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FEATURES

42  Natural Claims
52  Consumer Demographics
66  Omega-3 Market and Science
82  Outsourcing
88  Men’s Health
94  Children’s Health
102 Pet Health
108 Bone Health
116  Plant Protein
122 Vegan Supplements
124  Melatonin Misconceptions
126 Phospholipids

On the Cover:
UP FRONT

10 From the Editor
12 News
Two big wins for supplement industry in FDA's new NDI draft guidance; FDA issues GRAS final rule

COLUMNS

22 Global Regulations
Regulators are increasingly scrutinizing brain-health product claims.

26 Global Regulations
How to create a successful GRAS notification for medical foods

32 Global Regulations
Whatever happened to common-use GRAS?

38 Marketing
Sports performance products are gaining fans everywhere.

60 Supplement Science
Can natural supplements be as effective as drugs—or at least complementary?

RESOURCES

130 Research Update
131 Classified
132 Advertiser Index
134 Last Bite
Cranberry

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FDA’s revised new dietary ingredient (NDI) draft guidance debuted to decidedly mixed reviews from the dietary supplement industry in August. Just among heads of associations, responses ranged from “guardedly optimistic” to calling the guidance flat-out “depressing.”

While the revised guidance puts a few wins back in industry’s court (see page 12), there is still enough language remaining from the heavily criticized July 2011 draft guidance to distress many. At this point, there’s no telling exactly how strong industry pushback on the guidance will be until we actually see public comments. But early indications are that the response will be more measured this time around.

As industry representatives lead the response to the guidance, there is a general sense of treading more carefully because criticisms of the industry are extremely high right now. Since July 2011 when FDA released the first draft guidance, the industry has undergone investigations from attorneys general, probes by lawmakers, and negative coverage from mainstream media, all shedding doubt among consumers about the safety, efficacy, and trustworthiness of dietary supplements.

“Certainly we’re very concerned about the public-relations media perceptions and consumer perceptions around these issues,” said Loren Israelsen, president of the United Natural Products Alliance, during an August NDI webcast. “We also know that if this issue [of responding to the NDI guidance] is not managed carefully and thoughtfully, that it will likely fan the flames of [criticism that the dietary supplement industry is unregulated].”

If industry members push back too hard, “will we appear to be an industry that is not interested in doing the sort of safety work that is expected of us?” Israelsen asked. “Or is our argument that FDA has simply imposed so many burdensome requirements that it’s simply not possible to do what they asked?”

None of this is to undercut the fact that there are legitimate concerns from industry that portions of the revised guidance are unclear or that some of the guidance may go beyond the scope of what is prescribed by the laws governing supplements. “There’s a lot of work that still needs to be done to pull this guidance back into a stricter compliance with the statutory framework and with our actual obligations under the law,” said Michael McGuffin, president of the American Herbal Products Association (AHPA), during an AHPA NDI webcast.

But industry must also face the possibility that FDA may decline to amend the guidance much further. Some, like A. Wes Siegner, Jr., an attorney at Hyman, Phelps & McNamara, don’t believe the agency is likely to make drastic revisions. “My feeling...is that we didn’t make a lot of progress last time, and filing critical comments again this time is likely to have much the same effect,” he said during the AHPA webcast. “I do think that some progress can be made, and I’m not saying that the trade associations should not continue efforts to push back. That clearly needs to be done. But I don’t expect that the final guidance, if it is ever issued, will be all that much different.”

Ultimately, the final guidance may not be something industry loves but instead something industry will need to learn to live with. Steve Mister, president and CEO of the Council for Responsible Nutrition, pointed out. What’s more, that doesn’t have to mean the end of the world.

For one thing, guidance is not binding regulation. And while “law-abiding companies will want to follow” FDA’s NDI guidelines, “my point is if there are particular issues where we just fundamentally disagree with the agency, we can continue to fundamentally disagree” and take up the challenge elsewhere, such as in the courts, Mister said.

Dan Fabricant, CEO of the Natural Products Association, also said that there may still be alternative paths to market for some NDI ingredients, “and as long as you can get to the market, that’s the key thing.” He said, “I think that’s how people need to look at this. Is their market access being restricted? If it is, okay, fine, there’s a real issue there. But if it’s not, and it’s just an issue of semantics, well, that’s not the hill I think the industry wants to die on.”

Those are the matters industry members will want to balance as they craft their public comments to FDA. Getting on the same page in this era of industry scrutiny is also important. As Israelsen said, while there are “different views about all of this at the moment in the industry,” it will be “really critical to see if we can get to harmonized points of understanding so that we speak with one voice.”

Jennifer Grebow
Editor-in-Chief
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FDA finally released its long-awaited revised new dietary ingredient (NDI) draft guidance on August 11, with two major changes the dietary supplement industry will likely hail as good news. On these two points, FDA and the industry seem to have found middle ground.

The new draft guidance is a revision of the agency’s July 2011 NDI draft guidance.

No Longer NDI Notifications for Every Finished Product

Industry will be relieved to find FDA has dropped its earlier suggestion that companies submit separate NDI notifications for every single finished product on the market containing an NDI ingredient. This provision in the original July 2011 version of the draft guidance sparked huge objection from the industry, with some calling it tantamount to unprecedented, and potentially unlawful, premarket product approval.

In the new draft guidance, FDA said it would instead allow a company to create a single NDI notification (an “NDI master file”) that would cover a wide range of product formulations. The notifier would need to list a range of dosages for the NDI, as well as possible combinations of the NDI with other ingredients, that would still be reasonably expected to be safe.

In addition, the notification would need to list other parameters, including potential daily intake levels, serving sizes, duration of use, frequency of intake, target population, and dosage forms that would still render a product containing the NDI to be reasonably expected to be safe. Companies would only need to submit a new NDI notification if their use of the NDI ingredient fell outside of the original notification’s specifications.

Companies may not be able to anticipate today every future ingredient dose and ingredient combination for an NDI ingredient and may, sometime down the road, need to submit a new notification to account for new uses. Still, this master-file option would drastically reduce the number of NDI notifications industry would need to submit and reduce the cost of submitting multiple NDI notifications as originally proposed.

As is the case today, it’s largely expected that ingredient suppliers will be the ones submitting NDI notifications for their ingredients. An ingredient supplier could submit one NDI notification spanning multiple uses for its branded ingredient, for instance, and all companies and distributors using that exact ingredient thereafter could rely on the supplier’s master file, as long as their use of the ingredient fell within the notification’s usage parameters.

The supplements industry will no doubt find this master-file proposal a happy compromise.

"I think this absolutely is a place where FDA is trying to move to common ground. They certainly heard our concerns from the marketplace side that what was in the first guidance was not workable," said Steve Mister, president and CEO of the Council for Responsible Nutrition (CRN; Washington, DC), in an interview with Nutritional Outlook, noting that his association had proposed the master-file concept over many meetings with FDA.

The solution may not please everyone, but Mister said, "I think it is absolutely a middle ground that the industry should learn to live with."
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He elaborated: "Because on the one hand, it protects FDA; they’re concerned about the safety of ingredients, and they want to be sure that if one company comes up with an ingredient and then somebody else comes along with a copycat and says mine is the same, they want some assurance that it is in fact made the same way and has the same safety profile. But from the industry standpoint, we want our finished-product folks to be able to rely on their ingredient supplier. And if the ingredient supplier goes and does all of this work, we want the people who buy from that vendor to be able to rely on [the supplier’s NDI notification], as long as they’re buying [that same NDI ingredient] from that vendor.”

“It’s a balancing act,” he said.

FDA’s requirements may also help level the playing field between two companies producing similar ingredients. The new draft guidance says that if a company has submitted an NDI notification for its ingredient, another ingredient supplier making what it claims to be a similar ingredient would still need to submit its own NDI notification to prove that its version of the ingredient is safe.

“If somebody else pops up and says, ‘Oh, I have a me-too, I’m made the same way, buy from me, and I’m cheaper,’ that company is still going to be required to do a full NDI and show that, yes, in fact they are making it in the same way and that it is as safe as the other ingredient,” Mister said. “And that’s as it should be. But for companies who are buying from the innovator who filed the first ingredient notification, they ought to be able to rely on [the master file], and this appears to be letting them do that.”

No Longer Holding Supplements to Redbook Safety Standards

FDA has also moved away from requiring NDI ingredients to abide by the stringent Redbook premarket-approval food-safety standard. In its original July 2011 draft guidance, the agency referred specifically to the Redbook and its safety standard of “reasonable certainty of no harm.” But those references are absent from the new text.

Industry pushed back forcefully on the Redbook language, underlining that the NDI standard Congress approved under the Dietary Supplement Health and Education Act of 1994 (DSHEA) is the lower-tier “reasonable certainty of no harm” standard. “That’s something we pushed for very much in our comments [to FDA] five years ago,” Mister said, adding that the food-additive standard is “a much higher standard because it was created for synthetic, manufactured food chemicals and food colorings and preservatives where people were creating completely new chemical entities and putting them in foods to make them look better or last longer.”
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"We are very pleased to see FDA backing away from references to the Redbook and backing away from that standard, which was not the standard for dietary ingredients," he said.

Of course, there's a lot more to unpack from the new guidance, including points discussed briefly below that industry may not find so welcome. Visit www.Nutrition- alOutlook.com for continued analysis on these issues.

**Grandfathered-Ingredient Lists**

In the revised draft guidance, FDA repeats what it said in its July 2011 guidance—that it still will not recognize any third-party lists denoting grandfathered ingredients that don't require NDI notification.

"Some trade associations and other industry groups have compiled lists of 'old dietary ingredients', though FDA is unable to verify the accuracy of these lists because we have not seen documentation showing that the ingredients on such lists were marketed as dietary ingredients prior to October 15, 1994," the guidance states.

Instead, FDA says it is "prepared" to create its own "authoritative list of pre-DSHEA ingredients." To create this list, it says, it would need industry to help provide marketing records and other documentation to prove that ingredients were on the market in dietary supplements in the U.S. prior to October 15, 1994.

**Manufacturing Processes and Chemical Alteration**

Which modern-day manufacturing processes will render an ingredient "chemically altered" and thus require NDI notification? In the new draft guidance, FDA revised the original text to more explicitly explain what the agency considers to be manufacturing processes that result in chemical alteration.

The good news for industry is that the agency now clarifies that a Congressional provision in a number of warning letters over the last five years, so we have seen evidence that they are not backing down on that. So seeing it in the guidance is not a big surprise."

However, he said, FDA may be offering some flexibility here. "They are showing at least some willingness to work with industry by signaling that even if it can't be a botanical or an herbal, it might be able to be a dietary ingredient under one of the other prongs of the statute."

The guidance states: "Because the 'dietary substance' category is defined in part by history of use, a synthetic copy of a botanical ingredient may qualify as a dietary ingredient under section 201(ff)(1)(E) of the FDCA if the synthetic copy has been used as a lawfully marketed ingredient in the conventional food supply." The guidance points to examples of vanillin and cinnamic acid as two botanical derivatives made synthetically as food flavorings that fall in this category.

 Processes to strengthen ingredient purity and decrease impurities would also widely be considered beneficial—but, again, in FDAs eyes could trigger the need for an NDI notification. Concentrating active constituents to increase an ingredient’s potency would also be on the radar. And ingredient extracts and tinctures could call for an NDI notification if they use solvents other than water or aqueous ethanol. "I think this is a big one," Talati said, adding that many companies today use solvents other than water or aqueous ethanol.

"The manufacturing changes and chemical alteration [portion of the guidance] are two of the biggest things that will impact everyone—or the majority of companies," said Talati.

Expect industry to have much more to say on this topic in its comments to FDA.

**Synthetic Botanical Ingredients**

The guidance says that synthetic herbal-botanical ingredients are still not considered dietary ingredients. "I'm not surprised by the agency's position here," CRN’s Mister said. "We did push back on them, that we felt like synthetic ingredients could be dietary ingredients if they could be shown to be identical. FDA has referenced this provision in a number of warning letters over the last five years, so we have seen evidence that they are not backing down on that. So seeing it in the guidance is not a big surprise."

During the Natural Products Association’s (NPA; Washington, DC) "emergency NDI webcast" held on August 17, speaker Ashish Talati, a member of law firm Amin Talati & Upadhye, pointed out that the types of processes that can change the physicochemical structure of an ingredient include common changes related to pH, solubility, particle size, melting or boiling point, or refractive index. What’s more, supplement companies often seek to improve ingredient bioavailability.

During the Natural Products Association’s (NPA; Washington, DC) "emergency NDI webcast" held on August 17, speaker Ashish Talati, a member of law firm Amin Talati & Upadhye, pointed out that the types of processes that can change the physicochemical structure of an ingredient include common changes related to pH, solubility, particle size, melting or boiling point, or refractive index. What’s more, supplement companies often seek to improve ingredient bioavailability.
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Probiotics
Companies argued that the original July 2011 draft guidance was vague when it came to probiotics, only stating that “Not all bacterial microorganisms are dietary ingredients, and a microorganism that is not a dietary ingredient cannot be an NDI.” The new draft guidance repeats this language, without much more elaboration provided in the original guidance.

More Clarity Is Good
The draft guidance’s two-month public comment period is now open. In late August, CRN and NPA both asked FDA to further extend the deadline.

Mister, in his August 11 interview with *Nutritional Outlook*, said CRN was still reviewing the fine print of the new draft guidance. But he did provide a positive takeaway.

“I think just having the guidance out is a win for the industry. It’s taken us four years since [FDA] promised to give us a new draft, and I think the fact that we have it at all is going to do a lot towards giving more transparency and more certainty in the industry. It gives the industry a clear roadmap as to what FDA expects.”

“Even if we don’t always agree with everything that FDA says, it’s a big victory just to know what the agency’s interpretation is, with clarity. And I think we’re getting that today.”

FDA Issues GRAS Final Rule, Officially Ushers In Voluntary Notification
Just one day after FDA finally issued its revised NDI draft guidance for dietary supplements, the agency on August 12 released its Generally Recognized as Safe (GRAS) final rule for food ingredients for humans and animals. As it was widely expected to do, the agency has officially replaced the GRAS petitioning/affirmation system with a voluntary GRAS notification system.

In 1997, FDA issued a proposed final rule introducing the concept of a voluntary notification process that would exist concurrently with FDA’s more resource-intensive GRAS petitioning process. Under the petitioning process, individuals could petition FDA to review the safety information for an ingredient not currently on the list of ingredients FDA considers GRAS. Through this petitioning process, if FDA reviewed the data and decided to add the ingredient to the GRAS list, it would issue a new GRAS regulation through rulemaking—a resource-intensive process.

To ease the burden, in 1997, the agency introduced the concept of the additional...
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voluntary notification process. Under this voluntary notification process, individuals could ask qualified experts to instead review an ingredient’s safety data and determine whether or not the ingredient was GRAS. Individuals could then voluntarily notify FDA that the ingredient had been deemed GRAS. Even if an individual chose not to notify FDA, the ingredient could be sold in food as long as qualified experts deemed it GRAS.

Before August 12 of this year, FDA had not issued a final GRAS rule cementing this voluntary notification process even though many companies have been operating under voluntary notification, versus petitioning, in the two decades since FDA issued its 1997 proposed rule.

With the new final rule, however, FDA confirmed it is officially doing away with the petitioning process and ushering in the notification process.

One of the biggest critiques of the voluntary GRAS notification system is that companies can choose not to notify the agency of new GRAS ingredients on the market, meaning that FDA does not review the safety of every single GRAS ingredient on the market. For this reason, some comments the agency received during the 2010 comment period questioned whether getting rid of the petitioning process, the most stringent arm of the GRAS program, is a bad idea.

In the final rule, FDA responded to these comments by pointing out that the number of GRAS notifications the agency has received thus far outpaces the small number of GRAS petitions received, meaning that more companies already favor the notification route over petitioning.

The agency said in the final rule, “We believe that our filing of more than 600 GRAS notices for substances used in human food is evidence that the substitution of a GRAS notification procedure for the GRAS affirmation petition process has benefits for consumers, FDA, the regulated industry, and other stakeholders...We note that CFSAN filed more than 600 GRAS notices during the time period 1998 through 2015...for an average of approximately 34 GRAS notices per year, including 69 GRAS notices filed during 2014 and 51 GRAS notices filed during 2015. By contrast, during that time CFSAN finalized six GRAS affirmation regulations. We believe that the ongoing submission of GRAS notices is evidence that our response to a GRAS notice can support the marketing of a food substance.”

In a public statement announcing the new final rule, FDA encouraged companies to continue notifying the agency of GRAS status. “The FDA strongly encourages companies to inform the agency of GRAS conclusions through the notification procedure finalized with today’s rule. While the FDA can question the basis for an independent GRAS conclusion, whether notified or not, and take action as appropriate, the notification procedure yields important information that aids the agency’s food-safety monitoring efforts.”

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Marketers, Be Smart

Regulators are increasingly scrutinizing product claims in the booming brain-health market.

BY KRISTI WOLFF, KELLEY DRYE & WARREN LLP

B
een forgetting things lately? Maybe your keys? Your sunglasses? Where you parked at the supermarket? Never fear. Brain-health and cognitive-function products have flooded the market in recent years. These products come in all forms, from beverages and dietary supplements to app-based games, and often promote claims of better brain development, function, and even disease protection and recovery. And while many of the products are directed toward the aging baby boomer set, there are products out there for all age groups. As consumer interest in brain-health products grows, regulators are taking a closer look at the products and the claims manufacturers make about them.

Beverages and dietary supplements making brain-health claims fall within the joint jurisdictions of the FDA and the FTC. Games and learning programs that feature similar claims typically would be solely within the FTC’s jurisdiction, unless their claims would cause them to be considered FDA-regulated medical devices. Ahead, we look at examples of how regulators scrutinize these products.

Case Study: How FDA Analyzes Brain-Health Beverages

The March 2015 warning letter FDA sent to the Bebida Beverage Company regarding its product Koma Unwind Liquid Relaxation is a good example outlining FDA’s concerns over brain-health products, particularly those sold as beverages.

In the warning letter, FDA discussed Koma’s labeling and ingredients. FDA pointed out that the product’s website used language consistent with food products by referencing the terms “relaxation drink” and “lightly carbonated beverage.” The product also had a Nutrition Facts panel and was created from ingredients commonly found in soft drinks.

One ingredient in particular, melatonin, was particularly concerning to the agency. FDA pointed out that, as a food product, Koma Unwind Liquid Relaxation was subject to FDA’s food additive regulations. But melatonin, while commonly used in pill-form dietary supplements, is not an authorized food additive and is not considered generally recognized as safe (GRAS) for food use. Thus, when included in a beverage sold as a conventional food, the melatonin, FDA said, rendered the product both misbranded and adulterated.

Companies marketing food or dietary supplement products making brain-health claims can use the Bebida Beverage Company warning letter as a helpful guide. Identifying any ingredient-specific limitations that could impact a product’s classification—e.g., whether it is a food additive or whether it would actually be considered a new dietary ingredient—is key. In addition, ensuring that claims on websites are consistent with how the product is labeled can help avoid unwanted agency attention. Companies should also refer to FDA’s guidance for distinguishing liquid dietary supplements from beverages, including labeling and verbiage considerations.

FTC Focuses on Substantiation: Looking for Gaps between Evidence and Advertising Claims

FTC’s analysis of brain-health claims focuses solely on product claims, without regard to product classification. The FTC looks at...
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Seniors are especially vulnerable to bogus brain-health claims, and regulators know it. Last summer, U.S. Senators Claire McCaskill (D-MO) and Susan M. Collins (R-ME) wrote letters to FDA and 15 retailers of dietary supplements inquiring about safeguards surrounding supplements marketed to seniors.

both express claims (the claims a company makes) and implied claims (what a consumer may infer about a product from a claim, even if not expressly stated), and determines whether those claims are supported by "competent and reliable scientific evidence."

"Competent and reliable scientific evidence" is a flexible standard, but those who have paid attention to FTC’s enforcement actions in recent years know that the agency's expectations for substantiation are high. In 2014, for instance, the agency found that claims that i-Health’s Brainstrong supplements were “clinically shown to give your memory a boost” were not substantiated— even though the product was supported by a 485-person finished-product clinical study showing certain types of memory improvement. The agency said its concern was that the study did not show improvement in all types of memory and, thus, could not substantiate a broad, “clinically shown to give your memory a boost” claim.

More recently, the FTC has taken enforcement action against makers of certain “brain building” programs, such as Learning Rx. According to the FTC’s complaint to LearningRx Franchise Corp. and its CEO, Dr. Ken Gibson, the company’s claims were deceptive. The claims stated that the brain-training programs were clinically proven to permanently improve serious health conditions like ADHD, autism, dementia, Alzheimer’s disease, stroke, and concussions, and, additionally, that the training substantially improved school grades and college admission test scores, career earnings, and job and athletic performance.

Learning Rx defended its product claims, posting a detailed statement about the FTC settlement and the company’s claims substantiation and explaining that the firm’s ultimate decision to settle was pragmatic. The company discussed how it had “completed randomized, controlled trials on cognitive skills and IQ as well as several quasi-experimental controlled studies and numerous observational studies using pre- and post-standardized assessments from thousands of clients.”

“This large body of clinical data demonstrates that LearningRx brain-training programs increase cognitive skills (including clients with diagnoses), IQ scores, reading skills, and standardized reading and math test scores for their clients regardless of previous diagnosis,” the company said.

In addition, Learning Rx’s expert, Dr. Howard Wainer, examined the firm’s research and data. According to the company, Wainer concluded that LearningRx had competent and scientifically reliable evidence to back claims made for cognitive skills, IQ, reading, and training in different populations, including seniors and people with autism, ADHD, traumatic brain injury, and dyslexia.

Although the FTC’s most recent brain-health enforcement has involved non-nutritional products, the lessons from these cases still apply to foods and dietary supplements. Specifically, they signal that brain-health claims remain an enforcement priority for the FTC. In addition, they demonstrate how carefully the FTC is examining the evidence put before them and how closely it matches advertising claims.

Practical Tips to Help Avoid Agency Enforcement
Here are a few takeaways to help firms operate within the heavily scrutinized brain-health market.

First, a company should make sure that it does its research well before a product launches, not at the end of production. This includes ingredients, label considerations, and advertising claims.

In addition, companies should evaluate all of the relevant research related to a topic, not just the studies that support its claims, and consider whether the study subjects and doses used are consistent with their specific product and any directions for use. This means also keeping up to date on research related to claims after a product has launched.

Third, and perhaps most importantly, companies should always be on the lookout for any gaps between the science supporting their claims and the claims they make. Keep these goals in mind, and smart companies can help keep regulatory heat off of their products.

Kristi Wolff is a partner in the Advertising and Food and Drug Law practice of Kelley Drye & Warren LLP.

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Medical Foods Playbook

How do you create a successful GRAS notification for medical foods?

BY GINNY BANK AND CHERYL DICKS, MS, RAC, GRAS ASSOCIATES

Medical food is a growing specialty product category that gives food and dietary supplement manufacturers interesting business opportunities for expanding the market of an ingredient or final product. But marketing a medical food is not always simple given the "gray zone" of FDA regulation and guidance for medical foods. In addition, marketers in general are often confused over what separates a medical food from a conventional food.

First off, medical foods must comply with all applicable food-manufacturing requirements. Ingredients used in medical foods must be Generally Recognized as Safe (GRAS) as approved food additives, or, if the ingredients are not already GRAS affirmed, they must be the subject of exemption for investigational use (21 U.S.C. 321 and 348). If your ingredient has already completed a FDA GRAS notification for conventional foods and you would like to add medical foods as an intended use, you may submit an amendment to the original GRAS dossier to cover its use in medical foods. Many GRAS notifications include both conventional foods and medical foods as their intended use.

What is the best way to ensure a GRAS notification for an ingredient’s use in medical foods will receive a “No Questions” letter from FDA? One way is to better understand FDA’s viewpoint of medical foods by reviewing GRAS notifications for which the agency has already issued “No Questions” responses. Ahead, we take a look at some of these notifications and how the notifiers describe their ingredient’s use in medical foods.

FDA Medical Foods Regulation Overview
It is first helpful to understand what a medical food is. A “medical food” is defined in section 5(b)(3) of the 1988 Orphan Drug Act (ODA) (21 U.S.C. 360ee(b)(3)). The definition is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

In 2013, FDA published a revised version of its 2007 draft guidance for medical foods, Draft Guidance for Industry: Frequently Asked Questions about Medical Foods, Second Edition. Following that, FDA recently published Final Guidance on Frequently Asked Questions about Medical Foods. This guidance reflects FDA’s viewpoint that the statutory definition of medical food is narrowly constrained to the types of products that fit within this category of food. According to the final guidance, a medical food:

- Can be food intended for persons not able to ingest food in certain physical forms (i.e., partial or exclusive oral intake or enteral tube feeding)
- Is an integral part of the patient’s clinical management under medical supervision
- Is intended for the “specific dietary management” of a disease or condition
- Is a food that is processed or specially formulated and not in its "natural" state

Among industry, there is still much confusion around what type of food or dietary ingredient qualifies as a medical food. It is important to note that medical foods are not foods used in their “natural state”, nor are they dietary supplements simply recommended by a physician as part of an overall diet to manage the symptoms or
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**GRAS Notifications and Medical Foods**

A number of companies have notified FDA of GRAS determinations for ingredients with an intended use in medical foods. A summary of these ingredients can be found in the online version of this article at NutritionalOutlook.com/regulatory/1609/GRAS. Our review investigated whether these GRAS notifications treated the intended use of an ingredient in medical foods differently than the ingredient’s intended use in conventional foods.

One thing we looked at is how specifically these notifications described just how an ingredient would be used in a medical food. While some GRAS notifications definitively outlined the intended use of an ingredient in medical foods differently than the ingredient’s intended use in conventional foods, others did not. All of the notifications described herein reflect notifications that received “No Questions” letters from FDA.

**Getting Specific about Medical Foods**

Here are some GRAS notifications that made more-specific mentions of their ingredient’s intended uses within the medical foods framework.

A GRAS notification for the use of palm oil–derived carotenoids noted a specific medical food use for the treatment of erythropoietic protoporphyria, a metabolic disorder that can manifest in skin hypersensitivity.

The medical food use of selenium received a “No Questions” response from FDA for use to “facilitate avoidance of selenium deficiency to this essential micronutrient.” The notification proposed that the medical food uses would replace 20 servings per day of traditional foods and further noted that the medical food use is to be under the supervision of a physician and that intake of the ingredient would be monitored to ensure safe use.

A second notification for selenium also described the use of medical foods as a supplement to the typical diet (when the medical food is not the sole source of the diet). This notification added that because medical foods are administered under physician supervision, it is “likely that the physician is cognizant of the need for adequate amounts of selenium and the possible overdosing of selenium and, therefore, will advise the patient to avoid other dietary sources rich in selenium.” In addition, the submission included a detailed description of the definition and categories of medical foods, as well as medical conditions for which medical foods are used (renal disease, hypermetabolic states, and malabsorption). Although the notifier did not specifically state that the ingredient would be used in medical foods to treat these conditions, this is certainly inferred.

GRAS notifications for dietary sources of omega-3 fatty acids DHA and EPA, including krill oil, phosphatidylserine from fish, and phosphatidylserine from krill, pointedly separated medical food uses from the other food categories by noting a much higher...
dosage rate if used in medical foods, and including a brief definition of the Orphan Drug Act.

A GRAS notification for long-chain inulin likewise provided a very detailed intended-use description for medical foods. The notifier indicated that the intended uses for this long-chain inulin do not include conventional foods; only medical foods and infant and toddler formulas. This submission noted that medical foods are used under physician supervision as supplemental or sole source of nutrition for those “who are unable to ingest sufficient nutrition from conventional foods.” Medical food uses included nutritionally incomplete oral products, nutritionally complete oral products, tube feedings, and pediatric nutritional. Each of these categories was described in detail, with examples of conditions the medical food addressed.

Less Specific
On the other end of the spectrum, some GRAS notifications did not directly state the intended use and usage levels of their ingredient in medical foods; instead, they alluded to medical food use by referencing all or some part of the medical food definition. For example, although some GRAS notifications for dietary fiber provided very little detail about the ingredient’s specific use in medical foods and did not discuss the difference between the ingredient’s intended use in medical foods versus conventional foods, they did allude to medical food use by point-

Not all foods fed to sick patients are medical foods.

ing out that applications in medical food are monitored by the healthcare provider, or they “estimated” the use rate of medical foods based on the number of average servings of a medical food.

Whether submitted to FDA or done via self-determination, a GRAS notification should clearly define the intended use and use levels in a medical food.

FDA: Few Mentions of Medical Food Except in Warning Letters
As mentioned, all of the GRAS notifications described previously did receive “No Objections” letters from FDA. How specific does FDA itself get when referring to medical foods in GRAS responses?
In fact, FDA made little mention of medical foods when
responding to these notifications. In its response letters to these GRAS notifications, FDA made no reference to medical foods other than to include a detailed definition of a medical food per the Orphan Drug Act.

What’s more, FDA said the agency’s response had no bearing on whether a finished product would legally be considered a medical food. As the letters stated, FDA’s response “does not address the question of whether any particular food product that contains (the ingredient name) would be a medical food within the meaning of section 5(b) of the Orphan Drug Act, and thus would be exempt from the requirements for nutritional labeling, nutrient content claims, and health claims.” Rather, it is up to marketers to correctly sell these products within the confines of medical food regulations.

In warning letters, however, FDA did provide some insight on when products are not considered medical foods. A search of FDA warning letters using the term medical foods returned 10 letters sent between 2006 and 2013. Most of these warning letters appear to have been sent because companies were attempting to market products that are clearly dietary supplements as medical foods.

In each letter, FDA informed each manufacturer that its product was misbranded. “Because these products are intended to support diseases or conditions that do not have distinct requirements for certain nutrients, these products do not meet the statutory definition or regulatory criterion for medical foods set forth in 21 CFR 101.9(j)(8)(ii),” it said. In addition, FDA informed manufacturers that because they were making disease claims, their products were also considered “new unapproved drugs.” FDA then requested prompt action to correct the violations.

**Industry Takeaways**

Despite haziness around the regulations for medical foods, marketers can glean some key insight about what FDA views as permissible for medical foods based on the agency’s “No Objections” to GRAS notifications as well as its warning letters.

First and foremost, it is clear that it would be difficult for any ingredient that is not a well-recognized nutrient to get through the notification process unless it has very specific use for a condition as defined in the Orphan Drug Act and meets the criteria FDA laid out in the revised guidance.

While some GRAS notifications supplied very little detail on the use of the ingredient in medical foods, most included some simple elements to assure FDA that the notifier is aware that the use of the ingredient in medical foods requires meeting certain requirements. We recommend that the following elements be included in any GRAS notification for use in medical foods:

1. Detailed definition of medical foods as per the Orphan Drug Act
2. A separate calculation of estimated dietary exposure in medical foods. This provides additional evidence that the manufacturer perceives the use of the ingredient in medical food as either a replacement of conventional food servings and/or for use by only a small population of individuals (e.g., those with genetic disorders)
3. Convey awareness that medical foods require physician supervision, which helps eliminate concerns of exceeding maximum use levels
4. A statement that the intended use of the ingredient in medical foods will follow all applicable regulations
5. In cases in which a deficiency of the nutrient ingredient causes no specific disease or syndrome, a statement that the ingredient will be used only in foods already determined to be medical foods

It is also important to have on hand substantial clinical support to demonstrate the efficacy and nutrient requirement of the medical food use through the “gold standard” of clinical trials (double-blind, randomized trials) that address nutrient deficiency and effect on targeted disease. This information should be part of a comprehensive product-development plan, creating a synergistic strategy for market placement and regulatory compliance for your medical food.

**Ready to seek GRAS status for your medical food ingredient?** Ginny Bank (associate) and Cheryl Dicks (senior regulatory affairs scientist) support GRAS Associates (Bonita Springs, FL), which has extensive experience in medical food compliance, as well as the submission of GRAS notifications to the FDA.
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Whatever Happened to Common-Use GRAS?

Common-use GRAS determinations are no longer common.

BY CARRIE KENNEDY, PMP, RAC, AND GEORGE BURDOCK, PHD

It’s a thought disturbing to some: since 1938, drugs have required FDA premarket approval, but it was not until 1958 that ingredients added to food had a similar requirement. The end of the 20-year delay and subsequent regulatory changes came about as the result of several converging issues. These issues included the rapid growth of the post–World War II population (the baby boomers) and the benefits of chemical advances made during the war, especially in pesticides and food preservation, which led to a demand for the convenience food we have today.

When regulators finally began developing these requirements for foods in the early 1950s, Congressional hearings—the Delaney Hearings—on the issue of food chemicals made it plain that a balance between four competing issues had to be met:

1. Address the safety of the public and public concerns regarding transparency of the vetting process for food ingredients
2. Help the food industry avoid an undue financial obligation, including prolonged safety testing for substances such as spices that had proven themselves safe over scores or hundreds of years
3. Ensure unwieldy regulatory burdens on manufacturers did not stifle innovation of food products
4. Preserve the effectiveness of FDA regulatory oversight by avoiding a potential landslide of hundreds of food additive petitions

Having successfully balanced the aforementioned issues, the 1958 Amendment to the Federal Food, Drug, and Cosmetic Act was written into law, codifying the requirements for ingredient approval. In a commendably pragmatic move, Congress decided that ingredients, such as spices, that had been safely used for hundreds or even thousands of years and thus had already demonstrated safety through prolonged use could be declared Generally Recognized as Safe (GRAS). Further, GRAS ingredients could be determined to be such by two methods: “scientific procedures” (a safety decision based on animal testing) or “common use in food.” Common use in food required that a company demonstrate that a substance had been safely used in food prior to January 1, 1958. Those ingredients that could not meet the GRAS criteria would need to undergo the more complicated food additives process, which requires approval by FDA.

In either approach to GRAS—scientific procedures or history of use—the basis of whether an ingredient qualifies as GRAS depends on the intended use of that ingredient. An ingredient’s intended use must be described in a company’s support of its GRAS determination, along with the physical and chemical characteristics of an ingredient, its origin, estimated daily intake, and the foods to which it may be added. Of note, an often-overlooked aspect of the GRAS process are the methods by which an ingredient is manufactured and by which quality and safety controls are implemented.

In execution, GRAS determinations require there to be common knowledge about the substance within the scientific community, usually through peer-reviewed publication, as well as the convening of an expert panel to determine if the substance is GRAS. As a result, every GRAS determination has a sound basis in science.

The Challenges of GRAS by Common Use

The general recognition of safety by common use in food is not achieved through grandfathering per se, because a GRAS determination still requires a review by experts to confirm that the historical exposure level was safe at less than or equal to the proposed estimated daily intake as a result of the new, modern use. The first several hundred ingredients affirmed as GRAS likely drew heavily on this historical-use provision—either as whole-food products (such as cloves or dill) or their historically produced extractives listed in 21 CFR 172.510. However, in the modern scientific and regulatory climate, obtaining GRAS by common use is potentially the hardest path...
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by which a food ingredient can become federally compliant. As a result, the common-use GRAS route is now rarely used.

For common-use GRAS, a manufacturer must provide at least two independent pieces of information documenting the ingredient’s common use. This information must also demonstrate that the specifications and (generally the same) process at the time of the GRAS evaluation match those processes pre-dating 1958. This is often a challenging task because the literature and documentation supporting manufacturing processes and food quality were lacking prior to the 1950s, a question addressed in the 1958 Food Additive Amendment. Further, techniques used to isolate a substance have evolved substantially since 1958, enabling a manufacturer to isolate a previously elusive substance with potentially greater purity and in much larger quantities, for instance, such that the new isolate can be used in higher quantities not available in pre-1958 years. And therein lies the rub: because the use of a higher quantity of the ingredient is not supported by a history of safe use, the ingredient may not be eligible for the common-use GRAS provision.

Potentially making things even more challenging, the regulation (21 CFR 170.30(c)) notes that FDA “should” be consulted and concur with a determination of GRAS on the basis of common use if historical data is cited from a country other than the United States. In fact, this suggestion holds no enforceable weight because notifying FDA of any GRAS determination is entirely optional; companies that do choose to submit their GRAS determinations to FDA to review do so voluntarily. Still, the word “should” in the regulation likely influences some.

Until 1983, there were no common-use GRAS guidelines for foods of non-U.S. historical origin. In 1983, FDA’s requirement that information supporting common use in food had to derive from the United States was overturned in a court appeal regarding a substance used in China prior to January 1, 1958. The decision from the appeals court was essentially that safe consumption of food is not an exclusive habit of U.S. citizens and, therefore, evidence from other countries must be given equal consideration as historical support in a common-use GRAS evaluation.

While the court’s decision led some to believe that a flood of ingredients from outside the United States would likely gain approval for addition to food in the United States by means of common-use GRAS—a belief expected to be bolstered by an increase in GRAS filings with FDA for foreign foods—what actually happened was quite different. In fact, data indicate a conceivable disappearance of common-use GRAS determinations in the early 2000s. (See Figure 1.)

To create Figure 1, we determined the number of common-use GRAS ingredients versus those GRAS ingredients resulting from formal ingredient filings with FDA from industry. The number of common-use GRAS ingredients is based on estimates presented by FDA staff. Approximately 20% of the ingredients eventually included in Section 184 of the Code of Federal Regulations (for common-use ingredients) were included as a result of industry-submitted GRAS affirmations. The net remaining ingredients in Section 184 were presumed to have originated on the basis of common use prior to review by the Select Committee on GRAS Substances.

In reviewing a search of the current FDA GRAS Notification (GRN) database, less than 1% of those GRAS notifications describing a record filing by means of the common-use method of GRAS were acknowledged with “No Questions” from FDA. All other historical-use submissions were either found to not have a basis for GRAS or were resubmitted through scientific procedures and then met with “No Questions.” Just three notifications (covering 10 enzyme preparations as food processing aids), and one notification (covering three herbal preparations for herbal tea flavors which received favorable FDA responses), are the sole ingredients FDA has acknowledged on the basis of common use in the last 18 years. (See Table 1 on the next page.)

Why the Decline of Common-Use GRAS Determinations?
The steep decline in common-use GRAS filings/findings warrants at least some speculation as to the origin of the trend. There are two historically accepted explanations for its decline: 1) that most of the substances that could be supported by history of use have already been GRAS affirmed and/or were simply added to food with the presumption they were GRAS, and/or 2) that the substances were not notified because FDA might not have agreed with the basis of the GRAS (i.e., an “inadequate basis for GRAS” letter would have been issued). The most likely explanation is that both of these forces have been at work in influencing common-use GRAS filings to date.

There is another previously unexplored explanation, too, centering on the advances made in food ingredient production over time. The majority of food additives and ingredients reviewed and approved for use
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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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in the late 1950s and throughout the 1960s were approved for use in their natural state or in a state (e.g., extract, oil) that could be developed in a lab and transferred to large-scale production, with minimal effort or risk, and that were deemed to resemble the ingredient pre-1958 (based upon science of the time). As time passed, and given the cultural, industrial, and technological shifts that happened in the 1980s through 2010s, however, the further from 1958 a GRAS determination was reviewed, common use as an argument for safety became progressively less possible because fewer and fewer cases could be made that a product and its use, including the level of consumption, were equivalent to a pre-1958 version. (As an example, see Figure 2 showing growth in the number of patents filed related to food and technology, and food and extraction, pre-2000 compared to number filed in 2001–2016.)

Advancing Common Use through the Modern Science of GRAS

The decision to allow historical use or common use of a food substance as a route to GRAS determination has been an undisputed success. Since its creation in 1958, the common-use provision of GRAS has saved companies time and large investment required to bring products to market, while promoting innovation in food science. How can we ensure that common-use GRAS remains a viable route to companies seeking GRAS affirmation?

First, we suggest that the cut-off date be changed. Instead of requiring that all common-use substances be used in the market...
prior to January 1, 1958, the provision should be changed to allow any substance having been in common use for at least 20 years prior. This also benefits ingredients of non-U.S. historical origin. Although substances used in the U.S. would have already been determined to be GRAS or have been approved as a food additive, substances in use in any other country (for example, an EU country, ANZUS, or China) would become eligible if they were used for at least 20 years. Currently, use of such foreign substances do not qualify for the common-use GRAS provision if the period of historical use was January 1, 1958, through the present, amounting to an omission of more than 50 critical and modern years of food safety, solely because the product was in use outside America’s borders.

There is no disputing that a substance in a food should only be used at a level shown to be safe; however, to limit the common-use provision to those uses prior to January 1, 1958, fails to capitalize on a successful process for vetting substances for safety. What better measure of safety than safe use by consumers for a fixed period of time in the era of food safety modernization, at home or abroad?

The current cut-off date may be a crucial reason why we have seen the use of common-use GRAS determinations fall off in recent years. Simply put, the date is outdated. We therefore propose that FDA extend the common-use provision to include the safe use of a food ingredient to 20 relative years in order to eliminate this arbitrary cut-off date to allow food manufacturers to more easily innovate with a global supply of historically safe ingredients.

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Burdock Group is a scientific and regulatory consulting firm specializing in the food/beverage, dietary supplement, personal care, and pet food industries. Services include GRAS affirmation, claims substantiation, label reviews, NDI notifications, and nanotechnology risk-assessment.
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Sports nutrition is the science of delivering targeted nutrition at precise windows of opportunity, enabling athletes and sportspeople to compete at their best. These days, sports nutrition extends far beyond strength trainers (weightlifters, bodybuilders) and endurance athletes (cyclers, runners, swimmers, etc.). Consumer demand is growing for all kinds of “performance” products—recreational, lifestyle, and everything in between. Here is a breakdown of some of the new-product activity happening globally and in the U.S.

Demand from U.S. and Beyond
The United States has always led the sports nutrition category but may now be ceding market share to other global entities. Between April 2015 and April 2016, the U.S. still accounted for a significant 30% of global sports nutrition new-product launches. Note, however, that this was down from 45% five years previously. Indeed, customers in other parts of the world, particularly Europe, are interested in sports nutrition now. Expect this trend to continue in the coming years.

Sports Powders
Traditional sports powders still dominate the arena. In the 12 months ending April 2016, powders accounted for nearly 58% of total global new-product launches, and as much as 64% of launches in the United States.

Despite being a category mainstay, powders must also compete with other, more convenient ready-to-use sports nutrition products, including ready-to-drink (RTD) beverages. As a result, sports-powder marketers are working harder than ever to make the powder format more convenient for users, going beyond traditional bulk tubs and into portable packaging like pouches. In addition, powder products are embracing new ingredient compositions and new flavors, such as the dessert and cookie-style flavors trending in the broader food and drinks market.

Sports Bars
Sports bars came in second. Globally, sports bars accounted for 13.6% of total global sports nutrition new-product launches and nearly 12% of launches in the United States.

The high-protein trend in the food and drinks industry is growing in sports bars, too. Protein is now a key marketing claim for sports bars. Nearly 85% of global sports bar launches, and up to 90% of U.S. sports bar launches, featured an “added protein,” “high in protein,” or “source of protein” claim.

High-protein claims are also popular in the general nutrition bars market, indicating that protein bars have graduated from being specialized products for endurance and performance athletes to becoming mainstream products for general consumers seeking protein’s additional benefits like satiety, weight management, muscle building, and increased energy. Forty-three percent of

His-and-her workout powders? 1 Up Nutrition recently launched two versions of a new sports powder. One is for men and contains a targeted mixture of branched-chain amino acids, including L-carnitine and Kyowa-Hakko USA’s (New York City) branded Sustamine ingredient (a dipeptide of glutamine that aids rehydration and muscle recovery and increases metabolic rate). The women’s version features Sustamine as well as collagen to support skin strength, elasticity, and structure.
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mainstream cereal and energy bar launches in the United States featured protein claims.

Launch activity is happening everywhere within bars: whey bars, nutrition bars, Paleo bars, and other protein-rich bars. In spring 2016, one of the pioneers of the sports and energy bars market, Powerbar (now owned by Post Cereals), relaunched its U.S. sports bars range with new products advertising ideal macronutrients, lower sugar, whole-food ingredients, clean labels, and superior taste. The products target a range of consumer needs, from endurance to general fitness.

Capsules, Tablets, and Drinks
Sports supplements, mainly in the form of capsules and tablets, ranked third behind sports powders and bars. Sports supplements accounted for 9.9% of global sports nutrition launches. In the United States, where dietary supplements tend to be more popular in general, sports supplements accounted for 11.6% of new-product launches, just behind sports bars.

In drinks, RTD sports drinks and protein sports drinks accounted for 6.2% and 4.6% of global launches, respectively. Other products like gels and chews claimed 7.8% of the market. In the U.S. specifically, RTD sports drinks clocked in at 5.6% of launches, while "other" products came in at 3.7% and RTD protein-based sports drinks at just over 3%.

Sports and performance drinks were the first sports nutrition products to go mainstream. Major U.S. soft drink brands like PepsiCo’s Gatorade and Coca-Cola’s Powerade were among the original pioneers. These brands continue to drive the market forward by introducing new flavors and product formats, plus high protein for casual users (such as Coca-Cola’s Core Power protein-rich dairy-based sports recovery beverage launched in 2012).

Coconut water is still growing as a natural isotonic alternative. Nearly 14% of U.S. RTD sports drinks Innova Market Insights tracked in 2015 featured coconuts, mainly in the form of coconut water but also including coconut flavors and ingredients. By contrast, in the non-sports-drinks market, coconut isn’t as popular. Excluding sports drinks, coconut ingredients were featured in just over 7% of soft drink launches and up to 12% of juice drink launches.

Promising Future
The sports nutrition market continues to diversify and reach out to new consumers. By including different sports, exercise regimes, and levels of activity, as well as different ages and genders, the opportunities are endless. Are you game?

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As FDA looks to define the term *natural* on food labeling, industry leaders are split on what exactly the term should mean.

**BY MICHAEL CRANE, ASSOCIATE EDITOR**

Take a stroll down any aisle in the grocery store and you’ll find one marketing term used as much as or more than any other: natural. Thousands of U.S. food and beverage companies parade their products under the banner of natural, but with no official definition for the word, each one is free to march to the beat of its own drum.

Despite what a large swath of Americans believe, FDA has never established a formal definition for the term natural on food labeling. That’s made it one of the most ambiguous words on the market, much to the chagrin of food companies embroiled in class action lawsuits attacking their use of natural or all natural claims.

Even more troubling is the fact that many consumers still appear to place great stock in the nebulous word. According to a 2015 survey conducted by the Natural Marketing Institute on behalf of the Organic & Natural Health Association (ONHA; Washington, DC), 46% of consumers believe the U.S. government regulates use of the term natural, while 36% of consumers think there is no difference at all between natural and organic, which is officially defined through USDA’s National Organic Program. Other 2015 surveys suggest majorities of consumers also mistakenly believe “natural” foods must be produced without pesticides or the genetic engineering of crops.

In short, natural remains an influential, widespread term on food labeling that essentially means nothing. But that may not be the case for much longer.

**FDA Dives In**

After years of complaints from courts, consumers, and the food industry, FDA announced last November it was seeking public comment on how natural should be defined on food labeling, if at all. FDA spokesperson Siobhan DeLancey told Nutritional Outlook the agency finally decided to consider the issue after it received three citizen petitions and multiple requests from federal courts asking for a...
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formal definition. By the time the comment period closed on May 10 this year, FDA had received more than 7,600 individual comments, DeLancey said.

One look at the comments and it immediately becomes clear why FDA waited so long to address the issue. Even just among trade groups in the natural products industry, the range of fundamentally different approaches to defining natural makes this one of the most challenging regulatory issues FDA has tackled in a decade.

The GMO Conundrum
As you might expect, the “naturalness” of genetically modified organisms (GMO) is one of the biggest fault lines running through this debate. Many industry groups, such as the American Herbal Products Association (AHPA; Silver Spring, MD), the Organic Trade Association (OTA; Washington, DC), and ONHA, believe natural should mean non-GMO. Others, including the Natural Products Association (NPA; Washington, DC) and the Grocery Manufacturers Association (GMA; Washington, DC), say GMO foods should still be considered natural.

On one level, where industry leaders stand on GMO foods being “natural” comes down to how much significance they place in current consumer attitudes.

“If you go ask consumers about what they think natural includes, they don’t think it includes genetically engineered ingredients,” explained Michael McGuffin, president of AHPA. “We think that the whole concept of federal labeling regulations is that consumers should not be fooled.”

Several recent surveys do seem to suggest a majority of consumers perceive natural to mean non-GMO. (The exact percentages vary significantly from survey to survey.) On the high end, an OTA survey of 3,400 parents conducted in December 2015 found that 70% of respondents believed “natural” products are produced without the use of GMOs. Meanwhile, a Consumer Reports phone survey of 1,005 U.S. adults, also conducted in December 2015, indicated that number was closer to 60%. The aforementioned Natural Marketing Institute survey, commissioned by ONHA, suggests it’s more like 50% of consumers who believe natural means non-GMO.

With such wide-ranging consumer data, NPA CEO and executive director Dan Fabricant, a supporter of including GMO foods in the natural definition, has called for more research to be done. But even then, Fabricant expressed “skepticism” toward relying solely on what consumers believe about GMO foods right now.

“When you have been taught that [“Jimmy Kimmel Live!”] bit on GM [foods] when he asked people what GMO was? He asked 10 different people and he got 11 different answers, and one was goofier than the next,” Fabricant said. “How about having a dialogue with the consumer versus just asking them gotcha questions?”

Unlike AHPA and NPA, the Council for Responsible Nutrition (CRN; Washington, DC), chose not to weigh in on the GMO issue. But Duffy MacKay, ND, senior vice president of scientific and regulatory affairs for CRN, also stressed the importance of additional consumer research.

“If there was an official consumer survey done by FDA, and it became evident that the overarching understanding was consumers think natural means non-GMO, well then that makes sense to use that data to help shape the definition,” MacKay said. “But without that we’re just running with people’s opinions and emotions and feelings about where GMO sits.”

FDA’s DeLancey said it was premature for FDA to speculate on next steps, such as FDA conducting a survey of its own. But she noted that “in the past, on select issues, the FDA has employed a variety of different consumer research methods.”

Natural doesn’t just refer to the state of ingredients in a particular product; many food and beverage manufacturers also use the term as part of their corporate identity. Some companies, such as Nature’s Way or Nordic Naturals, feature the word in their actual brand name, while others just use natural in general marketing materials. The question is, if FDA defines what a “natural” ingredient is, will it also define whether a company’s corporate identity can include natural?

“If FDA does not separate those [issues] and allow for people who have invested decades into their identity being around that term, that will be a huge problem for the industry,” said Duffy MacKay, CRN’s senior vice president of scientific and regulatory affairs.

FDA has not suggested it intends to restrict the use of natural in corporate identities, and the agency’s recent ruling on the KIND company’s use of the term healthy might indicate its thinking on the matter. After first warning KIND against using the term healthy on its products in 2015, FDA announced in May that KIND could continue to use the term because it is a statement of “corporate philosophy,” rather than a health claim, so long as healthy is not used in the same panel as the nutrition information. It’s possible FDA would take a similar approach to natural.

“There are no proposals on the table that would suggest FDA wouldn’t allow those companies to continue [using natural in their corporate identity], but it’s just something to keep an eye on,” MacKay said.

Making Natural Different from Organic
Aside from consumer perspectives, there’s also the issue of how natural should be different from the term it’s most often confused with—organic—which already includes non-GMO in its official definition. That’s another reason why NPA argues consumers are best served by a natural definition that’s distinct from anything else already defined on the market.
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“If natural became synonymous with non-GMO, there would be no difference between the terms natural and organic, and it would be pointless for FDA to undertake defining natural through federal rulemaking,” NPA said in its comments to FDA.

But even if both terms were to mean non-GMO, there could still be other places where natural and organic diverge, AHPA’s McGuffin pointed out. The USDA Organic Program, for instance, requires companies submit a farm plan that details sustainable farming techniques. Most of the proposed natural definitions, on the other hand, do not include this added element.

“Informed consumers should be aware that organic doesn’t just mean ‘absence of’ [non-organic ingredients]. It means affirmative and active and positive stewardship of that farm,” McGuffin said. “And that would not be included in natural as any of us have perceived it. If natural only means ‘absence of,’ then it won’t be the same as organic, to at least the sophisticated consumers.”

Permitted levels of chemical pesticides could also be a point of difference between the two terms, although surveys have suggested most consumers also believe natural already indicates an absence of chemical pesticides, AHPA noted.

Another distinguishing factor might be that USDA Organic is an actual certification. CRN, AHPA, and NPA have all called for FDA to define natural through rulemaking, rather than establish another, separate certification program for natural. The Organic Trade Association (OTA) disagreed, suggesting a third-party certification would be more appropriate than rulemaking for natural. (But OTA also took the position that natural should not be used on food labeling at all given the issue’s complexity and the time it will take to reach a definition.)

Considering FDA’s reluctance to address the issue for so many years, it’s likely the agency will go through rulemaking anyway, the simpler option of the two, McGuffin suggested. That could potentially ensure organic remains the more powerful of the two terms.

A More Accessible Option
Still, for NPA’s Fabricant, those differences aren’t enough to distinguish natural from organic. For natural to be useful, Fabricant said, it should be defined as a more accessible, lower-tier version of organic. And that’s

“NATURAL” PROCESSING TECHNIQUES

Debating which ingredient sources are “natural” is a first step, but what about the processes those ingredients undergo after harvest? In its request for public comment, FDA also asked whether the term natural should be applied to processed foods, and if so, which processing methods are considered natural.

The response from industry groups was relatively unanimous; simple, traditional processing techniques such as dehydration, distillation, fermentation, and water or alcohol extraction should be considered natural.

“We do want to allow foods that have been subject to traditional food processing, like extraction or fermentation,” said AHPA’s Michael McGuffin. “Those are natural processes. We’ve been doing them for thousands of years or more.”

But food processing that includes non-traditional steps, such as the use of certain extraction solvents or fermentation inoculates, should not be permitted in “natural” foods, according to AHPA.

Based on their recommendations, many commenters, including NPA, urged FDA to create a definitive list of processes that are permitted in the manufacturing of “natural” foods.
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“It’s too much black-or-white thinking, versus good, better, best thinking,” Fabricant said, explaining that natural ingredients should be defined as “better” than most food ingredients, but not be defined so strictly as to be conflated with organic; the “best” standard on the market. In his view, a natural definition that bans GMOs would “castigate those people who can’t meet USDA Organic.”

Fabricant also cautioned that a strictly non-GMO natural definition would make “natural” products more expensive and drive up the price of non-GMO seeds already in limited supply. The power of natural products more expensive and drive up the price of non-GMO seeds already in limited supply. The power of “natural” products more expensive and drive up the price of non-GMO seeds already in limited supply. The power of “natural” products more expensive and drive up the price of non-GMO seeds already in limited supply. The power of “natural” products more expensive and drive up the price of non-GMO seeds already in limited supply.

AHPA’s McGuffin said that kind of merging of the two terms would be an “unfortunate outcome,” although he said he suspected the added elements of a farm plan and third-party certification would be enough to maintain organic’s status as the gold standard.

“I can’t help but think that there’s still going to be a price premium for organic,” McGuffin said.

What’s Next?
To say that FDA has opened a can of worms would be putting it lightly. On top of the conflicting opinions from major industry associations, FDA has to consider all the comments submitted by consumer advocacy groups and others invested in natural. So what should we expect next, if anything?

Should natural be defined as a more accessible, lower-tier version of organic?

“FDA wants nothing to do with this. That’s the impression I’m getting,” said CRN’s MacKay. He added that FDA knows that “no matter what, they’ll make a lot of people upset.” Also, as FDA’s mandate is public health and safety, while the natural debate largely revolves around marketing issues, it’s likely to be lower on the agency’s list of priorities, MacKay suggested. But NPA’s Fabricant, who formerly served as director of the Division of Dietary Supplement Programs at FDA, was more optimistic about the agency’s timeline. “I would anticipate in the next 12–24 months they’ll have a proposed rule out there,” he said.

Once the proposed rule is announced, FDA will likely open another comment period for 3–6 months, followed by a process of drafting the final rule that could take anywhere from 12–24 months, Fabricant suggested. He added that there’s also pressure from Congress to move the rulemaking process along.

“So you’re looking at a good two- to three-year cycle to get a final rule out there,” Fabricant said. “But I think having a proposed rule at this point is incredibly important for the industry because then people can start going, ‘Okay, this is kind of where the tea leaves are going.’”

And even with the disparity of industry opinions on natural, Fabricant added that NPA is excited that industry and consumers finally have the chance to arrive at a technical standard.

“We haven’t had a scientific dialogue on natural, on GMO,” Fabricant said. “It’s all been emotional. It’s all been charged. This finally gives us the chance to talk about the technical aspects of what natural is.”

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This is 2016. Categorizing consumers into types based on their preferences, motivations, or purchasing behaviors is just so...Y2K. At least that’s what Julian Mellentin, director, New Nutrition Business (London), seems to think. As he puts it, “The person who listens to Bach’s Goldberg Variations while working at home also listens to Aerosmith or Black Sabbath while driving to work—and sometimes jazz.”

For a company with a product to market, this fluidity makes it all the more difficult to pin potential purchasers down. Indeed, as market researcher Innova Market Insights points out in its report “Fragmentation—Where and How?,” “It is a truism that markets and consumer tastes are ‘fragmenting,’ which for most consumer marketers means that big brands are no longer reaching broad audiences as easily as they did.”

With fealty to mass markets crumbling in this era of fragmentation, the consumer-as-moving-target may be the norm going forward. Indeed, says Mellentin, “The idea that you do not have to be loyal to one musical genre or style of eating”—that you can inhabit many identities at once—“infuses our culture and drives people’s beliefs and choices in every area of their lives.”

This includes their approach to healthcare, which consumers “seem to regard as an extensive menu of options from which to select what makes the most sense in the context of their individual beliefs, health needs, and lifestyles,” says Mellentin. That’s a far cry from the days when dietary supplement manufacturers could put out a multivitamin and maybe a few specialty formulas for the “average” shopper and call it a day.

There is a silver lining, though. While diversity in the supplement marketplace complicates how the industry serves its audience, it also expands the audience the industry can serve.

Taking Health into Their Hands
Mellentin and his colleagues first noted this personalization of healthcare around the turn of the century. More than ten years on, “The fragmented, individualized view of health that was emerging back in 2003 has, in 2016, become the defining force,” he says. And what undergirds its definition is the extent to which consumers are taking health into their own hands.

In a sense, you can’t blame them. “As a result of the economic downturn over the past decade, consumers have turned to self-diagnosis as a way of cutting costs,” says Kimberly Kawa, senior nutrition researcher, SPINS LLC, a leading information provider for the natural and specialty products industry. For better or worse, consumers have also begun seeing the Internet and social media as first responders, enabling them “to compile and analyze their symptoms with the click of a mouse,” Kawa adds.

Moreover, a barrage of pharmaceutical advertising has convinced consumers that they might know better than their doctors how best to optimize their health. While the supplement industry isn’t “at the forefront of
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Consumer Insights

this marketing,” Kawa says, it’s nonetheless helped foster “a culture of acceptance” toward self-diagnosis that supplement consumers are embracing “as they explore more alternatives to conventional, over-the-counter medicine,” she says. “Over the next few years, expect to see more supplements introduced as alternatives to conventional products to attract this emboldened consumer.”

Who’s Influencing Whom?
Judy Blatman, senior vice president, communications, Council for Responsible Nutrition (CRN; Washington DC), says CRN’s annual extensive shopper survey shows “that physicians are still the number-one trusted source for information on supplements.” Still, she notes, consumers’ “world of influencers is changing” all the while. Bloggers, celebrity endorsements, and old-fashioned hunches play a role, “particularly with younger generations,” she notes. These are consumers who are “questioning authority. They don’t want to be told what to do. They want to be part of that decision-making process, and I think that probably started with boomers,” Blatman says.

Jeff Hilton, partner and cofounder, BrandHive (Salt Lake City), observes that we’ve replaced the well-educated, health-aware female aged 45-plus who was the supplement shopper of yore with a consumer who’s “more diverse both ethnically and gender-wise.” Case in point: more men are discovering supplements and functional foods—traditionally the province of female shoppers—while more women are buying traditionally “manly” sports or active-nutrition products.

Add younger consumers to the mix and you get “a complex puzzle, primarily because millennials are rewriting all the rules,” Hilton says. He thinks millennials stand apart from their boomer counterparts in that they’re “looking to live life to the fullest and want products that facilitate their chosen lifestyles and activities.” Boomers, he wagers, “just want to live forever and enjoy continued good health.”

Millennial Hope or Hype?
But while some have exalted the millennial generation as a digitally driven shot in the arm to goose supplement sales, others are less sanguine. Take Barbara Katz, president, HealthFocus International (St. Petersburg, FL). “Here’s the rub,” she says: “While the millennial shopper shows a lot of enthusiasm and is very open to the connection between nutrition and health, it’s still the boomer who’s far more likely to tell us that they’re actually using vitamin and mineral
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supplements. So this may be a case of an enthusiastic younger market that isn’t actually taking action versus a somewhat more skeptical older one that is.

Sure enough, when Katz’s company surveyed consumer attitudes toward supplements, 44% of millennials expressed an inclination to give “reputable” companies the benefit of the doubt on label claims, while only 33% of boomers said they did the same. The lesson, Katz says, may be that though still a bedrock of the supplement market, boomers are “more likely to come into the discussion saying, ‘We’re open to trying things, but we’ve been around longer and seen claims that don’t hold true, so you’re going to have to work harder to prove this.’”

Motivating Factors
HealthFocus International’s study also found that millennials and boomers use supplements for very different reasons, with younger consumers “far more likely” to address need states like improved sleep and energy, stress reduction, skin health, and immunity, while older ones focus, not surprisingly, on improved memory, bone and joint health, cholesterol reduction, and heart health. “This is not to say that there’s no overlap,” Katz insists, but “that their key foci are different, as one would expect.”

Understanding and predicting those foci is getting harder as the audience for supplements diversifies. But despite all the churn, Blatman is quick to remind marketers that, according to CRN’s annual survey, “the number-one reason consumers take supplements is overall health and wellness.” The need to fill nutrient gaps continues to rank highly as a motivator, too, as does the pursuit of energy.

Delving more deeply into what motivates consumers, Blatman notes that some “are very committed to the category and interested in adding new supplements for new reasons at new times in their lives,” while others are seasonal users “who might take Echinacea if they feel a cold coming on.” And don’t forget what she calls the “core users,” who turn to multivitamins—or maybe even to a specific nutrient, like vitamin D or omega-3s—when their doctors advise them to.

Eleanor Dwyer, research associate, Euromonitor International (Chicago), points out that “extreme health enthusiasts have also historically made up a core group” of vitamin and dietary supplement consumers. Yet she believes it’s the growing influence of more “casual purchasers” that’s “the most salient trend” in the category today.

Embracing Integration
In any event, Blatman’s seen an upswing in interest in integrative health, pointing to the recent renaming of the National Center for Complementary and Alternative Health to the National Center for Complementary and Integrative Health. The seemingly minor change, she notes, “reflects a recognition that products previously thought to be alternative”—supplements as well as massage and acupuncture—“are really mainstream,” she says. “And that’s a big shift.”

Part of integrative care’s appeal stems from growing concerns about the cost of healthcare. Notes Dwyer, “Health insurance providers have responded to an increased burden by diligently promoting preventative care. These shifts have encouraged Americans to adopt healthier lifestyles, and many have turned to vitamin and dietary supplements as an easy first step in taking control of their future health.”

James S. Tonkin, founder and president, Healthy Brand Builders (Scottsdale, AZ), agrees—with caveats. Personal responsibility for health is “starting to take shape,” he says, but he’s yet to see evidence that most consumers are truly following through. “We still have a long way to go in educating people as to preventative care and lifestyle changes,” he believes. Even so, he sees a change coming, and bets that when it does, it may “eventually lower the total cost of healthcare in the U.S.”

Loyalty Oath
The take-home for marketers, Blatman says, is that “they really need to understand consumer segmentations in order to fine-tune...
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The kinds of products they’re selling. And as with all other industries, you have some consumers who are very brand loyal, and some who are price sensitive.”

The trend, though, appears to be toward the latter. In fact, some industry watchers think brand loyalty’s days are numbered. Take Hilton: “Brand loyalty is on the decline,” he says. Though boomers might still maintain some brand allegiance, “Millennials are less loyal, preferring niche brands that they can ‘own’ and champion.”

Though Tonkin himself professes to being “a brand guy,” as he looks ahead he believes “we’ll always have the private-label, alternative anti-brand shopper,” he says. “Trader Joe’s thrives on these people, as do dollar and ninety-nine-cent stores. It’s more about economics than anything, in my view.”

Get the Word Out
It’s also about trust. Consumers’ continued commitment to the category imposes a commitment upon marketers, Blatman believes. “We’re producing products that people put into their bodies,” she says. “From that standpoint, we need to be sure that we’re building trust and doing everything we can to deliver them high-quality, safe, beneficial products.” That’s why, in her mind, “Safety is the entry point.”

Companies also need to invest in science to substantiate their supplements’ benefits—and those that do, Blatman says, “will do better in the long run.” But once they have the science, how do they get the message out to a market that’s both diverse and widely dispersed?

“Good question!” says Laura A. Mahecha, industry manager, healthcare and I&I, Kline & Company (Parsippany, NJ). For starters, she encourages marketers to make use of good-old word of mouth. Today’s consumers “place a lot of emphasis on what their friends and relatives tell them and on their own research,” she notes. “Even more, perhaps, than on advertising or social media.”

That said, social media and online channels are where today’s consumers live. Which is why Mellentin sees “a growing importance for a brand to build an online and/or social-media presence.” Marketing digitally helps companies not only find their customers, but understand the finer points of who they are and what they want. “And because social media is interactive,” he adds, “it can also be used as a tool to generate feedback and analyze current trends.”

And lest marketers think that only digital natives are attached to their devices, Mellentin notes that the Pew Research Center’s “Older Adults and Internet Use” report found 67% of adults aged 65 and older using the Internet on a daily basis. “So we might be underestimating the size of the target group online.”

Marketers are taking these kinds of lessons to heart and learning to adapt their expectations. Because the one thing we can be sure of is that there is no longer—and perhaps never again will be—a singular supplement shopper.

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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Can natural supplements be as effective as drugs—or at least complementary?

BY IRFAN QURESHI, ND

Most mainstream consumers probably think of natural dietary supplements as ancillary products to be taken alongside a healthy diet and lifestyle—perhaps, even, alongside conventional drugs. Studies show, however, that natural products can provide powerful, therapeutic benefits on their own. Because they are powerful, several natural compounds can even interact with certain pharmaceuticals, which is why it’s always important to disclose the use of natural supplements to a healthcare provider if they are to be used concurrently with medication.

Here’s where supplements get really interesting, however: in a handful of cases, research even suggests that natural products may achieve results on par with conventional drugs. And, in other cases, researchers have studied how natural compounds can be used together with drugs to enhance a drug’s positive effects and perhaps even reduce its negative effects.

When all is said and done, regulators such as the U.S. FDA absolutely forbid drug-type claims for any dietary supplement product, and dietary supplement marketers should be extremely careful not to make claims that any supplement can “diagnose, treat, cure, or prevent” any disease.
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Looking at the science never hurts, though, so here are some recent studies comparing the performance of drugs and supplements, as well as trials evaluating when the two together may be beneficial.

**Working Together with Statin Drugs**

Some people who are sensitive to statin medications taken for high cholesterol may develop statin-related muscle pain (myalgia). Instead of prescribing these patients statins, physicians may instead prescribe an alternative, second-line therapy—the drug ezetimibe. Still, in many cases, the use of ezetimibe alone may not be enough to achieve targeted LDL cholesterol reductions. In these cases, these patients may benefit from a combined treatment of ezetimibe and alternative therapies.

In a recent study, Arrigo Cicero and colleagues retrospectively analyzed the charts of patients visiting the lipid clinic at the University of Bologna in Italy. These patients were moved to ezetimibe therapy due to statin-related myalgia¹ and were also prescribed additional therapeutics to further reduce LDL levels.

Ezetimibe treatment alone was associated with an average 17% LDL reduction. Several alternative treatments resulted in further LDL reductions, however, including:

1) A 19% reduction with a combination of red yeast rice (3 mg monacolin K) and berberine (500 mg),
2) A 17% reduction using berberine alone (500 mg twice daily), and
3) A 10% reduction with a combination of phytosterols (900 mg) and psyllium (3.5 g) taken twice daily. The alternatives were well tolerated and effective, indicating their potential benefits as adjunctive treatments for individuals intolerant to statin drugs.

**Curcumin vs. Ibuprofen**

Nonsteroidal anti-inflammatory drugs (NSAIDs) are ubiquitously used to relieve pain in osteoarthritis patients. But NSAIDS may come with their own adverse effects. Side effects can include ulcers, gastrointestinal bleeding, and perforation of the stomach or intestines. And because NSAIDs are often used long-term, medical researchers are intent on identifying effective alternatives with a more favorable safety profile.

A double-blind randomized controlled trial led by Vilai Kuptniratsaikul of Mahidol University in Bangkok, Thailand, compared the effectiveness of a botanical curcumin extract and ibuprofen (a commonly used NSAID) for pain relief and joint function in patients with knee osteoarthritis.²

For four weeks, a total of 367 individuals received a daily dose of either 1,200 mg...
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ibuprofen or 1,500 mg of *Curcuma domestica* extract comprising 75%–85% curcuminoids (curcumin’s active constituent).

Both groups saw significant improvements in total WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) scores as well as scores for joint function and pain compared to baseline levels. The magnitude of effect for both treatments was similar, indicating that curcumin was as effective as ibuprofen for pain-related symptoms of knee osteoarthritis.

**Celecoxib vs. Glucosamine + Chondroitin**

Celecoxib is a drug that inhibits the COX-2 (cyclooxygenase 2) enzyme, thereby reducing pain and inflammation in osteoarthritis patients. The use of this drug is associated with significant adverse effects, however, including up to a 37% increase in major vascular events as well as the gastrointestinal events associated with all NSAIDs.3

Glucosamine and chondroitin may be effective natural alternatives for osteoarthritis patients, showing significant benefits for osteoarthritis in earlier trials. The Glucosamine/Chondroitin Arthritis Intervention Trial (GAIT), for instance, found this combination effective at reducing discomfort in a subgroup of osteoarthritis patients suffering from moderate to severe pain.4

A decade later, March Hochberg and colleagues of the University of Maryland (College Park, MD) published results of a trial comparing the drug celecoxib (200 mg/day) and the combination of glucosamine hydrochloride (1,500 mg/day) and chondroitin sulfate (1,200 mg/day) in patients with knee osteoarthritis who were experiencing severe pain5. This six-month trial ultimately included 606 patients.

The glucosamine-chondroitin combo supplement led to a decrease in WOMAC pain scores of 50.1% compared to a 50.2% decrease with celecoxib. Looking closer at the results, both groups had a 50% reduction in measures of joint swelling. Scores for joint stiffness and functional improvement were also similar between the groups. These results indicate that glucosamine plus chondroitin is as effective as celecoxib for painful knee osteoarthritis.

**Garlic vs. Atenolol**

The number of people with high blood pressure continues to grow worldwide. Nearly 70 million Americans suffer from the condition, and only half have their condition under sufficient control. Cleary, there is need for effective interventions.

Herbs such as garlic may possess significant benefits for blood pressure. In a recent trial led by Rizwan Ashraf at King Khalid University (Abha, Saudi Arabia), researchers compared the effects of garlic supplementation to effects of the drug atenolol (a beta-blocker) and placebo in individuals with high blood pressure.7

In the 24-week study, 210 individuals with hypertension were divided into seven groups. Five groups consumed garlic in doses ranging from 300 mg daily to 1,500 mg daily. One group used atenolol (100 mg daily). One group consumed placebo. Blood pressure readings were taken at baseline, at week 12, and at week 24.

In the garlic groups, there was a significant dose-dependent reduction in systolic and diastolic blood pressure. The results of the higher-dose garlic groups were comparable to those achieved by the drug atenolol. In the group consuming 1,500 mg of the garlic preparation daily, the average systolic blood pressure reduction was 7.6 mm Hg, while with atenolol, the average decrease was 9.2 mm Hg. This study indicates that garlic preparations are effective for reducing blood pressure and that the results may be on par with first-line drug therapies.8

**References**


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The omega-3 market has had its share of obstacles in recent years: sales slumps, some negative publicity, and reliance on variable fish stocks. But industry pushes on. Sales are finally starting to grow again, albeit not yet to the levels seen during the ingredient’s heyday. The Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City) even went so far, as of this June, to predict 5% global growth—and even double-digit growth in Asia—through 2017.

Total growth will likely come from a combination of industry innovation and regulatory changes, both of which are ongoing around the world. Luckily, there’s exciting news in just about every corner of the omega-3 market, and there’s certainly more to come before year’s end.

### Fish Oil

Fish oil makes up a majority of omega-3 product sales. Changes in the fish oil market are happening both internationally and nationally. While the Peruvian anchoveta (*Engraulis ringens*) has historically been the world’s most-caught fish, this year marks the first time since 1998 that anchoveta is not the top-ranked species. According to the FAO’s latest State of World Fisheries and Aquaculture report (SOFIA), the title now belongs to the Alaskan pollock (*Theragra chalcogramma*). Industry experts believe this shift is largely due to environmental impacts of El Niño, which are worse on Peruvian anchoveta than they are on Alaskan pollock. (It’s worth noting, though, that the anchoveta population has bounced back from El Niño weather before.)

Setting aside the question of which fish species reigns supreme, industry members are actively lobbying for regulatory improvements to benefit fish oil of all major species. An FDA qualified health claim for omega-3s and blood pressure has been pending in the U.S. for years. Latest reports from GOED, which filed the original request, indicate the wait continues. The association says that on July 29, FDA requested (for the sixth time) to delay its response, this time for 180 days more until January 27, 2017.

The potential awarding of a health claim could, of course, dramatically influence omega-3 sales locally. Earlier this year, Canada approved a food health claim for omega-3 EPA and DHA for lowering triglycerides, and GOED has modest expectations...
for growth in that market, led by clinical and medical foods.

Though the omega-3 markets in the U.S. and Canada differ in size, the combined industries await a regulatory update that could benefit both countries: the creation of dietary reference intakes (DRIs). GOED petitioned the U.S. and Canadian governments for omega-3 EPA/DHA DRIs back in the summer of 2013. For now, two non–omega-3 ingredients, sodium and potassium, are proposed for DRI reviews in fall 2017. If EPA and DHA are next up for review, that could lead to omega-3 DRIs, which would serve as a basis for nutrient content claims—a huge opportunity for the omega-3 industry.

Globally, omega-3 suppliers also await Codex’s upcoming fish oil standard, which would also apply to krill oil. The current language, however, is considered problematic based on, among other things, a potential total arsenic limit that industry argues doesn’t take into consideration the fact that organic arsenic should be treated differently from inorganic arsenic present in omega-3 oils.

While lobbyists and government bodies continue to hash out guidance and laws, fish oil harvesters and manufacturers have taken matters into their own hands with various efforts to improve the efficiency and safety of their products. Last year, for instance, ingredient supplier Organic Technologies (Coshocton, OH) set a total oxidation limit of 5 for its entire AlaskOmega Alaskan Pollock fish oil line—a threshold that outperforms the industry standard. A fresher oil translates into better sensory characteristics for a more stable and appealing product, the company says.

“The feedback from our customers has been really positive,” says Steve Dillingham, global director, AlaskOmega ingredients. “We have experienced a significant increase in AlaskOmega customers wanting to co-brand their finished products with the AlaskOmega trademark to promote the quality of the omega-3 ingredient.”

Other suppliers are innovating to pack more EPA and DHA omega-3 fatty acids into a single dose. FMC/EPAX (Sandvika, Norway), DSM Nutritional Products ( Parsippany, NJ), and BASF (Florham Park, NJ) all introduced ultra-high concentrates last year.

Still others are hoping to capture new sales through appealing delivery systems. Glanbia Nutritional (Fitchburg, WI) and SternVitamin (Ahrensburg, Germany) now offer omega-3 powders suitable for tablets and other delivery formats beyond soft gels alone, with high stability and no fishy burps. Cargill (Minneapolis) continues its sales of IngreVita, a stable oil blending high-oleic canola oil, fish oil, and antioxidants, suited for a wide range of food and beverage applications. And Dillingham says Organic Technologies is seeing increased demand for its omega-3 triglyceride concentrates for use in liquid products.

Because marine omega-3 oils have unique qualities, Capsugel (Morristown, NJ) offers a portfolio of encapsulation platforms specifically suited for these oils, including fish and krill oil. Its Licaps OceanCaps capsules allow for the manufacture of an all-marine product, as they’re made with fish ingredients—“high-quality, farmed-fish gelatin, a renewable resource,” the firm says.

Krill Oil
Although krill oil sales pale in comparison to those of fish oil, krill oil’s market share is growing significantly. Aker BioMarine (Oslo, Norway), which harvests and processes Antarctic krill (Euphausia superba) in the Southern Ocean, says this single species now accounts for 20% of the omega-3 market globally, with consumer awareness at an all-time high.

There are numerous players in the Antarctic krill–fishing industry, but none bigger than Aker, which harvested more than 60% of last year’s total catch, according to the company. The Norwegian company is responsible for much of the innovation that’s improving krill oil as we know it—the latest being a new low-temperature fractionation method, dubbed Flexitech, that allows the company to better concentrate krill oil’s phospholipids and omega-3s, while at the same time removing the salts that negatively impact krill oil’s flavor and odor.

Using Flexitech, the company rolled out Superba 2 last year, the next generation of its flagship Superba krill oil, with better sensory and processing benefits. And at the Vitafoods Europe trade show this year, Aker introduced Superba Boost Caps, its first krill oil concentrate containing higher amounts of phospholipids, choline, and omega-3s, enabling potent doses in fewer capsules, which should especially benefit consumers who want (or are instructed by their physicians) to purchase high-dose omega-3 products. Manufacturers in the UK will be the first to benefit from these high doses. Recent Novel Foods approvals, specific to Aker, lets UK manufacturers formulate krill oil extract products at doses of up to 3000 mg of omega-3 EPA and DHA. Other
krill oil ingredients are still limited to 250 mg, the firm says.

Krill’s achievements are picking up in the human health market, but other sectors are also busy with this small crustacean. Lena Burri, Aker’s director of research and development for animal nutrition and health, says that partial replacement of fish feed with krill meal can help fish and shrimp farmers overcome palatability problems associated with feeds such as soybean meal—without adding costs. Limited research suggests that partial replacement with krill might even promote greater fish growth and shrimp growth. These are extra signs that krill can successfully penetrate a market where its direct competitor is fish (in this case, fish meal).

While Aker is spearheading many developments with krill, other European companies are very much involved, including Rimfrost (Ålesund, Norway), which introduced an ultra-high-phospholipid krill oil, and Enzymotec (Migda HaEmeq, Israel), which is now promoting low-sodium krill oil. And because a burgeoning krill oil market exists in China, the world’s second-largest consumer market, the country is working to build up its own krill fishery and harvest operations.

The perceived abundance of krill is one of its strongest selling points, compared to fish, and major players in the krill industry are still trying to uphold that idea with the help of independent conservation researchers, non-profit organizations, and the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR) that helps monitor the krill population and sets yearly fishing quotas. In October 2016, CCAMLR will review the latest krill-fishing data to determine if any changes to conservation measures are necessary.

According to Jon Corsiglia, media manager, USA, for fishery certifier the Marine Stewardship Council (MSC), Antarctic krill operations are still well within their quotas. “The population of krill in the fishery area is estimated at 62 million metric tons,” he says. “The total catch currently allowed from the entire fishery area is 1% of the population size. In 2014, less than half of the total 1% catch allowance was harvested by all krill-fishing vessels in the Antarctic. By any measure, these are extremely small catches of a very large krill population.”

MSC continues to expand its fishery-certification and seafood-labeling programs. “The blue MSC ecolabel assures consumers that the krill oil product they buy originates from a sustainable fishery,” Corsiglia says. He adds that two Antarctic krill fisheries now bear MSC certification, “which demonstrates that they are operating to the highest standards of environmental sustainability in order to protect the unique ecosystems and species in the Southern Ocean.”

Astellaxanthin

Whether marine- or land-derived, algae continue to expand in the health market and

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**MINIATURE SHRIMP OIL**

If marine omega-3 sources weren’t plentiful enough, a miniature shrimp has emerged with potential for market in the United Kingdom. It’s Calanus finmarchicus, one of the most abundant zooplankton species in the North Atlantic Ocean and a frequent food for Atlantic herring and salmon.

The biomarine company Calanus AS (Tromsø, Norway) petitioned for calanus oil Novel Food status back in 2011, and the UK Food Standards Agency is now evaluating the ingredient for legal use. The agency released a draft opinion this May, detailing the ingredient’s safety record and supporting health studies.

Calanus oil is rich in DHA and EPA, but it also contains astaxanthin. If these properties sound familiar, that’s because they’re also found in krill oil. Krill and calanus are both bottom feeders, so their oils are less likely than other species to carry marine pollutants. If approved for use in the UK, and perhaps elsewhere, Calanus’s oil will be available in powder and oil formats.
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Omega-3 Market

assume a lot of market share. Perhaps most notable among them is *Haematococcus pluvialis*, a microalga better known for astaxanthin, a red pigment and antioxidant that it produces.

While astaxanthin is already a well-established commodity, suppliers believe there is room for growth now that production is ramping up. Barrington Nutritional (Bountiful, UT), a distributor for Algotechnologies (Kibbutz Ketura, Israel), says that a previous shortage of astaxanthin compelled its supplier to improve its production capacity. Unsurprisingly, other astaxanthin growers have been working on their production capacity, too—and quantity isn’t all that these companies are concerned with. Earlier this year, BGG (Irvine, CA) obtained organic certification for its AstaZine astaxanthin farm, making it the first farm to offer certified-organic astaxanthin.

Although organic certification is a big achievement for astaxanthin, the promotion of natural has taken more prominence of late, as suppliers of natural astaxanthin attempt to distinguish themselves from suppliers of nature-identical, synthetic astaxanthin. The Natural Algae Astaxanthin Association (NAXA), composed of natural-astaxanthin producers, is actively working to communicate and elucidate what it says are drawbacks of synthetic astaxanthin, such as an alleged lack of safety testing and inferior quality.

Demand for astaxanthin is certainly global, and that’s evident in recent marketing efforts by AstaReal Inc. (Burlington, NJ) alone. The company has astaxanthin marketing offices in five countries and is planning to expand into several more international regions. In Canada in particular, AstaReal is witnessing an increase in sales thanks to a handful of recently approved Canadian health claims for AstaReal astaxanthin, including “source of/provides antioxidants,” “helps to improve muscle endurance,” and “helps to support eye health.”

With a steady supply of supporting research, astaxanthin is carving a space for itself in sports nutrition and skin care, among other human health markets. It’s also used as a natural colorant in a growing farmed-fish industry, as well as in human foods and drinks as part of a greater carotenoid family (including beta-carotene, lycopene, and others) that’s now estimated to be valued at $1.24 billion1.

Farmed Fish

As wild fisheries often deal with uncertainties in their fish stocks, aquaculture continues to grow in market share. The FAO predicts that farmed fish will account for 52% of fish consumed by 2025, up from the most recent estimate (44% for 2013–2015).

The move towards aquaculture should benefit the astaxanthin market, but whether it will impact fish oil is unclear. Some aquaculture operations already replace fish feed with terrestrial feeds such as soybean oil, resulting in farmed fish with, albeit, inferior omega-3 levels2; on the other hand, this presents an opportunity for algae supplementation, which can bolster omega-3 levels sustainably.

In partnership with Bunge Ltd. (White Plains, NY), TerraVia (San Francisco), which also supplies algae ingredients for human food, is making available a DHA-rich algae product intended for aquaculture. It’s a shortcut to optimum omega-3 nutrition because it’s sourced from the very algae that provide fish with their natural omega-3 levels in the wild—only now it’s made in fermentation tanks and sent to aquaculture farms that don’t pull resources from the ocean. The two companies are confident that growing fish oil demand, coupled with the risk of wild-caught fish, will create continued opportunities for the novel algal feed, which contains almost twice the level of DHA found in conventional fish oil.

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

References

1.  www.fao.org/3/a-i5555e.pdf
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Omega-3 Science

CATCH OF THE DAY

The latest crop of omega-3 research nets positive data for depression, eye health, children’s health, and more.

BY IRFAN QURESHI, ND

Omega-3 fatty acids from fish and other sources are fats with a uniquely diverse range of health applications. Boosting intake of these healthy fats—particularly eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)—through diet and supplementation can support the body in multiple ways.

For instance: aging results in lower neural concentrations of omega-3 fatty acids, leading to neuronal loss and a decline in cognitive function; however, recent studies show that omega-3 fats can enhance neuron signaling and synaptic plasticity, while preserving gray and white matter in the brain. Another example: inflammation is increasingly linked to chronic disease, but research shows that omega-3 fats play important roles in reducing inflammation by lowering the concentration of pro-inflammatory eicosanoids such as thromboxane B2 and leukotriene B4. And yet another example: studies show that omega-3 fatty acids may benefit arterial structure by reducing arterial stiffness and improving endothelial function, while simultaneously reducing oxidative stress and inflammation and favorably modifying the expression of enzymes involved in the process of atherosclerosis.

The ability of omega-3 fatty acids to influence so many processes in the human body is what makes omega-3 research so exciting. Ahead, we highlight some of the most recently published human studies showing beneficial effects of supplementation with omega-3 fatty acids on several health conditions.

Reducing Heart Risk: Omega-3s Plus Vitamin B12

Given the role omega-3 fats play in heart health and vascular health, Tao Huang and colleagues from Zhejiang University in China recently studied the effects of fish oil EPA and DHA on several risk factors of heart disease in healthy young adults. The researchers conducted blood tests to monitor the impact of supplementation on levels of plasma homocysteine, ferritin (a measure of iron status), triglycerides, uric acid, and C-reactive protein (a measure of inflammation). Measurements taken during the study at four and eight weeks showed that all groups experienced significant decreases in all measures. Plasma homocysteine concentration declined from baseline by 22% in the vitamin B12 group, by 19% in the
fish oil group, and by 39% in the combination-supplement group. While each nutrient individually was able to significantly lower markers of heart risk, the fish oil and vitamin B12 combination had a substantial synergistic impact, indicating a powerful benefit for heart and vascular health.

**Eye Health: Protecting Retinal Function**

X-linked retinitis pigmentosa is a genetic condition affecting the retina of the eye that leads to progressive vision loss in boys and young men. In those with the condition, night blindness occurs initially with progressive constriction of the visual field, leading to blindness at an average age of 45. Where do omega-3 fatty acids come in? Science indicates that individuals with this condition have a reduced ability to synthesize the omega-3 fatty acid DHA from other fatty acids. For this reason, researchers believe that oral supplementation with DHA may help bypass this defect and potentially slow the progression of the disease.

In an earlier, 2014-published trial—the DHAX (DHA in X-linked Retinitis Pigmentosa) trial—researchers found no effect from DHA supplementation on slowing the loss of cone or rod function in males with retinitis pigmentosa. Recently, however, those same researchers published a paper analyzing ancillary outcomes of the original trial. Specifically, they looked at the effects of DHA supplementation in those participants who completely adhered to the treatment protocol.

This ancillary analysis included 49 males who were 7 to 31 years old. Of those subjects, 29 had received DHA (30 mg/kg body weight daily in the triglyceride form), while 22 received a placebo, for four years. Visual parameters were measured yearly, while DHA concentrations were assessed every six months.

The researchers found that red blood cell levels of DHA increased fourfold over placebo in those supplementing with DHA. While visual parameters like visual acuity, ability to discriminate shapes, or the appearance of the fundus of the eye were not significantly different between groups, the researchers did detect statistically significant benefits in favor of DHA supplementation for reducing the progression of dark adapted thresholds, a measure of night vision. Furthermore, DHA supplementation also helped to attenuate the decline in visual field sensitivity over the four-year period. This sensitivity was determined to be linked to red blood cell levels of DHA—that is, higher concentrations of DHA led to less of a decline.

These findings indicate that DHA supplementation can benefit certain parameters of retinal health and visual function in individuals with retinitis pigmentosa.

The researchers further advocated for additional studies using higher doses of DHA in order to try to induce greater benefits. Based on the DHA dose of 30 mg/kg body...
weight administered in the study, red blood cell DHA concentrations averaged 10.9%. By extrapolating the results comparing the mean red blood cell levels of DHA and loss of visual field sensitivity, the authors postulated that a red blood cell DHA concentration of 17% could fully attenuate the loss of visual field sensitivity. An estimated DHA dose to attain this level of red blood cell saturation would be 45 mg/kg body weight per day.

Anti-Inflammatory Effects During Pregnancy

Obesity is a condition that can lead to the development of insulin resistance, with chronic metabolic inflammation a contributing factor. The onset of pregnancy in obese women often accelerates the development of insulin resistance, which can lead to complications for the developing fetus.8 Because omega-3 fatty acids have anti-inflammatory effects, theoretically they could help to lower inflammation in pregnant women who are obese.

Previous studies have shown benefits from increasing fish intake and omega-3 supplementation during pregnancy, including increasing gestation length and reducing the risk of pregnancy complications.9 A recently published study led by Maricela Haghiac from the Department of Reproductive Biology at MetroHealth Medical Center (Cleveland, OH) sought to evaluate the effects of omega-3 fatty acid supplementation in obese pregnant women on the inflammatory status of the placenta and adipose tissue.8

This randomized placebo-controlled trial enrolled pregnant women with a body mass index (BMI) greater than 25. The women were asked to consume a supplement containing DHA and EPA (2 g/day), or a placebo, from prior to 16 weeks of gestation until delivery. Blood measurements of cytokines and fasting glucose and insulin levels were conducted at enrollment and then again between weeks 34 and 36 of pregnancy. Placental samples and cord blood were obtained immediately after delivery. In the case of caesarean delivery, subcutaneous abdominal adipose tissue was taken. Samples were frozen in liquid nitrogen.

While omega-3 supplementation was not found to modify insulin resistance in this
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One of AREDS2’s ancillary studies also looked at how these nutrients influenced the risk of cognitive decline—specifically, Alzheimer’s disease—in the same AMD patients. Of the total AREDS2 patients, 89% agreed to participate in the cognitive arm of the study and undergo cognitive-function testing at baseline, at 2 years, and at 4 years. The tests evaluated immediate and delayed recall, attention and memory, and processing speed.

**The Findings**

At the end of the six-year trial the researchers analyzed the data, drawing, among others, the following conclusion: “Despite what observational data concerning the nature of the relationship between omega-3s and cognitive health—particularly the risk and onset of Alzheimer’s disease—has suggested, the findings of this study suggest that there is no statistically significant link between the two.”

“Contrary to popular belief, we didn’t see any benefit of omega-3 supplements for stopping cognitive decline,” said Emily Chew, MD, the study’s leader and deputy director of the Division of Epidemiology and Clinical Applications and deputy clinical director at the National Eye Institute (NEI), part of NIH.²

Though the results of the ancillary AREDS2 study may suggest, rather strongly, that the link between omega-3s and cognitive health may be weaker than previously believed, it’s important to remember that the study focused on only one specific form of cognitive decline—Alzheimer’s disease. As is almost always the case, without the support of additional studies, there’s a need to take the findings of this study with a figurative grain of salt. Considering past research done on other parameters of cognitive health, one can easily argue that there is still so much more to the “omega-3s and cognition” story than is being presented here.

In a press release announcing the study results, Lenore Launer, PhD, senior investigator in the Laboratory of Epidemiology and Population Science at the National Institute on Aging, pointed out, for instance, that more research can be done on targeting when supplementation should, if at all, commence. “It may be, for example, that the timing of nutrients, or consuming them in a certain dietary pattern, has an impact,” Launer said. “More research would be needed to see if dietary patterns or taking the supplements earlier in the development of diseases like Alzheimer’s would make a difference.”³

When it comes to the relationship between omega-3s and overall brain health, a large body of existing evidence suggests there may be links between the two. We also should not discount potential links to depression and other components of mental health.⁴ Given the undeniably complex nature of the human brain, it appears that the jury on brain health (including cognitive health) and omega-3s may still be out.

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

**References**

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homocysteine, a marker for heart and brain risk. For this reason, omega-3 supplements may be of benefit for psychiatric health. A recent meta-analysis including 19 randomized controlled trials found that supplementation with omega-3 fatty acids resulted in significant benefits in individuals diagnosed with major depression, as well as those with depressive symptoms but no diagnosis of major depression.\textsuperscript{10}

Lately, researchers have been narrowing in on the impact of oxidative stress in brain tissue on the progression of major depression. Shantel Duffy and colleagues at the Brain & Mind Research Institute of the University of Sydney in Australia set out to study the benefits of omega-3 fatty acids for the reduction of oxidative stress in the brain of adults at risk of depression.\textsuperscript{11}

Fifty-one adults were randomized to receive omega-3 fatty acid supplements (1200 mg DHA + 800 mg EPA daily) or a placebo for 12 weeks. Magnetic resonance imaging as well as neuropsychological and self-report assessments were performed at baseline and after 12 weeks. Depressive symptoms were tracked using a validated questionnaire. In addition, as an indicator of oxidative stress, glutathione levels were measured in the thalamus, a key area of the brain for processing sensory information. While glutathione is one of the most important antioxidants in the body, research has shown that increased thalamic glutathione levels are a marker for increased oxidative stress in brain tissue.

In the placebo group, glutathione concentration in the thalamus increased significantly by the end of the study, and the increase in thalamic glutathione concentration was associated with a rise in depressive symptoms. In the omega-3 supplement group, however, this increase was significantly attenuated.

This study demonstrates that omega-3 fatty acids may help improve symptoms of depression by effectively reducing the rise of oxidative stress levels in the brain.

**Improvement of Liver Function in Children**

The prevalence of childhood obesity grows hand in hand with associated health problems. A recent review of general population studies and studies in obese children suggests, for instance, that the occurrence of non-alcoholic fatty liver disease (NAFLD), a major cause of chronic liver conditions, is now approximately 7.6% in the general population of children under the age of 19; in obese children, this percentage is as high as 34.2%.\textsuperscript{12} Treatment protocols addressing NAFLD include dietary intervention and lifestyle modification. Additional targeted nutritional and drug therapies are often added as well, including those that address fat processing by the liver, insulin sensitivity, cholesterol lowering, and antioxidant support. Omega-3 fatty acids may play a significant role in addressing issues associated with NAFLD since these fatty acids control key pathways involved in liver fat metabolism.
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A recent 12-month double-blind placebo-controlled trial investigated the effects of omega-3 fatty acid supplementation in 138 obese children with NAFLD.\(^\text{1}\) Led by Mehmet Boyraz from Turgut Özal University in Turkey, the study involved two groups of children aged 9-17. The placebo group received a recommended reduced-calorie diet (a reduction of 25-30 calories/kg body weight per day) and lifestyle intervention (one hour of exercise three times per week) plus the placebo supplement. The second group underwent the diet and lifestyle interventions along with supplementation of 1,000 mg of omega-3 fatty acids daily.

BMI significantly decreased in both groups. The omega-3 intervention group, however, experienced the greatest benefits. This group saw a greater decrease in BMI, for instance (an average reduction of 6.0 kg/m\(^2\) with omega-3s compared to a 3.6 kg/m\(^2\) reduction in the placebo group). The omega-3–supplemented subjects also had significantly better HDL cholesterol and triglyceride levels, as well as fasting insulin levels, versus the placebo group. Fasting glucose levels and insulin sensitivity were significantly improved with the omega-3 intervention.

Reductions were found in liver enzyme values in both groups, with more pronounced reductions evident in the omega-3 group. Nearly 68% of those in the omega-3 group had decreased frequency of a fatty liver on ultrasound, while only 40.3% of the placebo group experienced the same decrease.

These results suggest that omega-3 supplementation is a useful intervention, along with dietary and lifestyle modifications, to support the health of children with NAFLD.

Plenty of Promise

Because of the numerous ways in which omega-3 fatty acids impact both structural and biochemical processes in the human body, they remain one of the most unique natural therapeutics for promoting health. With research on certain conditions just beginning, omega-3 fatty acids may one day prove to provide valuable benefits unsurpassed by other natural compounds.

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

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Outsourcing

HOME-FIELD ADVANTAGE

What does “Made in the USA” mean in a global age?

BY KIMBERLY J. DECKER

Seeing “Made in the USA” on a label can cause even a crusty old cynic’s heart to swell. And in this year of the Olympic Games, a presidential election, and an ambient sense that the world is coming unmoored, that pledge of domestic production is, for many Americans, especially grounding. So grounding, in fact, that a 2015 Consumer Reports survey found eight in 10 Americans claiming they’d rather buy an American-made product than an imported one, with more than six in 10 pledging a willingness to pay as much as 10% more for it.

Yet if “Made in the USA” declarations project patriotism, pride, or preferential trade policy to the purchaser of a watch or riding lawnmower, to the supplement shopper the claim’s implications are arguably more significant—namely, quality and safety. Or, as Eugene Ung, CEO, Best Formulations (City of Industry, CA), puts it, “There is an expectation, at least on the part of the U.S. consumer, that supplements should be made in the USA.” Their bottom line, he wagers, is that “with anything you put in your body, people get a little more concerned about its origins.”

This leaves today’s supplement marketers—who operate in a competitive global environment—balancing the financial as well as reputational costs of domestic versus overseas manufacturing when deciding where to produce their products. Not surprisingly, there’s no quick formula for balancing that equation, but there is hard-earned advice that can steer companies to solutions that work for them and their patrons.

“Made in the USA” Matters

When it comes to nutritional supplements, not to mention functional foods and beverages, “Made in the USA” is a valuable claim in the consumer’s eyes. And though nobody’s determined definitively what drives consumers to domestically produced health-and-wellness products, “It stands to reason that it could be a mixture of patriotism, the value placed on American jobs, or possibly some suspicion about the quality or safety of foreign-made products,” says John E. Villafranco, partner, Kelley Drye & Warren LLP (Washington, DC).

As someone who counsels clients on advertising law, product labeling, and health and safety claims, Villafranco knows where he speaks. And so does Ung, who works
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with marketers to produce nutritional supplements for consumers in the States and abroad. He’s found that not only is a claim to U.S. manufacture “really important in the dietary supplement market”; it’s more important there than it is in the market for, say, textiles or electronics, where “people just don’t seem to care.”

Leveraging the Claim

In one sense, the value of a “Made in the USA” claim is a product of people’s perceptions. But it’s also the result of a labeling regime, overseen by the Federal Trade Commission (FTC), that prescribes when a marketer can claim that something truly is made in the USA.

And yet the extent to which supplement shoppers or marketers fully grasp what the claim means—or what requirements a marketer must meet to legally proclaim it—remains slim. As Villafranco has observed, “Many product sellers seek to use ‘Made in the USA’ claims, or more qualified claims about U.S. origin, even if a ‘Made in the USA’ claim is not possible based on FTC standards.

In short, those standards dictate that “all or virtually all” of a product be made in the United States for a product legitimately to declare itself “Made in the USA.” And by “made,” Villafranco adds, what we’re talking about “comes down to both sourcing and the actual creation of the product.” Generally speaking, “If all ingredients are domestic and the product is manufactured in the United States,” he says, “the product will count as ‘Made in the USA.’”

Alas, says Ung, “I think there’s a lot of grey area, and some companies may stretch the ‘Made in the USA’ designation. For example, certain ingredients common to supplement formulations aren’t readily available from domestic sources; indeed, “in our industry, a lot of the raw materials are made in China,” Ung notes. “Whether the end-consumer knows that or not, it’s somewhat disguised because there are contract manufacturers in the middle.” And as if that’s not enough, when the contract manufacturers themselves operate abroad, a product’s origin story grows even harder to follow.

Mixed Picture

It’s worth noting that “abroad,” in the context of supplement contract manufacturing, more often than not equals “China.” And though it’s not the only name in town, Ung says, “As with everything else, it’s a big name in town.” It attracts marketers looking to contract production for two main reasons: price and availability. Operational and labor costs are lower overseas—both in China and elsewhere—and that’s a big motivating factor guiding manufacturers, especially the price-sensitive ones, to outsource supplement production, Ung says.

The catch, adds Villafranco, is that overseas manufacturers “may be less sophisticated in complying with U.S. regulatory laws, like GMPs.” And it’s no secret that China has struggled here. Its manufacturers “faced significant problems in the past with economic adulteration,” Villafranco notes. The addition of melamine to milk products and infant formula for the purpose of artificially boosting protein analysis is merely one of the higher-profile incidents to come to light.

“Chinese companies have not done themselves any favors by behaving as they have,” Ung says. “There’s not the same stigma for ‘Made in Australia,’ or New Zealand, or Western Europe, Japan, Korea—but ‘Made in China’ has a really negative stigma to it.”

And yet it doesn’t have to be this way, he believes. His own company knows what it’s like to work with a foreign-owned soft-gel manufacturing facility in China, having done so about a decade ago. With their goal being to produce more competitively priced commodity soft gels for its customers, Ung explains, “We built the facility, we designed it, and we ran it ourselves. What’s more, they purchased raw materials not in China but from “very well-known, quality-oriented suppliers from the U.S.”

Yet despite all their i-dotting and t-crossing, the venture “was just a no-go,” Ung concludes. “It was extremely difficult for us to sell the finished product because it was made in China. It just had that image.” Even though their customers were familiar with and trusted the company’s record, “they didn’t want to be made in China because they would have to put that on a label and it would be a problem for them.”

“With anything you put in your body, people get a little more concerned about its origins,” says Best Formulations’ Ung.
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Ultimately, he feels that the reputation unfairly paints Chinese manufacturing with a tarry brush that some individual manufacturers don’t deserve. “At our facility,” he points out, “we had no issues.”

Unfairly or not, overseas manufacturers may need to be even more transparent in order to set their clients’ minds at ease. “One of the most effective ways to help clients be satisfied with ingredients sourced outside the USA is by allowing them to review the raw-material supplier-qualification process and to show them how we ensure quality at all levels of the manufacturing process,” says Vincent Tricarico, vice president, contract manufacturing, NutraScience Labs (Farmingdale, NY). Firms can also seek guidance from an organization like the U.S.–China Health Products Association, whose goal is to promote the commerce of health products in China.

“It’s just like any other relationship in that you do the audits and you’re open about what’s happening behind closed doors,” Ung says. True, there’s a “dog-and-pony-show” aspect to oversight procedures in China—and for understandable reasons. “But it’s not the case that it can’t be successful; there are just a lot of challenges. And then it becomes a business decision as to whether it makes sense to outsource manufacturing to China.”

Bring It on Home

Since the recession, Ung says, “a lot of manufacturing outside our industry has returned to the U.S. because China is experiencing incredible inflation and the wages have risen significantly, so you don’t have the cost advantage today that you used to.” That may be reason enough to renew an embrace of “Made in the USA” and bring supplement production back home.

But every marketer’s decisions will differ. What’s most important, Ung believes, is “understanding the reason why they’re going overseas” in the first place. And when analyzing the costs versus benefits, marketers should account for the risks, he adds, but not just to a brand’s good name; the risks involved in dealing with customs, waiting out supply-chain and inspection delays, navigating a foreign environment. “There are just a lot of unknowns,” Ung says.

So, he advises, “have a strong understanding of what can happen when you do outsource manufacturing overseas.” And if it looks like more than you care to handle, it might feel good to come home and be “Made in the USA.”

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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Botanical ingredients for prostatic and urological health

BY ROBBY GARDNER

Testosterone tends to dominate any conversation about male sexual function; there are, however, other forces driving men’s health. Prostate complications, acute and severe, are a growing problem and one that researchers continue to evaluate in terms of both supplementation and diet. Equally pressing are concerns regarding urinary tract infections (men get them, too).

Considering all the potential complications men face in prostatic and urological health, there’s money to be made in marketing natural formulas that can help. Luckily, the pursuit of plant-based ingredient solutions is an active one.

Plum Bark

A sizable market exists for African cherry (Prunus africana) in the men’s health space. Its bark is sold in extracts intended to help with benign prostatic hyperplasia (BPH), or an enlarged prostate. But concerns about over-harvesting the African cherry tree to meet global extract demand is motivating one ingredient supplier to explore a more sustainable alternative.

After carefully reviewing the contents of numerous other Prunus species, Cepham Inc. (Piscataway, NJ) and other parties discovered that the common plum (Prunus domestica) most closely resembles African cherry in its bark contents, including key constituents such as beta-sitosterol and docosyl ferulate. Considering the strong similarities...
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of the two barks, Cepham believes plum bark should act on the human prostate in much the same way African cherry bark does—by blocking the action of androgens and stimulating the death of benign prostate cells, among numerous other proposed factors.

So far, preliminary results are encouraging. Cepham funded an animal study that found plum bark as effective as African cherry bark in stopping the proliferation of BPH in rats, and the company expects results of a human study to be published this November.

Unlike African cherry bark, which is typically wild-harvested, Cepham’s plum bark comes from privately managed plum tree farms at the foothills of the Himalayas. After farmers harvest their sweet fruits, the trees are pruned to stimulate more fruit production, and the byproduct of stems and branches becomes a bark extract.

Cepham is selling its plum bark extract (brand name Prosprune) to finished-product manufacturers in India and Thailand. The extract is available in paste form for soft gels and in powder form for hard gelatin capsules.

Cranberry
The tiny cranberry (Vaccinium macrocarpon) has made a name for itself in the urological field thanks to years of cultural use for treating urinary tract infections (UTIs). A large number of studies have since explored, and sometimes validated, the use of cranberry extracts for this condition. Although women are most prone to UTIs, men are also at risk of UTIs and, more commonly, lower urinary tract symptoms (LUTS), which can be caused by infections or prostate problems. Fortunately, cranberry may provide relief for LUTS.

In a “landmark study” published earlier this year, Naturex (South Hackensack, NJ) says its cranberry extract reduced LUTS in men over age 45. It appeared to improve urinary flow, international prostate symptom scores (IPSS), and other relevant health markers also used in pharma-level studies. According to Naturex, this is the first and only gold-standard study (randomized, double-blind, placebo-controlled human clinical) on cranberry and LUTS.

A lot of cranberry research has focused in narrowly on proanthocyanidins (PACs), chemical compounds present in these berries that experts say are highly responsible for positive results. Naturex, however, remains intent on marketing a full-spectrum cranberry extract that it says is biologically and clinically superior for urological health. The extract is sold as Flowens.

Tea
Although green tea (Camellia sinensis) and its fermented black variety are often the subject of prostate cancer studies, results have historically been inconsistent. Kemin (Des Moines, IA) is one supplier taking a different approach to tea and prostate health.

With the help of two clinical trials, Kemin is promoting AssuriTEA, a blend of green and black tea extracts already associated with improvement in LUTS, bladder emptying, and other sexual and non-sexual health factors in men. Though no additional trials are currently under way, Kemin says it is still seeing a gradual increase in global sales of its ingredient, thanks in part to its AssuriTEA science and the white space Kemin says still exists in this health category.
L-Citrulline is an amino acid that plays an important role in nitric oxide metabolism and regulation. L-Citrulline converts to L-Arginine in the body, which helps the body maintain healthy levels of both L-Arginine and nitric oxide (NO). Increased NO production, in turn, supports vascular dilation and blood circulation, which contribute to a healthy heart. In addition to its heart health benefits, L-Citrulline increases protein content by stimulating protein synthesis and is thought to relieve muscle fatigue through ammonia elimination, both of which can enhance the effects of exercise. So, whether you’re looking for cardiovascular or sports performance benefits, Kyowa L-Citrulline provides an ultra-pure, GRAS option that’s clinically researched. It’s the only L-Citrulline that’s made in the USA and backed by Kyowa Quality™.
Aside from green and black tea's nutrient profiles, AssuriTEA is further distinguished by its proprietary blend of antioxidants and other phytonutrients. Kemin says the formula provides antioxidant and anti-inflammatory properties that benefit men.

Flower Pollen

It isn’t just bark, fruits, and leaves that garner attention for prostate health. Some flowers show prostate potential, too. Take diminutive rye grass flowers (*Secale cereale*). Every year, farmers extract from them a pollen deemed safe for human use and sold in dietary supplements throughout the world.

What makes rye flower pollen appealing for men is its anti-inflammatory properties and its ability to act against androgens in the body. Such benefits are associated with reductions in chronic pelvic pain, also known as chronic prostatitis, which have been documented in past human clinical trials on flower pollen extracts. But although subjects have experienced prostate pain relief with flower pollen extract, manufacturers should be aware of the varying quality of flower pollen in supply today.

Griminex (Saginaw, MI), an established supplier of rye grass pollen extract, says that seasonal changes in moisture and pollen density, for instance, can create differences in pollen properties throughout the year. To keep its extracts standardized, Griminex maintains its own internal seed breeding and field management practices.

The market for flower pollen extracts is not new, but changing consumer behaviors are influencing the ways in which these extracts are sold. To that effect, Griminex offers a variety of extracts suitable for different needs, including chewables and beverages.

Lycopene

Lycopene, from which tomatoes get their red color, is no stranger to prostate-related research. The antioxidant has been studied for its potential use against prostatitis, prostate cancer, and associated conditions. But there’s no reason to limit such research to lycopene by itself.

In an ongoing attempt to find the most synergistic blends of lycopene and other nutritional ingredients, Lycored (Be’er Sheva, Israel) recently introduced a prostate health composition called Lycopro. The combination of lycopene, zinc, curcumin, and omega-3 was inspired by a six-month trial that deemed the ingredient blend effective for reducing prostate size. It’s also based on what Golan Raz, vice president of health nutrition at Lycored, calls “indication-specific nutritional technology” intended to ensure the most accurate ratios and potency of ingredients in Lycored nutrient complexes.

Lycopro is a part of a much larger portfolio of lycopene formulations intended for men and women. A lycopene sport product, which might complement Lycopro for the male market, is currently in development.

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

**References**

6. ClinicalTrials.gov Identifier: NCT00919893
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Children’s Health

**Kids’ Stuff**

Children’s supplements: Finding success at the intersection of sound science and appealing delivery forms

**BY MAUREEN KINGSLEY**

Multivitamins for children have been commercially available for decades. One of the most recognizable brands, Flintstones (by Bayer), debuted in 1968 and has been a mainstay of retail shelves ever since, with updated formulations and delivery forms appearing a handful of times in between.

While multivitamins for children remain popular with consumers, particularly in gummy form, other children’s supplements are increasingly gaining traction in the market, particularly those targeting specific wellness areas. Christopher Gavigan, co-founder and chief purpose officer of The Honest Company, says the emergence of more-targeted children’s supplements “helps consumers better navigate the crowded and confusing vitamin, mineral, and supplements aisle. That aisle contains many different ingredients, dosages, forms, and benefits being offered by many brands. By focusing on specific wellness benefits, we at Honest Company are able to clearly communicate the benefit the consumers will receive and eliminate the guesswork for them of finding the right ingredient, dosage, and form for that benefit.”

Megan DeStefano, Probiotics Global Marketing Leader, DuPont Nutrition & Health (Copenhagen), makes the point that “as birth rates decline globally, there is more money to spend on each child in a household.” DuPont has been watching the children’s health and wellness market “for some time,” she says, and believes there is “tremendous opportunity for food, beverage, and supplement brands targeting children to be very successful—if they can deliver healthy and convenient products that appeal to children’s tastes and parents’ sensitivities,” DeStefano says.

**Leading the Pack: Supplements for Immune Health**

DeStefano says DuPont surveyed parents and found that a top concern among them is their children’s immune health, and she points to the common cold and allergies in particular.

For this reason, she says, “Consumer interest in probiotics is growing for all age groups. We believe more and more pediatricians are recommending probiotics for children, and we believe that as parents adopt probiotics into their daily routine, they will also introduce probiotics to their children.”

DuPont offers the HOWARU Protect line of probiotics for children. HOWARU Protect Kids is “a unique and proprietary blend of probiotics that helps keep children healthy during cold and flu season,” according to DeStefano, while HOWARU Protect EarlyLife “supports immune health of expectant mothers and infants.” Applications for these ingredients include capsules, tablets, powders, and functional-food products.

Nena Dockery of Stratum Nutrition (St. Louis), which supplies the BLIS K12 and BLIS M18 probiotic ingredients formulated to function within the oral cavity, says “some of the original probiotics research in children focused on the investigation...
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Children’s Health

of potential benefits of certain probiotic strains in reducing the symptoms of post-antibiotic and infectious diarrhea.” But as the body of knowledge regarding the importance of indigenous bacteria has grown, Dockery points out, “so has the research delving into other areas where probiotics might be of value,” such as in oral health.

“We are now aware that specific oral-cavity bacteria provide unique dental and immune-health benefits in individuals for whom these microbes are part of the normal microbiota. This in part explains the rapid increase in interest in our BLIS probiotics,” she says. These ingredients, which are intended to remain within the oral cavity rather than fully enter the digestive system, are well suited to kid-friendly lozenge, chewing-gum, stick-pack, and chewable-tablet delivery forms.

Ingredient supplier Kerry’s (Beloit, WI) R&D director, Donald Cox, PhD, agrees with DeStefano and Dockery that targeted children’s supplements, particularly those focused on immunity, are taking hold and positioned for future growth. “The market opportunity is big for things like specialty supplements, and functional foods and beverages are growing. We are seeing an increase in more immune-health–targeted formulations for children,” he says. He adds that Kerry has found that “parents tend to drive demand for immune-health products, because when a child gets sick, it impacts the whole family. The growing awareness of the importance of nutrition to help keep children healthy is moving consumers away from reactive, short-term fixes to more proactive, preventative approaches to health and wellness,” such as consumption of functional foods and supplements.

Kerry’s Wellmune ingredient, a beta-1,3/1,6-glucan derived from the cell wall of a proprietary strain of yeast, is a “100% natural food, beverage, and supplement ingredient clinically proven to strengthen the immune system,” Cox says. Applications include a variety of functional foods and supplements.

Wellmune is currently incorporated into the OLLY-brand children’s gummy supplement, as well as a ready-to-drink dairy-based children’s beverage (Star of Hope Children’s Milk Smart) launched recently in China, and a fruity water beverage called Nurture for children aged two- to five-years-old that is marketed in the United Kingdom.

Supplements for Bone Health, Cardiovascular Health, and Increased Protein Intake

While children’s formulations geared toward immune health may currently reign, those targeting other wellness goals are gaining and maintaining popularity as well. Bone health, cardiovascular health, and increased protein intake rank among these, according to manufacturers and suppliers alike.

Wiley’s Finest, for one, recently formulated, manufactured, and brought to market its Beginners DHA product line, which confers both bone and cardiovascular benefits to children, says Christopher Speed, global sales manager and dietician at the company.

Smash-hit infant and children’s brand The Honest Company, Inc., added non-GMO gummy vitamins to its lineup this year.
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"We felt there was an enormous opportunity to address the nutritional needs of children, who are mostly all deficient in dietary vitamin K2, especially in the MenaQ7 vitamin K2 form [supplied by NattoPharma]," Speed says. "This ingredient, as well as omega-3s DHA and EPA, make this product line unique and worthwhile. Demand for it is very high, and we have been thrilled by the launch." He adds, "It is different from other omega-3 products aimed at kids because it is the first child-specific product featuring MenaQ7 K2 on the market."

Eric Anderson, senior vice president of global sales and marketing for MenaQ7 supplier NattoPharma USA (Oslo, Norway), explains the mechanisms by which the MenaQ7 ingredient works: "K2 activates specific proteins that are circulating in the body but are inert. Two such proteins proven to be reanimated by K2 are Matrix GLA Protein [MGP] and osteocalcin, which directly support cardiovascular and bone health, respectively."

Mineral supplier Balchem/Albion (Clearfield, UT) sees "steady growth" in the children's bone-health space and others, says senior director of marketing Todd Johnson, Sr. He adds that "research seems to be shifting from 'essentiality' for bone health to perturbations in the normal metabolism of these ingredients, and the subsequent effect on bone health." This type of research is looking at genetic, biochemical, and metabolic changes that affect bone health, he says.

"However," Johnson says, "minerals are essential and proven for supporting children's health, and Albion continues to see steady growth in this space, particularly with its calcium, magnesium, iron, and zinc." The supplier's most-requested mineral forms for children's supplements are Calcium Bisglycinate Chelate, Magnesium Bisglycinate Taste-Free, Iron Taste-Free, and Zinc Bisglycinate Chelate Taste-Free.

Answering heavy consumer demand for children's health and nutritional products formulated with more protein and less sugar is E-hydrate’s KIDS Protein On-the-Go product. "There needed to be a product that addressed the ongoing sugar issue," says E-hydrate’s Head of Social Marketing Michael Howard. "There is nothing like [Protein On-the-Go] on the market: low sugar, low calories, high protein. We were able to formulate a kids’ product with all of these benefits without sacrificing taste."

The product is a pre-portioned, ready-to-mix protein and electrolyte beverage containing 10 g of tri-whey protein, 70 calories, and 4 g of sugar. It is offered in cinnamon roll and milk chocolate flavors and has been "our fastest-growing SKU to date," Howard says. The product is intended for children ages three years and older, but Howard adds that it’s also suitable for adults looking for a healthy snack, thereby opening up the market to any consumer aiming to increase protein intake in snack form via functional food.

Special Considerations for Children’s Supplements: Safety First! Sweetness Second

Marketers, manufacturers, and suppliers alike all point to safety as being of primary importance when formulating supplements for children.

"Safety and efficacy are a constant consideration for dietary supplements, but it is never so important than when one is formulating for children," says Speed at Wiley’s Finest. "Manufacturers must consider the
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** Bohbot J. The Gynaecologist's and Obstetrician's Journal 2007. Special Issue from the CCD Laboratory.
NEXT UP: MOOD AND MENTAL-FOCUS PRODUCTS FOR KIDS?

Formulations for immune support, bone health, and cardiovascular health are hot right now, but what are some other wellness targets for which marketers of kids’ supplements might develop products in the next few years?

DSM’s Hugh Welsh predicts that parents will increasingly seek out mood and mental-focus products for their kids in the future; however, “many botanical products traditionally used for these products targeting adults have not been sufficiently studied in children,” he says. “Products developed for this application will need to pass a lot of scrutiny. The materials used will need to be backed with sound science and will likely also need to have a healthy ‘aura’ surrounding them if they intend to gain wide acceptance.”

For mood and mental-focus supplements, Welsh forecasts such ingredients as omega-3s, choline, magnesium, and B vitamins will remain popular, but others not currently seen much in children’s products, such as echinacea, chamomile, ginseng, ginkgo, and bacopa, “may all have a place in future mood and focus products for children as more studies are conducted.”

ingredients they are selecting, focusing on clinically validated ingredients demonstrating efficacious doses and proven mechanisms of action.”

Hugh Welsh, President, General Counsel & Secretary, DSM North America ( Parsippany, NJ), a supplier of nutrient premixes and custom formulations, adds that when developing children’s products, “the scientific background of the materials used needs to be specifically looked at with children in mind. It is also critical to define the quantity of nutrients being delivered in a serving, and these need to be carefully evaluated for the target consumer.”

Echoing Speed and Welsh, Stratum’s Dockery states, “Foremost to consider is the safety and appropriateness of the ingredient or product. Multiple research studies should be conducted to establish efficacy and safety. This is particularly true for supplements intended for vulnerable populations, including children, pregnant and lactating women, and the elderly.” She also adds that dosing is another important concern. “If the ingredient has been deemed to be safe,” she explains, “there must be some way to establish proper dosing in children to take into consideration their developing bodies. The effectiveness and safety of many ingredients depend on certain digestive processes as well as absorption into circulation. Metabolism in the liver must be taken into account, as a child’s body may metabolize certain active components much more efficiently than an adult’s.”

After safety and science, flavor, method of delivery, and palatability are chief concerns for children’s formulations. “The biggest thing you need to get right when producing for kids is that the product is palatable,” says Wiley’s Speed. “Flavoring, serving size, and mode of delivery are important. That’s why we created Beginner’s DHA with a strawberry/watermelon flavor: one small serving provides a lot of nutrition, and it also includes a syringe for easy delivery.”

Kerry’s Cox adds that “innovation is key” and can be accomplished within formulation (“manufacturers should leverage color, shape, and size without pushing taste boundaries,” he explains), packaging (“think convenience, portion control, and ‘play-ability’”), and credibility (in the form of “science-backed products”).

DSM’s Welsh agrees that format, flavor, and sweetness need to be developed for the child’s palette. “The product needs to be attractive to the parents who do the purchasing, but also needs to appeal to the child for repeat purchase,” he says. He admits there are challenges, too, to providing palatable, kid-friendly formulas. One of these is making the product sweet without including a large amount of sugar—a red-flag ingredient for today’s parents.

“In many products, high-intensity sweeteners and sugar alcohols can be used in place of sugar, but these changes can require modification to the product matrix,” Welsh explains. “Another challenge is to deliver flavors from fruit concentrates and powders, because the required volume can be difficult to incorporate into gummies and chewables. This is easier in instant beverages, but in those products nutrient solubility can present an additional challenge.”

Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.
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The pet industry is prospering, thanks to an aging adult population seeking companion animals and a shifting cultural view of pets as “fur babies” who are increasingly important elements of family life. Even during the economic downturn that began in late 2007 and early 2008, the dog and cat industries in particular continued to grow, albeit more slowly than they had previously, says Bill Bookout, founder and CEO of the National Animal Supplement Council (NASC). Those industries have since recovered and are again growing strong, Bookout adds, and he estimates total consumer spending on companion animals (including cats, dogs, and horses) to be about $1.8 billion annually.

It’s not surprising, then, that manufacturers and marketers of dietary supplements and functional foods for humans are expanding into the pet market in increasing numbers. Among those who have blazed that path in recent years are NutraMax Laboratories, GNC (who “really led the way” to the pet market when it partnered with pet-supply retailer PetSmart to launch a line of pet supplements, Bookout says), NOW Foods, Mercola, and Thorne Research, to name a few. For these originally human-focused nutrition and supplement companies, entering the pet market was a natural lateral expansion that made sense for them as certain human-supplement market segments matured, Bookout explains. Additionally, offers Lisa Harter, who manages global business development for Ribus, a supplier of rice-based ingredients, human and pet supplements tend to require many of the same certifications (organic, for instance, or gluten-free), which eases crossover from one market to the other.

Bookout adds that the pet-supplements marketplace is becoming more and more competitive, with low barriers to entry. But, he says, over time, barriers to entry will increase as regulatory requirements increase, and expanding into this market will become more expensive. (See sidebar, “Compliance 101: A Quick Primer on Animal-Supplement Regulation,” on the next page.)

Product Trends: What’s Good for the Owner Is Good for the Pet
Products containing such well-known ingredients as glucosamine, chondroitin, MSM, and hyaluronic acid are always popular in the pet-supplements market, Bookout says. Essential fatty acids, digestive aids, and probiotics are selling well, too. In general, Bookout states, supplement trends in the pet market follow human-supplement trends, with some lag time. Many supplement manufacturers—and those who supply to them—recognize this opportunity and are targeting the pet-supplement and pet-nutrition markets accordingly.
Sabinsa (East Windsor, NJ), a supplier to supplement, food, and pharmaceutical manufacturers, is one such company. It launched a line of pet products in 2014 called VetVitals. Shaheen Majeed, Sabinsa’s marketing director, has seen increased demand for probiotics for pet health in the past year or two, and the company’s LactoSpore probiotic ingredient for pet foods and supplements is answering that call. “Pet products require a very stable probiotic strain that can stay viable in processing as well as during the storage of pet food,” Majeed explains. “LactoSpore is able to do both.” The product’s stability at high processing temperatures and its long shelf life are attractive to customers in both the pet-food and pet-supplements industries, he says.

Deerland Enzymes (Kennesaw, GA), another supplier to both the human- and pet-supplement markets, echoes Sabinsa’s observations. “The popularity of formulating with ingredients such as probiotics, prebiotics, and digestive enzymes is on the rise,” says Tod Burgess, Deerland’s vice president of sales. He points to digestive health as being one of the fastest-growing segments in the animal-supplements market and says Deerland’s customers are “seeking out custom blends of enzymes and probiotics” that they can incorporate into treats or powder supplements. The company’s ProHydrolase enzyme blend, to aid protein digestion, and its DE111 strain of *Bacillus subtilis* are two such products, Burgess notes.

Botanical ingredients, too, are in demand within the pet-products market. NP Nutra (Gardena, CA) launched its Nutra Pet line of mostly organic powdered plant-based ingredients in March 2015 in response to a call from its customers for “premium, human-grade ingredients that could be used in pet formulations,” says the company’s director of marketing, Margaret Gomes. That line includes organic alfalfa-grass powder, organic barley-grass powder, organic beetroot-juice powder, organic carrot-juice powder, organic lemon-juice powder, organic sweet potato powder, organic turmeric-root powder, and more.

Similarly, NutriFusion (Hilton Head, SC), yet another supplier to the human-supplements industry expanding into pet nutrition, markets a version of its GrandFusion fruit- and vegetable-based nutrient blend to pet-food and -supplement manufacturers. Company CEO Bill Grand touts the strong bioavailability of his company’s GrandFusion product and says it is customizable for various pet-industry customers. The product can be incorporated into pet food or treats, or sprinkled directly onto pet food as a supplement. Grand says the pet market will continue to represent a large part of his company’s business, and he anticipates continued movement into that market.

Even ingredients to support weight control and healthy body weight—ever popular in human dietary supplements—are finding

**COMPLIANCE 101: A QUICK PRIMER ON ANIMAL-SUPPLEMENT REGULATION**

It is important for those in industry to know that animal supplements are not subject to the same regulatory requirements as human supplements. The Dietary Supplement Health and Education Act of 1994, with which marketers of dietary supplements for people are likely quite familiar, does not apply to animal supplements.

You might be surprised to learn that dietary supplements for companion animals are, in fact, not recognized by FDA as a class of products. Under the Federal Food, Drug, and Cosmetic Act, products marketed as dietary supplements for use in animals are classified as either food or drugs, depending on their use.

Those supplements classified as food, or that are mainly nutritional in nature, are ultimately subject to the oversight of FDA’s Center for Veterinary Medicine as well as state regulators. The Food Safety Modernization Act, signed into law in 2011 and encompassing animal nutrition, hits its first implementation dates in Fall 2016. Pet food and supplements categorized as food (general vitamins and minerals, essential fatty acids, nutritional products to promote a healthy coat, etc.) will be subject to this law.

Pet supplements intended for health-target purposes (such as those for cardiovascular health, eye health, and kidney health) are not categorized as food, yet they are not approved drugs. For these products and their marketers, NASC provides a “complete regulatory roadmap,” explains NASC president Bill Bookout. This roadmap includes current good manufacturing practices, adverse-event reporting, a product-tracking system, and labeling/claims guidance that was developed with the input of FDA and state regulators. The relationship between NASC and federal and state regulators remains very active. (See NASC’s website, www.nasc.cc, for more information.)
a place within the pet market. Pharmachem Laboratories’ (Kearny, NJ) Phase2 Pet product, for instance, is incorporated into pet supplements, treats, and foods and promotes weight loss in dogs, says Mitch Skop, the company’s senior director, new product development. The ingredient binds with alpha-amylase, the enzyme that digests starches, thereby allowing a portion of consumed starches to pass through a dog’s digestive system undigested, as fiber does, Skop explains. “Because the facts show that dogs and cats are growing more and more overweight,” he adds, “we see tremendous opportunities here.”

**Palatability Is Key: Special Considerations for the Pet Market**

One of the biggest differences between manufacturing and marketing supplements for pets and doing the same for people is compliance. Human beings, of course, will accept a variety of supplement delivery forms: tablets, capsules, liquids, dissolvable powders, and more, and are motivated by factors far beyond flavor and texture to comply with dosage instructions.

Animals, on the other hand, “are tougher,” says NASC’s Bookout. “You can have the greatest product in the world, but if the animal isn’t going to consume it, then people won’t

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Pet Health

As regulatory requirements escalate over time, expanding into the pet-supplements market will become more expensive, says NASC’s Bookout.

continue to buy it. Palatability and delivery system are extremely important.” He continues, “I would argue that palatability and acceptance by the animal are equally as important as the functional benefit of the product, maybe more so.”

To that end, companies like Kemin (Des Moines, IA) offer products to enhance palatability of pet-nutrition products and increase their acceptance by the animal. Kemin’s Palasure line includes palatability-enhancing liquids and dry powders for cat and dog supplements, treats, and foods, as well as “unique granulated palatability enhancers designed for high-speed tableting applications,” says Bob Shamblin, Kemin’s senior sales manager. The company’s chicken-liver–based palatants, in particular, when included in a pet supplement or nutritional pet treat, “will compensate for unpleasant-tasting or -smelling ingredients and provide an enjoyable experience for the cat or dog,” Shamblin adds.

Formulations and dosages of key ingredients for pet applications may also need tweaking, depending on the pet. “You have different types of pets, canine versus feline versus equine, that require different delivery vehicles and dosages,” says Larry Kolb, co-founder and president, TSI USA (Missoula, MT), which supplies glucosamine/chondroitin and other ingredients to both the human and pet markets. “You have to convert the science from one animal to the other.”

He adds, “Normally, the companies we’re working with, the branded players, have knowledge of this in house and can typically convert a human dossier to an animal one. But there is certainly a process manufacturers go through to understand how these particular active ingredients sit within that pet-nutrition market.”

A Market with Bite

Pet-health products, including supplements and specialty foods, appear to be positioned for continued growth over the next few years. Sabinsa’s Majeed points to “the increasing number of pet owners making the connection that many of the supplements they depend on can also benefit their beloved companion animals.” Deerland’s Burgess calls the pet-supplement market in particular “likely still in its infancy with tremendous opportunity for growth. Forward-thinking companies recognize that we are seeing an evolution of the supplement market, as the humanization of pets is a growing trend.” He adds that “pets are living longer on average,” and pet owners want to provide preemptive healthcare for their animals as they do for themselves.

Bookout predicts hemp ingredients, including hemp cannabidiol (CBD), and the leucine derivative HMB to be among the more interesting future ingredient offerings as the pet-supplement industry grows. (TSI’s Kolb sees potential in the emerging science of HMB coupled with vitamin D, in particular.) These three ingredients are garnering attention on the human side, too, and Bookout says that CBD and hemp, especially, were hot topics at the recent NASC annual conference. “There’s much more research being done overall on new and innovative ingredients that provide benefits in certain categories,” he adds.

In addition to introducing more and more cutting-edge ingredients, pet-supplement manufacturers and suppliers will continue meeting consumer demand for “clean” labeling and the marketing of natural and organic products, say all of the industry representatives interviewed for this story.

All told, the pet-supplement market is “pretty interesting, robust, and compelling,” summarizes TSI’s Kolb. “It is a natural fit for successful market launches on the human side to cross over into pet supplements.”

Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.
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BUILDING FROM THE GROUND UP

Natural ingredients for bone support span time-tested vitamins and minerals, as well as novel ingredients and creative delivery systems.

BY MELISSA KVIDAHL

Once considered an unpleasant and unavoidable part of getting older, low bone mass and osteoporosis are now regarded as a major health threat for Americans, according to the International Osteoporosis Foundation. Despite celebrity “Got Milk” campaigns and the proliferation of calcium supplements on the market, the foundation estimates that 55% of women and men in the U.S. aged 50 and older (almost 44 million) are at risk of osteoporosis. By 2020, as many as 61 million could be at risk.

“As the population ages and the percentage of adults, men and women, older than 80 increases, bone fractures from falls have become a major health concern to the medical community,” says Cecilia McCollum, executive vice president of ingredients firm Blue California (Rancho Santa Margarita, CA). “Obviously, prevention is key, and a healthier bone density will prevent fractures that can significantly reduce the quality of life of the patient and may very likely reduce the lifespan of the patient as well.”

Though calcium remains the poster child in this area, new research shows that many
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nutrients are worthy of supporting—if not starring—roles in the fight against bone density loss. For established ingredients like vitamin D, the research is driven by curiosity and a desire to have a better understanding of the relationship between nutrition, health, and disease, explains Duffy MacKay, ND, senior vice president of scientific and regulatory affairs at the Council for Responsible Nutrition (CRN; Washington, DC). “For novel and new ingredients, research is necessary to establish the benefit with scientific evidence, which is required for compliance with regulations.”

**Vitamins and Minerals**

Calcium is a bone-health mainstay with ongoing research. In a new seven-year study, female subjects who took a plant-based calcium supplement (as the brand AlgaeCal) also enriched with magnesium, strontium, boron, and vitamins D3, K2, and C experienced an uptick in bone mineral density, to the tune of about 1% per year, amounting to a 7.3% bone mineral density increase over the course of the seven-year study. For comparison, the researchers pointed out that normal age-related annual bone loss is about 1% per year after midlife.

And though bone loss is primarily seen as an issue affecting older individuals, prevention can start much earlier, according to a new study published in the *Journal of Bone and Mineral Research*. In this study, researchers demonstrated a beneficial effect of vitamin D supplementation that, in adolescent girls, lasted well beyond the duration of the one-year treatment. Researchers assigned 167 adolescent girls and boys to take either vitamin D supplementation or placebo for 12 months, measuring bone mineral content and density at baseline, at 12 months when the study completed, and again at 24 months, fully one year after the study’s completion. Girls who took vitamin D during the trial had a significantly larger bone mineral content increase at 24 months over baseline when compared to those assigned placebo, meaning the beneficial effects of D supplementation lasted one year after the trial completed. There was, however, no significant difference in bone mass changes between the groups of boys.

Vitamin K2 MK-4 is a form of vitamin K2 found in animal products like meat, cheese, and eggs, with benefits for bone health. Recently, a mouse study found that vitamin K2 MK-4 may induce recovery from bone mineral loss caused by stress. In this study, researchers divided mice into three groups: control, stress, and stress with MK-4 treatment. Stress was induced via water-immersion restraint. The stressed groups experienced significantly lower bone mineral density than the control group, which researchers chalked up to the high bone turnover that stress causes; however, the MK-4 group did experience a suppression of bone breakdown, leading to better recovery from the bone loss.

Another study on vitamin K2 focused on its bioavailability in a creative delivery format: yogurt. Published in the *European Journal of Clinical Nutrition* earlier this year, researchers found that NattoPharma’s (Oslo, Norway) MenaQ7—MK-7 derived from *Bacillus subtilis* natto fermentation—is highly bioavailable when ingested via yogurt and soft gel capsules. These results, the company said, demonstrate that MenaQ7 is effective in both food and supplement formats, broadening its appeal to an even wider population of individuals.

In the study, researchers compared three different deliveries over the course of eight weeks: 1) yogurt that researchers dubbed Kplus, fortified with MenaQ7 Pure (a nature-identical version of the original MenaQ7 ingredient) plus vitamins D3 and C, magnesium, and omega-3 polyunsaturated fatty acids, 2) yogurt fortified with MenaQ7 Pure only, and 3) MenaQ7 Pure soft gel capsules. Researchers then compared the fasting concentrations of plasma MK-7 among the participants.

“The increase in plasma MK-7 with the yogurt Kplus product was more pronounced than the increase in MK-7 with the capsules. However, circulating desphospho-uncarboxylated matrix Gla-protein and uncarboxylated osteocalcin were significantly lowered after consumption of both the yogurt products and the MK-7 capsules, reflecting vitamin K status improvement from both delivery methods,” says Eric Anderson, the company’s senior vice president of global sales and marketing. “In other words, both the yogurt products and the capsule effectively lowered inactive osteocalcin (a K-dependent protein that binds calcium to the bone matrix when it’s activated by vitamin K2), which means more osteocalcin was in fact activated and put to use in the body to support bone health.”

The future of vitamin K will undoubtedly include more innovation on the delivery front, as studies point to efficacy in fortified foods that rivals that of supplements. Of vitamin K2 MK-4, Blue California’s McCollum says, “I would recommend making this product more accessible, producing chewable tablets and adding it to dietary supplements in many different categories, including sports, functional beverages, antiaging, and weight-loss products, as well as products formulated specifically for the elderly.”

Vitamin E has also recently entered the spotlight for potential bone-health benefits. Published earlier this year in the *British Journal of Nutrition*, one study associated greater consumption of vitamin E with greater bone mineral density in
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**Crossover Ingredients**

In addition to the minerals and vitamins that dominate the bone-health category, formulators are looking to other proven ingredients.

Known primarily as a beauty supplement ingredient, collagen is making a name for itself as a cutting-edge ingredient for bone health. "Bone itself is a living tissue comprising 75% inorganic materials, primarily calcium phosphate crystals, and 25% collagen calculated by dry mass," says Eden Somberg, MS, LAc, director of business development at AIDP (City of Industry, CA). "So when we supplement with minerals and vitamins only, we’re not addressing over one-quarter of the structural composition, and that’s a significant number."

AIDP first completed a three-month study on women, focused on calcium-collagen chelate supplementation; recently, the company followed this study up with a longer-term evaluation, completed in 2015. Performed at Florida State University, AIDP’s KoACT ingredient was put to the test for helping to prevent or reverse bone loss in postmenopausal women. The study protocol also included a calcium supplement, says Somberg, which allowed researchers to compare the ingredients head-to-head. "The study concluded that KoACT prevented bone loss in the patient population when calcium could not prevent bone loss in the same study group," Somberg explains. "The duration of the study was one year, and it demonstrated that KoACT significantly increased biomarkers of bone synthesis."

KoACT is not merely a blend of calcium and collagen, the company explains; rather, it is a matrix including both ingredients that specifically enhances the efficacy of each, the company says. It’s appropriate in a variety of applications, from capsules to bars, beverages, and stick packs.

Yet another crossover ingredient that formulators are exploring when it comes to bone health is antioxidants—specifically, carotenoids. A study published this year in *Osteoporosis International* correlated a high concentration of serum carotenoids with high bone mineral density in middle-aged and elderly adults, especially women. In this study, researchers followed 1,898 Chinese women and 933 Chinese men aged 50 to 75 years for a duration of about three years. They analyzed serum alpha-carotene, beta-cryptoxanthin, lycopene, zeaxanthin, and lutein by liquid chromatography, and gauged bone mineral density of the whole body as well as targeted areas like the lumbar spine, total hip, and femur regions. They found that high levels of alpha-carotene, lycopene, and beta-cryptoxanthin were associated with higher bone...
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mineral densities at most of the skeletal sites in the postmenopausal women, and higher alpha-carotene levels were significantly associated with higher bone mineral density in the hips of the women. In men, only high serum alpha-carotene was significantly associated with increased density, and at all sites but the lumbar spine.

“This research supports the use of natural mixed carotenoids for maintenance of bone mineral density in adults, and especially women,” says Bryan See, regional product manager for ExcelVite Inc., a Malaysia-based company that offers EVTene, a carotenoid ingredient which mirrors the content of carrots (35% alpha-carotene, 65% beta-carotene). “Women are generally at higher risk of losing bone mass because women have smaller bones compared to men. This study suggested that increased intake of mixed carotenoid with high content of alpha-carotene benefits both men and women.”

Soy isoflavones, well known for their heart health benefits, are gaining traction in the bone health category thanks to new research showing their effects on postmenopausal bone calcium retention. Researchers tested risedronate (a bisphosphonate) as well as five different soy isoflavone oral supplements (two doses of a genistein-rich soy supplement, and three doses of mixed isoflavones in various proportions) on a group of 24 women. Each formula was tested separately, with each treatment lasting 50 days and separated by a 50-day washout period. The most effective isoflavone intervention delivered 105 mg of isoflavones as genistein, daidzein, and glycitein in natural ratios. It increased bone calcium retention by 7.6%. And although risedronate delivered a 15.3% increase in bone calcium retention, researchers concluded that the soy isoflavones were nonetheless an effective bone-preserving agent.

Indeed, going forward, the bone health category can only benefit from research that focuses on novel ingredients and creative delivery systems that broaden overall access to bone-building and bone-protecting supplements. “When we expected to live to be 70, we did not care too much about the possibility of falling and breaking a hip. Now that we can expect to live to our 90s, protecting old bones is crucial to our quality of life,” says Blue California’s McCollum.

References

Melissa Kvidahl is a freelance journalist and copywriter specializing in the health and wellness industry.
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How to Diversify Your Plant-Protein Portfolio

Here are some emerging plant-protein sources you won’t want to miss.

BY KIMBERLY J. DECKER

Hands down, protein is today’s nutrition superstar. Protein’s health benefits are well-nigh indisputable, serving not only as building blocks for the body but also capturing consumer attention with catchy benefits like weight management and satiety. Plant-based proteins are especially fashionable these days, with fans ranging from trendy millennials to flexitarians, who represent approximately 25% of the U.S. population, according to Udi Alroy, vice president, marketing and business development, Hinoman (Tel Aviv, Israel). As flexitarians explore new plant-based protein sources, he says, they’re “creating a whole new market for new products and are moving the industry away from animal-based proteins.”

“This is not a passing fad,” says Rikka Cornelia, product manager, BI Nutraceuticals (Long Beach, CA). “Consumer awareness and demand for protein are only going to increase.” Though meeting that demand could raise challenges, she says, “it’ll more likely be a great opportunity for brands and ingredient suppliers to think outside the box and innovate when it comes to developing new protein sources.”

Without further ado, here are a few plant-protein options to keep your eye on now.

Ancient Grains
The vogue for ancient grains has made what’s old new again, particularly among nutrition enthusiasts. Nowhere is that more the case than with quinoa (Chenopodium quinoa), that ubiquitous “supergrain” of Andean origin that had quite a moment several years back. Cornelia credits the gluten-free trend for sparking consumers’ interest in ancient grains like quinoa—but, she adds, they’re “also touted for their high protein content.”

And for good reason: Unlike many plant proteins, quinoa has a complete complement of amino acids—including lysine, which usually limits the nutritional quality of plant sources. Jeff Brucker, vice president of marketing, Genesis Today (Austin, TX), adds that quinoa protein “is also non-allergenic and is a natural source of fiber, magnesium, B vitamins, and antioxidants and has a low glycemic index.”

Industry developers are putting those properties to use by including quinoa protein in plant-based nutritional powders, ready-to-drink protein shakes, and bars, Brucker says.

Spilling the Beans…and Nuts and Seeds
Of course, the granddaddy of plant-based proteins is soy, which “still has the most
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complete amino-acid profile when compared to animal protein,” notes Lesley Nicholson, marketing manager, ADM/WILD Flavors & Specialty Ingredients (Decatur, IL). But soy is in excellent company among its fellow legumes, as bean, pea, and pulse proteins are all increasingly popular choices.

Pea protein is already a sensation, and now proteins extracted from lentils (Lens culinaris) and faba beans (or fava beans; Vicia faba) are also gaining attention. What makes them special? “First off, the starting materials are extremely popular with consumers,” Cornelia says. Such proteins also check off all the allergen-free, clean-label, and sustainable boxes that are on so many consumers’ lists. What’s more, she adds, “They have more favorable taste profiles than soy protein.”

Similar advantages are boosting the profile of seed-based proteins, like those found in sunflower and pumpkin seeds—the latter of which Cornelia describes as having “a roasted nutty aroma with a consistently mild taste.”

Nicholson adds that ADM/WILD’s plant-based protein portfolio now includes nuts, nut butters, and peanut flowers, too. “Nut butters, such as almond or cashew butter, have great bland taste profiles and are easy to incorporate into formulas,” she says.

For now, you’ll find these bean and seed proteins mainly in meal-replacement and sports-nutrition shakes and bars, Cornelia says. “However, with protein achieving mainstream popularity, we’re seeing these options incorporated into a broader range of products, like baked goods, cereals, and snacks.”

**Hemp**

Yes, our founding fathers grew hemp—for industrial, not recreational, purposes. But more than 200 years later, Cannabis sativa L. is finally getting its due as a nutritional ingredient.

“Hemp in general is experiencing a revival of interest, and if we can get over certain stigmas and regulatory inhibitions, then hemp protein could have a strong supply chain and environmentally friendly image,” says Alan Rillorta, director of protein and branded ingredient sales, AIDP Inc. (City of Industry, CA). Hemp’s protein quality is on par with that of meat, dairy, eggs, and soy when it comes to amino-acid content. And as if that weren’t enough, hemp seed itself is a rich source of dietary fiber, B vitamins, and minerals, including iron and zinc.

Rillorta notes that hemp proteins are currently getting strong play in ready-to-mix powdered nutritional supplements. “But already,” he says, “we’re seeing some movement into the food and beverage spaces.” The possibilities for product development are tantalizing. “Imagine using the fibers to make clothes and industrial building materials, the oils for cooking, and the protein for nutrition,” he says. Imagine, indeed.

**Duck, Duck...Duckweed**

Processors are finding novel proteins in pretty unexpected places. And as far as Hinoman’s Alroy is concerned, “The new wave of green options will come from the duckweed family.” That’s right: duckweed, from the Lemnaceae family, which Alroy claims is “one of the most promising alternative sources of protein.”

This tiny flowering wetland plant has been a nutritious food in East Asia for generations. But now, companies like Alroy’s are cultivating duckweed strains via advanced hydroponic processes that not only yield higher-protein plants but do so year round and with fewer resources than traditional methods.

“The main advantage of duckweed is its ultimate sustainability,” Alroy says. “It requires no arable land, multiplies in mass over the course of a few days, and requires very little energy—and, as such, has the lowest ecological footprint of all protein sources currently available in the marketplace.” Oh, and duckweed is non-GMO and grown without pesticides, too.

Alroy says his company’s “precision agriculture model” enhances duckweed’s nutritional. At more than 45% protein, the plant, which Hinoman markets as “mankai,” boasts a balanced amino-acid profile, high digestibility, plenty of vitamins and minerals (A, B complex, E, K, calcium, iron, zinc and selenium, to name a few), and a fat complement that includes omega-3s.

And don’t let the spinach-green color fool you: Alroy says that mankai is surprisingly...
Hemp protein is a very promising protein source, “if we can get over certain stigmas and regulatory inhibitions,” says Alan Rillorta, director of protein and branded ingredient sales, AIDP Inc.

mild in flavor, enabling food and beverage manufacturers “to fortify their products with very little change to the flavor profiles.” And as a fine powder, the ingredient is “easy to incorporate into all sorts of foods,” from bars, powdered beverages, and meal replacements to baked goods.

“The combination of a superb amino-acid profile with vitamins and minerals and omega-3 levels makes this not only a highly nutritious vegetable protein source but a superfood that’s unprocessed and suitable for the clean labeling that consumers today prefer,” he says.

Green Is the New Black

There was a time when algae was something you paid a swimming-pool service to clean up. Now it’s an increasingly sought-after protein source for green and vegan formulations. And if you ask Mark Brooks, senior vice president of food and ingredients, TerraVia (San Francisco, CA), it’s about time.

“Algae contains the essential building blocks of nutrition: protein, fibers, healthy oils, macro- and micronutrients,” he says. That being the case, his company has developed a process that harnesses the fermentative proclivities of a non-GMO chlorella microalga to produce what it calls AlgaVia Protein-Rich Whole Algae Powder, a yellow,
nutty-tasting substance that’s 65% highly digestible protein and, in Brooks’s words, a “uniquely powerful food ingredient.”

It’s a handy one in applications, too. As Brooks explains, “Often, food and beverage manufacturers struggle with the gritty taste and texture that come with increasing protein content and that can force them to add stabilizing ingredients”—which label readers aren’t always keen to see. But because the algae protein and other nutrients in their powder naturally lie within the algal cell wall, interactions with other ingredients remain limited, “enabling increased fortification in a wide variety of foods,” Brooks says, including notoriously sensitive ones, like low-pH beverages, dressings, and crackers.

At this July’s Institute of Food Technologists Annual Meeting & Food Expo (IFT), TerraVia showed trade show visitors how its algae-based powders and oils really can work in everything, from French fries to cookies. The company sampled a cheese cracker containing AlgaVia Protein-Rich Whole Algae Powder “in which we’re able to double the protein content and actually double the fiber,” as well, because our product has 63% protein and 15% fiber,” said Katie Ringer, associate director of marketing and communications, TerraVia. The protein powder alone had a subtle, nutty flavor reminiscent of pistachios or cashews. “But it’s still neutral enough that it works in both savory and sweet applications,” Ringer said.

TerraVia is showing that algae just isn’t the green slime it used to be. “Our team has conducted extensive consumer research and evaluated industry trends to learn about what consumers are looking for in their food products,” Brooks says. And the results make “clear” that there’s “a high degree of consumer acceptance for algae-based ingredients” among consumers, nutrition professionals, and industry alike.

Ringer said IFT gave the company an opportunity to “reassure visitors that this tastes great. It doesn’t taste like algae or the sea or what people would expect with algae. It’s really neutral.” Still hesitant? She said the company “works side by side” with customers to help them figure out how to successfully use the ingredients in their products. [i]

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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Vegan-friendly dietary supplement options are on the rise.

BY ROBBY GARDNER

Dietary supplement marketers are experiencing growing demand for everything vegan these days from customers seeking to fill nutrient gaps in the vegan diet or to replace animal byproducts. What’s more, vegans aren’t the only purchasers of vegan products. A recent SPINS report highlighted the overall growing public appetite for “plant-centric diets”—an opinion seconded by market researcher Innova Market Insights this summer, which reported that “new opportunities are emerging, too, for so-called ‘flexitarians’ who mainly eat a plant-based diet but do occasionally eat meat.”

These consumers are drawn to other attributes associated with the vegan diet, too, such as whole-food, organic, ancient grain, and sprouted, SPINS said. It cited growing U.S. sales for vegan products, especially among “chips, pretzels, and snacks,” the largest category by far. (Source: SPINSscan Natural, 52 weeks ending 10/4/2015.) And Innova Market Insights reported a jump in 2011–2015 global vegan food and drink launches, as well as an estimated 60%+ rise in launches touting a vegetarian claim.

Fortunately for dietary supplement makers, the number of vegan ingredient options is growing. Here’s a brief look at recent vegan market innovations for supplements, from highly sophisticated ingredients to quite basic ones, as well as delivery systems.

Iron
A key concern for vegans and vegetarians is iron intake. Studies on both populations show that iron deficiencies often occur, especially in females. For this reason, Frutarom (Haifa, Israel) is now marketing a novel, encapsulated-iron ingredient to the vegan/vegetarian market.

The ingredient, AB-Fortis, is encapsulated so that iron is not distributed freely into food and beverage matrices. The process keeps free iron from dispersing, thereby reducing the metallic taste and oxidation that can be common in iron supplements. It also reduces any side-effect challenges related to digesting iron.

“Because iron isn’t as easily absorbed from plant sources, the recommended intake of iron for vegetarians (and vegans) is almost double that of non-vegetarians,” said Frutarom Health Product Manager Wouter Haazen in a recent press release. “It’s hard to increase iron intake from food alone.”

Vitamin D
Although vegans can supplement with vitamin D, they have historically had to resort to the vitamin D₂ (ergocalciferol) form, which can be sourced from irradiated mushrooms, instead of vitamin D₃ (cholecalciferol) typically sourced from sheep’s wool. Limited but continuing research, however, suggests that D₃ is actually a more bioavailable form of vitamin D. Now, vegans looking for D₃ but from a non-animal source have another option: a recently identified plant source of vitamin D₃.

According to The GHT Companies (Vista, CA), lichen is the only known source of vegan cholecalciferol. U.S. manufacturers can obtain it from The GHT Companies, which claims to own the exclusive North American rights to this D₃ material as well as global distribution rights to any products containing the material. Last year, the company introduced the ingredient in a three-flavored gummy prototype product.

“Previously, as D₃ usually comes from lanolin extracted from sheep’s wool grease, vegans would have had to settle for vitamin D₂, the less-effective ergocalciferol form. The trademarked Vitashine ingredient is the only vegan vitamin D₃ registered with several worldwide organizations, including the UK Vegan Society,” the company stated in a press release.
**Seaweed and Other Water-Based Plants**

A unique characteristic of some plants that grow in water is that their nutrients address common vegan deficiencies, such as a lack of vitamin B$_{12}$, selenium, and iodine. Dulse, spirulina, and chlorella are a few examples. Dulse is available in a red flake form, while spirulina and chlorella offer green–blue hues as powders and liquids.

There’s a great diversity of plant-based products available for dietary supplements, and the many water-based ones offer unique positioning, such as water-saving harvesting practices. A new duckweed protein from Hinoman (Tel Aviv, Israel), for example, runs on hydroponic growing practices that reuse water.

**First Peas, Hemp, Rice…and Now Grass Protein**

Protein fortification is already increasingly done with plants, including peas, hemp, rice, and a variety of other vegan-friendly ingredients. Alongside the wide variety of plant proteins already on the market, Taiyo GmbH (Schwelm, Germany) just introduced a new grass protein, according to Food Ingredients First.

What distinguishes Taiyo’s grass protein isn’t just its source of six different sweet grasses and legume species; it’s that this mix is rich in protein and gaba-aminobutyric acid (GABA). Since GABA is associated with calming and de-stressing qualities in published research, the notion of protein and GABA in a post-workout formula should generate consumer interest.

“The grass grows so fast, it can be cut four or five times a year and is completely natural and sustainable,” said Taiyo GmbH managing director Stefan Siebrecht in an interview with Food Ingredients First. “Normally it ends up in the biogas industry to form gas and electricity, but now we can make food out of it.”

If Taiyo has a successful campaign with this vegan protein in Europe, U.S. manufacturers might eventually get access to the ingredient via the company’s Minneapolis distribution hub.

**Glucosamine**

Glucosamine is one of the most popular ingredients for managing joint health; unfortunately, the majority of glucosamine on the market comes from shellfish, which can only be harvested seasonally. In light of the production issue, suppliers have for years offered a renewable, vegan-friendly alternative.

A handful of suppliers create glucosamine ingredients out of various fermentation and fungal processes. These include Cargill’s (Minneapolis) Regenasure ingredient, TSI USA’s (Mossoua, MT) GlucosaGreen, and Ethical Naturals’ (San Anselmo, CA) Green-Grown glucosamine.

The resulting glucosamine isn’t just plant-based; it also doesn’t require an allergy warning, and it tends to be whiter in color. Because it’s produced in labs, vegan-friendly glucosamine is both sustainable and renewable.

**BCAAs**

Highly sophisticated sports ingredients can also be vegan, as evidenced by a recent offering from Innobio Ltd. (Dalian, China). In 2014, the company introduced a vegan branched-chain amino acid (BCAA) powder that’s microencapsulated with sunflower lecithin. Beyond being allergy free thanks to the source, Innobio’s vegan BCAA powder is quickly dispersible in water. This makes it a potential choice for sports beverages as well as bulk powders.

While other vegan BCAAs may vary in their precise amino-acid contents, Innobio’s is a mixture of L-leucine, L-isoleucine, and L-valine in a 2:1:1 ratio.

**Capsules**

A vegan supplement’s outfit is just as important as its contents, and so vegan capsule sales are on the rise. In response to the growing demand for all things vegan and vegetarian, capsules solutions provider Capsugel (Greenwood, SC) recently injected $25 million into its production capacity for vegetarian capsules. It also has made several recent innovations in its Vcaps vegetarian capsules.

The company also recently certified its Vcaps capsules under the Certified Vegan seal, ensuring its capsules are not just sourced from vegan ingredients but also are free of cross-contamination with any ingredients that are not. According to Capsugel, a new organic capsule is in the works.

**Industry Representation**

While vegan products can be represented with value-added seals, this has often been the extent of marketing support for vegan sales. A newly formed industry organization, however, hopes to change that.

The Plant-Based Foods Association was recently created with a mission to increase the visibility of plant-based foods and to ensure fair and competitive markets for plant-based goods through a variety of media and legal strategies. Many manufacturers and ingredient suppliers have already joined the organization.

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

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**References**

2. ClinicalTrials.gov Identifier: NCT01139840
Melatonin supplements are currently widely available in the United States without a prescription and in many delivery forms: capsules, tablets, fast-dissolve tablets, gummies, and liquids. Marketed in the United States to both adults and children as a safe and natural sleep aid, melatonin supplements and the mechanism by which they induce drowsiness in humans do not yet seem to be fully understood by general consumers. Additionally, more long-term studies of melatonin’s effects are needed, particularly in the area of pediatrics.

Michael Grandner, PhD, MTR, CBSM, FAASM, assistant professor of psychiatry and director of the Sleep and Health Research Program, College of Medicine, University of Arizona, calls melatonin supplements “quite safe, especially compared with sleeping medications.” However, the United States “may be the only developed country in which melatonin is sold as a supplement without a prescription,” he adds.

Melatonin-supplement users will want to weigh their pros and cons and make sure they don’t fall for three common misconceptions regarding melatonin supplements.

**Misconception #1: Melatonin Is a Sleeping Pill**

“It’s actually more complicated than that,” Grandner says. “Melatonin is way more than a chemical that tells the body to sleep. It’s a chemical that tells our bodies it’s nighttime, and nighttime is the time that we try to sleep. Melatonin is not a sleep inducer; it’s a signal to the body of where the clock is.”

Grandner explains further that the body’s natural melatonin-secretion process works something like this: The brain, which knows nighttime is here thanks to its internal clock working in tandem with signals from the environment (such as lack of sunlight), directs the pineal gland to secrete melatonin. This hormone then travels around the body binding to melatonin receptors within all the different cell systems, alerting these systems that nighttime has arrived. Melatonin essentially “puts all cells, tissues, and systems into ‘night mode’ and keeps them all on the same page,” Grandner says. Night mode triggers different actions in various body systems; for instance, it may stimulate the liver to start making cholesterol. It also triggers drowsiness.

Supplementing with additional melatonin, Grandner explains, “nudges the hands on your internal clock a little bit.” Taking melatonin as early as an hour or two before...
bed, when one’s natural melatonin levels are low but rising, will shift that clock forward somewhat and induce drowsiness sooner than normal. Likewise, taking melatonin “first thing in the morning, as your levels are dropping, can extend your biological night a little bit,” Grandner says.

A sleeping pill, on the other hand, “has very little to do with the clock,” he states.

**Misconception #2:**
**The More Melatonin a Person Takes, the Better It Works**
No dose-response effect exists for melatonin supplements, Grandner says. “It doesn’t necessarily work better the more you take. If anything, the opposite is true.”

Grandner explains that the standard supplemental-melatonin dose for “the vast majority of adults” is 0.5 mg up to about 3 mg. “But if you take two tablets, you are not going to have double the effect,” he states, and he adds that a lower dose often works better. “You’re trying to nudge the internal clock, not overpower it,” he says.

**Misconception #3:**
**Melatonin Is Natural and Therefore Guaranteed Safe for All**
Some might think that because melatonin is a natural hormone secreted by our own bodies, melatonin supplementation carries absolutely no risk and is 100% safe. It is true that melatonin supplements are quite safe for most adults and less risky than pharmacetical sleep-inducing drugs; however, there can be some negative effects. For instance, Grandner says, side effects can include headaches or dizziness and unpleasant stomach symptoms. For some adults, melatonin supplements can cause sufficient drowsiness as to make driving unsafe, and they can potentially negatively affect mood.

Additionally, “melatonin does other things in the human body beyond telling the body’s systems that nighttime has arrived,” Grandner explains. “For example, there is a lot of melatonin in the digestive system that has nothing to do with signaling nighttime, and there is melatonin within the cardiovascular system that is not necessarily related to nighttime signaling, either.” For this reason, taking supplemental melatonin may present some risk. Grandner also describes how, when provided with supplemental melatonin over the long term (several months), the human body may lower its own melatonin production.

One area of controversy for which a significant dearth of knowledge exists is pediatric melatonin supplementation. Katherine M. Sharkey, MD, PhD, FAASM, assistant professor, Alpert Medical School of Brown University (Providence, RI), says that most of the studies of melatonin supplementation in pediatric populations have been in small samples of children with neurologic disabilities or psychiatric disorders, and in those populations, melatonin supplements do appear to help improve sleep duration and latency to sleep onset in children with “very irregular, disrupted sleep-wake patterns.” However, very little data exists on giving melatonin to otherwise healthy children with insomnia, Sharkey explains. She adds that melatonin is known to affect growth hormone and play a role in pubertal onset. “Disorders of the hypothalamic-pituitary-gonadal axis, such as delayed puberty, precocious puberty, and amenorrhea, have been associated with abnormal plasma melatonin secretion patterns,” she says, and cites a review article by David Kennaway published last year in the *Journal of Paediatrics and Child Health.*

In the pediatric population, much more research on melatonin supplementation is needed.

**Reference**
Phospholipids

Phospholipid molecules are crucial components of cell membranes. They act as building blocks for cells and participate in the transmission of signals while facilitating the transport of nutrients into and out of cells. Phosphatidylserine (PS) in particular is a key phospholipid concentrated in high amounts in brain tissue. PS makes up nearly 20% of the phospholipid mass of adult human plasma and intracellular membranes. Apart from its structural role, PS plays a critical role in the brain by influencing the metabolism of several neurotransmitters, including acetylcholine, norepinephrine, serotonin, and dopamine.¹

The latest round of research studies continues to confirm the brain-health benefits of phospholipids, including PS specifically. Ahead, we look at four new trials on memory, stress, attention, and hyperactivity, plus other areas of health science developing around PS and other critical phospholipids.

**PS+PA Benefits for Dementia, Alzheimer’s Disease**

A double-blind, placebo-controlled trial on seniors with dementia studied the effects of a soy-derived phospholipid mixture on memory, cognitive function, and mood.² Margret Moré and colleagues from Berlin, Germany, looked at what happened when non-depressed patients with dementia were given three capsules of a blend of soy phospholipids—100 mg PS + 80 mg phosphatidic acid (PA)—daily for three months. Another group of subjects with Alzheimer’s disease was given the same supplement, but for two months instead of three months.

Compared to placebo, the supplement significantly improved memory and enhanced mood in the elderly population with dementia. In the individuals with Alzheimer’s disease, the supplement stabilized measures of daily functioning as well as emotional state, compared to the placebo group, which saw daily functioning and emotional state deteriorate. Ingredient supplier Lipogen (Haifa, Israel) supplied the PS used in the study.

**Supporting Memory in Healthy Adults**

PS and the omega-3 fatty acid docosahexaenoic acid (DHA) are both structural components for brain health and integrity. An earlier double-blind placebo-controlled study³ evaluated how PS enriched with...
DHA affected cognitive performance in elderly individuals with memory complaints, but who had no diagnosis of dementia. Those researchers found that administering daily 300 mg of PS enriched with DHA for 15 weeks significantly enhanced subjects’ verbal immediate recall. Furthermore, subgroup analysis found that subjects who had higher baseline cognitive status were more likely to respond to the PS-DHA complex.

In a follow-up study to that original trial, researchers chose 122 individuals (61 from the original treatment group and 61 from the placebo group) to continue taking the PS-DHA combination—this time, a dosage of 100 mg/day PS plus DHA—for an additional 15 weeks.

According to the researchers, those who continued on with supplementation maintained the cognitive improvements they had gained by the end of the first trial’s 15-week supplementation period. What’s more, those originally in the first study’s placebo group experienced significant improvements in sustained attention and memory recognition after taking the PS-DHA combination during the second trial. Both trials studied Enzymotec’s (Migdal HaEmeq, Israel) ingredient.

**Chronic Stress**

A placebo-controlled study investigated the effects of a PS+PA supplement in chronically stressed males. Led by Juliane Hellhammer of the Diagnostic Assessment and Clinical Research Organization (Daarco) in Trier, Germany, researchers assigned 75 healthy males with chronic stress (stratified by stress levels) to receive a placebo or supplementation with the phospholipid combination in one of two doses—200 mg PS + 200 mg PA, or 400 mg PS + 400 mg PA. The subjects supplemented daily for six weeks. At baseline and at the end of the trial period, researchers measured levels of adrenocorticotrophic hormone (ACTH), a pituitary hormone that regulates the release of cortisol from the adrenal glands, as well as salivary and serum levels of the stress hormone cortisol.

The 400-mg dose of PS+PA, but not the 200-mg dose, normalized ACTH and salivary and serum cortisol responses in those with chronically high stress levels, indicating a blunting of the physiological response to chronic stress. Thus, PS+PA could prove useful in supporting the body’s response to chronically high stress levels. Lipogen supplied the ingredients under study.

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**A FLURRY OF PHOSPHOLIPID INNOVATION**

Ingredient suppliers are giving phospholipids new life.

In case you haven’t noticed, innovation around phospholipids is in high gear these days. Why the push? Suppliers say the reason is demand. Quite simply, demand for phospholipid products is growing, and companies want to be there with cutting-edge ingredients.

In April, American Lecithin Company (Oxford, CT) launched a new line of phospholipids and lecithins, including phosphatidylserine, all derived from sunflower. The firm says the ingredients are label-friendly alternatives to phospholipids derived from soy.

“With this launch, American Lecithin becomes the only company that offers both sunflower-derived phosphatidylserine (PS) and sunflower-derived glycerophosphocholine (GPC),” said Randy Zigmont, the firm’s president.

In March, Chemi Nutra (Austin, TX) added water-dispersible versions of its popular SerinAid PS and Mediator phosphatidic acid (PA) ingredients, all with an eye toward functional beverages.

Suppliers of marine-derived phospholipids are also keeping busy. Last fall, krill oil supplier Rimfrost (Fosnavåg, Norway) introduced an ultra-high-phospholipid ingredient called Sublime PL60. The ingredient contains krill oil omega-3 phospholipids plus other supportive nutrients like choline, omega-3 polyunsaturated fatty acids, and astaxanthin. At the Vitafoods trade show in May, the company introduced Sublime PL60 to the wider European market. “Rimfrost Sublime PL60 Antarctic krill extract is much more than...”
**A FLURRY OF PHOSPHOLIPID INNOVATION**

an omega-3 ingredient; it is a nature-made, multi-nutrient formulation,” said company managing director John Cameron in a press release.

In May, ingredients firm Valensa (Orlando, FL) launched an ecologically sustainable vegetarian product called Ocean Caviar, which it described as “a first-of-its-kind omega-3 phospholipid supplement that contains no fish oil.” Derived from North Atlantic herring roe (herring eggs), the supplement also contains algae-sourced astaxanthin, EPA and DHA omega-3 fatty acids, and the omega-3 fatty acid alpha-linolenic acid (ALA) from the firm’s phospholipid-rich Verilla perilla seed oil. (Turn to page 67 to read more about Ocean Caviar.)

In addition to overhauling form and function, phospholipid suppliers are investing in new research expanding their ingredients’ potential.

Aker BioMarine (Oslo, Norway) put its omega-3 phospholipid-rich Superba krill oil to the test for exercise recovery. Last October, the company announced results published in PLoS One showing that 2 g of krill oil daily for six weeks strengthened athletes’ immune function after exercising. During the trial, supplementation increased subjects’ production of interleukin-2 (IL-2), a cytokine molecule that helps regulate the immune system, as well as natural killer (NK) cells, a crucial component of the immune response. Researchers concluded that krill oil may be able to increase immune support following intense exercise.

Phosphatidylcholine (PC) is a key brain-health phospholipid, and alpha-glycerylphosphorylcholine (A-GPC) is a precursor to PC. Last year, Chemi Nutra promoted a new study on its AlphaSize A-GPC ingredient suggesting that A-GPC supplementation may also benefit sports performance by improving lower-body muscle strength. According to the firm, by stimulating the production of key neurotransmitters, A-GPC may help counter impaired motor neuron activity that may become compromised during “exhaustive and repeated exercise.”

Sports aside, in March, Lipogen (Haifa, Israel) announced a new U.S. patent that proposes using a specific phospholipid formula to address symptoms of premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD). The basis for the patent is a recent study that revealed a previously unrecognized PMS/PMDD benefit of Lipogen’s PS Plus ingredient, the firm said.

Beside investing in ingredient introductions and research, suppliers are also working to expand their phospholipid operations to support growing business.

Lipogen recently announced plans to expand its production facilities, doubling its production capacity for PS and PA, as well as building a new phospholipids R&D center. The firm attributes these moves to a “rapid 50% jump in sales of brain- and stress-health solutions in Q1–Q3 2015.”

Lipogen CEO David Rutenberg underlined the growing demand for phospholipids at large. “The phospholipids market is expanding from traditional brain-function support to new brain-health concepts, including stress management, cortisol control, ADHD mitigation, sports nutrition, and more,” he said. With so much happening, and so much at stake, the future for phospholipids has never been brighter.

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**Attention and Hyperactivity**

Attention-deficit hyperactivity disorder (ADHD) impacts 3%–5% of school-aged children. A recent study evaluated the ability of soy-derived PS to help manage certain aspects of this condition.

Led by investigators from the Department of Childhood Education and Care, Kurashiki City College, in Okayama, Japan, 36 children aged 4-14 with ADHD who were not receiving drug therapy were administered 200 mg of PS or placebo daily for two months.

PS supplementation improved several ADHD symptoms, including attention deficit, hyperactivity, inattention, and impulsivity. Furthermore, the study showed that PS was safe and well-tolerated in this young population. If larger studies corroborate this research, PS could be considered a novel alternative to standard, drug-based therapies for ADHD.

**Phosphatidylserine: Beyond the Brain**

Research on PS over the years well supports the benefits of supplementation for brain health. But newer research also points to other potential benefits, including for skin health and sports nutrition. In fact, it’s possible that research on the healthy
benefits of PS is only at the early stage. “PS is a health ingredient with a really big future,” says Ariel Katz, PhD, president and CEO of Enzymotec.

Take skin health, he says. Studies show that PS may help promote collagen development as well as restore skin moisture.

Meanwhile, in sports nutrition, PS has been shown to increase athletes’ time to exhaustion by up to 30% and reduce muscle soreness by as much as 50%. PS may also reduce levels of cortisol and increase levels of testosterone, helping promote muscle recovery.

“It’s got so much to offer,” Katz says. “It will continue to be strongly associated with cognitive health, but wider awareness of its benefits will mean that at last PS can reach its full potential.”

References


Irfan Qureshi is executive director, research and regulatory affairs, for Healthy Directions.
Probiotic plus Protein May Reduce Muscle Damage, Enhance Recovery

Jäger R et al., "Probiotic Bacillus coagulans GBI-30, 6086 reduces exercise-induced muscle damage and increases recovery," PeerJ. Published online July 21, 2016.

Recent study results shared by probiotics firm Ganeden (Cleveland) indicate its Ganeden BC30 (Bacillus coagulans GBI-30, 6086) probiotic strain may be an effective partner to casein protein at providing multiple sports-related benefits. Compared to casein protein alone, the combination of Ganeden BC30 and casein protein was found to be more effective at significantly increasing recovery, reducing indices of muscle damage, and maintaining physical performance following damaging exercise.

The newly published trial—the 24th peer-reviewed and published study of Ganeden BC30—is "the first study of a probiotic showing ergogenic effects in athletes, with results benefitting the sports nutrition and protein functional food and beverage categories," according to Ganeden.

Writing in PeerJ, researchers assessed the effect of the probiotic and protein combination in 29 recreationally trained men. After two weeks of supplementation, study subjects participated in a damaging exercise bout with a subsequent analysis of perceptual measures, athletic performance, and muscle damage.

"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 in the study announcement.

The crossover, diet-controlled study included 29 men with a mean age of 21.5 +/- 2.8 who consumed either 20 g of casein alone or 20 g of casein plus 1 billion CFU of Ganeden BC30. At the end of the two-week supplementation period, participants engaged in a damaging, single-leg exercise bout, with researchers analyzing subsequent athletic performance, muscle damage, and participant perceptual measures.

Compared to casein alone, casein plus probiotics was found to significantly increase recovery at 24 and 72 hours after exercise, and decrease soreness at 72 hours after exercise. The probiotics-and-casein group also displayed a trend toward reduced muscle damage and maintenance of athletic performance in subsequent exercises. Compare that to the casein-only administration, after which participants experienced a significant reduction of athletic performance following the damaging exercise bout.

"In conclusion, the probiotic supplement tended to protect the muscle from damage and may have helped recovery of physical performance," researchers wrote.

Re-Esterified Omega-3s Offer Benefits for Dry Eyes?


Re-esterified omega-3 fatty acids from fish oil may offer significant improvements to several symptoms of dry eyes, according to new study results published in Cornea. Researchers found that 12-week supplementation with PRN Dry Eye Omega Benefits, a commercial supplement containing 1680 mg EPA and 560 mg DHA from Physician Recommended Nutriceuticals (Plymouth Meeting, PA), resulted in significant improvements to tear osmolarity, tear break-up time, and the ocular surface disease index.

Several past studies have found omega-3s to be effective at alleviating symptoms of dry eyes—often caused by dysfunction of the meibomian glands—but researchers in this study looked specifically at the effects of re-esterified omega-3s.

The prospective, placebo-controlled, double-masked study included 105 participants who were randomized to consume four softgels containing either the re-esterified omega-3 supplement or a placebo once daily for 12 weeks. All participants had a previously confirmed diagnosis of dry eye disease, but only those with stage 1 or 2 of meibomian gland dysfunction (MGD) were included in the trial. Participants in the omega-3 group had a mean age of 57 +/- 16.8, while participants in the placebo group had a mean age of 56.5 +/- 17.3.

At both six and 12 weeks after subjects began supplementation, researchers observed a statistically significant reduction in tear osmolarity in the omega-3 group compared to the control group. Additionally, at the end of the experimental period, the omega-3 group showed a significant increase in omega-3 index levels and tear break-up time, as well as significant reductions to matrix metalloproteinase-9 and the ocular surface disease index. Based on these findings, researchers concluded that the re-esterified omega-3 supplement “improved both signs and symptoms of dry eyes over a 12-week period.”

“The findings here are game-changing,” said Alice T. Epitropoulos, lead investigator of the study, in the study announcement. "The research shows that omega-3s administered in the proper dose and in a cleaned triglyceride form can not only provide the necessary lipids for the tear film to impact tear osmolarity and tear break-up time, the data also demonstrates that re-esterified triglyceride omega-3 fatty acid supplementation is a vital option for patients with meibomian gland disease and should be considered by all ophthalmologists treating dry eye patients."
THREE-PEAT!!!

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Anyone who’s followed ingredient sales in recent years won’t be surprised to hear that cranberry is once again posting stellar growth in dietary supplements. Propelled by mounting research behind the anti-adhesive benefits of cranberry proanthocyanidins (PACs) for urinary tract infections (UTIs) and other health areas, sales of supplements with cranberry as a primary ingredient grew by approximately 22% in the past year to reach a total U.S. market value of nearly $80 million, according to SPINS.¹

That’s exciting, but what might be even more thrilling is the rapid rise of cranberry food and drinks. Over the same period, food and drinks featuring cranberry as a primary ingredient grew by more than 117% to reach total U.S. sales of more than $21 million.

Given cranberry’s long history on the market, why the sudden interest from consumers?

Water, Peanut Butter Cups, and More

One factor driving growth may be the sheer number of new cranberry products that have emerged in the past couple of years. Cranberry supplier Fruit d’Or Nutraceuticals (Notre-Dame-de-Lourdes, QC, Canada), for instance, recently unveiled a chocolate peanut butter cup with cranberry seed protein powder and probiotics that’s now on its way to market. Also in the development pipeline are cranberry–probiotic gummies and new organic cranberry juice powders, according to Fruit d’Or.

One of the most visible brands in the cranberry space, Ocean Spray (Lakeville-Middleboro, MA), says different delivery systems are proving popular with consumers. In addition to its PACt cranberry extract water, which debuted in late 2014, Ocean Spray has seen success with its cranberry mango juice drink, Cran-Mango, as well as its line of Craisins dried cranberry snacks.

“The cranberry is such a versatile, amazing fruit,” says Patrick Cramb, Ocean Spray’s director of marketing for beverages. “The possibilities are endless.”

The Best Message

There are several different philosophies on which cranberry marketing message works best on consumers. Should the power of cranberry PACs, for instance, be a key selling point?

According to Cramb, “While consumers may be more familiar with terms like antioxidants, they do understand that other components, like PACs, provide valuable health benefits.”

Stephen Lukawski, director of business development and global sales for Fruit d’Or, agrees. He’s urging manufacturers to embrace PACs in marketing campaigns so consumers have an efficacious component of the cranberry to focus on.

“Without the story of PACs, there is no identification for the consumers to connect with,” Lukawski says.

Meanwhile, Dan Souza, vice president of sales and marketing for botanicals firm Naturex (Avignon, France), claims it’s actually cranberry’s researched health benefits that should be front and center.

“Formulators in the know are moving away from focusing on a single marker such as PACs and seeking out ingredients with published clinical results for targeted health benefits,” he says.

Dean Mosca, president of cranberry supplier Proprietary Nutritional (Kearny, NJ), also believes consumers are relatively unfamiliar with PACs. But he also cautions against focusing too closely on particular health areas, instead advising marketers to more generally share how PACs work.

“American consumers are conditioned to be skeptical of multiple powers of one ingredient,” Mosca says. “So, the way to tie in all three areas is by virtue of its key mechanism of action—focus on its anti-adhesion power as the primary benefit, and explain that anti-adhesion supports urinary tract, gut, and oral health.”

Perhaps, as the cranberry food market matures, a more uniform marketing consensus will emerge. But, then again, judging by the sales figures, maybe consumers like all these messages just fine.

Reference

¹. Sales data represent year-over-year sales for the 52 weeks ending August 7, 2016. These figures are aggregated across all three SPINS reporting channels: SPINsScan Natural, SPINsScan Specialty Gourmet, and SPINsScan Conventional.
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