health,” she says.

Another point in enzymes’ favor is that consumers can actually feel the relief they get from digestive enzyme supplementation fairly quickly, which sets this ingredient category apart from others, says Mike Smith, vice president at Specialty Enzymes & Biotechnologies (Chino, CA). Once this happens, he says, word-of-mouth becomes a powerful tool. “When something works, people talk,” he says.

At Sabinsa (East Windsor, NJ), vice president of scientific affairs Anurag Pande, PhD, believes there are many catalysts working together to propel digestive enzymes to the forefront: increased awareness of the fact that digestion naturally becomes less efficient with age; increased intake of processed foods across the board; and digestive disturbances caused by food consumption patterns, travel, weather changes, lack of sleep, or stress. “These facts affect young adults, middle-aged working people, and elderly people,” he says, so it should come as no surprise that digestion is still the top reason consumers seek out enzymes.

However, it’s no longer the only reason.

Sports Nutrition
With the sports nutrition market proliferating among practically every consumer demographic—from aging consumers looking to fuel casual workouts to seasoned athletes looking for an edge—more people are consuming whey protein than ever before, says Scott Ravech, CEO, Deerland Enzymes (Kennesaw, GA). Fortunately, enzymes make a perfect pairing with whey protein formulas.

“Enzymes for protein hydrolysis are an ideal complement to these types of protein supplements,” Ravech says. Deerland Enzymes’ ProHydrolase blend, for instance, has been shown to “break down protein into smaller peptides in order for it to be used by the body for muscle recovery as intended,” while also reducing the potential for digestive discomfort stemming from protein intake, he says. Not only that, but ProHydrolase is also effective for the trend- ing subset of sports nutrition consumers using plant proteins like pea or hemp, he adds.

National Enzyme’s BioCore AminoTap blend, an exclusive blend of proteolytic en- zymes combined with zinc targeting the sports market, has also been shown to hy- drolyze a wide range of protein types. According to the company, in vitro studies, the blend was shown to break down the proteins in whey isolate and concentrate, casein, pea, soy, rice, whole egg, and a vegan protein blend. The firm further explains that “the addition of zinc enhances enzyme ac- tivity, accelerating their release and improving the body’s ability to hydrolyze proteins commonly used in muscle-building protein supplements.” As a result, it says, “when Bio- Core AminoTap was added to all these protein supplements, the release of cumulative BCAAs and glutamine nearly doubled.”

Sabinsa’s Pande also categorizes sports nutrition as a key area for enzymes, not just because enzymes can facilitate efficacious protein digestion and absorption, but also because they can be helpful to those suffering from lactose intolerance, for whom dairy- and milk-based sports nutrition prod- ucts can be an issue. “Enzyme blends like Sabinsa’s DigeZyme, which contain enzymes such as lactase, can be very helpful in changing that scenario,” he explains. DigeZyme can even be included within a protein blend to improve digestibility.

Food Allergens and Sensitivities
Just as enzymes can help lactose-intolerant sports nutrition consumers, there is an oppor- tunity for growth in the wider food al- lergens and sensitivities market. “General digestion is still the largest category, though enzymes directed at food sensitivities have become a significant factor in gluten tolerance isn’t necessarily limited to ca- nines with sensitive stomachs or ‘senior’

The way forward for enzymes will be to address broader body benefits.
pets; enzymes also have a role to play when transitioning a dog’s food, which happens at least twice in every dog’s life, he says.

And, mirroring the ways in which enzymes are used in humans, modern enzyme offerings for pets are increasingly focusing on other areas beyond digestion, such as joint health. "Beyond digestion, proteolytic enzyme serrapeptidase breaks down the proteins associated with inflammation, making it an ideal choice for a joint-health formula," he says.

Systemic Enzymes
The way forward for enzymes will be addressing broader body benefits, companies say. Though lesser known, systemic enzymes are "the cutting edge in enzyme therapy," according to Smith. "Systemic enzyme products concentrate on cardiovascular health, joint health, and inflammation," he explains. These include proteases of varying kinds, mostly nattokinase (such as Specialty Enzymes & Biotechnologies’ NattoSEB ingredient) and serratiopeptidase (like the firm’s Peptizyme SP), he says. "They are often combined with other proteases and a few other enzymes to form a very effective systemic enzyme blend."

According to Ravech, protease enzymes have been studied for their systemic benefits "due to their ability to degrade certain proteins associated with blood clot formation, such as fibrin." At Deerland, the solution takes the shape of enzyme blends that incorporate proteolytic enzymes like bromelain, nattokinase, serratiopeptidase, and papain, he says.

What’s Next?
American Laboratories’ Brown believes that there is room for additional growth in the enzyme category, thanks to consumer education efforts as well as the nature of enzymes themselves, which boast "a broad range of applications and sources" that appeal to just about anyone, from vegetarians and athletes to pet owners, gluten-free eaters, and more.

And while blends are already commonplace for enzyme supplement formulators, Dr. Naeem Shaikh, vice president of research and innovation, formulations, at National Enzyme Co., believes the future will include second-generation blends, in the form of pairing enzymes with probiotics, prebiotics, and herbals.

And so the opportunities for enzymes continues. "The gut microbiome is one of the most exciting areas of science today, and the relevance of the microbiome to our health beyond digestion is a hot area for research," says Deerland’s Ravech. "Research over the past two decades has revealed that gut health is critical to overall wellness and immunity, and that an unhealthy gut contributes to a wide range of health challenges."

Melissa Kvidahl is a freelance journalist and copywriter specializing in the health and wellness industry.
Curcumin Improves Endothelial Function in Young Adults, Study Suggests

Oliver JM et al., “Novel form of curcumin improves endothelial function in young, healthy individuals: a double-blind placebo controlled study,” Journal of Nutrition and Metabolism. Published online July 17, 2016.

New study results shared by OmniActive Health Technologies (Morristown, NJ) suggest its CurcuWin curcumin extract enhances vascular function by improving flow-mediated dilation (FMD) in healthy young adults.

Writing in the Journal of Nutrition and Metabolism, researchers report that adults aged 19–29 who supplemented with 1000 mg of CurcuWin for eight weeks experienced a significant improvement in FMD over baseline. FMD values, which are themselves measured by a percentage metric, increased by approximately 3% FMD over the course of the study to reach more than 10% FMD—an overall increase of 37% over baseline.

The study, titled FloMeD, also found a slight improvement in FMD levels from a 250-mg dose of CurcuWin, although this outcome was not found to be “clinically decisive.”

Lower FMD values are associated with higher cardiovascular disease (CVD) risk, OmniActive explains, so CurcuWin’s apparent ability to raise FMD levels is promising. “What’s really exciting about the FloMeD study is that CurcuWin may potentially reduce CVD risk by 27%–52% because every one percentage point increase in FMD potentially reduces cardiovascular risk by 9%–17%,” said Lynda Doyle, senior vice president of global marketing for OmniActive Health Technologies, in the study announcement.

The double-blind, placebo-controlled study included 59 healthy young adults who were randomized to consume a placebo, 250 mg of CurcuWin, or 1000 mg of CurcuWin, with the CurcuWin supplements containing 50 mg or 200 mg of curcumin, respectively.

Additionally, in a subset population of study participants with baseline FMD of less than 7%, both the 250-mg and the 1000-mg doses of CurcuWin resulted in a significant increase of 3.3%-3.6% FMD at the end of the eight-week experimental period.

OmniActive notes this study builds on past CurcuWin research indicating its curcumin extract may be up to 46 times more bioavailable than other forms of curcumin.

“We’re excited to show that this new study further supports how CurcuWin’s greater bioavailability correlates to efficacy at a lower dose and demonstrates a unique benefit for vascular and heart health,” Doyle said. “CurcuWin offers a great alternative to standard curcumin ingredients or when considering a bioavailable curcumin for your formulations.”

French Oak Extract May Boost Athletic Performance, Recovery


Horphag Research (Hoboken, NJ) recently shared study results for its Robuvit French oak-wood (Quercus robur) extract that suggest the ingredient may improve triathlon performance, endurance, and recovery in athletes aged 30–40. The announcement comes just a few months after Horphag Research first made Robuvit available in the United States.

The 2015 study included 54 amateur athletes, half of whom consumed 300 mg of Robuvit daily for two weeks. Supplementation groups were not randomized, but instead based on participant choice following a preliminary briefing. The remaining 27 participants served as a control group that did not consume a placebo. Both groups adhered to the same training routine, but overall nutrition choices were “completely left to the participant," study authors explain.

Following two weeks of triathlon training, researchers found that the Robuvit group experienced greater improvements in swimming and biking times than the control group, as well as a greater decrease in average running time (12.32% decrease for Robuvit versus 3.6% decrease for the control). Overall, total triathlon time improved by -10.56% in the Robuvit group, compared to -3.41% in the control group.

“The -10.56% shorter total triathlon time was considered as a very good improvement, considering that for this type of athlete, being almost at the top of their form, it is difficult to improve even further without severe training,” researchers noted.

Beyond the performance improvements, researchers also noted that several markers of recovery, including post-run muscular pain, cramps, straining, localized pain, and recovery time, “were all considered better” in the Robuvit group, based on subjective assessments completed by study participants. Plasma free radical (PFR) values taken one hour after the final run were also an average of 16.98% higher in the control group, which may indicate higher levels of oxidative stress in the control group than in the Robuvit group.

Researchers used a photometric system to measure reactive oxygen metabolites with the d-ROMS test.

“The presence of post-exercise plasma free radicals is what has been associated with the delayed-onset muscle fatigue that many individuals can experience after a triathlon, or even activity their body isn’t accustomed to,” says Frank Schoenlau, PhD, director of scientific communications at Horphag Research.

Fred Pescatore, MD, nutraceutical consultant for Horphag Research, explains that Robuvit “cuts down on the chemical processes that impede your top performance,” such as oxidative stress.

“For many, the muscle soreness that can linger days afterward is what keeps them out of their gym and off their routine," Pescatore says. "Robuvit greatly reduces the length and severity of this, empowering you to keep training and keep pushing through."
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Puff the Magic Grain

Puffed ancient grains bring a satisfying texture to snacks and cereals.

BY MICHAEL CRANE, ASSOCIATE EDITOR

Once a relatively fringe class of ingredients, ancient grains have come a long way. Whether it’s starring in new cereal launches from packaged-food giants General Mills and Kellogg’s, or shooting up the mass-market sales charts, ingredients like quinoa, chia, and amaranth are quickly becoming household names. The goal for food makers now is to make these grains even more accessible.

“Puffed” products are one emerging strategy. Food and agribusiness company Bunge (White Plains, NY), for instance, has plans to begin offering puffed and flaked ancient grains in the first quarter of 2017, says Mark Stavro, senior director of marketing for Bunge in North America. He adds that he has seen demand rising recently for puffed ancient grains in on-the-go snacks, cereals, and bakery applications in particular.

What’s the big appeal of puffed ancient grains? First and foremost, their light texture makes puffed grains approachable ingredients that require little or no additional preparation work.

“The texture of puffed ancient grains is great for breakfast cereals, as the grains are small and soft—perfect for soaking up cold milk,” says Caroline Caligari, marketing manager for packaged-foods brand Purely Elizabeth. “They are also nutrient-rich and have a mild flavor, so you can incorporate them into a lot of different recipes.”

Purely Elizabeth has been using ancient grains in its products for more than seven years. Its line includes Ancient Grain Granola + Puffs Cereal featuring puffed amaranth and puffed millet. Puffed grains also appear in Purely Elizabeth’s oatmeal and muesli products.

Caligari adds that puffing an ancient grain does not affect the ingredient’s nutritional characteristics; it simply allows for “a texture and presentation that is easier for a consumer to eat as is, right out of the package.”

Puff-Friendly Grains

While most ancient grains can be puffed, sorghum, millet, and quinoa are particularly well-suited to the process, explains Bunge’s Stavro. These three ingredients will all be included in Bunge’s 2017 puffed-grains launches, with the possibility of other ancient grain ingredients being added to the list down the road.

“Sorghum, millet, and quinoa each have a really nice, neutral flavor that makes it easy to season with a variety of flavors,” Stavro says. “Furthermore, across different applications, they provide the crunch that so many consumers are looking for in grain-based snacks and cereals.”

Amaranth may be another strong candidate for puffed applications. Earlier this year, organic food company Happy Family rolled out its first puffed ancient grain snack, Happy Tot Superfoods Dinos, which combines puffed brown rice, quinoa, and amaranth in the form of a puffed dinosaur snack. Available in two flavors—kale, spinach, and cheddar, as well as tomato, basil, and cheddar—the snack and its puffed texture are perfect for small children.

“Puffed ancient grains are crunchy but also light in texture and somewhat airy, so they are easy for babies and young toddlers to eat,” says Anne Laraway, senior vice president of business development at Happy Family. She adds that she has seen puffed ancient grains achieve more success in snacks than in cereals, both in terms of sales growth and total number of products.

And while all grains can be puffed, Laraway says, formulators may want to keep a close eye on the fat, fiber, and starch content of any ancient grain ingredient they want to puff, as these factors can affect both how the grain expands as well as the texture of the finished product.
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Taking the Right Road

Over a year ago, New York Attorney General Eric Schneiderman’s investigation of herbal dietary supplements took the industry by surprise and alarm. On the industry’s side, what followed was a year of vigilance and discussion about how the industry stands at a crossroads: show critics and regulators that the industry is serious about committing to quality and transparency, or risk further bad press and eroding consumer trust. From what I’ve seen, the industry is taking the right road.

Take DNA testing, the technology on which Schneiderman’s investigation hinged. While acknowledging that DNA testing can, if properly applied, be a valuable tool in quality assurance, industry leaders pointed out that, in Schneiderman’s case, traditional DNA test methods were likely not fit for his purpose of testing finished, highly processed herbal extracts. Fast-forward to 2016, and industry leaders are actively helping to hone next-level DNA test methods that can handle more complex product profiles so that the supplements industry can embrace this important technology in a more meaningful way. NSF AuthenTechnologies, one of the leaders in this space, talks about one of these next-level DNA tests on page 18.

Quality-control discussions don’t stop at product testing; they include all cogs of the QC wheel. So it was notable when one of the industry’s biggest giants, GNC, announced this past February that it is implementing a sweeping set of mandatory Good Manufacturing Practices (GMP) requirements for all of its ingredient suppliers. Neither GNC, nor its ingredient suppliers, had to do this because ingredient suppliers are not beholden to FDA’s GMP rule for dietary supplements. But by taking this industry-leading step, GNC’s actions could inspire other firms, big and small, to take a second look at their own supply chain practices.

There have been other actions to indicate that the industry realizes it needs to take concrete steps to show that it is improving attention to quality and transparency. The examples go on, including the development of a new dietary supplement product registry being led by industry association The Council for Responsible Nutrition (CRN). With the Supplement Online Wellness Library (Supplement OWL) now in beta-testing among a handful of leading companies, CRN’s president and CEO, Steve Mister, said, “The product registry is a potential game-changer for our industry” because it will make more information about the supplements in the market more widely available to both regulators and consumers, including product labels for each product, brand name, ingredients, allergen statements, number of servings, and more.

Another measure of how industry intends to move forward will be how it responds to FDA’s revised new dietary ingredient (NDI) draft guidance. When I spoke to Mister back in August, he said that, from what he had seen, FDA and the industry are trying to move closer together on developing appropriate regulations for the supplements industry.

“The industry is evolving and trying to be more accountable to its consumer, and it’s nice to see, at the same time, that the agency is also trying to be more transparent with the industry by giving us this guidance that lets us see how they interpret the law,” he said. “I think both of these efforts signal a maturity going on within the market.” (Read Mister’s byline on page 10.)

There is no finish line when it comes to quality control because there is always room to improve, to grow. It appears many are focused on the latter now. All eyes will be on the supplements industry as it takes the next big leap into the future of quality control, one that hopefully brings consumers greater peace of mind.

Jennifer Grebow
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FDA warning letters over the past year target everything from hangover products to CBD supplements.

BY KIMBERLY J. DECKER

Reading FDA warning letters is akin to trolling online celebrity mugshots: “They busted who for what?!” But familiarizing yourself with these letters should be more than just an exercise in gawking; warning letters are a valuable window into how FDA is scrutinizing the dietary supplement industry and, in return, how well (or not) the supplement industry is adhering to current good manufacturing practices (cGMPs). Simply put, FDA warning letters are a cautionary lesson for marketers and manufacturers who prefer to avoid getting such letters in the first place.

So, just how is industry GMP compliance these days? “This is a tough one to answer,” says Justin J. Prochnow, shareholder, Greenberg Traurig LLP (Denver, CO). While he doesn’t think the number of warning letters is increasing, his sense is that, if nothing else, the number of FDA inspections “has remained steady, if not increased.”

If, during a facility inspection, FDA determines that a firm has violated GMP regulations, the agency will issue a Form 483. If companies don’t respond adequately to the Form 483, the agency may then go on to send the company a warning letter. Cheryl Luther, DC, general manager, dietary supplements and functional beverages, NSF International (Ann Arbor, MI), believes there’s been “an uptick” in the number of 483s issued over the past year, if not actual warning letters. “This is partly due to the lack of trust that the government’s regulatory agencies have in industry’s ability to regulate itself,” she notes, though she emphasizes that “dietary supplement companies are striving to restore and maintain brand integrity by demonstrating their commitment to producing safer products for their customers.”

Injecting some cold, hard data into the discussion, Cynthia A. Ipach, president, Compliance Insight Inc. (Fairfield, OH), claims that a brief search of FDA warning letters to dietary supplement manufacturers reveals 19 such letters issued in the first half of 2016, compared to 27 in 2015 and 44 in all of 2014. So far, so good?

That depends—not only on how the year’s second half goes, but on the nature of the observations noted in the letters, as well. And though complete 483 summaries for 2016 won’t drop until 2017, Ipach says that common themes in the warning letters released thus far run to misbranding due to misrepresentations in labeling; failure to establish or follow standard operating procedures or quality-control responsibilities; and failure to establish, follow, or provide sufficient specifications and batch production records.

So, just a bunch of technicalities, then? Not as far as Ipach is concerned. “This is not a matter of i-dotting and t-crossing,” she says. “Based on these observations, the industry continues to struggle with the same issues.” After all, when a “technicality” involves failing to document contamination or what’s in a batch of product, people can be harmed.

Says Ipach, “Dietary supplement manufacturers need to focus on and provide training on the regulations.” But on the bright side, she adds, if all the documentation failures merely reflect the missteps of new companies entering the market, the future may bode well.

Here’s a look at some recent FDA warning letters, and why you should care. We thank Marc Ullman, of counsel, Rivkin Radler, and his industry newsletter, for these tips.

High and Dry

It’s no secret that as more localities legalize marijuana and “medible” products gain steam, FDA will be clamping down on dietary supplement and functional food manufacturers who appear to be taking advantage of the “Wild West” atmosphere.

That’s just what the agency did on February 4, 2016, when it sent warning letters to eight companies marketing foods and dietary supplements containing cannabidiol, or CBD—a non-psychoactive cousin of the tetrahydrocannabinol (THC) found in Cannabis sativa.

This isn’t the first time FDA has slapped the wrists of companies marketing CBD supplements. But while previous warnings called out marketers for making improper health claims, the current crop of letters focus on a more serious issue—namely, questioning the legitimacy of CBD as a dietary...
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Warning Letters

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ingredient entirely. Because CBD is the subject of two drug applications currently under consideration, the agency says that CBD could be “outside the definition of a dietary supplement.” The takeaway for CBD firms? Be careful, and stay tuned.

False Appearances
Is getting old a disease? It sure feels like it. And as far as FDA is concerned, it might as well be, for the agency sent a warning letter on July 15, 2016, to Annmarie Gianni Skin Care for making what the agency deemed drug claims on its website.

In question were the company’s Repair Serum, Anti-Aging Eye Cream, and Anti-Aging Serum, for which web copy touted benefits ranging from “helps prolong and regenerate the skin cell” (“Anti-Aging Serum”) and “boosts cell regeneration” (“Anti-Aging Eye Cream”) to “ideal for treating sun spots, age spots, acne scarring, hyperpigmentation” (“Repair Serum”).

Such claims were a bridge too far for FDA, which determined that they established the products as drugs “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or any function of the human body.”

Pets Are People, Too
Sleep soundly knowing that FDA has Fido’s back. For the agency doesn’t just police dietary supplements for us human animals; it keeps an eye on products marketed for the rest of the animal kingdom, too.

Case in point: On December 17, 2015, Advantage Biosciences Inc. received an FDA warning letter regarding its marketing of nutritional supplements for animals: Resvantage Canine, Resvantage Feline, and Resvantage Equine.

Taking exception to claims that the products “provide an effective new therapy for treating type II diabetes,” “can be used as a cancer therapy by itself or combined with other therapies,” and “consistently prolong the life of several different animal groups,” the agency classified the products as new animal drugs “not generally recognized among experts...as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.”

Weighty Issues
A corner of the supplement industry familiar with scrutiny is the weight-loss sector. High-profile FDA actions coupled with an overweight nation’s desperation to shed pounds has focused special attention—from Congress, no less—on products that promise more than they deliver and contain ingredients they shouldn’t.

So when FDA sent warning letters on March 31, 2016, to Nutraclipse Inc. and M4 Nutrition Companies about the unauthorized presence of methylsynephrine, 1,3-dimethylbutylamine (DMBA) and picamilon in their weight-loss supplements, it must have given Senator Claire McCaskill (D-MO) cause to smile.

Why? The senator last year asked ten major retailers to pull picamilon-containing supplements from their shelves while also chiding FDA for its inaction on the ingredient, which is a derivative of GABA (gamma-aminobutyric acid) and nicotinic acid developed in 1969 in the Soviet Union as a pharmaceutical.

Think Again
Interest in brain-health dietary supplements is growing fast, but supplement manufacturers marketing toward this class of cognitively concerned consumers best beware what they say—and where they say it.

Witness the warning letter FDA sent to MPH Nutrition LLC on October 1, 2015. The agency apparently did an inventory of the company’s entire website, citing claims made for its Re:Mind Recover omega-3 product not only in web copy but in videos, white papers—even “likes” on its Facebook page. In sum, it determined the claims made regarding “concussion recovery” to be “therapeutic” and, therefore, sufficient to establish the product as a drug.

The Morning After
The best cure for a hangover is time. But FDA found a company—Life Support Development Ltd.—claiming that its Life Support Hangover Relief supplement could do the job just as well, if not better.

In a warning letter dated September 17, 2015, FDA called out the company for marketing Life Support Hangover Relief as an unapproved new drug. It pointed to statements that the product’s “cutting-edge formula contains an extract from the fruit of the Japanese Raisin Tree, known specifically to aid in the recovery from alcohol intoxication,” and that the product “can protect the liver and brain from damage.” But that’s not all. The letter went on to enumerate almost a dozen cGMP violations observed during a facilities inspection, not least of which were failures to collect and hold reserve samples of each lot of packaged product, or to maintain its physical plant in a clean and sanitary condition.

What’s in a Name?
FDA requires marketers of products containing new dietary ingredients (NDIs) to notify the agency about the ingredients, providing evidence that the products can reasonably be assumed to be safe. Failure to do so whilst still sending products into interstate commerce can earn the marketer an FDA warning letter like the one that went to Rightway Nutrition Marketing LLC on March 7, 2016.

Pointing to the presence of Acacia rigidula powder in the company’s Green Coffee Bean Extract + Energy supplement, FDA declared the powder an NDI and thus cited the product as adulterated under the terms of the Federal Food, Drug and Cosmetic Act.

Passing the Buck
There are plenty of ways that a dietary supplement marketer could run afoul of FDA. But one area that “still seems not to be clear to many companies,” says Prochnow, is the balance of responsibility between private-label owners and the contract manufacturers who produce products for them.

For even if someone else is doing the manufacturing for you—and, presumably, the recordkeeping and due diligence that FDA requires—label owners “are still obligated to ensure that products are being manufactured pursuant to the GMPs,” Prochnow says.

Or, as FDA said in a bill of particulars sent to Tibetan Herbal Balance Inc. on January 1, 2016, “Although your firm may contract out certain dietary supplement manufacturing operations, it cannot, by the same token, contract out its ultimate responsibility” to ensure that supplements comply with cGMP requirements. The lesson? A reminder that, at the end of the day, the manufacturer is ultimately responsible for adherence to GMPs—or the lack thereof.

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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Two Steps Forward; No Steps Back

Why industry should stop fighting and move forward now that FDA’s new NDI draft guidance and GRAS final rule are here.

By Steve Mister, President & CEO, Council for Responsible Nutrition (CRN)

Regardless of where I go—a dinner party, a Capitol Hill reception, a parent meeting at my son’s school—when people learn that I work in the dietary supplement field, they always ask, “Are they really safe?” It’s a constant reminder to me of how fragile the relationship of trust between supplements and their consumers really is; one safety scare could ripple through the entire industry.

In August, FDA took two steps toward changing that dynamic with the release of both the revised new dietary ingredient (NDI) draft guidance and the final GRAS regulation, only a day apart. And although neither is perfect, I think it’s time the industry embraced both as forward momentum toward changing the concerns toward dietary supplements and the functional foods that contain these same dietary ingredients.

In both cases (dietary supplements and new food ingredients), the law has long recognized that FDA should not have the same, painstaking oversight of the introduction of new supplement products that it has for pharmaceuticals. And for good reason: drug-like premarket approval over either the dietary supplement or food ingredient category would stifle innovation and escalate the prices of these products. It would mire manufacturers in years and millions of dollars of research that would be rigorous enough to satisfy an agency whose very raison d’être is to protect public health by erring on the side of saying “no.”

However, that doesn’t mean industry should cry foul and declare war on FDA every time the agency issues a document implementing its statutory authority. This is especially true for dietary supplements because the industry had a large hand in negotiating the Dietary Supplement Health & Education Act (DSHEA). Part of that bargain was the NDI provision of the law. In return for getting out from under the FDA’s attempts to regulate dietary ingredients like food additives, we agreed to provide premarket notice to the agency for new ingredients starting in 1994. We promised Congress, FDA, and the American consumer that the industry would provide evidence that its new ingredients, and the products that included them, would be reasonably expected to be safe. The GRAS provision in the Food, Drug, and Cosmetic Act has a somewhat different history, but even there, the food industry committed years ago to assemble evidence and self-affirm through its own expert panels that new food ingredients would be demonstrated to be safe, instead of having to maneuver through the food-additive requirements for every new ingredient.

Both the newly revised NDI guidance and the GRAS regulation are illustrations of FDA simply implementing a statute that expressly gives the agency the very authority it is now exercising. One can make the case that FDA is taking an overly strict interpretation of some aspects of the law—and we will. For example, CRN will surely raise objections in its comments on the NDI guidance with regard to FDA’s burdensome requirements for younger companies to demonstrate that an ingredient was marketed prior to 1994. We will also likely raise objections to the guidance’s expansive interpretation that even minor changes in manufacturing would make an old ingredient a “new” one that would require notification.

But at the end of the day, that law we helped enact 22 years ago explicitly requires manufacturers to demonstrate to FDA that new ingredients are reasonably expected to be safe. The supplement marketplace has enjoyed dramatic growth, and our customers expect FDA to have a role in assuring that new products are safe to use. Consumers of functional foods assume that marketers of new ingredients stand behind the safety of those ingredients, too, by allowing experts in the field to rigorously evaluate the evidence of their safety.

Today’s marketplace demands that products consumers put into their bodies are safe. We can fight FDA and risk losing the trust of our consumers, or we can embrace the underlying principles to move the industry forward. To battle pointlessly only gives the industry’s critics further ammunition that we oppose any effort to rein in the bad actors that lurk around the fringes of the industry. So we can fight, or we can move forward with two new tools that help assure that every dietary supplement and functional food is safe.

Steve Mister is the president/CEO of the Council for Responsible Nutrition (CRN; Washington, DC), the leading trade association for the dietary supplement and functional food industry.
Plagiarizing Quality Control

What happens when your Certificate of Analysis is a fake?

By Elan Sudberg, CEO, Alkemist Labs

It’s no secret in our industry that combating adulteration takes the whole village. It’s also no secret that the threat of adulteration often comes from within our industry itself. As an industry, one of the best tools we have for fighting adulteration, in addition to robust testing by top-notch labs, is education and communication among ourselves. So it’s important to talk about a problem we see happening today: Certificate of Analysis adulteration.

A Certificate of Analysis by its very nature represents quality control by documenting the testing performed on an ingredient. As I tell every new employee, adulteration is lurking around each corner. That is why testing labs like us exist. I explain that every measurement has a meaning and makes a product better, and that each of the intricate standard operating procedures we follow helps to populate high-quality data packages that protect our industry from adulteration and, most importantly, protect consumers from harmful ingredients. Certificates of Analysis are a critical part of those standard operating procedures. We must safeguard the high level of credibility the Certificate of Analysis represents, and that is why we, as a testing lab, go through so much effort to protect our final product.

In early 2016, it came to our company’s attention that there were Certificates of Analysis circulating among the industry that highly resembled the distinctive, customized format of the Alkemist Labs Certificate of Analysis. Unfortunately, these Certificates of Analysis were not genuine.

The first indication that something insidious was afoot came in the form of an e-mail from a trusted colleague and industry guru. This was the gist of the message: “Hey, Elan, check out this e-mail. Do you guys really test this garbage? This looks like your Certificate of Analysis.” The colleague then forwarded an e-mail sales solicitation for some superfruits to meet their food product safety, transportation, and quality guidelines. Analysis.

In fact, it was so similar that I searched the Alkemist Labs Information Management Software (LIMS) for the lot and sample numbers in order to confirm that it was not our analysis. It was evident that someone had worked hard to make the Certificate of Analysis look like an Alkemist Certificate of Analysis. I received several other inquiries from folks who also thought the certificate was ours but who were checking to confirm.

What’s most alarming is that it’s likely that some companies simply assumed, based on these plagiarized Certificates of Analysis, that Alkemist Labs had in fact confirmed the ingredient’s identity and potency, and, assuming this, allowed this batch of substandard material into their products.

We’ve seen this happen before. Several times over the last 20 years, we’ve discovered adulterated or plagiarized copies of our company’s Certificate of Analysis. More often than not, the subject of these certificates was some trendy natural product, such as hoodia, green coffee bean extract, or fruits from South America. Subjects also included the usual suspects, such as green tea, ginkgo, and ginseng extract.

How does one go about plagiarizing or adulterating a Certificate of Analysis? By switching lot numbers, changing test results, or creating a Certificate of Analysis that looks so close to the Certificate of Analysis from a premier lab that even discerning customers can’t tell the copy is a fake. While I don’t have confirmation of whether this has happened to other labs, I’d be very surprised if it hasn’t.

And so I urge the industry to be on alert for fraudulent Certificates of Analysis. How do you combat Certificate of Analysis adulteration? It’s simple. When you see a Certificate of Analysis in a company’s marketing materials, ask the company which lab did the testing, and call the lab to verify that it did the testing. Confidentiality agreements may prevent their telling you, but it’s worth asking. And if you have a testing lab, don’t copy my Certificate of Analysis. Design your own.

Trust in the industry has been eroded by negative media coverage. We’re under a high level of scrutiny these days, so we all need to be vigilant in recognizing the tricks and scams used by those just in it for a quick buck.
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FEELING the Sting

The New York Attorney General’s investigation, two years later

BY KIMBERLY J. DECKER

No matter how you feel about Donald J. Trump, you can at least grant him this: He may have inadvertently distracted New York State Attorney General Eric T. Schneiderman from further lifting the curtain on how the supplement industry does its business. For as long as Schneiderman and his office are combing through financial records at the Trump Foundation or spearheading lawsuits against Trump University, they aren’t analyzing DNA test results from a market basket of supplements.

Of course, their diverted focus doesn’t consign the state’s investigation—opened after University of Guelph researchers found widespread contamination and substitution in herbal products—to ancient history. Nor does it undo the damage that Schneiderman inflicted in early 2015 when he very publicly directed four major retailers to stop selling some popular herbal supplements after DNA barcoding revealed not only the absence of plant materials listed on labels, but the presence of potential contaminants, to boot.

It does, however, suggest that the Empire State’s chief law-enforcement officer is frying other fish for the present. And it
gives those in the supplement industry—not just retailers but suppliers, manufacturers, and marketers alike—a much-deserved time-out in which to take a breath, take stock of the investigation’s fallout, and take a good hard look at how they’ve been operating, and improving, since.

Faulty Premise
It would be hard to underestimate just how black an eye the “New York affair” gave the supplement world. As Elan Sudberg, CEO, Alkemist Labs (Costa Mesa, CA), says, “Between the media and the AG, the industry was dished a huge platter of scrutiny last year that changed how it’s viewed universally.” And despite the current lull, that attention hasn’t fully let up.

After all, says Steve Mister, president and CEO of the Council for Responsible Nutrition (CRN; Washington, DC), attorneys general are tenacious creatures, and “once they open an investigation, they want to pull out a win.” But to Schneiderman’s likely consternation, “There may not be a win here for him to have,” Mister surmises.

For that, thank the DNA barcoding, or fingerprinting, from which the attorney general extracted his evidence. As Anurag Pande, PhD, vice president, scientific affairs, Sabinsa (East Windsor, NJ), explains, “While DNA fingerprinting can definitely help in identifying the right species of raw material, this technique has limited application when applied to plant extracts”—like those implicated in the sting—“which may not contain any DNA.” He adds that the method has limitations not only when evaluating finished products, but also when identifying plant parts or the possibility of chemical and inorganic contaminants, as well.

Nevertheless, DNA barcoding was “thrust onto frontstage for show,” Sudberg supposes, because “General Schneiderman found the shiniest ball and made it a requirement when, actually, the technology is barely ready to serve our industry.” He believes that companies quick to adopt DNA testing “have done so under misguided pressure or purely to appear ahead of the game to the media and industry.”

FDA itself issued a statement in response to an inquiry from Senators Orrin Hatch (R-UT) and Martin Heinrich (D-NM) noting that the agency neither uses nor requires DNA barcoding and would need to evaluate any methodology aimed at a specific product before determining whether the method was appropriate and scientifically valid for the product. “Even GMP regulations say that you must use at least one appropriate test to verify ingredient identity,” Mister adds, “but don’t say what that test is, because a test that’s appropriate for chondroitin may not be appropriate for ginkgo.”

Silver Linings
Yet such arguments may prove too little, too late, in the face of continued attention from states attorneys, the media, regulators, Congress, industry watchdogs and—oh yeah—consumers. Schneiderman’s investigation, Mister says, “emboldened all of them.”

But the upshot isn’t all downside. For despite using “a few bad apples to paint the whole industry as bad” and drawing its conclusions from a “questionable methodology,” Schneiderman’s action, Pande says, “still raised important questions about supply chain transparency and, in many cases, the authenticity of supplements sold in the market.” And if there’s a silver lining to be mined from this experience, that’s where it lies.

Looking back with the benefit of hindsight, Mister believes the investigation “brought to the surface a concern that lots of people in the industry had, which is, ‘How are we guaranteeing the safety, purity, and identity of these products?’” And how can industry gird itself for the next time an attorney general comes knocking? “We need a better answer to show that we’re protecting our supply chains all the way back to the plant’s harvest so that we have a better story to tell.”

The supplement community is drafting that new narrative right now, Mister says, and their work is playing out in “several major quality initiatives within industry that were already being talked about but needed an impetus and momentum to go forward.”

Taking Initiative
Principal among them is CRN’s Supplement Online Wellness Library (Supplement OWL), developed and run in conjunction with UL and launched into “beta test” amongst nine companies in mid-September. The registry collects information about supplement products on two tiers, the first of which details basic like product name, ingredients, and allergens, and requires that companies supply manufacturing and packaging facility information for FDAs exclusive access.

The second tier lets companies, for a nominal fee, reveal more about their products and upload supporting quality documentation, such as sustainability certificates and evidence of GMP compliance. This tier is open to view by retailers and regulators on a permission-only basis that listing companies can grant. And though Mister says that CRN’s board discussed the establishment of such a registry as far back as December 2014, “after New York, there was a lot more enthusiasm for doing it.”

Cheryl Luther, DC, general manager, dietary supplements and functional beverages, NSF International (Ann Arbor, MI), also believes the New York investigation has “driven the industry to become less fragmented and more unified in self-regulating,” and she cites increasing participation in the Global Retailer and Manufacturer Alliance (GRMA) as a “sign of industry unification.”

The alliance is a product of NSF’s efforts to gather major retailers, manufacturers, trade groups, certification bodies, academia, government agencies, and other stakeholders to create a new, consensus-based GMP standard for the dietary supplement sector that’s approved by the American National Standard Institute (ANSI). Such a standard, NSF notes in a press release, would “reduce the number and associated costs of audits, while strengthening safety, quality, and trust throughout the supply chain.” And hopes run high. “We expect that the industry will work together in groups such as the GRMA and on future endeavors with a focus on ingredients and suppliers,” Luther says.

The Third Party’s the Charm
The mission of groups like the GRMA underscores the role of third parties in measuring and certifying such groups’ success. Luther emphasizes that her organization “fully believes that third-party independent certification is the key to assuring consumers’ confidence in the supplements they take.” And
IS NEGATIVE ATTENTION FROM STATE ATTORNEYS GENERAL “DIMINISHING”?  

BY MICHAEL CRANE, ASSOCIATE EDITOR

This time last year, the dietary supplements industry was still swimming in negative headlines about ongoing industry scrutiny from several state attorneys general (AGs), prompted in part by an investigation New York AG Eric T. Schneiderman launched into herbal supplement products. But flash forward to July of 2016 and the Conference of Western Attorneys General (CWAG), and there were signs that many AGs are taking a more positive tone in their approach to the industry.

Former Maryland AG Douglas Gansler, who is working with the American Herbal Products Association (AHPA; Silver Spring, MD) and the United Natural Products Association (UNPA; Salt Lake City) on an AG outreach campaign, shared his take on the CWAG meeting, which took place in Sun Valley, ID, from July 17–20. The meeting included a nutritional supplement panel, the results of which Gansler said indicated “that perhaps negative attention from state AGs is diminishing.”

“Unlike previous supplement panels held during the National Association of Attorneys General meeting last year in St. Louis, the panel at CWAG was notably positive and congenial,” Gansler reported. Eighteen AGs attended the panel, with panelists including Lori Kalani, co-chair of the State Attorneys General Practice of law firm Cozen O’Connor; Paul Bolar, vice president of regulatory affairs for Pharmavite (Mission Hills, CA); Ben Firschein, director of U.S. government affairs for the U.S. Pharmacopeia (USP; Rockville, MD); and Idaho Deputy AG Brian Kane. The panel was moderated by Colorado AG Cynthia Coffman.

Kalani and Bolar provided an overview of the industry and existing state and federal regulations related to dietary supplements, while Kane “stressed the positive strides the industry has made” and noted the importance of continuing efforts to enhance self-regulation, according to Gansler.

“The panel also demonstrated that attitudes on both sides are shifting—the industry is heeding the call for honest dialogue about its shortcomings and need for increased self-regulation, and state AGs are beginning to distinguish the responsible industry as a whole from the few bad actors,” Gansler said.

Questions Remain

Even with the warmer industry reception, several attorneys general still voiced significant concerns. For instance, Hawaii AG Doug Chin and Iowa AG Tom Miller both asked about assurances of supplement efficacy and premarket testing, Gansler said. Miller also “questioned the wisdom of regulating dietary supplements differently than drugs.”

“In response, the panelists, in particular [Pharmavite’s] Bolar, discussed the role of third-party testing and that, for the most part, products do what they say they will and will not do,” Gansler said.

“Bolar emphasized the distinction between bad actors and the industry as a whole.”

Gansler also noted that several states remain regulatory hotspots, including Oregon, New York, Iowa, and Hawaii.

Role of Facility Tours

Several of the AGs in attendance also shared positive experiences from tours of company facilities. For instance, Idaho AG Lawrence Wasden toured Thorne Research’s (Dover, ID) facility; Alabama AG Luther Strange toured a Pharmavite facility; and District of Columbia AG Karl Racine toured the USP facility in Rockville.

AHPA and UNPA encourage other companies with “top-flight facilities” to host tours for their state AGs. Earlier this year, the two associations launched a joint campaign to educate state AGs about the herbal supplements industry and develop working relationships. While efforts like these appear to be paying off, AHPA notes, it’s crucial for industry to continue its outreach efforts to the AGs.

“The responsibility rests with the industry to continue educating state AGs and working with them to identify and prosecute criminal actors,” Gansler said. “Genuine discussion by some major industry players of the need for enhanced self-regulation is also helping to reduce tension and scrutiny. But the work is only beginning and must continue.”

as consumers demand more transparency before they buy, “manufacturers are listening and increasingly looking to authenticate their ingredients and finished products,” she says.

Mister agrees. “I think these third-party auditors and certification bodies are becoming increasingly important to the industry as a result of New York,” he says. “and industry is getting increasingly comfortable with having third parties out there.”

Indeed, fully 14 years ago, NSF developed a third-party dietary-supplement certification standard that requires twice-annual GMP audits, as well as regular testing at NSF labs to verify compliance with the NSF/ANSI 173 American National Standard for dietary supplements, which oversees items like label claims, content verification, and contaminant levels. “The number of certified products has doubled in the last year,” Luther notes.

And for what it’s worth, she adds, “Just as we certify companies to verify that they comply with the requirements of our standards, we're held to high standards ourselves through accreditation by independent, third-party organizations, including ANSI. Our ANSI accreditation is an independent verification of our compliance to accepted standards of performance. These organizations ensure that we maintain compliance to standards, such as ISO/IEC 17065 for certification and 17025 for testing.”

Put to the Test

It’s no coincidence that Luther mentions testing, as its use—or, in the opinion of
some, abuse—helped land the industry in hot water in the first place. And even as the debate over DNA barcoding proceeds apace, the New York investigation’s effects also “bring to light an engorged tolerance for proprietary methods and ‘secret sauces,’” Sudberg says, “which, in turn, has introduced dialogue amongst most testing labs on fit-for-purpose methods.” He says his company has committed “significant resources” to both broadening the understanding of testing and advocating for “open and transparent communication between suppliers, manufacturers, and testing labs.”

The route toward that goal may throw up some bumps, though, as “buyers begin requesting higher quality backed by independent lab testing with full method disclosure,” Sudberg points out. “The price will go up as more expert eyes fall onto a material.” And he predicts that production may also slow, “as sourcing will be backed by a smaller selection of vendors who are in compliance and transparent.”

Another potential obstacle: “Testing methods that are validated and agreed upon take time to establish and often need to be refined as the marketplace evolves,” Sudberg says. But the payoff in credibility, he believes, is worth the struggle: “This is a process that requires the collaboration of experts with real-world experience on the variables, adulterants, and other monkey-wrenches that force pure science to meet real-world uses and challenges.”

### Smarter DNA Testing

And what role might DNA play in this brave new testing world? While conceding the technology’s limits, Pande acknowledges that DNA barcoding “has a lot to offer.” But with scientific opinion still divided as to its application in finished products, he says, “Our concern is how the technology is currently used.” Nonetheless, his company has introduced DNA fingerprinting for selected herbs in cases where customers “believe that this additional information can help them in their marketing.”

And while DNA barcoding has become synonymous with DNA testing or authentication, “There are numerous other ways to perform DNA testing,” Luther points out. For instance, NSF AuthenTechnologies, part of NSF’s network of labs, promotes its Target-Specific DNA Sequencing (TSDS) as “a next-generation DNA-sequencing process” specific enough to identify “almost any species, even in materials processed in a way that removes or fragments much of the DNA,” Luther says. Unlike DNA barcoding, which analyzes fairly long gene sequences, the new method “targets much smaller, unique regions of the genome,” she explains. In addition to authenticating plant species, this technique can identify adulterants and, coupled with chemical and morphological tests, “offers a comprehensive range of testing services for the dietary supplement industry.” (Read more about TSDS on page 18.)

### Changing Chains

These developments are happening not a moment too soon, for just as the New York Attorney General’s investigation forced industry to reexamine its testing regimes, it also shined a bright—and sometimes harsh—light on supply chains.

The 16 years separating the Dietary Supplement Health and Education Act (DSHEA) of 1994 and Congress’s passage in 2010 of the Food Safety Modernization Act (FSMA) saw unprecedented change in how industry sources ingredients, Mister says, with the days when deals were “done with a handshake on the goodwill and honor of your vendor” long over. “In a global economy where you’ve got raw material coming from all over the world and it no longer even looks like the original plant,” he declares, “if you don’t have the ability to look at it yourself and determine what it is, this notion of ‘trust, but verify’ becomes more important.”

Pande says Sahinsa “has been talking about the need to pay more attention to the supply chain for years,” he says. Long before the New York investigation, the company, which markets more than 120 extracts for supplement use in the states and internationally, had a vendor-qualification system in place for materials it doesn’t grow itself. This system covers documentation to identify plant species and cultivar, and phytochemical analysis to ensure quality and the presence of bioactive compounds. It also serves as a compliance check on pesticide and heavy metals levels, microbial load, and the presence of other contaminants, Pande says.

“Sourcing raw materials may well be the most significant phase of the product life cycle,” Pande says. “A good raw-material supplier should be able to provide all the information related to quality, transparency, authenticity, safety, and efficacy, while ensuring proper cGMP compliance. Sometimes the price of cheap ingredients can be very high, indeed.”

### Future Focus

Supplement professionals should print that message on t-shirts to sell at tradeshows. Because there’s one thing you can be sure of: This won’t be the last time that industry meets criticism. “We have reason to believe that while General Schneiderman appears to be focused on sports betting, Trump University, and bad banks, he has a list, possibly provided by our industry itself, that he’ll hunt from next,” Sudberg suspects.

And while he’s loathe to give the attorney general ammunition, he believes “there are some vulnerable botanicals that he might attack based on technicalities in nomenclature,” and foresees finished-product quality coming in for increased scrutiny “as regulators more often ask the question, ‘Was this test method developed, verified, or validated for your unique finished-product blend?’” The answer, he fears, “will be, overwhelmingly, No.”

Potential hot spots on Pande’s radar include laws related to GMO and non-GMO verification, FSMA, the definition of natural, and “Made in the USA” labels for finished products containing raw materials sourced outside the U.S. And keep your eye on safety. While newly released guidance documents provide detailed standards for safety testing, “In most cases, supplement manufacturers depend on the ingredient provider for safety information,” Pande says, “and I’d be curious to know how deeply some brand owners look into this when sourcing materials.”

If they’re not looking too deeply, brace yourself for another round of recriminations, and keep the antacids handy. But remember: “Events like this are painful learning opportunities where those that were ‘sort of compliant’ finally have incentive to increase their compliance,” says Sudberg.
DNA analysis is one way of testing botanical materials to determine whether other plant species are present in the sample. For instance, many don’t know that grasses such as oat grass and barley grass, as well as alfalfa, can sometimes contain other plants’ DNA. In fact, in a recent analysis, one of the top-selling herbs that can be found in kitchens around the world—oregano—was found to often contain DNA from other plants.

According to an NSF AuthenTechnologies annual review of over 1200 samples from nearly 250 different plant species, over 82% of the oregano samples we tested using DNA analysis were found to contain another plant species. (This review was conducted at our next-generation DNA testing lab in California.) Our results indicated that half of the oregano samples tested contained bindweed (*Convolvulus arvensis*), a potentially toxic common weed found on roadways around the world. And, in fact, more than 5% of all botanical samples that we tested over the past year contained bindweed DNA.

In our annual review, NSF AuthenTechnologies found that more than 50% of the plant samples we tested contained DNA from other botanical species. In addition to bindweed, our annual botanical-testing review detected nearly 30 other potentially toxic plant species in nearly 150 plant samples, including several herbs used as substitutes for recreational drugs. One of these herbs, kratom (*Mitragyna speciosa*), was detected in an everyday cinnamon sample. In September, the U.S. Drug Enforcement Agency asked FDA to add kratom to the agency’s list of Schedule I drugs. On FDA’s import-alert website, FDA says, "there does not appear to be a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient. In fact, the scientific literature disclosed serious concerns regarding the toxicity of kratom in multiple organ systems. Consumption of kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms."

DNA testing is a good first step toward identifying the presence of other botanical species. With DNA testing, we can identify which species are in the sample. However, chemical testing is needed to quantify the DNA in order to indicate how much of another botanical species is in the sample. Additional testing, such as microscopy or organoleptic testing, may also be warranted. If, after these tests, a problem is identified, it may alert a manufacturer or supplier of a potential issue with its supply chain.

The Value of Targeted Next-Generation DNA Sequencing

It is crucial to identify good tools to authenticate species in a sample. DNA testing is a method with a growing profile in recent years. When used in combination with other valid test methods, DNA testing can be a valuable component of the testing toolbox.

There is no denying that DNA testing has changed the landscape of numerous fields, such as forensics and medical diagnostics. Like computer microchips that get smaller, faster, and more powerful every year, DNA testing methodologies are becoming cheaper, faster, and more accurate.

Traditional DNA testing techniques have their limitations, however. DNA barcoding,
for instance, which uses Sanger Sequencing and universal primers, falls short in authenticating samples that are processed, including impure samples of commercial products. Luckily, there’s a next generation of DNA sequencing that can help identify numerous species in a wide range of processed materials, and in only a few hours and for less, compared to many other traditional methods.

We call this technology Target-Specific DNA Sequencing (TSDS). TSDS detects and identifies the target species and potential other species including contaminants such as allergens. Because the test methods are unbiased, TSDS is also a great method for assessing current trends in impurities throughout the natural product supply chain, from seed to shelf.

Using the power of Next-Generation Sequencing (NGS) technology, TSDS applies specific tests that target unique regions of the genome and that can both authenticate the plant species and help to identify other species. Each specific test relies on a unique combination of polymerase chain reaction (PCR) primers, or probes, which produce millions of copies of each species in the material. Unlike traditional barcoding, which uses only long, universally available PCR primers for all species, the TSDS process also uses unique, short, genus-specific primers. These short primers allow the technology to test a much wider range of products than traditional DNA barcoding can handle, including products that are heated, processed, and extracted.

Once the DNA copies are produced, an NGS machine will elucidate the unique arrangement of bases (A, C, G, T) in the sequence. Each sequence is then compared to a validated reference DNA database for identification.

What Can TSDS Do?
In addition to identifying the target and other species and contaminants in a sample, TSDS can indicate the potential presence of an allergen or other potentially harmful species. In a recent study we conducted of ground black and white pepper samples purchased from multiple retailers around the world, we found that the white pepper samples frequently contained DNA of wheat or rice flour, posing a potentially serious health risk to those with related allergies. Even products labeled as “non-GMO” and “organic” were not immune to impurities by these fillers and allergens.

Novel methods such as TSDS are uncovering important trends in botanical impurities. This information can be useful to suppliers, manufacturers, and retailers as an early warning system for possible issues that could be detrimental to their businesses and may require further action in areas such as cleaning procedures, cross-contamination in the field or facility, or issues even further down the supply chain.

Danica Harbaugh Reynaud, PhD, is Global Director of Scientific Innovation for NSF International (Ann Arbor, MI) and co-founder of NSF AuthenTechnologies. NSF AuthenTechnologies is the first contract laboratory in the country to specialize in DNA authentication testing of natural products and their ingredients, offering ISO/IEC accredited next-generation DNA authentication testing services for natural products and their ingredients, including plants, animals, fungi, and probiotics. NSF AuthenTechnologies’ parent company, NSF International, offers a wide range of complementary chemical testing, including high-performance thin-layer chromatography (HPTLC) and high-performance liquid chromatography (HPLC) for quality control of natural products.
Those who make health and nutrition products are under constant pressure to be “cost leaders”—to operate under leaner budgets while producing new products more quickly and economically to satisfy the requirements of new consumer channels and to outperform the competition. Traditionally, manufacturers trim margins by axing the cost of raw materials. But what does this do to product quality at the end of the day? It’s no surprise that this narrow approach can come with some serious downsides. Cheaper materials can be cumbersome to produce, for instance, and fall short on performance or even result in costly after-market issues.

A more successful, proactive model is “total cost management,” or “quality by design.” Under this model, quality, including end-cost value, is built in from inception to final product.

Take capsule filling. Both the capsule itself and the capsule-filling machine impact one another throughout the capsule-filling process. The “quality by design” model finds the best match of capsule-filling machine and capsule for a specific formula, optimizing efficient production. Not only that, this approach also involves guidance from technical operators who plan, adjust, and manage each component’s contribution in the process.

By thinking about quality holistically in this way, you can improve yields, accelerate filling, and cut downtime—three key, interdependent influences on cost. Gain advantages in one area, and you’ll probably gain advantages in the others. The result of this approach is often financial and time savings, speedier market delivery, and, most importantly, the assurance of achieving target quality.

We have seen these results time and time again. Take the following two examples.

Company A wanted to switch a product from a tablet to a capsule in order to achieve a cleaner label, but when the firm began encapsulation, it found it hard to maintain the capsule’s target weight. Subsequently, the firm experienced large losses. A service engineer’s evaluation, however, found that because of the powder formulation’s very fine nature, it was not compacting well on the capsule-filling machine. So the customer found an alternative supplier who could provide the raw material in a more granular powder. The result? The newly blended product enabled better weight control for the style of dosing being used. Changing the physical characteristics of the blend enabled a 17% increase in yield and a 90-minute reduction in downtime for cleaning and adjustments, resulting in savings exceeding $9,700 for every one million capsules produced.

Another example: Company B faced a recurring problem during loading and separation of its capsules on the capsule-filling machine. A service engineer’s evaluation revealed that productivity was being impacted because the filling machine tooling had worn down over time. Machine operators were instructed on new techniques for

CAPSULE FILLING: QUALITY BY DESIGN

How to control costs while optimizing capsule-filling productivity and performance

BY JOHN DAVIDSON, CAPSUGEL
evaluating tooling and discerning when parts were damaged or worn out. By applying these diagnostic techniques and correcting issues earlier, the company saw a significant increase in yield and a reduction in downtime for troubleshooting. Because of these improvements, the company saw a $330,000 annual savings in the production of its most common product.

**Quantifying Savings**

These are the results we have seen from taking a more holistic, overall quality-minded approach to capsule-filling operations. In a 2015 review of case studies from 33 of our customers who followed this approach, customers saw 1) an average line-speed increase of 49%, 2) an average yield increase of 6.1% resulting from fewer losses to starting materials and less time and energy used to churn out fewer filled capsules that cannot be sold, and 3) an average downtime reduction of 109 minutes in an 8-hour shift, for an average downtime improvement of 49%. As a result, the 33 companies saved a combined $9 million, or $273,000 on average per company, due to improvements in productivity.

Machines that are properly fitted to the right formula and capsule and that are maintained routinely run longer, better, and make more product in less time and, consequently, result in less cost. Efficiency upgrades are also vital. Evaluations may result in recommendations for equipment purchase for fill products, process flow appraisals, training on equipment adjustments, and more, from the beginning of the process to the end.

It’s also equally critical for a company to be able to measure the financial gains and business impacts of these upgrades. A “savings calculator” can aggregate all cost drivers, including labor and overhead, to more correctly and comprehensively compute financial savings. These reports can help to endorse key investments in maintenance as well as to help dodge unnecessary costs. They also allow manufacturers to better defend and obtain resources to make the changes that improve productivity of their capsule-filling operations.

So the next time you’re looking to save costs in capsule filling, take a moment to view the entire process through the lens of maintaining quality first, and then tackling costs. With this path in mind, you can make smarter decisions that will make you a true cost leader.

*With contributions by Paul Davis and Tim Sopko, members of Capsugel’s (Greenwood, SC) Quality Engineering Services Team. Written by John Davidson, Director of Americas Supply Chain and Technical Service, Capsugel.*
Find the Adulterant!

How well do you know some of today's most common botanical adulterants?

With the threat of botanical adulteration ever-present, dietary supplement firms must always be vigilant in order to stop the wrong ingredients from sneaking into their supply. Even with the appropriate testing techniques, adulterants may go undetected if firms don’t know what to look for. Take our quiz, and see if you can match each botanical ingredient with its corresponding adulterant.*

Botanical Ingredients

1. Ginkgo (Ginkgo biloba)

2. European grape (Vitis vinifera)

3. St. John’s wort (Hypericum perforatum)

4. Hoodia (Hoodia gordonii)

5. Goldenseal (Hydrastis canadensis)

6. Blue skullcap (Scutellaria lateriflora)

Adulterants

A. Peanut (Arachis hypogaea)

B. Germander (Teucrium spp.)

C. Barbary fig (Opuntia ficus-indica)

D. Buckwheat (Fagopyrum esculentum)

E. Chinese goldthread (Coptis chinensis)

F. Synthetic dyes

*Adulterant ingredient list provided by Sidney Sudberg, LAc, DC, president and CSO of Alkemist Labs (Costa Mesa, CA).
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