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Misleading Consumers During a Pandemic

Consumers are seeking ways to stay healthy during the COVID-19 pandemic. Many are buying dietary supplements to support their health, especially their immune health. With many supplement companies now ramping up immune health benefit claims about their products or ingredients, consumers are unfortunately at more risk today than ever of being misled by advertising about supplements and their ability to support immune health.

Nutritional Outlook hosted a webcast on May 29 on this topic, titled “COVID-19 and Immune Health Claims: What Not to Say (Dos and Don’ts).” Webcast speaker, pharmacist and author David Foreman, known as “The Herbal Pharmacist,” discussed how consumers are vulnerable to deceptive immune health product information. Foreman has advised consumers in his role as a pharmacist as well as companies in the nutraceutical industry as a consultant.

Consumers are vulnerable to misleading information because of their “lack of knowledge,” Foreman said. “The average consumer doesn’t know if an ingredient is or is not really for immune health. They don’t necessarily know. They’re trusting us or whoever is putting out that finished product.”

Supplement companies bear responsibility for ensuring that consumers are getting accurate information about the products they’re buying. For instance, ideally companies should explain how quickly a product will work. “How long does it take to work? How long should it be taken?” Foreman asked. “The other day, someone approached me in the industry about a nutritional ingredient, and I said, ‘If I am starting to feel something, I’m starting to come down with a cold or a flu, that ingredient is not going to help me today. I need something that’s going to stimulate my immune system and fire it up, not support it.’ Ingredients that support immune health benefit claims about their products or ingredients, consumers are unfortunately at more risk today than ever of being misled by advertising about supplements and their ability to support immune health.

“Pixie dusting” is also deceptive and unethical. Foreman used the example of an omega-3 product being advertised as “now containing additional vitamin C for immune support.” The 20 mg of vitamin C in the product is far from an efficacious dose, Foreman pointed out. “Adding that little whiff of vitamin C is very deceptive. At the end of the day, it’s harmful to the consumer, and they’re not going to get the results that they are seeking.”

Dosing regimens also determine how effective a product will be, something that companies should ensure consumers understand. Foreman pointed to the example of another vitamin C product. “That product actually does have a high dose of vitamin C. It’s a little over 1000 mg, but it says to take one a day. We know in science that a therapeutic dose of vitamin C, 1000 mg, is barely going to pump your immune system. If someone really wants to take this to fire up their immune system, they’re going to need to take probably two of these, at two doses, at the same time, and they’re going to have to repeat it throughout the day because that type of immune stimulation maybe lasts 6 to 12 hours.”

Exaggerating the relationship of a supplement product and the immune system—for instance, suggesting that a supplement has more of a direct impact on the immune system than it really does—is also deceptive. Asked Foreman: “What type of immune system support does it really give? Because a lot of immune support could be reducing inflammatory cytokines, which means it’s going to help my joint health, but it’s not the type of immune support that I need to help boost my immune system, which is what people are looking at doing—supporting their immune system overall so that they don’t get sick from coronavirus or any other bacterial or viral infection out there.”

Unfortunately, he said, “there are products out there on the market right now...where the labeling or the advertising says it’s immune support when really it’s not.” One example he gave is CBD. “CBD has no direct connection to immune health whatsoever,” he said, although people might try to infer it does because it could support sleep or stress relief. Another example he pointed to is omega-3 fish oil. He highlighted a company’s product listing on Amazon.com. “They’ve changed their ad on Amazon, so the first thing it says is ‘Immune and Heart Support,’ Omega-3s have really no effect on the part of the immune system that we want when we’re talking about colds, flu, and bacteria. Zero. It’s more of on that inflammatory effect that the immune system has. So, for me, is it a true statement? Yes, it’s immune support, but it’s not the type of immune support that I think people really understand.”

“These are things that can really hurt the consumer at the end of the day,” Foreman said.

Supplement companies should always ensure that they are conveying correct information to their customers and not exaggerating product claims. If you missed our webcast, you can still watch it for free at www.NutritionalOutlook.com/no_s/covid19_immunehealth.

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Editor-in-Chief
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On April 23, Texas’s Health and Human Services Commission proposed new rules to see “consumable hemp and hemp-derived products” such as hemp cannabidiol (CBD) regulated as food. Daniel Fabricant, PhD, CEO of the Natural Products Association (NPA; Washington, DC), explains that the new proposal in Texas would authorize CBD products to be sold where food is sold, no longer restricting it to being sold in dispensaries.

“Before, you could sell CBD within a hemp shop, such as in California and Colorado,” Fabricant explains. The new Texas proposal “is effectively making CBD a lawful commodity that you could have anywhere retail food is sold.”

This move by states to begin regulating hemp cannabinoids like CBD as food is a game changer, Fabricant explains. Most importantly, he says, it could lead to a patchwork of similar nationwide policies. Texas is the second state to propose state rules for CBD products. In April, Virginia Governor Ralph Northam signed a bill to classify hemp extracts as food. Fabricant says West Virginia has entertained similar proposals, but so far has not acted on them.

According to Fabricant, the fact that FDA at the federal level still does not authorize CBD consumable retail products has created a regulatory vacuum that states are now trying to fill themselves by releasing their own policy proposals. For instance, he says, it’s been nearly a year since FDA first held a public meeting to discuss regulatory issues related to cannabis compounds. “That was the end of last May,” Fabricant says. “Nothing’s happened since then.”

This inaction is now causing states to take matters into their own hands, Fabricant says. In an April 16 Associated Press article announcing Virginia’s signed bill, Kyle Shreve, executive director of the Virginia Agribusiness Council, stated: “If the FDA does not start approving CBD products, people are going to take them without regulation. That’s what the bill says, we are going to treat them like they are approved by the FDA so we can start regulating them.”

Fabricant says he expects more states in the coming months to start proposing their own CBD regulatory policies. “I think the dominos are going to start falling,” he says. “I think you’ll see more and more states follow suit because they realize there’s been a demand [for these products], they realize there’s an interest, and they also realize that FDA’s asleep at the wheel.”

Fabricant says that while he understands why states feel the need to act on their own, whether or not these state regulations are beneficial depends on what the regulations entail. “The devil is in the details,” he says. Of Texas’s regulations, which cover not only retail rules but also regulations related to manufacturing and testing, Fabricant says: “They seem fairly reasonable. The issue is how they are implemented.”

As states construct their own policies, there are numerous concerns including how complicated it will become for those who manufacture and sell CBD products to navigate a patchwork of regulations. Take testing standards, he says. “If Virginia is going to have a different set of testing standards or say, ‘Hey, you can only use this lab in Virginia,’ and Texas does the same thing, it’s going to be challenging.”

A regulatory patchwork will also impact consumers, who may have trouble making sense of the rules, he adds. “You could have labeling requirements for one state that you don’t have in another state. That’s going to make it crazy for consumers. How do they know what product is what?”

The ideal, he says, would be for FDA to issue federal regulations. “There should only be one set of rules. We don’t need a patchwork of 50 sets of rules,” Fabricant says. “That’s where there’s really an environment for confusion, and the consumer loses out.”

He continues: “We’ve really got to be careful on details because you could end up with really very different provisions in two different areas. So, we’ll look forward to working with the states. We certainly applaud and understand why they did what they did, because FDA’s just been completely slow, but ultimately, we’re going to need one set of standards on this. One set of rules...It’s time for FDA to get in the game and act, because otherwise I think you’re just going to see more and more states follow suit.”
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Navigating a Claims Minefield

Attorneys discuss the hazards of making immune health claims against the backdrop of the COVID-19 pandemic.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

It’s no secret that immune health and wellness products have fared especially well with consumers during the COVID-19 pandemic. Market researchers have reported seeing unprecedented dietary supplement sales gains in the U.S. in the initial weeks of the pandemic as consumers turned to supplements to support their health. Immune health ingredients such as vitamin C and elderberry have become clear winners during the pandemic, with near-term sales spikes to make any supplement marketer’s head spin. With so much consumer demand for immune health products today, companies, both on the retail end and on the ingredient supply end, are seeing value in lasering in on their immune health product portfolios—and advertising their immune health products. Caution should be taken, however, in how a company frames its products or ingredients especially during the time of this pandemic. Nutritional Outlook hosted a webcast on May 29 titled “COVID-19 and Immune Health Claims: What Not to Say (Do’s and Don’ts),” during which attorneys discussed why companies need to tread the immune health space very carefully especially during this time. (Another speaker at the event was pharmacist and author David Foreman, who discussed the many ways in which consumers can be misled by deceptive immune health marketing. Turn to page 7 to read more of his insights.)

Who’s Watching?

During the webcast, two speakers—attorney Katie Bond, a partner at the law firm of Amin Talati Wasserman LLP, and Megan Olsen, vice president and associate general counsel for the Council for Responsible Nutrition (CRN; Washington, DC)—stressed that dietary supplement claims are being heavily scrutinized amidst the pandemic by regulators at both the federal and the state level. Olsen said that since the beginning of this year, when news about the COVID-19 crisis began spreading globally, FDA, either alone or in conjunction with the FTC, has issued more than 60 warning letters, a vast majority of which involve products illegally marketed as dietary supplements. The products run...
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the gamut, including both ingestible and topical products, and ranging from vitamins and cannabidiol (CBD) to herbal products, zinc, colloidal silver, and elderberry.

State attorneys general are also closely watching this space. Oregon regulators even enacted an emergency rule (Rule 137-020-0260) to deal with products making illegal COVID-19 claims, said Olsen. And then there are other groups like the National Advertising Division of the BBB National Programs and the consumer advocacy group Truth in Advertising (TINA) who are actively scrutinizing supplement claims.

Types of Claims

Bond and Olsen discussed the types of product claims that can run companies into trouble.

First and foremost, of course, are blatantly illegal disease claims. It goes without saying that disease-treatment claims are not allowed within the realm of dietary supplements and that no one should be claiming that their natural product or ingredient can treat or prevent COVID-19. Yet, FDA and FTC warning letters demonstrate that companies are making express claims that their products can prevent, treat, mitigate, diagnose, or cure COVID-19.

FDA has prioritized going after such egregious disease claims, the low-hanging fruit, said Olsen. "Looking at the warning letters that FDA has put out over the last year, I will say that all the warning letters did appear to include at least an explicit mention of coronavirus or COVID-19," she said. "I don't think this is surprising. FDA has limited resources, so they truly are trying to go after the products that are likely the most harmful to consumers because they actually talk about their effect on coronavirus and COVID-19."

While many responsible companies know to refrain from making such express disease claims, they can run into trouble when it comes to "softer," implied claims, both attorneys said. These are claims or other advertising or marketing elements that, "by implication, suggest that the product can have an effect on coronavirus or COVID-19, either preventing you from getting it or treating it," said Olsen. "Companies...are making those softer claims that are still disease claims nonetheless, talking about, 'Hey, we can help boost your immune system in these times of a global health crisis.'"

She continued: "Companies, even if they may not be getting on FDA's radar" with disease claims, "could still be making implied claims about coronavirus and about how a product could help you during these very difficult and scary health times, could find themselves the subject of scrutiny by other organizations or class action attorneys."

So, what has FDA said is allowed to be said about immune health products? Said Olsen: "FDA [says] an immune health claim can be appropriate when you are simply talking about ongoing support for your immune system, not suggesting that it's going to stop you from getting diseases or [issues] threatening your health in other ways."

Ahead are some of the takeaways from Bond and Olsen's presentations.

Don't make disease claims or mention COVID-19.

Companies should not say that their supplement product can address any identifiable characteristics or signs/symptoms of the disease. "I think it's fairly obvious to say you can't talk about coronavirus or COVID-19," said Olsen. "But companies should also be very careful that they're not saying or implying through the context of their ads that their product could have an effect on a respiratory illness. Or some of the things I've seen are talking about inflammation and the anti-inflammatory effects of a product, because my understanding at least with coronavirus is that there's concern about inflammation within cells and how that affects your immune system. And so, just be careful that you aren't moving into those territories where you're suggesting that the product not only would have an effect on the actual disease itself but the signs or symptoms of the disease." Firms should avoid "anti-inflammatory" and "antiviral" claims, she said.

Companies should also refrain from saying that a product could help mitigate adverse effects of any COVID-19 pharmaceutical treatment.

Added Bond: "You mention coronavirus, you mention COVID-19 in the context of your product sales and marketing, and that alone is going to really increase your risk of getting one of these letters...For example, saying 'COVID-19 defense product: These are all a bad idea in terms of risk.' Don't make claims like "natural prevention for coronavirus" or "natural virus remedies" either, she said.

Don't make implied claims linking your product to COVID-19.

Bond highlighted one warning letter FTC sent to a company. The company said in its marketing that a social media influencer would be using the company's product daily while traveling during this time. "The FTC took the position that is implying that it's going to apply some kind of disease treatment or prevention of coronavirus. Again, a very bad idea. Very risky," she said. Making indirect references to the current pandemic by saying things like "These are the times you need to protect yourself" is also risky, she said.

Don't use words like boost, defend, or protect.

When regulators "see that kind of language, they up the ante," said Bond. "They think that that kind of language conveys to the consumer that this is going to boost, defend, or protect you against a certain disease. In the past, she said, regulators would flag this language related to illnesses like cold or flu, but now they are specifically looking for these claims in association with COVID-19. Bond added: "You put these words with any kind of reference to COVID-19...it's just incredibly risky." And the FTC will certainly demand a "very well-controlled clinical test in humans" to substantiate such a claim.

Even the word build can be risky, she said. She pointed out that in a warning letter, FTC flagged a company's claim that "Many mushrooms can help build your immune system. I take reishi frequently simply for general health."

On the other hand, she said, using words like immune support is generally more acceptable. "An 'immune support' claim is pretty vague, pretty fluffy, and in general, they're not going to require something like a well-controlled clinical trial to make that kind of claim. They're going to allow something lesser, maybe even something like a good in vitro study on a biomarker of immune function, that in many cases is going to be good enough."
Another risky word is *therapeutic*, said both Bond and Olsen, due to its association with medical terminology. Instead of using that term, they suggested using a word like *effective*.

What if words like *defense* or *protect* are part of your product’s name? This could cause a company to be looked at more closely, said Olsen, and so she advised that companies be extra careful to make sure that their other claims are compliant with the law.

**Watch your website, blog, newsletter, and social media behavior.**

Specifically, watch what you’re linking to. “The FTC as well as the FDA have taken issue with companies providing a link to an article on COVID-19 and then, in the same breath, on the same website, or in the same social media, linking to where products can be purchased,” said Bond.

Other advice from Bond: Don’t use the words *coronavirus* or *COVID-19* as a tag on a product website. She said, “Be sure you have an eye on how you’re optimizing your website, what meta tags you’re using, keywords, AdWords, hashtags, domain names, all of that. In the very technical sense, FTC and FDA typically do not treat a meta tag or a keyword alone as an advertising claim...That being said, if it links up to something deceptive, they will go ahead” and enforce against it.

**Be careful when citing research studies.**

“I know there have been a number of studies that have come out or are ongoing about how certain vitamins, for example, could have an effect on coronavirus or COVID-19,” said Olsen. “But be very, very careful if you want to cite the research to consumers, because especially in a lot of these studies, the study title itself will talk about coronavirus and COVID-19, and that could be a red flag to regulators that you’re moving over into disease claim territory.”

**Watch how you show up in Internet searches.**

Said Olsen: “Maybe the product itself, when you look at the ad or look at the page where you can buy the product, says nothing about coronavirus, but FDA and FTC are looking at the fact that, ‘Did your ad pop up when I searched for ‘How do I support my immune system?’”

**Can you still talk about your company’s charitable works associated with COVID-19?**

In a nutshell, yes, said the speakers, as long as you are not suggesting something like your product is being used in a COVID-19–related clinical study.

**Ingredient suppliers should also exercise caution.**

While it’s true that regulators tend to focus more of their claims scrutiny on consumer-facing product marketers, ingredient suppliers can and have in the past gotten in trouble with regulators for making unscrupulous product claims. And if a finished-product marketer starts making disease claims based on claims the ingredient supplier has made, those claims could be traced back to the ingredient supplier. Conversely, ingredient suppliers should also keep track of how the companies they sell their ingredients to are making claims about a supplier’s ingredient, to make sure they are compliant.

**Retailers should also be cautious.**

Some FDA warning letters of late cc’d retailer Amazon.com because the product that was the subject of the warning letter was sold through the Amazon Associates Program. “Now, the letters don’t actually accuse Amazon of doing anything wrong here, but it seems to be FDA’s signal that because of the serious nature of these claims, they really are looking at retailers to hold them accountable for the types of claims that they’re making money off of because companies are selling these products through these platforms or in their stores.”

**The Stakes Are High**

Regulators are not only scrutinizing supplement claims in a big way during the pandemic, they are so concerned that they’ve even created consumer education websites to tell consumers about products that have received warning letters, said Olsen.

Expect this kind of scrutiny to continue, said both Olsen and Bond. As more state attorneys general start to take their own actions toward regulating this space, they will also trigger more class action lawsuits not just for disease claims but also implied claims that plaintiffs will argue run afoul of legal structure-function claim rules.

If you missed this webcast, you can still watch it for free on demand at: *www.NutritionalOutlook.com/no_s/covid19immunehealth*
The human microbiome—that vast collection of bacteria, fungi, and viruses occupying the human body—comprises trillions of microorganisms, outnumbering our own cells by 10 to one, per some estimates. And if we look really, really closely, we can find at least one million of those microbes on each square centimeter of skin.

Not long ago, the logical response to such a foreign presence would have been obliteration: Scrub the gunk away. But the more we learn about our skin's microbiome, the more friend than foe these organisms appear to be.

This isn’t news to Paul Schulick, cofounder of For The Biome (Dummerston, VT), a skincare company that views the microbiome as the route to healthy skin. “The general population is beginning to understand that the innate resilience of the skin lies in the skin-microbiome relationship,” he says. “As more consumers become educated on the skin-microbiome relationship, they’ll naturally want to do a better job nourishing and protecting their skin’s microbial environment.”

On the Surface

With the value of the U.S. probiotic cosmetics market set to hit $37.8 million by 2025, per market researcher Hexa Research last April, those consumers will have their pick of products promising to do just that.

“Awareness of the skin’s microbiome is still in its infancy,” Schulick says, “but it’s being helped by the fairly well-established understanding of the gut microbiome. The concept of taking probiotics for a healthy gut is now shifting to, ‘Okay, how do we do this for skin?’”

The conversation is already playing out on social media, notes Cécile Kalem, global marketing, active ingredients, BASF Beauty Creations (Pulnoy, France). “Consumers are fully aware of the value of preserving their skin microbiome,” she says, and a recent BASF analysis found females aged 13 to 24 leading the discussion on Instagram, in particular.
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Hot topics include dry and sensitive skin, from redness and rashes to eczema and psoriasis; aging concerns like wrinkles, expression lines, and crow’s feet; and the consequences of oily skin: blackheads, pimples, scars, and their respective treatments.

Savvy brands are listening. As such, says Paula Simpson, beauty market expert and founder of Nutribloom Consulting, "There’s been an influx of microbiome-friendly skincare products hitting the market. Research on the human microbiome has exploded in the last 10 years, and with new discoveries about how microbes affect our health, a diverse skin microbiome is now considered key to keeping skin healthy."

**Frontline Defense**

The reason is elementary. The skin is the body’s largest organ—its frontline barrier against the elements, infection, toxins, and the loss of water and nutrients.

At the very front of that frontline is what’s known as the visual stratum corneum, which is the uppermost, nonliving layer of the epidermis and “also the most active site where the skin microbiome resides,” Simpson explains.

“The microfloral component of the skin’s barrier is in constant contact with our environment, and works collectively to protect against invading pathogens, to influence or alter the immune response, to provide a source of nourishment to skin cells, and to break down natural metabolites on the skin.”

**Our Microbiomes, Ourselves**

This symbiosis between our microflora, our environment, and ourselves is consistent with “holo-genome theory,” which Schulick describes as “an acknowledgment that the whole, or ‘holo,’ of our microbial and human DNA, or genome, is a collective community: a ‘hologenome.’”

The upshot: We don’t evolve alone. “Our microbiome acts as our copilot in this process and, in many ways, is as much a part of us as our human cells,” he says. “We’re part of a vast, independent network of nature’s kingdoms and the environment—all connecting, communicating, competing, and cooperating with each other for resources, survival, longevity, and legacy.”

**In the Balance**

That’s an intense relationship, and one that our modern world too often upsets—with the consequences plain to see.

Clinical studies associate skin conditions ranging from accelerated aging and skin sensitivity to atopic dermatitis and even dandruff with some level of what Simpson calls microbial “dysbiosis.” That could mean an over- or under-population of the bacterial genera or subspecies normally present on healthy skin, or a flourishing of transient or pathogenic bacteria that perturb otherwise balanced skin microflora.

For example, evidence hints that eczema could reflect a depleted skin microbiome, Schulick notes, “which, in turn, affects the skin’s ability to retain hydration, while increasing reactivity.” Meanwhile, acne may signal a diet- or stressed-induced imbalance of what he calls “commensal” bacterial strains. “The point,” he says, “is that all of this is connected: the skin, the microbiome, and the way we live our lives.”

Thus, he views such conditions less as “problems” than as messages from our skin. “What’s interesting,” he says, “is that when someone is experiencing chronic stress, eating a nutrient-deficient diet, or struggling with mental health, they most likely have an unbalanced microbiome.”

**Down and Dirty**

Another habit wreaking havoc on a healthy skin microbiome is “our societal obsession with cleanliness and lack of awareness as to what harsh skincare ingredients do to our microbiome’s health,” Schulick continues. “Our microbiomes are part of us, yet we constantly stress and strip them.”

Simpson agrees: “Part of the problem is over-cleansing, over-treating, and using too many products that congest, strip, or break down a healthy, balanced skin microbiome.” Yes, exfoliation and peels decongest and reveal new skin cells, but they also eradicate the oils and microbes that moisturize, balance, and guard against skin damage.

So, a case of dermal dryness may not be a call to moisturize. “The issue,” Schulick says, “could be the trans-epidermal water loss that can occur in skin whose microbiome is continuously stressed or wiped out with harsh products.”

What to do? “Repopulating a rich and biodiverse microbiome is a great place to start,” he suggests, “and typically shows rewarding cosmetic results while helping skin adapt gracefully as it ages. Giving the skin a ‘breather’ allows the microbiome to recalibrate and flourish. Eliminating harsh ingredients is one of the best things to do for microbiome health, and one of the easiest to enact.” Formulators: take note.

**From Science to Skincare**

“We know that certain ingredients disrupt the skin’s natural processes,” Schulick continues. “So, the obvious approach is to exclude these ingredients from product formulations and focus on the nutrients that feed the skin’s microbiome.”

Prime among those are probiotics. “As science and research advance,” Simpson says, “skincare and nutraceutical formulations will become more specialized and targeted. Clinical studies already correlate and target specific bacterial genera, subspecies, and strains to specific skin-health conditions, and integrated approaches via nutrition, supplementation, and skincare will continue to evolve.”

She’s particularly bullish on the nutrition arm, as evidence suggests that probiotics’ effects on skin—to say nothing of systemic health—are superior through diet and supplementation over topical skincare alone,” she says.

In the gut, for example, “probiotics influence skin through the immune system, regulating inflammation and supporting the skin’s metabolism and barrier function to promote a balanced skin microbiome,” she explains. “Probiotics also detoxify and rid the body of pathogens or bad bacteria in the gut before they’re absorbed into the bloodstream. This communicative process between the gut and skin depends upon the trillions of microbes in the gut that trigger immune-communicative receptors that then influence skin—the gut-skin axis.”

That said, a role for topical application remains. “Applied topically, probiotics can complement nutrition by helping rebalance...
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the skin’s ecosystem while controlling or destroying harmful bacteria that aggravate the skin,” she says. “They calm and nourish skin cells, and encourage water retention and skin moisture by strengthening the skin barrier—the primary active site of the skin microbiome—and provide extra support and protection against environmental and chemical pollutants and the harmful pathogens we expose or apply to our skin each day.”

Adds Shaheen Majeed, president worldwide, Sabinsa (East Windsor, NJ), “Because products in topical format are comparably less complex to develop and face less rigorous regulations, they can be developed more quickly than most other delivery systems.” Another advantage: most skincare formulations are applied topically—so they have the familiarity factor—and “yield results rapidly since they’re used directly at the affected site.”

In both topical and ingested formats, the species, subspecies, or strain makes or breaks the product. Unfortunately, current topicals usually mount what Schulick calls “a spray-and-pray approach: spraying yourself or ingesting strains that may not be compatible with your skin or gut’s commensal bacteria. You don’t know for sure which strains will take root or if they’ll encourage a healthy microbiome.”

The lesson, says Simpson, is that “not all probiotics are created equal. It’s imperative to use the correct bacterium according to the mechanism of action on the skin. For example, S. thermophilus has been found to promote skin hydration and ceramide production; other strains may help calm inflamed or blemished skin. To be effective, a product must provide a formulation with appropriate, viable strains.”

Preposterous

Probiotics are hardly the only game in town for formulating microbiome-based skincare. As Schulick says, “We’re seeing that the most effective way to nourish the skin’s microbiome is with prebiotic and postbiotic nutrients.”

He describes the former as “like a fertilizer for your microbiome,” while the latter are “invaluable nutrients created during fermentation.” Fermenting whole ingredients with strains like L. reuteri, L. rhamnosus, and L. plantarum produces “remarkable results for the skin,” he notes, adding that the postbiotic nutrients they create “truly ignite communication between the skin and its microbiome, helping to nourish the connection between the skin and all its response systems.”

BASF’s Kalem notes that the cosmetic use of fermented postbiotic ingredients first took root in Asia but is expanding as options and awareness grow. For its part, BASF produces its Phytofirm Biotic ingredient by fermenting non-GMO, traceable European soybeans with a specific strain of L. plantarum. In vitro and in vivo tests show that the peptide- and lactic acid–rich extract increases production of the dermis’ key architectural proteins collagen and elastin, promoting a more youthful appearance, she says.

As for prebiotics, Sabrina Leoty-Okombi, R&D project leader at BASF Beauty Creations, notes, “Oligosaccharides are the first molecules we think about—both for the benefits of their film-forming action, which improves the skin barrier and maintains good hydration—and for their sensorial properties, which are interesting for formulas.”

Majeed notes that xylitol, rhamnose, fructooligosaccharides, and inulin “are the most widely used prebiotics for nourishing probiotics. Obviously, it’s important to choose a prebiotic that can enhance the growth of the specific microorganism of interest, so that only a selective microbiome is propagated.”

Prebiotics also promote scalp health. “Our researchers studied the specific microbiotic composition of an oily scalp versus a normal scalp and highlighted the existence of six bacterial species more abundant on a healthy scalp,” Kalem explains. The result is Scalposine, a BASF ingredient that she says rebalances the scalp’s unique microbiome. An internal clinical study showed that it acts prebiotically to allow the recolonization of oily scalps with the beneficial strains, with in vivo results showing increased scalp comfort and longer time to hair re-greasing between washes.

Rabbit Holes and Roads Ahead

So, what’s next for microbiome skincare? A mix of opportunities and challenges, say the experts.

“In other fields,” notes Aurélie Courtois, scientific communication at BASF, “living bacteria have proven their effectiveness in nutraceutical and pharmaceutical applications, but little data currently exists on the ingredients incorporated into cosmetic formulas. That’s now the most challenging goal of the cosmetics industry: the introduction of live bacteria into cosmetic formulations.”

Simpson is optimistic. “Higher grades of efficacy and formulas tailored to specific skin conditions will improve and expand as science and formulation stability evolve,” she believes.

Nevertheless, the science supporting microbiome-based skincare is complex stuff, not to mention “a shift from how we’ve normally cared for our skin,” she says. So, when it comes to consumer demand, “There’s still a lot of work to do.”

No wonder Schulick considers education “the biggest challenge. This concept requires an acceptance of the interconnectedness of whole-body and mental wellness and how this impacts the health of the microbiome and, in turn, the skin.”

It may be something of a “rabbit hole,” he says, “but it’s one that most will be glad they jumped into. I know I am, and it’s what continues driving my motivation to grow public awareness.”

Reference

RENOWNED PHLEBOLOGIST, Dr Frédéric VIN discusses a syndrome that is much more common than we think and its prevention with grape seed OPCs.

What is Heavy Legs Syndrome?
Heavy legs syndrome is an associative syndrome, often indicative of a chronic venous insufficiency. It may be accompanied by pain, heaviness, paresthesia, tingling or cramps, sometimes with swelling in the ankles and legs. The principal characteristic is that it occurs in the upright position and regresses during decubitus, which is indicative of a relationship with orthostatism and venous stasis. Aggravated by heat and during premenstrual periods, heavy legs syndrome is more common in people working in a standing position. It sometimes appears even before the presence of varicose veins and shows signs of parietal pain probably related to tissue oxidation of the venous wall.

How prevalent is it?
Between 20% and 30% of the general population could be affected. Epidemiological studies, in particular the Edinburgh Vein Study, involving 2912 subjects, have shown that leg heaviness is more frequent in women than in men and that its intensity worsens with time and age. There is also an increase in its prevalence during the course of the disease, with the increased frequency of heavy legs often associated with valvular insufficiency of the saphenous trunks. There is no doubt that the symptomatology of heavy legs has socio-professional repercussions due to the discomfort it generates on a daily basis.

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Better than Botox.” That’s what I overheard the lady at my gym say about her new cannabidiol (CBD) night cream. And from the looks of her, she appeared to be onto something.

Of course, my instincts as a health-and-wellness journalist automatically filtered her claim through a sieve of skepticism. But my 44-year-old forehead and I really wanted to believe.

So should we?

Not exactly, says Ari Sherman, president and cofounder, Evo Hemp (Boulder, CO). “I can understand where she was coming from,” he concedes, “but I don’t think anyone should expect similar results to Botox injections from CBD.”

They should expect something, though, right? After all, why else would everyone from beauty brand Kiehl’s to national pharmacy chain CVS be opening their doors to cannabis skincare products?

“There are tremendous benefits to using CBD in skincare,” says Sherman. It’s just that we’re only beginning to understand what, precisely, those benefits are, how CBD produces them, and how skincare products can deliver them to consumers who really want to believe.

What’s in a Name?

Writing last year in Here Comes Cannabis: How Legalization Will Disrupt Global Industries, Zora Milenkovic, head of drinks and tobacco at Euromonitor International (Chicago), noted that “[h]empseed oil beauty and personal care products have been on the market for decades.”

But merely declaring “hemp” on a label no longer creates the buzz it once did. “The new superhero ingredient in beauty, CBD, has replaced hemp in references,” she says.

Of course, some may be wondering, “What’s the difference?” Given all the hemp, CBD, and other cannabis ingredients in personal-care products, you can’t blame them.

Simply put, all cannabis plants—including industrial hemp and marijuana—produce cannabinoids, naturally occurring compounds that defend the plants against environmental threats. Of the more than 100 cannabinoids that cannabis plants produce, CBD and tetrahydrocannabinol (THC) are the most well-known.

These cannabinoids trip endogenous cannabinoid receptors in their source plant to effect changes in the plant’s cells—which makes sense: that’s what they evolved to do. But what’s more surprising is that they do the same in us, acting on the human endocannabinoid system to produce therapeutic effects in CBD’s case—and psychoactive ones in THC’s—as well.

But while CBD—which can account for as much as 40% of a cannabis plant’s extract—is distributed throughout the stems, stalks, and flowers, you won’t find any in hemp oil. That’s because hemp oil—also billed as hempseed oil or Cannabis sativa seed oil—is pressed from hemp seeds, which contain no CBD at all.

Grow Operation

Notes Julie Winter, founding partner and COO of CBD For Life (Red Bank, NJ), “While hempseed oil doesn’t have the same benefits as CBD, it’s extremely high in antioxidants and omega-3 and -6 fatty acids.” In other words, it’s still good for you.

But as “one of the most abundant and heavily researched cannabinoids,” Winter continues, CBD remains the big draw.

Indeed, Jeanette Jacknin, MD, a holistic dermatologist speaking on behalf of Medterra (Irvine, CA), points to an increase of 370% in the
Your Source for Quality Botanical Extracts
Beauty viewed by FDA as drug claims.”

In the cosmetics world, beauty is skin noticing benefits will mark the products or “otherwise alter the appearance of products may only claim to “cleanse,” claims—which, at this point, are pret must still be safe and bear permissible brands containing CBD and hemp products “gateway applications for companies looking to dip at least their toes into the pool of hemp and CBD formulation.”

Why? “One of the main reasons is that FDA’s publicly stated position on CBD as not permissible in a dietary supplement, food, or beverage does not extend to non-ingestible products like topical skincare,” he says. Rather, as long as hemp and CBD ingredients meet the definition of *industrial hemp*—containing 0.3% THC or less—they’re fair game in topicals.

This loophole hasn’t escaped Ari Sherman, president and cofounder, Evo Hemp (Boulder, CO). “There’s no doubt in my mind that the recent explosion of CBD in skincare is completely because of FDA, from retailers down to brands,” he says. His company works with retailers like CVS and Whole Foods, whose legal teams draw the line at topical CBD products. “So if the lawyers tell the retailers,” Sherman says, “the retailers tell the brands. And the brands decide what to manufacture based on the channels they sell to.”

Granted, Prochnow notes, skincare products containing CBD and hemp must still be safe and bear permissible claims—which, at this point, are pretty limited. Because nondrug topical products may only claim to “cleansing,” “beautifying,” “promote attractiveness,” or “otherwise alter the appearance of the skin,” claims that tout more enticing benefits will mark the products as drugs with FDA. As Prochnow says, “In the cosmetics world, beauty is skin deep—and so are claims. Any claims related to something deeper than the surface of the skin are likely to be viewed by FDA as drug claims.”

number of online search trends for “CBD beauty” in the first two months of 2019 alone. Such interest, she believes, “is aided by the fact that today’s consumers want more natural products instead of laboratory-synthesized ones.”

Caution Ahead

But along with an increase in online searches for CBD skincare, we’re likely to see an increase in misleading information about the science behind its efficacy, as well.

“The body of scientific literature on CBD is growing rapidly, with studies ranging from *in vitro* tests to trials in humans,” says a representative of Aceso Wellness, a subsidiary of Denver-based Dixie Brands. However, it’s still the case that “Right now, a simple Google search can produce a wealth of anecdotal stories about CBD’s benefits, but it can also provide a terrible amount of misinformation,” the task facing researchers and industry is thus to separate anecdote from actual benefit.

What we can say with confidence right now is that CBD, in concert with other active ingredients, “can work wonderfully on the skin,” CBD For Life’s Winter says. “CBD itself helps to calm and provide comfort. It’s a fantastic ingredient for anyone with sensitive skin, or anyone experiencing breakouts.”

Evo Hemp’s Sherman thinks that rather than likening CBD to Botox, a comparison with resveratrol—the polyphenolic antioxidant found in wine, berries, and other plant foods—is more apt. Resveratrol “has been clinically shown to help reduce signs of aging and repair and protect skin,” he says; CBD, similarly, “is also a really powerful antioxidant and anti-inflammatory.”

In fact, Sherman points to a growing number of government-approved clinical trials corroborating CBD’s antioxidant activity. He also notes that cannabis plants produce CBD and other cannabinoids as natural protectants against ultraviolet light—“so it’s the plant’s natural sunscreen, and it has these incredible properties that are great at not only protecting our skin but repairing it, too.”

Top-Level Benefits

It’s worth asking whether or not skincare’s topical application and transdermal absorption sufficiently convey CBD’s benefits to skin. According to Medterra’s Jacknin, they do. “CBD is readily effective when applied topically, as the skin has a huge endocannabinoid signaling system with cannabinoid receptors in keratinocytes, sebaceous glands, hair follicles, nerves on the hair follicles, and dermal immune cells,” she explains. “They, in turn, work on the immune system via cytokines, mast cells, and other immune cells, as well as other types of receptors.”

The effect is rapid. “Ingested CBD takes as much as thirty minutes to several hours to produce the desired outcome, depending on the patient’s GI tract transit time, absorption, and liver function—after which the CBD passes into the bloodstream to the organs,” Jacknin points out. By contrast, “Topical CBD products applied directly to the skin and problem areas can be designed to be absorbed rapidly, and they don’t have to go through the lungs or GI tract to eventually get a partial amount to the skin.”

And while Sherman notes that the skin’s barrier function is hard to breach, he concedes that dermal CBD application represents “a super-effective way of helping heal the top layer of skin. Just like a lot of other skincare products, it’s going to help improve the skin’s look, reduce the signs of aging, and more.”

Dose Response

Determining how much CBD to incorporate into a skincare product is another challenge in light of the vagaries of topical application and the influence of other actives in the formula.

Adds Jacknin, “Each individual responds differently to dosing with cannabinoids just as with other remedies and drugs. So some people with thin skin, a large peripheral blood supply, and certain genetics will respond to a much greater degree than others.”

Sherman admits there “haven’t been a ton of trials on dosing, especially on topical products,” which can give dose determination a guesswork feel. But he says that skincare products will often declare the total amount of CBD per package—as, for example, the 175 mg of CBD in his company’s 1-oz roll-on, or the 750 mg in the line’s 4-oz tube of cream.

And to account for loss through skin, his company tends to settle on a 25- to 30-mg transdermal dose as roughly equivalent to a 15-mg oral dose.
Entourage Effect

Then again, a skincare product’s CBD dose may matter less than any adjunct ingredients the formulation contains to enhance absorption. As Aceso’s spokesperson reiterates, “In these applications, the CBD or hemp extract can be combined with emollients or other ingredients to enhance absorption by the skin.”

Even better, formulators can take advantage of naturally occurring compounds in the cannabis plant that potentiate CBD’s effects, as well.

That’s because although isolated CBD has advantages as an ingredient—an unobtrusive aroma; an easy-to-use powdered or crystalline format—it lacks many of the adjutant compounds, “like polyphenols and other antioxidants, ketones, and omega fatty acids,” Sherman says, “that are proven to be beneficial.”

By contrast, full- and broad-spectrum hemp extracts contain these compounds. “That’s why I always try to educate people on the broad benefits of hemp extract and not to get so tied up in the hype of CBD,” Sherman says. “CBD itself is great, but the true benefit that’s driving a lot of the health benefits we’re seeing is this group of other compounds in the hemp plant.”

Forward Focus

And researchers are learning more about them by the day.

Jacknin notes that Raphael Mechoulam, the Israeli organic chemist who in the 1960s first identified THC, recently announced the stabilization and synthesis of CBDA, a cannabinoid that he and his research team estimates is 1,000 times as potent as CBD. “I think there will be truly amazing strides in research in the new few decades,” Jacknin says. “We haven’t hit the tip of the iceberg in the science behind CBD and skincare.”

Sherman also anticipates research into novel cannabinoids. “CBD is awesome,” he says, “but there are all these other great cannabinoids that have tremendous benefits within the hemp plant, like CBG (cannabigerol), CBN (cannabinol), or CBC (cannabichromene).”

He even encourages more government involvement in the science. Why? “So that next time I have this conversation, there will be a tremendous amount more that we can base statistics and claims on,” he says. “I’m hoping that in the near future our government restrictions will open the floodgates to research, because that’s when things will get really interesting.”

Reference


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.
The COVID-19 pandemic, and society’s response to it, has strained every aspect of our lives, from our social connections and work routines to the public-health infrastructure and global supply chains. But it did help cannabis, at least at the start, says one market research firm, Headset, who noted sales gains for edibles and cannabis-containing beverages of 28% and 14%, respectively, as of April 2. Since then, other reports have emerged at industry events generally observing a potential leveling off of CBD product sales as the pandemic persists. Still, the fact remains that there is a sizeable group of customers interested in these products.

Of course, these discussions are happening notwithstanding the fact that it remains illegal, per FDA regulation, to introduce into interstate commerce foods or beverages that contain hemp-derived cannabidiol, or CBD, the non-psychoactive cannabinoid that’s become one of the buzziest health-and-wellness ingredients of the decade.

Which raises the question: With FDA busy vetting coronavirus tests, therapeutics, and—one can hope—an eventual vaccine, will the agency have the bandwidth to develop a regulatory framework for permitting CBD’s use in foods and beverages? And if the answer is no, what does that mean for FDA enforcement, the sector’s future, and—most crucially—consumer safety?

Under Investigation
Those questions remain as unsettled as they were in December 2018, when President Donald Trump signed into law the 2018 Farm Bill.

For while that bill legalized industrial hemp—provided it contain less than 0.3% tetrahydrocannabinol (THC) content—and removed it from Schedule I of the Controlled Substances Act, it did not set out a legal pathway for formulating foods, beverages, or dietary supplements to include hemp-derived CBD.

Thus, says Marc Ullman, of counsel, Rivkin Radler LLP (Uniondale, NY), “FDA’s position remains the same as it’s been since day one: CBD is not a lawful ingredient in foods or dietary supplements.”

The agency arrives at this position via a plain reading of the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibiting the use of an approved drug or investigational new drug (IND) that’s been the subject of “substantial clinical investigations”—which is precisely what pharmaceutical-grade CBD isolate was in the research that GW Pharmaceuticals conducted on its groundbreaking anti-seizure drug Epidiolex, which remains the first and only CBD product to enjoy FDA approval.

In other words, the FD&C Act stipulates that if a party makes the effort to investigate a substance’s potential as a drug—as GW Pharma did with CBD—that party essentially gets “first dibs” on the substance’s commercial use, and that its subsequent appearance as
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Any Questions?

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Food and Drink

a garden-varietiy dietary ingredient in foods, drinks, or supplements is outside the law.

Room to Maneuver

Unless, that is, “FDA exercises its power of enforcement discretion to allow it onto the market as a dietary ingredient,” says Megan Olsen, vice president and associate general counsel, Council for Responsible Nutrition (CRN; Washington, DC).

So crystal-clear, right?

“What’s even less clear,” says Justin J. Prochnow, shareholder, Greenberg Traurig LLP (Denver), “is whether FDA’s prohibition applies specifically to CBD isolate”—the subject of GW Pharma’s investigations—or more widely to “anything with CBD in it, like full-spectrum or broad-spectrum hemp extract.”

His reading: “FDA’s been purposefully vague about this distinction.” While he views the agency’s approach as technically in accordance with the law, expanding that approach beyond a strict consideration of CBD isolate to cover all CBD-containing ingredients would be—“again, in my opinion”—an overextension.

“The law states that the article investigated is excluded,” he reiterates. “But does the investigation of CBD isolate extend to anything with CBD in it? I don’t think that’s the intention or spirit of the law.”

Too Hot or Too Cold?

For his part, Ullman sees FDA’s approach as “on one hand, overly legalistic, and on the other, dangerously lax.”

Evidence of excessive legalism lies in the agency’s plain-language interpretation that the FD&C Act prohibits CBD’s food and supplement use “with no apparent openness to any serious dialogue about alternate pathways to market,” he says.

Dangerous laxity arises in FDA’s refusal “to take action against any foods or supplements marketed as containing CBD in the absence of unapproved new drug claims,” he says—this despite the agency’s “serious concerns about the lack of any adequate regulatory filings for the GRAS [Generally Recognized as Safe] use of CBD in food, or as a new dietary ingredient [NDI] for use in supplements.”

Fair Warning

Prochnow, too, sees gaps in FDA’s enforcement. “It certainly hasn’t been proactive,” he notes. “It’s been very reactive, and it’s only taken action in the form of warning letters to companies that have painted FDA into a corner by making egregious disease claims. It still seems that FDA doesn’t really know what to do.”

Of the batch of warnings that FDA dropped in November 2019, for example, several took aim at companies promoting gummies as foods or claiming that their products “treat” inflammation, diabetes, and other conditions, Prochnow notes.

And now that some CBD brands have even made treatment and prevention claims in the COVID-19 space, FDA’s had to lay the hammer down there, as well. Says Prochnow, “Out of 60-plus letters, only one didn’t take a company to task for egregious disease claims.” Let that be a lesson.

Food for Thought

Also aware of the wild claims out there, Olsen nevertheless views FDA’s treatment of the CBD question as in line with its treatment of other regulatory questions before it. “They’re a science-based organization,” she says, “and they’ve been very clear that their number-one mission, whatever ends up on the market, is to protect public health.”

Which is what makes the question of allowing CBD in foods and beverages so tricky—even more than in supplements. As Olsen points out, there are “nuanced differences” between CBD’s safety profile in foods and beverages and its profile in supplements.

Douglas “Duffy” MacKay, ND, senior vice president of scientific and regulatory affairs, CV Sciences Inc. (San Diego, CA), agrees. Consider the scientific gaps in establishing CBD’s safety in children and during pregnancy. “This isn’t because CBD is known to be unsafe,” he explains, “but because there’s limited scientific information about its use in sensitive populations.”

Conventional food regulations don’t easily accommodate the labeling of, say, granola bars, candy, and soda as “Not for use during pregnancy and/or in children,” either, he continues. By contrast, “Dietary supplement labels can clearly say, ‘Not for use in children under 18’ or ‘Do not use if pregnant.’”

And food- and beverage-manufacturing standards “aren’t set up” to deliver specific amounts of a biologically active substance like CBD per bite or serving, MacKay claims. Once again, supplements by regulation must supply a specific amount of an active per serving.

“Finally,” he says, “there’s no post-market adverse-event reporting for foods and beverages like there is for dietary supplements.” And that surveillance, he insists, “is important to herbal-product safety.”

No wonder CV Sciences predicted that FDA wouldn’t permit the food or beverage use of CBD. “In fact, we included this opinion in our public comments at the FDA public meeting on May 31, 2019,” MacKay notes. “Our observation has been that entrepreneurs have been so excited about CBD’s business potential that the scientific and regulatory facts and our opinions were largely dismissed.” In the meantime, CV Sciences is focusing on a path toward CBDs use in supplements first.

Show Them the Data

It’s not as though companies like CV Sciences, or an association like CRN, for that
matter, oppose an eventual road toward delivering CBD via foods and beverages. Rather, Olsen says, “We just think that FDA should tackle the easier issue — how to approach this in supplements — and understand that the food path might take longer.”

Either way, FDA says it needs more, and better, data before it can render a prudent decision.

Ullman can’t blame them. While ceding the ultimate analysis to the toxicologists, he says, “In my experience, there seems to be a lack of serious, published literature that could be used to support FDA’s effort to provide a pathway for moving, should it choose to do so.” Brands can better make their case, he believes, if they supply “serious, science-driven published data.”

FDA recently removed a hurdle to their doing so by allowing companies to protect proprietary data — and their investment in it — from the disclosures required by the normal NDI notification process. Now companies can submit data to the docket confidentially, Olsen says, and CRN is encouraging them to do so.

As far back as 2018, CV Sciences published preclinical toxicology studies on its food-fiber hemp CO₂ extract to establish a GRAS intake level. “Now,” says MacKay, “as companies wake up to the reality of FDA regulation, we see more serious companies following our lead and publishing their own toxicology data.”

**Hurry Up and Wait**

Even so, they may have to hurry up and wait before FDA uses this data to inform its decision-making. As Ullman says, “The vast majority of the agency’s resources and scientific expertise are rightly focused on dealing with COVID-19. So, I would expect a slowing — even from FDA’s normal glacial speed — on this.”

Unfortunately, he continues, “Because FDA’s taken the position that CBD cannot legally be an ingredient in food or supplements, it has created a situation where it’s unable to conduct any real regulatory inspections of companies producing these products. Failure to have adequate quality or GMP programs in place is potentially a serious vulnerability to a large segment of the trade.”

The agency has already expressed concerns about the category’s heavy-metals content, Olsen notes; but if they were enforcing inspection regulations — that is, if they’d spelled out a legal route to market — they could handle such concerns with CBD just as they do with any dietary ingredients. “It’s another botanical,” Olsen says. “Companies know how to deal with heavy metals in botanicals and put into place appropriate good manufacturing processes. It harms consumers the longer they let this market linger without any effective oversight.”

Ultimately, Olsen concedes, “We respect that this is a challenging question that they’ve never confronted.” But the progress that advocates had made before the COVID-19 crisis is worth sustaining. “As the country hopefully begins to return to normal over the next few months,” she says, “we can build on that progress, maybe even as early as the fall. Because this needs to be solved, sooner rather than later.”

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.
There’s no regulatory definition for the term clean energy in the food, beverage, and dietary supplements space. But that doesn’t mean there aren’t responsible ingredient suppliers defining the category, developing standards based on partnerships with finished product manufacturers (and ultimately demand from consumers), and then doing due diligence to ensure their standards are met and their promises are delivered.

And that hasn’t stopped consumer interest in a category that Brian Zapp, director of marketing, Applied Food Sciences (Austin, TX), refers to as “a movement,” one that he believes is evolving with the consumer base.

Brian Appell, director, global communications, OmniActive Health Technologies (Morristown, NJ), points to Nutrition Business Journal’s “2019 Condition-Specific Report,” which placed the energy supplement category at $4.3 billion, representing nearly 10% of supplement market sales. And supplements are just one of the categories that include energy ingredients.

According to Lu Ann Williams, director of innovation for market researcher Innova Market Insights, new product launches in the U.S. market featuring energy/alertness claims in the food and beverage category (including supplements) grew by 12% from 2015 to 2019.

Williams further advises that clean labels and natural energy concepts are on the move. Based on labels from new product launches in the food and beverage and supplement space, she reports an increase from 2015 to 2019 in use of the following attributes: “no additives/preservatives” (up 17%), “GMO-free” (up 13%), “gluten-free” (up 13%), and “natural” (up 9%).

Appell points out that the clean-energy category “continues to evolve as consumers redefine what clean means to them.” As an example, he refers to sugar, which he says by all accounts is considered natural but “has become a target to avoid by many scrutinizing consumers.”

The Appeal of Clean Energy
Without a clear-cut regulatory definition, is clean the new natural, a marketing term that appeals to consumers because it represents seemingly healthy lifestyle choices and earth-friendly values that especially appeal to up and coming generations of Americans?

“Defining clean energy may also come down to the source of the active and what other ingredients or excipients are used to make the product,” says Appell. “For example, OmniActive’s Xtenergy is naturally sourced from coffee beans using a natural extraction process and a solvent-free coating. Traceability and sustainability may also check a box for clean energy as consumers continue to weigh their purchase decisions against how they impact people and the environment.”
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Marianne McDonagh, vice president, sales, Bioenergy Life Science (Ham Lake, MN), says her company “defines clean-energy ingredients as all encompassing in other words, clean ingredients are all natural, clean label, third-party quality tested, and sourced from a consistent and transparent supply chain from batch to batch.” The company’s Bioenergy Ribose, a fully soluble, versatile, unique five-carbon carbohydrate and a staple ingredient for more than 30 years, exemplifies these standards, says McDonagh.

She’s also on board with growth in the category, verifying that “from our own sales data within the past 12 months, demand for clean-label, energy-enhancing ingredients has increased steadily.”

Applied Food Sciences, too, is energized by where it sees clean-energy products going. Zapp indicates that the company’s clean-energy/focus ingredients account for about 70% of its customer inquiries. With four ingredients in this category—including PurCaf Organic Caffeine, a highly water soluble, organic powered extract, standardized at 95% pure caffeine and extracted from green coffee beans—Zapp views the term clean as a philosophy of what his company strives to accomplish.

“In all practical functions, the philosophy driving the clean label is really that evolution of free-from,” Zapp says. Does the label have 40 ingredients with long chemical names that require 30 trips to Dictionary.com to understand? “I think the proof of a clean label is in the pudding,” he says.

When it comes to his company’s philosophy, Zapp focuses beyond the label. “We define clean as aligning with the entire demonstration of the transparency as a whole. We want to make sure we’re providing clean ingredients from the seed all the way to the label. It’s the bigger picture of it all,” he says.

**Added Functionality Fuels Clean-Energy Market**

Zapp cites added functionality as a key trend to hit the clean-energy market. Referring to products that go beyond the initial function of energy drinks, he uses an example that might appeal to someone in an office job: the addition of branched-chain amino acids (BCAA) in combination with caffeine, providing functionality for mental focus.

“Physical energy is important to consumers, but equally important, and even more so according to some experts, is mental energy,” says Appell.

He refers to a November 2019 Euromonitor report noting that energy drinks are popular with consumers because they provide a mental boost during their busy day. But, Appell points out, the report also indicates that the energy category is evolving beyond just the boost, that formulas are targeting more specific benefits like mental focus and alertness.

RiaGev, Bioenergy Life Science’s latest propriety ingredient formulation, also fits the added functionality trend. McDonagh says that although the ingredient focuses more on healthy aging than just energy, “it was inspired by our desire to develop a product that controls metabolism while enhancing energy.” By combining Bioenergy Ribose with nicotinamide, an ingredient that delivers unique cellular benefits which promote healthy aging, RiaGev boosts energy while balancing the stress associated with energy production, says McDonagh.

Zapp mentions a second trend that involves companies marketing premium energy products that take a holistic, simplistic, minimalistic, and clean approach.

“You’d be looking for six ingredients or less, very clean in nature, a sparkling water energy drink. A little bit of flavor, no sugar, no carbs, zero calories, organic certified, but still with caffeine. Cleanly presented,” says Zapp.

**Marketing to the Millennial Mindset**

According to Zapp, Millennials were responsible for the explosion of energy drinks back in the late nineties. Today, he believes, those same Millennials, now older and more mature, with families, and money to burn, are also the drivers of the clean-energy market.

“The market has evolved with the consumer base,” he says. And that evolution is a revolution of sorts. Millennials’ more settled lifestyles have converted their interest from these “very loud, monstrous energy drinks, more geared for hanging out with your buddies,” says Zapp, to energy products that fit their new station in life.

Millennials don’t want to leave the energy category because, Zapp says, “they’re accustomed to energy drinks.” But, he adds, “they’re evolving into something that’s more natural looking, maybe something with a tea-based caffeine.”

Another piece of the puzzle for Millennials, says Zapp, is transparency and authenticity. “There is a really deep-rooted experience that Millennials have about lack of trust or skepticism with the capitalistic mindset. And so, the more manufacturers say, the less these consumers are inclined to believe it.” Zapp recognizes it’s a tricky audience to market to because if you’re trying to sell a premium product, you want to talk about what makes it premium. But with a skeptical consumer base, he advises “show me, don’t tell me.”

“We’ve had a couple of our customers come with us to our organic coffee farm in southern India,” says Zapp. “They bring their own videographer with them and capture them helping with the harvest and talking with pickers and farmers—demonstrating ‘this is where your caffeine comes from, where your key active is sourced.’”

In turn this allows consumers to hear and see a story, to couple their values with the products they’re researching. “And now,” says Zapp, “the consumer starts to tell their own story about [the brand]. They start to build their own trust value in it and are more inclined to share it with others as well.”

**The Yin and Yang of Caffeine**

Caffeine can be considered king of the energy category. Citing research from Innova Market Insights, Zapp notes that caffeine is still the go-to choice to energize, with caffeine representing 34% of new food and beverage (including supplements) launches tracked with energy/alertness claims in the U.S. in 2019.

Delivery methods are increasing, too. Says Zapp, “people are trying to figure out a way to get caffeine into everything. That’s certainly one area of innovation.”
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“Companies are looking for alternative options in their formulations besides caffeine,” says Bioenergy Life Science’s Marianne McDonagh.

And while caffeine’s not likely to be dethroned any time soon, “Companies are looking for alternative options in their formulations besides caffeine, because consumers are driving this new demand,” says McDonagh. Bioenergy Life Science’s two energy-related ingredients, Bioenergy Ribose and RiaGev, are both caffeine free.

Appell concurs about caffeine’s popularity, calling it “the most popular commodity for energy.” But, like McDonagh, he sees a consumer demand in the making.

To fill that demand, innovators are producing caffeine ingredients that maintain the benefits of caffeine—increased energy, decreased fatigue, and improved focus and concentration—but without the detrimental side effects such as jitters and crashes.

In short, Appell says, “Companies are developing solutions to make ingredients like caffeine work better.”

His firm developed Xtenergy to preserve the nootropic effects of caffeine and avoid the undesirable effects. Says Appell, “OmniActive’s Xtenergy sustained-release caffeine is built on a spray-melt technology that provides a very consistent payload of natural caffeine over an eight-hour time period, without reported jitters, tenselessness, or crash typically experienced with instant-relief caffeine.”

However, Appell also notes the need to innovate with caffeine-free ingredients. “Consumers are increasingly looking for alternatives to caffeine that can deliver the same effects. This is, perhaps, the biggest area of innovation because caffeine itself is highly commoditized, and new formulas offer new opportunities to differentiate with unique benefits.” OmniActive offers enXtra, made from a proprietary blend of Alpinia galanga, a commonly used spice in Asian cooking, as that caffeine-free alternative. Appell advises that several studies have shown that enXtra provides a same-day effect in supporting mental energy, specifically alertness and better focus.

Applied Food Sciences’ clean-energy ingredients all contain caffeine, but in a nod to innovation, the company’s Amatea Organic Guayusa Extract is standardized at 20% caffeine and is extracted from an Amazonian super-leaf that is a cousin to yerba mate, but with more antioxidants. Zapp says that with guayusa, there is a mechanism triggered which helps slow down the fluttersy, anxious feelings some people get from caffeine.

**Science Drives Innovation, Safety, Category Growth**

For any product category that includes products that are consumed, a dedication to scientific research and science-based principles may not be considered trendy but should be considered as a foundation that drives the category forward. It’s science with a twist that drives innovation.

Appell is interested in science for specific benefits, claiming that “energy is no longer the benefit. It’s what energy means to the consumer that needs to be supported by science.” He explains: “Consumers are looking for specific benefits that suit their current needs. Whether it’s mental energy or physical energy, companies are starting to define their energy solutions by those benefits.”

Zapp is most intrigued by a human clinical trial his company is currently conducting in the eSports community of competitive, organized video gamers, a population that requires keen focus, steady energy, and mental stamina to succeed. Specifically, the research study population is Fortnite players, with the intention to compare guayusa to other caffeine sources and placebo, with results covering overall game performance, accuracy, reflexes, memory recall, and more. The trial is expected to be completed this year.

Bioenergy Life Science adds another consideration for innovation. “Focus upon research continues to drive innovation in the category with scientific methods and standards that are closer to the pharmaceutical model,” advises Michael Crabtree, ND, the company’s director of science. “The natural progression of research through animal testing into human testing, the acquisition of feedback, and carefully modeling the potential for adverse events prior to marketing campaigns ensures safety to the end user. The European model for regulating dietary supplements is probably closer to what the U.S. will see in the future.”

Whatever the future holds for energy products, the “clean” concept appears to have sustainability.

Judy Blatman Communications LLC specializes in strategic counsel, media training, writing, and talent solutions. Her company philosophy is: “When life gives you lemons, make guacamole.”

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Antioxidants represent a staple category in the dietary supplement market. But there has always been fierce debate about how much consumers really understand about the term antioxidants. Plenty of people support the term and believe in its health relevance, and yet others think antioxidants has lost a lot of its meaning over time.

Is the Term Antioxidant Still Relevant to Consumers?

On a very basic level, Ross Pelton, scientific director, Essential Formulas (Irving, TX), believes the term antioxidant still resonates well with people. “The generation of free radicals is one of the primary causes of biological aging, and an antioxidant’s ‘job’ is to neutralize excess free radicals,” he says. “For this reason, antioxidants will always be relevant.”

On the other hand, Morris Zelkha, CEO, TriNutra (Ness Ziona, Israel), believes the term antioxidant is too general and not strong enough on its own to create sales. “Consumers are looking for more focused activities, and labels should clearly indicate what the extract is and what it has been clinically researched to do,” he comments.

Marcia da Silva Pinto, PhD, technical sales and customer support manager for Evolva (Reinach, Switzerland), thinks antioxidants have more of a holistic connotation. “Consumers are more aware that the ‘antioxidant’ benefit carries a more holistic meaning because it comprises benefits in several areas such as brain health, skin health, heart health, and, lately, immune health,” she says.

Evolva’s David Tetzlaf, director of marketing, adds his perspectives on this issue. “Data from Innova show that while there is healthy growth in products marketed as ‘antioxidants,’ most manufacturers are introducing products based on health indications, such as brain health, bone and joint health, eye health, heart health, and immune health,” he says. “These health indications are what drive consumers’ online searches or in-store purchases. Therefore, while antioxidant is still relevant as many consumers understand the term, it is not the primary driver of consumer purchases as they evaluate products more holistically.”

Antioxidants have broad appeal because they have been linked to disease prevention and health maintenance, notes Steve Holtby, president and CEO, Soft Gel Technologies Inc. (Los Angeles), who says educating consumers about antioxidants has not been easy because it requires an understanding of cellular biochemistry and physiology. “Marketers have simply touted that antioxidants help protect the body against oxidative damage caused by free radicals,” he says. “Properly promoting these key nutrients...
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requires taking scientific evidence and presenting it to the consumer in a simple, understandable manner.”

**Antioxidants Lifted by COVID-19 Pandemic**

TriNutra’s Zelkha believes the COVID-19 pandemic has increased supplement sales exponentially, particularly products that support immune health—and that consumers may classify antioxidant ingredients in this group. “Consumers are also looking outside of the supplement aisle and looking to food, beverage, and even cosmetics with added antioxidants,” he claims.

Elyse Lovett, senior marketing manager, Kyowa Hakko (New York City), has also noticed an uptick in demand for antioxidants that support immune function during this time. “While antioxidants can’t prevent against the virus, I think it’s important to understand that there are ways consumers can maintain or increase their immunity with supplements,” she adds.

Kyowa Hakko manufactures Setria, a branded form of glutathione. Known as a “master antioxidant,” glutathione is found naturally in most cells in the body and can regenerate other antioxidants like vitamins C and E. It, too, offers immunity and detoxification benefits, the company says.

Since the novel coronavirus pandemic unfolded, veteran antioxidants like vitamin C are once again surging in popularity given their connections to immunity.

According to Rob Brewster, president of Ingredients by Nature (Montclair, CA), consumers are looking to do anything that helps them feel more in control of their health, and taking immune support supplements is a way they can do that. “Some antioxidants are even able to function synergistically for better results,” he adds. “Citrus flavonoids, for example, are recognized for their synergistic benefits with vitamin C to improve bioavailability and enhance support against free radical production.”

Soft Gel’s Holtby also believes that antioxidants tend to have more strength together than alone. “Some antioxidants may not have relevant biological activity on their own and they do not work through identical biochemical mechanisms. Together, however, antioxidants constitute an interlinked defense system that protects against diseases associated with oxidative stress,” he says. Holtby also points out that most antioxidants lose their protective power once they have quenched a single free radical.

“Five antioxidants—alpha-lipoic acid, the complete vitamin E complex (tocopherols and tocotrienols), vitamin C (in both fat- and water-soluble forms), glutathione, and coenzyme Q10—are unique in their synergistic ability to ‘recycle’ one another into their active antioxidant forms,” he explains. “Selenium, an essential cofactor of the enzyme thioredoxin reductase, and flavonoids are also proven antioxidants in the body’s defense system against oxidation,” he adds.

Bruce Brown, president of Natreon (New Brunswick, NJ), considers antioxidants that support immune health one of the fastest growing markets today. He offers some examples of where he sees potential.

“Many consumers are aware of the benefits of potential immune-boosting properties of vitamin C and elderberry, but there are so many other options that provide immune support along with a variety of health benefits,” he says. “Natreon provides unique adaptogens standardized to bioactives with antioxidant potential. For instance, the bioactives in Sensoril ashwagandha support a healthy immune response and have been shown to reduce everyday stress, improve sleep and the ability to focus—all of which are needed during these unique times.”

He goes on to say that the potent polyphenols in another of the company’s ingredients, Capros amla, used to support healthy circulation, support a healthy immune response. The same goes for the company’s PrimaVie Shilajit, an herb standardized to fulvic acid, a bioactive that has been shown to modulate a healthy immune response, the company says.

**Breakout Trends in Antioxidants**

Among the notable trends in today’s antioxidant market, Evolva’s Tetzlaf notes higher demand for beauty-from-within products, which often include antioxidants for skin health. For resveratrol products specifically, he says more than 31% of product launches in 2019 featured an antioxidant claim and nearly 20% of those launches were for skin health, which was higher than any other indication, including heart health.

There are, however, some terms that have become turnoffs for consumers, such as antiaging, according to Sam Michini, vice president of marketing and strategy, Deerland Probiotics & Enzymes, (Kennesaw, GA). He insists consumers are turning away from any product shouting that it is “antiaging,” and embracing terms like healthy aging and mindful aging, and that there is a subtle but important difference between these terms. “Healthy aging and mindful aging suggest that an individual has more control over how he or she constructs a healthy regimen that addresses the physical, mental, emotional, spiritual, and social,” Michini says.

Finally, as trends have encouraged the idea of adopting healthy, balanced diets, Sevanti Mehta, president of Unibar (Houston, TX), believes the opportunities to supplement a vast array of carotenoid antioxidants has become more possible, especially in replacing synthetic ones with natural versions.

“For the last few years, the food industry has also been making a switch from an abundance of synthetic antioxidants to natural ones,” Mehta points out. “Natural antioxidants are more environmentally friendly and safe and provide a solution for consumers that abstain from synthetic additives. Studies have also shown that natural antioxidants are able to be completely metabolized, in contrast to synthetic.”

**A Roundup of New Antioxidant Developments**

From 2015 to 2019, the antioxidant category witnessed a 5.7% increase in the number of product launches with antioxidant claims, in-line with the growth of general vitamins and minerals, which grew around 5% during the same period, according to market researcher Innova Market Insights. Helping fuel this growth were several new product introductions and recent research from various antioxidant suppliers.

Solarplast is Deerland Probiotics & Enzymes’ latest antioxidant entrant. An extract of organic spinach, Solarplast is enzymatically enhanced through a proprietary manufacturing process.
“Chloroplasts, such as those found abundantly in spinach and other leafy greens, are organelles within a plant that help it convert sunlight into energy, which helps the plant to grow,” Michini explains. “Chloroplasts in Solarplast contain a natural abundance of antioxidants, energy molecules, and molecular chaperones, and each plays a role in healthy aging by encouraging proteins to fold and refold. Chloroplasts also contain antioxidants that provide the components required to perpetuate the glutathione recycling mechanism (the recycling of spent antioxidants). Solarplast contains all the elements necessary for production and regeneration of glutathione.”

Eevia Health Oy (Seinäjoki, Finland) provides wild-harvested chaga from subarctic forests. Chaga, the company says, has been recorded as the strongest antioxidant ever registered in any natural food, and is particularly regarded for its anti-inflammatory and detoxifying properties. “Our pure, 100%-traceable extract is currently undergoing ex vivo models, but we may have novel focus in terms of looking at accumulated effects and total leverage of the product through indirect mechanisms,” says company CEO Stein Ulve. “For instance, any mode of action that promotes translation and activity of endogenous antioxidative enzymes is facilitating exponential antioxidative efficacy. A single enzyme can catalyze tens if not hundreds of thousands of antioxidative reactions, while a single antioxidative molecule can perform only one reaction.”

In 2019, Evolva introduced Veri-Sperse resveratrol, which brings increased bioavailability that is nearly twice as high compared to standard resveratrol, according to a recent human clinical trial. “This innovative product answers consumers’ concerns around bioavailability, in addition to increasing the accessibility of easy-to-take products such as fortified instant powder beverages, on-the-go gels, chocolate bars, and melt-in-mouth powder sticks,” says Tetzlaf. Veri-Sperse resveratrol allows formulators the flexibility and ability to meet rising consumer demand for improved absorption.

And that’s not all. In summer 2020, the company expects to introduce what it calls Veri-te Aqua resveratrol, says Clare Panchoo, vice president of health ingredients at Evolva. Veri-te Aqua is the first water-soluble resveratrol on the market, combining NovaSOL technology from German company Aquanova AG and Evolva’s Veri-te resveratrol. This new ingredient, Panchoo says, will give formulators the ability to develop crystal clear functional beverages, liquid shots, and liquid capsules.

Most recently for HP Ingredients (Bradenton, FL), its ParActin Andrographis paniculata has been revealed to have a new mechanism of action. “Oxidative stress occurs when there are too many free radicals for the body to neutralize,” says CEO Annie Eng. “Prolonged oxidative stress may cause damage to DNA and activates NF-κB, which leads to inflammation.” ParActin’s chief active ingredient, andrographolide, has been shown to create an increase in the Nrfl2-Keap1-antioxidant response element (ARE) pathway. Andrographolide increases Nrfl2 activity, cleaving it from KEAP1, allowing the body to increase antioxidant proteins and enzymes, such as glutathione, superoxide dismutase (SOD), and catalase (CAT),
which leads to a reduction in oxidative stress and inflammation.

Brewster from Ingredients by Nature says the company’s lemon flavonoid blend, Eriomin Glucose, is unlike many others in that its antioxidant ability plays an integral part in helping to properly manage prediabetes as a result of supporting the body’s efforts to normalize blood glucose levels. By addressing oxidative stress and the production of free radicals, Brewster says the blend’s primary flavonoid eriocitrin helps to directly support the pathways that suppress cytokine generation and insulin resistance.

With the release of a new ingredient, Eriomin Esport, Brewster says its lemon flavonoids play an integral role in managing oxidative stress and balancing the level of free radicals in the brain, thereby helping neurons to communicate optimally. “Interest in video games continues to rise, and the trend is seen among all demographics because of their accessibility via smartphone, computer, or video game consoles,” he adds. “Now more than ever, video gamers need health solutions, and antioxidants like citrus flavonoids represent a perfect opportunity to address that demand.”

Natreon’s antioxidants are focused on skin health both topically and via “beauty from within.” In human clinical studies, the company says PrimaVie Shilajit has been shown to support the development and maintenance of skin health. “Internally, PrimaVie Shilajit has been shown to increase collagen synthesis, which is the key structural component of the skin, while externally PrimaVie Shilajit has been shown to improve the surface integrity of the skin,” Brown explains.

NextFerm (Yokneam Illit, Israel) just recently conducted a single-center, open-label, single-dose study on 12 healthy adults. Ex vivo analysis of human serum samples showed that Astaferm, the company’s astaxanthin derived from Phaffia rhodozyma, offers significant protection against lipid peroxidation, indicating strong antioxidant activity.

Meanwhile at TriNutra, the company has unveiled ThymoQuin, which it says is the first cold-press standardized black seed oil on the market. It is naturally standardized to 3% thymoquinone, which is its key phytonutrient. In addition, the free fatty acid content of ThymoQuin is below 2%, which helps amplify its anti-inflammatory effect, the company says. The product recently received self-affirmed GRAS status, as well as the recent publication of a study demonstrating its beneficial effects on the reduction of blood pressure in healthy adults.

Unibar just launched CapsiClear, which is the first xanthophyll carotenoid extract to be standardized to 50% capsanthin. “Capsanthin has little to no previous research, but two recent studies show that it has a wide range of benefits for eye health. Carotenoids like lutein and zeaxanthin have shown an ability to improve protection against blue light, but capsanthin has a benefit profile that extends beyond what other carotenoids have displayed,” Mehta says. “When standardized to 50%, capsanthin becomes bioavailable enough to be able to help reduce intraocular pressure via oral administration, which is very unique.”

Soft Gel Technologies offers an exclusive, patented hops resin extract in softgels called Perluxan, which provides natural, fast-acting relief for minor aches and pains, without the side effects commonly associated with prescription anti-inflammatory products. “The alpha acids in Perluxan are potent antioxidants and are effective at both scavenging free radicals and inhibiting the chemical processes that cause oxidation,” Holtby explains. “Extensive laboratory tests have shown that Perluxan consistently exhibits low IC50 values for both Random Scavenging Activity (RSA) and Lipid Peroxidation Inhibiting Activity (LIA), with a strong effect upon copper induced oxidation in LDL.”

“Recent research has also demonstrated that up to 40% of pain-causing biochemicals (e.g., PGE2) in the body come from a non-enzymatic pathway related to free radicals; it is now considered that a viable anti-inflammatory agent should also have antioxidant activity,” Holtby adds.}

**From 2015 to 2019, the antioxidant category saw a 5.7% increase in the number of product launches with antioxidant claims, says market researcher Innova Market Insights.**

Becky Wright has more than 20 years of experience in the nutritional field as a writer and marketer. For the first part of her career, she spent 13 years as the editor of an industry trade publication called Nutraceuticals World. Most recently, she served as marketing manager, innovation, at Omnisource Technologies, and before that as director of marketing and communications for Aker BioMarine’s Superba krill oil brand. She currently runs Wright On Marketing & Communications, a small independent agency that offers a variety of marketing and communication services to clients, with a particular emphasis on the nutraceuticals market. She can be reached at becky@wrightonmarketing.com.
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Pet Nutrition’s Trans-"fur"-mation

Pet food and supplements are getting healthier and more functional.

BY MIKE STRAUS

The pet nutrition market is undergoing a shift that mirrors recent trends in the human market. As more consumers become conscious of their own diets, they are also increasingly asking questions about what they’re feeding their pets and searching for ingredients on par with what they would consume themselves. Data from Nielsen indicate that in 2018, American consumers spent $33 million on pet food that contains human-grade ingredients. Meanwhile, the U.S. pet supplement market reached a value of $636 million in 2018, according to Packaged Facts.

Pet owners are scrutinizing pet products more closely. Whether they’re looking for a dietary remedy for a condition, responding to a pet’s allergy, or simply seeking out more nutritious pet food, consumers are judging pet foods and pet supplements on nutritional content, functional benefits, composition and filler, and even packaging. As demand for healthier pet products continues to grow, formulators are expanding their product lines with clean-label and functional ingredients that pet owners can feel good about buying. Here are some of the ways that formulators are changing their products to appeal to health-conscious pet owners.

Curcumin Increasingly Popular for Joint Health

Functional benefits are driving the pet health market, and one of the most popular functions that consumers seek out is anti-inflammation activity for joint health. Joint pain is among the most common health problems that pets face. One cross-sectional observational study of radiographic images from 100 cats found that 91% of cats suffer from a degenerative joint disease, such as osteoarthritis, in at least one joint. The study also found that while there is a strong correlation between age and prevalence of osteoarthritis, even young cats are susceptible to the disease.

Leisha Jenkins, marketing associate for Verdure Sciences (Noblesville, IN), says...
that joint health and motor function support are some of the functions driving interest in turmeric and curcumin products for animal health. Jenkins says that joint health is increasingly becoming a top concern for the equine market. Larger animals like horses tend to be more prone to joint problems, Jenkins notes, and also require larger doses. “The equine market is seeking solutions for inflammation and joint health because of the propensity of joint injuries and joint issues in horses,” Jenkins says.

She continues: “For large animals like horses, price per dose becomes a concern for added functional ingredients,” which is why her company’s curcumin, Longvida, “offers a dose that is attractive and manageable for owners. There may be a significant opportunity in the equine market for an added ingredient that specifically targets issues like lameness, joint health, and inflammation.”

Curcumin’s performance in clinical trials is fueling its rise in popularity for joint health applications. One 2012 animal study on 18 kennel dogs examined the effects of curcumin and NSAIDs on the genetic expression of peripheral white blood cells in cases of osteoarthritis. The dogs were divided into two randomly assigned groups of dogs with osteoarthritis (n=6 and n=6) and one group of healthy dogs (n=6). The osteoarthritis groups were given either a twice-daily 4 mg/kg dose of curcumin, or a 5 mg/kg/day dose of the NSAID firocoxib, for 20 days. The control group did not receive any drug or supplement. Blood samples on all three groups were taken at baseline and after 20 days.

The study authors found that curcumin and firocoxib had similar effects on gene markers for osteoarthritis. However, curcumin specifically targeted the interleukin-18 pathway, while firocoxib did not. The study authors concluded that this different mechanism of action makes curcumin an effective complementary remedy. The curcumin ingredient used in this study is a curcumin phytosome ingredient called CurcuVET from supplier Indena S.p.A. (Milan, Italy).

Verdure’s Jenkins says that curcumin is being incorporated in several pet formulations, and formulators are increasingly targeting functional ingredients toward specific health applications. Branded ingredients in particular, she says, are becoming popular among finished-product formulators. “Incorporating branded ingredients into a product is another way to offer consumers an additional layer of confidence,” she says. “Branded ingredients offer a
layer of consistency and quality to support clean, reliable ingredients.”

**Specialty Formulations Target Working & Competitive Animals**

One emerging extension of the pet health market that is driving significant innovation is the professional animal market. Competitive animals like racehorses, as well as working animals like search and rescue dogs, have specific nutritional needs beyond those of house pets. Clinical data is showing that there may be benefits in tailoring specialty formulations to these kinds of animals.

One 2017 animal trial followed 16 search and rescue dogs for three months. The dogs were fed a high-protein, energy-dense diet according to each dog’s nutritional requirements based on body condition, body weight, and training activity. However, the dogs were randomly assigned to receive a diet that was either high (n=8) or low (n=8) in EPA and DHA omega-3 fatty acids, chondroitin sulphate, and glucosamine. All of the dogs were given hematology and clinical chemistry blood analysis tests, as well as lameness and joint pain evaluations, at baseline and once every 30 days. After three months, the dogs in the high-supplementation diet group showed higher values of erythrocytes, hemoglobin, and PCV/hematocrit relative to those on the low-supplementation diet. The study authors concluded that a high-supplementation diet may increase energy production during exercise and therefore improve dog performance during search and rescue tasks.5

Michael Crabtree, ND, director of scientific affairs for Bioenergy Life Science (BLS; Ham Lake, MN), says that protein-based fortification and supplementation is an effective means of improving diet for animals that struggle to meet their daily dietary requirements. “Food manufacturers often think in terms of vitamin fortification, which involves adding nutrients back in after processing,” he says. “But what isn’t usually discussed is the impoverishment of the energy content of food after processing. Adding high-energy molecules like D-ribose, vitamin B3, electrolytes, or CoQ10 provides a distinct advantage.”

Crabtree says that energy and protein fortification could be an effective and budget-conscious way to ensure that high-activity animals meet their daily nutritional intake requirements. His colleague, Vice President of Sales Marianne McDonagh, adds that functional ingredients like Bioenergy’s branded D-ribose are continuing to expand into the animal market for this exact reason. “BLS entered the equine performance market years ago, and we saw a lot of racehorse owners using Bioenergy Ribose for performance, recovery, and endurance. The success of that market prompted us to invest more research into animal nutrition, and last year we announced our decision to enter the pet nutrition market and help dogs, cats, and other animals around the world.”

**ALGORITHMS LEAD TO SMARTER FORMULATIONS**

Data and tech are now enabling brands to create custom pet health formulations. Direct-to-consumer brand Goodboy (Atlanta, GA), for instance, uses a computer algorithm to formulate customized functional supplements according to breed, age, gender, and weight.

**Grain-Free Fiber to Support Digestion**

Pet foods are increasingly diversifying their functional claims, with specific SKUs now tailored for specific purposes. Sandra Perryman, director of quality, food safety, and co-manufacturing for pet food company “I and love you” (Boulder, CO), says that there is a growing demand for customized pet food formulations that support particular life stages, breeds, or aspects of health.

“Foods that resonate with consumers contain ingredients that serve a purpose,” Perryman says. “For example, miscanthus grass is an alternative fiber source that is showing promise for digestive health support in dogs and cats. Miscanthus grass could serve as a substitute for cellulose or beet pulp in formulations.”

Perryman says that consumers are also seeking out pet food products that contain real meat, are grain-free, and consist of raw ingredients. Real meat, she says, provides essential nutrients and amino acids for dogs and cats that are often difficult to find from other sources. She notes that grain-free cat food is an essential requirement, as cats are obligate carnivores. For dogs, though, grain-free food is ideal for a dog with a grain allergy or intolerance. As for raw foods, consumers are looking for trustworthy brands that take the proper precautions.

“Many raw pet foods can be risky due to a higher risk of illness from salmonella,” Perryman says. “Our Stir & Boom product uses meat that is considered to be raw, but undergoes a proprietary high-pressure pasteurization process designed to reduce the risk of salmonella contamination.”

**Pet Owners Go Online for Human-Quality Ingredients**

While pet supplement usage is growing, pet owners are increasingly treating pet food as a first line of defense against various pet health issues, often treating pet food as a first line of defense against various pet health issues, often seeking out pet food products that contain real meat, are grain-free, and consist of raw ingredients. Real meat, she says, provides essential nutrients and amino acids for dogs and cats that are often difficult to find from other sources. She notes that grain-free cat food is an essential requirement, as cats are obligate carnivores. For dogs, though, grain-free food is ideal for a dog with a grain allergy or intolerance. As for raw foods, consumers are looking for trustworthy brands that take the proper precautions.

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**SUSTAINABILITY INITIATIVES IN PET SUPPLEMENTS**

Some pet health brands are moving toward sustainable packaging materials. Late last year, PureForm Pet Health Supplements (Chilliwack, BC, Canada) introduced the pet health industry’s first biodegradable canister and compostable shipping packaging.6
ailments. Functional ingredients are showing up in products with preventative, maintenance, and treatment claims for specific areas of pet health. Patrick Luchsinger, marketing manager, nutrition and pet food, for Ingredion (Westchester, IL), says that manufacturers are seeing an explosion in online sales. "There has been huge growth in online pet food sales, both on websites like Amazon as well as pet-specific shopping sites. Pet owners are using the Internet to become more informed on pet care, including how the latest ingredients can meet their pets’ changing health and wellness needs."

Luchsinger points to the humanization of pets as a strong driving force behind consumers’ buying habits. Consumers are increasingly perceiving their pets to be members of their family, he says, and are consequently including their pets in their lifestyle choices. “As many consumers consider themselves to be parents to their pets, they are feeding their pets high-quality food with clean-label ingredients like pea protein. Human eating trends like clean eating and non-GMO are consistently trickling over into pet foods, as pet parents want their pets’ diets to match their own diets.”

Pet Ingredients Offer Opportunities for Brands

Consumers now view pets as members of their families. As pet parents seek out natural, clean-label nutritional products for themselves, they will also look for those same trends in their pets’ food and supplements. Formulators and finished-product brands can capitalize on this trend by creating and marketing specialty products with human-quality ingredients, zero fillers, and specific, research-validated functional claims.

Mike Straus is a freelance writer living in Kelowna, Canada. He has written for publications including Canadian Chiropractor, Grow Opportunity, and Massage Therapy Canada.

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Novel Probiotic Combination May Improve Amino Acid Absorption from Plant Protein


A study recently published in Probiotics and Antimicrobial Proteins found that supplementation with certain probiotic strains improved amino acid absorption from plant protein.

In the study, 15 physically active men ingested 20 g of pea protein and were randomized to either receive placebo or AminoAlta (from SOFAR Americas Inc.; Petaluma, CA), a multistrain probiotic containing 5 billion CFU of Lactobacillus paracasei LP-DG (CNCM I-1572) and 5 billion CFU of L. paracasei LPC-S01 (DSM 26760), for two weeks. Following a four-week washout period, the groups crossed over. Blood samples were taken at baseline and at 30, 60, 120, and 180 minutes post-ingestion and analyzed for amino acid content.

Results showed that probiotic administration significantly increased the area under the curve for methionine (+20.0%), histidine (+40.4%), valine (+21.5%), leucine (+23.3%), isoleucine (+26.0%), tyrosine (+16.0%), total branched-chain amino acid (+22.8%), and total essential amino acid (+16.0%) concentrations.

“These physiologically significant gains suggest an attractive potential for administering probiotic organisms to optimize amino acid absorption following pea protein consumption,” said Ralf Jäger of Increnova, the scientific lead on the study, in a press release. “Taken together, this clinical study illustrates what could be an important nutritional strategy, not only to improve postprandial changes in blood amino acids, but also to overcome compositional shortcomings of plant proteins.”

As plant proteins often lack the robust amino acid profile of animal proteins, the accelerated transition to plant proteins has created concerns about the adequacy of the amount of amino acids available for the body to absorb, said Gregory Bonfilio, president and CEO of SOFAR Americas. “There are many subjects, primarily athletes, but also the elderly, pregnant or breastfeeding women, children, some vegetarians or vegans, who may need greater protein supplementation for different functions of the body. The diet, however, is not always able to supply adequate amounts of these macronutrients. As seen in our study, probiotic strains can help by acting as ‘boosters’ in the absorption of amino acids from plant proteins.”

Black Seed Oil May Support Healthy Blood Pressure


A study found that supplementation with a standardized black seed oil (ThymoQuin from TriNutra; Harrison, NY) supported blood pressure in healthy subjects. In the study, 20 subjects with normal blood pressure were all treated with a daily dose of black seed oil for six weeks. Following a three-week washout period, patients were given a placebo treatment for another six weeks. Subjects had their blood pressure tested daily throughout the study.

Results showed that following the six weeks of supplementation with the black seed oil, systolic blood pressure decreased in subjects by 11.2% and diastolic blood pressure decreased by 12.2%. An initial significant decline in blood pressure was observed in as little as two days. Following six weeks of placebo, subjects’ blood pressure elevated slightly.

“Almost a third of the adult population in America experience hypertension, and natural products, including Nigella sativa oil, have long been considered as a therapeutic remedy in many traditional medicine practices across the world,” said Morris Zelkha, CEO of TriNutra, in a press release. “This study demonstrated how ThymoQuin can help provide significant improvement towards healthy blood circulation measurements, which has not been seen from other more common varieties of black seed oil.”

ThymoQuin’s exclusive North America distributor is Barrington Nutritional (Harrison, NY).
Sabinsa has a range of functional ingredients which may find a suitable place in various functional food categories. Our versatile list of functional ingredients include Curcumin C3 Complex®, Curcumin C3 Reduct®, BioPerine®, Citrin® K BG, LactoSpore®, Saberry®, Selenium SeLECT® and Cococin™, which can be conveniently incorporated into specified foods as well as non-alcoholic beverages. All of these ingredients are GRAS-affirmed.
BioCell Collagen Protects Skin from UVB-Induced Photoaging in Animal Study


An animal study recently published in the Journal of Functional Foods found that supplementation with a patented hydrolyzed chicken sternum cartilage extract (BioCell Collagen from BioCell Technology in Irvine, CA) protected skin against UVB-induced photoaging. The ingredient contains naturally occurring hydrolyzed type II collagen peptides, chondroitin sulfate, and hyaluronic acid.

In the study, 40 hairless mice were either given placebo without UVB exposure, placebo with UVB exposure, 200 mg/kg collagen with UVB exposure, or 600 mg/kg with UVB exposure every day for 14 weeks.

Study results showed that supplementation with the collagen extract at both doses significantly improved skin elasticity compared to control, significantly reduced transepidermal water loss at 600 mg/kg, and statistically improved wrinkles. At 200 mg/kg, mice saw a 23.6% reduction in total wrinkle length compared to controls. At 600 mg/kg, mice saw a 28% reduction in wrinkle area, an 18% reduction in number of wrinkles, a 28% reduction in wrinkle length, and a 22% reduction in wrinkle depth compared to controls.

“These findings are consistent with prior research on the efficacy of BioCell Collagen as a safe and effective component to a skin health routine,” said Suhail Ishaq, president of BioCell Technology, in a press release. “Photoaging affects nearly everyone and is responsible for a vast majority of visible skin damage. While BioCell Collagen cannot replace your sunscreen, this study is further evidence that BioCell Collagen can serve as a safe, easy-to-take, noninvasive addition to a skincare regimen. Pairing daily oral supplementation of BioCell Collagen with a quality topical sunscreen to prevent damage can be the foundation of a good year-round skincare routine.”

Natural Pterostilbene Supports Skin Aging and Has SPF Benefits, Say Two Studies


Two recently published studies found that a natural pterostilbene (pTeroWhite from Sabinsa Corp.; East Windsor, NJ), isolated and purified from Pterocarpus marsupium heartwood and formulated as a cream, may provide antiaging, skin brightening, and natural SPF protection. In the first study, an open-label, single-arm, monocentric efficacy investigation published in Clinical, Cosmetic and Investigational Dermatology, 38 healthy volunteers applied the cream containing 0.4% pterostilbene for eight weeks.

Compared to baseline, dermatological assessment, together with instrumental and image analysis, found that pterostilbene improved skin brightness and elasticity, reduced the appearance of fine lines and wrinkles, and improved skin texture. Subjects also saw significant improvements in undereye fine lines at all time points, as well as in wrinkles, frown lines, and crow’s feet at the end of the study.

The second study published in the journal Cosmetics demonstrated that the ingredient has an SPF value both in vivo and in vitro, concluding that it would be a safe ingredient in topical sun protective formulations.

“We’ve long thought that natural pterostilbene had tremendous potential in cosmeceutical applications, which is why we began conducting research,” said Sabinsa founder and chairman Muhammed Majeed, PhD. “Investigations are continuing to further expand our knowledge to support new product applications.”

Fenugreek Extract Improves Strength and Muscle Mass in Recent Study


A study recently published in Translational Sports Medicine found that supplementation with a patented fenugreek extract called Testofen from Gencor (Irvine, CA) increased strength and muscle mass.

In the study, 138 males received either 600 mg of Testofen, 300 mg of Testofen, or placebo every day for eight weeks. Researchers measured muscle strength and endurance, functional threshold power, body composition, and sex hormones at baseline, week 4, and week 8.

Results showed that subjects given Testofen saw significant improvements in maximal leg presses compared to placebo. In the 600-mg group, subjects saw decreases in body mass of 1.2 kg, a 1.4% decrease in body fat, and an increase in lean mass by 1.8% at eight weeks. This same group also saw increases in testosterone concentrations compared to baseline at eight weeks.

“After years of research showing Testofen’s positive effects for men, we wanted to assess its efficacy on muscle strength and endurance,” said R.V. Venkatesh, managing director at Gencor, in a press release. “The results verified the powerful effects of Testofen and supported our initial hypothesis that participants would experience improvements in body composition, muscle performance, and endurance.”

“These significant and positive results show that Testofen may be an effective ergogenic aid for those wanting to rapidly improve their exercise performance and body composition above and beyond exercise training only,” added Chase Shroyoc, vice president of sales and business development. “We are thrilled about the results of this study and look forward to incorporating Testofen into its next sports nutrition product.”
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Any Questions?

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We are excited to announce our fifth Maggie Award from the Western Publishing Association for our article “Scaling Up Stevia.” Thank you to all our readers for making this award possible!

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Natural Sweeteners: The Next Generation

Stevia is innovating, but are other competitors on the rise?

BY SEBASTIAN KRAWIEC, ASSOCIATE EDITOR

T here is no shortage of innovation when it comes to natural sweeteners. Ingredient manufacturers are constantly improving their products and pushing the boundaries of what they can accomplish. Stevia sweeteners are an excellent example, because while they have been associated with certain formulation and flavor limitations, stevia manufacturers have made these concerns practically irrelevant.

“The majority of stevia product launches are new products, not reformulations, so these ingredients are also prompting significant innovation in many product categories, from energy drinks and baked goods to frozen treats and desserts,” says Andy Ohmes, global director of high-intensity sweeteners, Cargill (Minneapolis). “As a result, the market is now seeing expanding product launches featuring low-, no-, or reduced-sugar claims, especially in segments like bakery and dairy products.”

One such innovation is the use of fermentation to produce minor steviol glycosides such as Rebudioside M (Reb M) and Reb D, which offer a sugar-like sweetness without the perceived bitterness of other steviol glycosides such as Reb A. Cargill’s EverSweet ingredient is an example of fermentation-derived Reb M and Reb D. Other stevia firms like PureCircle (Chicago) use more typical leaf extraction for Reb M and Reb D production and have increased stevia acreage and bred stevia plants to have a naturally high Reb M and D content.

One of the few remaining challenges in the alternative sweetener space involves the functionality of alternative sweeteners in specific applications, particularly bakery. Sugar is highly functional when baking, providing not only sweetness but mouthfeel, texture, and structure. Stevia alone cannot provide the ideal texture and mouthfeel for a baked good, therefore the addition of bulking agents such as the alternative sweetener erythritol as well as a fiber sweetener such as chicory root fiber can help.

New Competitors

Stevia is not the only player in the natural sweeteners game. Continued innovation from other ingredient sources showcases just how competitive the natural sweeteners space is.

For example, one brand called Purecane (Amyris Inc.; Emeryville, CA) manufactures a Reb M product derived from sugarcane. This is accomplished by pressing the sugarcane to remove the juices and adding them to fermentation tanks filled with yeast. The fermentation process converts the sugar into Reb M, says Beth Bannerman, senior vice president of corporate communications and engagement at Purecane. The Reb M is then separated from the yeast. The finished product is a zero-calorie, zero-glycemic-index sweetener with the functionality of traditional sugar, says Bannerman.

“Our process produces the best tasting, zero-calorie sweetener that is healthy and uses about 10 times less land than stevia farms use,” explains Bannerman. “And we use Brazilian sugarcane, which is one of the most regenerative and sustainable plants on the planet.”

Standing Out

Ingredients like Purecane could pose a challenge to other natural sweetener companies because sugarcane already enjoys name recognition with consumers. So, while stevia has been the most successful natural sweetener of late, it should not turn its back on competitors coming up in the natural sweetener chain.

Above all, sweetener companies and formulators stay mindful that innovation and differentiation are important but only go so far if consumers don’t understand what they’re buying. For example, in a consumer survey conducted by Kerry International (Beloit, WI), stevia was just behind honey, sugar, and maple syrup as a preferred natural sweetener, but only 46% of the 760 surveyed consumers perceived stevia as natural. Other important and functional sweeteners were among those least preferred by consumers, including erythritol, monk fruit, and xylitol.

On the other hand, research from Mintel from 2019 shows that 59% of U.S. consumers would like to see more foods and beverages with naturally sourced sweeteners. So, as the market becomes more crowded, the way to compete for consumer spend may be through educational branding and helping consumers make informed decisions so that they can select the right natural sweetener for them.

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