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Nutritional OUTLOOK

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

October 2015
Vol. 18, No. 8

Industry in the **Crosshairs**

Dietary supplement quality control is a growing target, **p. 24**

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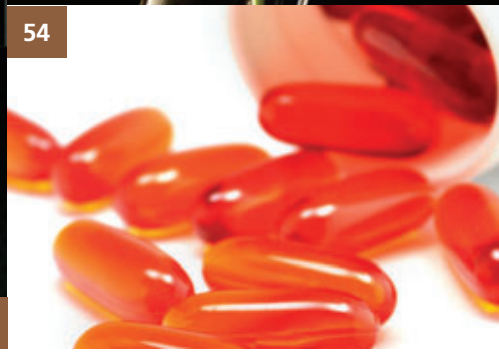

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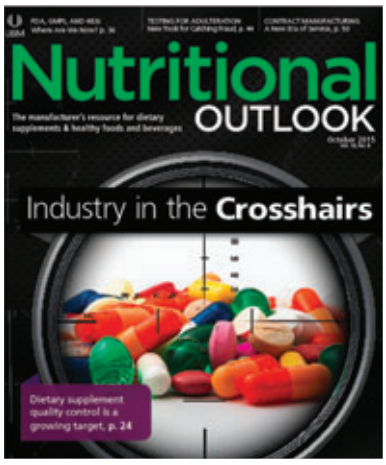

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Turning Up the Volume on Quality Control

This edition of *Nutritional Outlook*, dubbed our "Quality Issue," comes at a critical time for the dietary supplements industry. While debates over topics such as economically motivated fraud and illegal spiking are not new to industry, what *is* new is a sharpening public focus on current regulations and growing demands for quality control.

Criticisms of the supplements industry came to a head in February when New York Attorney General (NY AG) Eric Schneiderman ordered herbal-supplement retailers and manufacturers to pull products from shelves. Since then, the NY AG has not let up on his mission to root out what he calls "serious problems in the herbal supplements industry," along the way assembling a coalition of attorneys general who have asked FDA and Congress to revisit and toughen U.S. supplement regulations. Most recently, in September, AG Schneiderman went after devil's claw products, alleging they are misbranded and "yet another sign that weaknesses in the supplements industry's approach to quality control are having real-world consequences for consumers." (Turn to page 14 for more on that latest investigation.)

Schneiderman's cries of foul play have garnered significant media coverage, piling on top of years of building headlines about disappointing studies, recalls, etc.

But are consumers hearing his cry?

So far, no, per market estimates. On page 26 of this issue, Kim Kawa, BSc, natural products specialist at SPINS and one of our editorial advisory board members, reports that sales of herbal supplements over the past year (up until August 9, 2015) had actually gone up 9% in all retail channels that SPINS tracks. We'll know more when complete 2015 numbers are in, but longtime industry member Scott Steinford, executive director and president of the CoQ10 Association and the Natural Algae Astaxanthin Association, shares another example—the fact that share prices of leading supplement brands show stronger, not weaker, performance.

Still, it's quite appropriate to say that the stakes have never been higher for the dietary supplements industry; to sustain any kind of growth, the industry moving forward must prove to the public that it is well regulated and sells safe, efficacious, and high-quality products.

The Dietary Supplement Health and Education Act (DSHEA) has ruled the supplement landscape for over 20 years now. Some might call that more than enough time for an industry to demonstrate whether its regulations work, while others say that the industry is relatively young and still adjusting to compliance under more-recent rules like current Good Manufacturing Practices (cGMP). (Turn to page 36 for an updated look at industry-wide cGMP performance.)

Will dietary supplement regulations look the same way in 10 years that they do today? Some hope so; some don't. Industryfolk are the first to say that this year's events have been a hard pill to swallow. They also acknowledge that there are problems that need fixing, as with any industry dealing with outliers acting illegally.

The supplement manufacturers we spoke to know that they are competing in a time of higher scrutiny. No matter what comes next, all industry members must face head-on debates over whether the industry needs premarket approval, whether ingredient suppliers should also answer to cGMP regulations, or whether DSHEA is the source of problems, not solutions. No one can shy away from answering these questions, not anymore. So, while investigations must be fair, moving forward, industry members should arm themselves with thoughtful, substantive answers and be prepared to put quality control front and center where it belongs.

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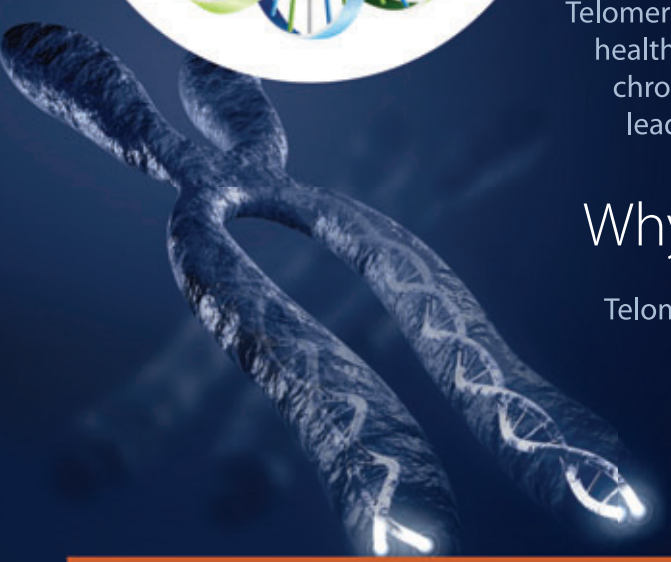

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U.S. Herbal Supplement Sales Up 6.8% in 2014

U.S. herbal supplement sales continued their 11-year upward streak in 2014, growing 6.8% in 2014 to reach $6.4 billion, according to *Nutrition Business Journal* (NBJ) estimates. The data is part of *HerbalGram*'s annual, comprehensive herbal supplements sales report, now published in the American Botanical Council (ABC; Austin, TX) journal.

Growth in the natural channel again outpaced growth in the mainstream market. In 2014, natural and health food retail sales (excluding Whole Foods Market) grew by 5.2% over 2013, to $330 million. But sales still grew mainstream, too, ticking up by 2.1% in 2014 over 2013 to reach between $802 million–$1.12 billion in food/drug/mass, military commissary, dollar, and club stores.

And in the direct-sales channel, the report noted a 6.7% growth in 2014 over 2013, reaching nearly $200 million. The report also covers sales of single versus combination supplements, with gains reported for both types.

Mainstream Channel

Leading the mainstream market's bestsellers, the most popular ingredient in 2014 was again horehound (*Marrubium vulgare*), an ingredient popular for throat lozenges, with sales of nearly $106 million. The next bestsellers were cranberry (*Vaccinium macrocarpon*), echinacea (*Echinacea* spp.), black cohosh (*Actaea racemosa*), and flax or flaxseed oil (*Linum usitatissimum*).

"Ginkgo [*Ginkgo biloba*], garlic [*Allium sativum*], valerian [*Valeriana officinalis*], and milk thistle [*Silybum marianum*] ranked among the 20 top-selling herbs; total sales for these supplements were also some of the least changed from 2013, suggesting their continued mainstream acceptance," the *HerbalGram* report added.

Some ingredients, like ivy leaf (*Hedera helix*), rhodiola (*Rhodiola* spp.), guarana (*Paullinia cupana*), and wheat/barley grass (*Triticum aestivum* and *Hordeum vulgare*, respectively), made the top-40 list for the first time; by contrast, bromelain, artichoke, slippery elm, and acai each fell off the top-40 list in 2014.

Other notable mainstream standouts included coconut oil, which is "enjoying booming sales in the mainstream channel," the report stated, and double-digit growth for fenugreek, echinacea, elderberry, plant sterols, and turmeric.

The top-10 mainstream sellers were:

1. Horehound (*Marrubium vulgare*)
2. Cranberry (*Vaccinium macrocarpon*)
3. Echinacea (*Echinacea* spp.)
4. Black cohosh (*Actaea racemosa*)
5. Flax/flaxseed oil (*Linum usitatissimum*)
6. Valerian (*Valeriana officinalis*)
7. Yohimbe (*Pausinystalia yohimbe*)
8. Bioflavonoid Complex
9. Saw palmetto (*Serenoa repens*)
10. Ginger (*Zingiber officinale*)

Natural Channel

In the natural channel, turmeric (*Curcuma longa*) again held the top spot in 2014, as it did in 2013, with almost 31% sales growth over 2013, up to $26 million. It was followed by wheatgrass and barley grass, flaxseed and/or flax oil, *Aloe vera,* and spirulina/blue-green algae (*Arthrospira* spp.). Growth did fall off for some ingredients, including stevia, but others saw notable gains in the natural channel, including maca (*Lepidium meyenii*) and oregano (*Origanum vulgare*).

The top-10 natural-channel sellers were:

1. Turmeric (*Curcuma longa*)
2. Wheatgrass and barley grass (*Triticum aestivum* and *Hordeum vulgare*)
3. Flaxseed (*Linum usitatissimum*)/flax oil
4. *Aloe vera*
5. Spirulina/blue-green algae (*Arthrospira* spp.)
6. Milk thistle (*Silybum marianum*)
7. Elderberry (*Sambucus nigra*)
8. Maca (*Lepidium meyenii*)
9. Echinacea (*Echinacea* spp.)
10. Oregano (*Origanum vulgare*)

*Consult the *HerbalGram* report for the complete lists of top-40 sellers in both the mainstream and natural channels.

Pretty on Par with Years Past

The 6.8% overall herbal supplement sales growth in 2014 was not quite as high as growth in 2013, when a 7.9% spike marked the category's highest growth since the 1990s. But the upward trajectory still indicates that consumers are finding more value in herbal products. For instance, according to NBJ numbers, consumers have spent $1 billion more on these products since 2011 and $400 million more than they did since 2013.

"These figures suggest a clear trend: Americans are continuing to rely on botanical products for various aspects of their wellbeing and other personal needs," *HerbalGram* said.

The report also noted the ongoing investigation of herbal supplements started this year and led by New York Attorney General (NY AG) Eric Schneiderman and addressed whether resulting negative press might impact impending 2015 herbal sales data. But the report also pointed to a NutraIngredients-USA article indicating SPINS data showing that sales of herbal formula combination supplements in the year ending mid-July 2015 were actually up 12.6% compared to the year earlier, suggesting that negative

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[1] Nutr Metab (Lond.) **2013**, 10:57. [2] J Int Soc Sports Nutr **2013**, 10(Suppl 1):P16. [3] J Int Soc Sports Nutr **2012**, 9:48.

press from the investigation has not hurt consumer sales.

"Consumers continue to demonstrate their interest and confidence in botanical dietary supplements for a wide variety of health reasons," said Mark Blumenthal, founder and executive director of ABC and editor-in-chief of *HerbalGram*, in a press release discussing the new *HerbalGram* report.

ABC compiled the annual data together with *Nutrition Business Journal* and market researchers SPINS and IRI. Of note, the report covers herbal dietary supplements only and excludes sales of most herbal teas, botanicals for cosmetics, and herbals sold as over-the-counter medicines. Data does not reflect sales in Whole Foods Market or in convenience stores.

NY AG Investigation Goes after "Misbranded" Devil's Claw Products

NY AG Eric Schneiderman's dietary supplements investigation has resurfaced—this time issuing cease-and-desist letters to makers of devil's claw supplements sold in the state of New York.

On September 9, AG Schneiderman's office sent letters to 13 supplement companies, including NBTY, Now Foods, Thorne Research, Nutraceutical International Corp., and Nature's Sunshine Products, alleging that their products contain a plant species that is not in fact the more-expensive devil's claw species *Harpagophytum procumbens*. Schneiderman ordered the companies to recall the products and to compensate consumers who purchased them.

To test the products, the NY AG's office once again employed DNA barcode testing, a method his office has relied on throughout its investigation of the herbal supplements industry, which began in February when his office ordered numerous herbal supplements off retail shelves. The dietary supplements industry has heavily criticized his use of DNA testing to censure finished herbal products, explaining that DNA may no longer be intact in finished herbal products to enable accurate testing.

In its press release announcing the devil's claw probe, the NY AG's office said that DNA testing performed by the New York Botanical Garden found that the supplements in question contained a "cheaper related species that is considered less desirable": namely, related devil's claw species *Harpagophytum zeyheri*, "which contains some—but not all—of the same chemicals" as *Harpagophytum procumbens*, his office said. Of the 16 supplements in which DNA could be detected, tests allegedly found that all contained *Harpagophytum zeyheri*, either alone (81%) or in mixture with *Harpagophytum procumbens* (19%).

But in an American Botanical Council press release, medicinal plant expert Thomas Brendler, editor of the *African Herbal Pharmacopeia*, said that, "While both species differ marginally in shape and chemical composition, both are considered equally effective." And, the ABC press release pointed out, some government pharmacopeias consider the two species interchangeable in terms of anti-inflammatory properties and benefits for osteoarthritis, and that it is not uncommon to find devil's claw extract in the global market containing both devil's claw species. "According to various government-recognized medicine evaluation bodies and pharmacopeias, the two species of devil's claw are considered interchangeable for the purpose of their use for their medicinal actions," it said.

Mark Blumenthal, founder and executive director of ABC, said in the press release that while his group appreciates the NY AG's interest in herbal supplement quality, "splitting the devil's claw genus in the very narrow way that they have done in this investigation is akin to splitting hairs—it has no real meaning or value to anyone, particularly the herb consumer."

"This may be a hair-splitting botanical distinction," noted Blumenthal, "but it certainly is not a legal or regulatory one, especially since authoritative sources recognize both species as being 'devil's claw.'" Blumenthal also said that devil's claw is a relatively low-selling herb in the United States, with total sales in the country ranging from $250,000–$500,000.

One Company Settles

The NY AG office said that it reached agreement with one supplement firm, Nature's Way, which, unlike the others, did label its product as combining *Harpagophytum zeyheri* and *Harpagophytum procumbens*. The NY AG said the firm agreed to refund customers and to employ DNA barcode testing in its operations in order to ensure that devil's claw products do not contain *Harpagophytum zeyheri*. The AG advised, "The manufacturers receiving letters from my office should follow the lead of Nature's Way and address these gaps immediately."

Among industry reactions to this latest NY AG probe, Dan Fabricant, PhD, executive director and CEO of the Natural Products Association, stated: "More than six months have passed since the [NY AG] first began this inquiry, and two critical issues remain. First, he has yet to make public or subject to peer review the questionable 'science' or 'research' on which this action is based, and second, he has not pursued prosecutorial actions in either case. We encourage [FDA] and other public health interests to ask the [NY AG] to release his findings immediately so they can do the most good for consumer protection in the quickest fashion possible."

Steve Mister, president and CEO of the Council for Responsible Nutrition, said, "Supply chain integrity is of the utmost importance to the dietary supplement industry. There are multiple ways to qualify the supply chain, to identify ingredients, and to detect adulterants in products. The companies involved should be permitted to defend their methods of ingredient testing and to justify their use of particular species of botanicals before being declared to be misbranded or adulterated by the [NY AG]. The federal law for dietary supplements requires that what's in the bottle is on the label. Proper identification of ingredients is a requirement of federal law, and we expect all companies to stand behind the quality of their products. As we have seen before, investigations by the [NY AG's] office are rarely as clear-cut as they might seem."

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Quality Control around the World

How do U.S. dietary supplement regulations compare to the rest of the world's?

BY JAMES C. GRIFFITHS, PHD, COUNCIL FOR RESPONSIBLE NUTRITION

"Quality in a product or service is not what the supplier puts in. It is what the customer gets out and is willing to pay for. A product is not quality because it is hard to make and costs a lot of money, as manufacturers typically believe. This is incompetence. Customers pay only for what is of use to them and gives them value. Nothing else constitutes quality."[1]

This quote by Peter Drucker is relevant and true, irrespective of the product or market. But what role does regulation play in producing quality products?

Currently, global regulations allowing or restricting market access to dietary supplements are inconsistent, partially due to differences in market maturity, manufacturer savvy, customer expectations, and inherent regulatory philosophy. An ever-expanding global economy with country-to-country raw-material channels and finished-product trade would benefit from true regulatory harmonization—as long as the most restrictive are not deemed the definitive common denominator.

The U.S. Model

In the United States, the Dietary Supplement Health and Education Act (DSHEA) was passed in 1994, but it is only in more recent years that FDA has begun to use the tools at its disposal, starting with enforcement of stringent current Good Manufacturing Practices (cGMPs) in the manufacture of products and supplemented by detailed adverse-event reporting (AER) requirements. These regulatory components, not found in many other countries, take consumer accountability seriously and rely on the expectation of a loyal and long-term seller-buyer relationship. Those dietary supplement manufacturers in the business for the long run respectfully engage with various national regulatory agencies to meet applicable regulations and to provide products that the population seeks.

These two actions—careful attention to cGMPs during manufacture and vigilance in monitoring AER signals when on the market—help ensure the quality of the product at launch and through the market life span.

But the regulators that are empowered to monitor and take action against any deviations from either cGMP or AER regulations must be swift and sufficiently severe to remove irresponsible players and/or coerce improved behavior.

Regulatory Paradigms Elsewhere

Different countries/regions regulate what we term "dietary supplements" differently, but that isn't necessarily better. Outside the United States, these products may be termed "natural health products," "food supplements," "foods for special dietary uses/

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specified health uses," etc., and often the regulatory expectations may more closely parallel pharmaceutical regulations than in the U.S. where dietary supplements are regulated as a category of food. Many jurisdictions rely on a premarket approval process—sometimes referred to as a registration—before allowing a product or new ingredient within a product on the market. These premarket dossiers are detailed, expensive, and result in lengthy regulatory review and approval, often interfering with providing consumer access in a reasonable timeframe.

For example, in Australia, the Therapeutic Goods Authority (TGA) authorizes ingredients and claims, as does the European Food Safety Authority (EFSA). In some cases, the allowable claims are quite restrictive to a relatively small set of verbatim statements and then only permitted after extensive human clinical studies that take years and cost millions. EFSA develops positive lists containing well-characterized ingredients and negative lists with forbidden or tightly circumscribed ingredients, but this approach tends to significantly diminish entrepreneurial innovation. Unfortunately, some countries sideline "botanicals" as being too complex and thorny an issue to delve into within current nutrient regulations, resulting in stagnation for this interesting category.

Most non-U.S. paradigms rely on the case-by-case evaluation of the safety and quality of the ingredient or product prior to market launch, rather than relying on stringent cGMPs.

In fact, most non-U.S. paradigms rely on the case-by-case evaluation of the safety and quality of the ingredient or product prior to market launch, rather than relying on stringent cGMPs; however, there's no indication this method results in additional consumer safety. The countries relying on these premarket restrictions generally have in place weak or nonexistent prescribed cGMP provisions and weak or nonexistent prescribed AER provisions.

Following the DSHEA Model

A DSHEA-like model that utilizes cGMPs and serious adverse-event reporting, coupled with aggressive and prompt regulatory action against non-compliance and/or willful criminal activity, can serve the same level of safety, with greater availability of quality products, than the narrow bottleneck prescribed by a ponderous premarket registration process. N

1. Peter F. Drucker quote (American Educator and Writer, b.1909)

Jim Griffiths *is the vice president of scientific and international affairs for the Council for Responsible Nutrition (CRN; Washington, DC), the leading trade association for the dietary supplement and functional food industry.*

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Regaining Trust

The U.S. supplements industry has lost some credibility with media and consumers. Could a proposal based on the pharmaceutical industry that is *not* premarket approval help to alleviate concerns?

By Mark A. LeDoux, Natural Alternatives International Inc.

Drug-like premarket approval may not make sense for supplements, but a system mimicking drug-code labels might.

Mark LeDoux

The past several months have seen a lot of activity in the dietary supplement industry in the United States. One of the precipitating events that caused significant media attention was the Office of the Attorney General of New York's (NY AG) issuance of cease-and-desist orders to four retailers in his state, presumably to remove herbal extract products that did not meet label claims. These retailers are national chains, so the NY AG's actions immediately got some serious press coverage. Supplement industry leaders have largely criticized the Attorney General's office, which, in its investigation, contracted with a Canadian firm to initiate DNA testing on finished herbal extract products—a method which has not been widely used or validated by industry in the United States, and, frankly, elsewhere.

As of this date, one retailer has negotiated out of the cease-and-desist and has resumed selling products. Some in industry believe that the settlement with the NY AG was premature; others believe it was a reasonable action in light of mounting class action lawsuits filed against the several targets of this investigation. The ensuing discussions in the press, the concerns expressed by doctors and media alike regarding the "unregulated" industry, reached a cacophony of sorts, and the resultant impact has been a reduction of consumer confidence, as measured by a recent *Nutrition Business Journal* study.

It is not my intent to cast opinion or judgment on the players in this drama, but rather to suggest a way to help alleviate the ongoing lament of often ill-informed media that the dietary supplement industry is unregulated by FDA. Those of us in industry know this is not the case, as do the recipients of warning letters and recall notices by the agency. The consumer does not know this, however, and therein lies the difficulty in assuaging consumer concerns and restoring credibility.

The facts are as follows:

- FDA, the agency tasked with oversight, is probably undermanned and underresourced to oversee the evaluation of this burgeoning industry at the production and supply chain level.
- The areas of enforcement oversight of Good Manufacturing Practices requirements (21 *CFR* 111) seem to vary widely between inspectors and districts.
- There are too many Form 483s (noting GMP infractions) and too many warning letters being issued—often which take over a year to get issued from the bureaucracy in Washington.
- The industry has a credibility problem with the consumer and now with influential lawmakers and regulators.
- It is time for a commonsense solution involving premarket notification or registration with an appropriate agency.

Could the National Drug Code Serve as a Role Model?

Consumers want to believe that the supplements they use are safe, pure, effective, and unadulterated. I choose my words carefully, because that is the type of language that FDA utilizes when it discovers a serious problem with a product in the field. So how can we deliver the assurance of safety, purity, and efficacy? A system implemented by the pharmaceutical industry could hold the answer.

When one goes to purchase over-the-counter medication, on every consumer package is a code number that ties directly into a database managed by FDA. This is called the National Drug Code, or NDC Labeler Code (NDC). On a bottle of Aleve (naproxen sodium) or a generic version thereof, one finds on the front label of the container the following (using two generic versions sourced at Costco and Walgreens as examples):

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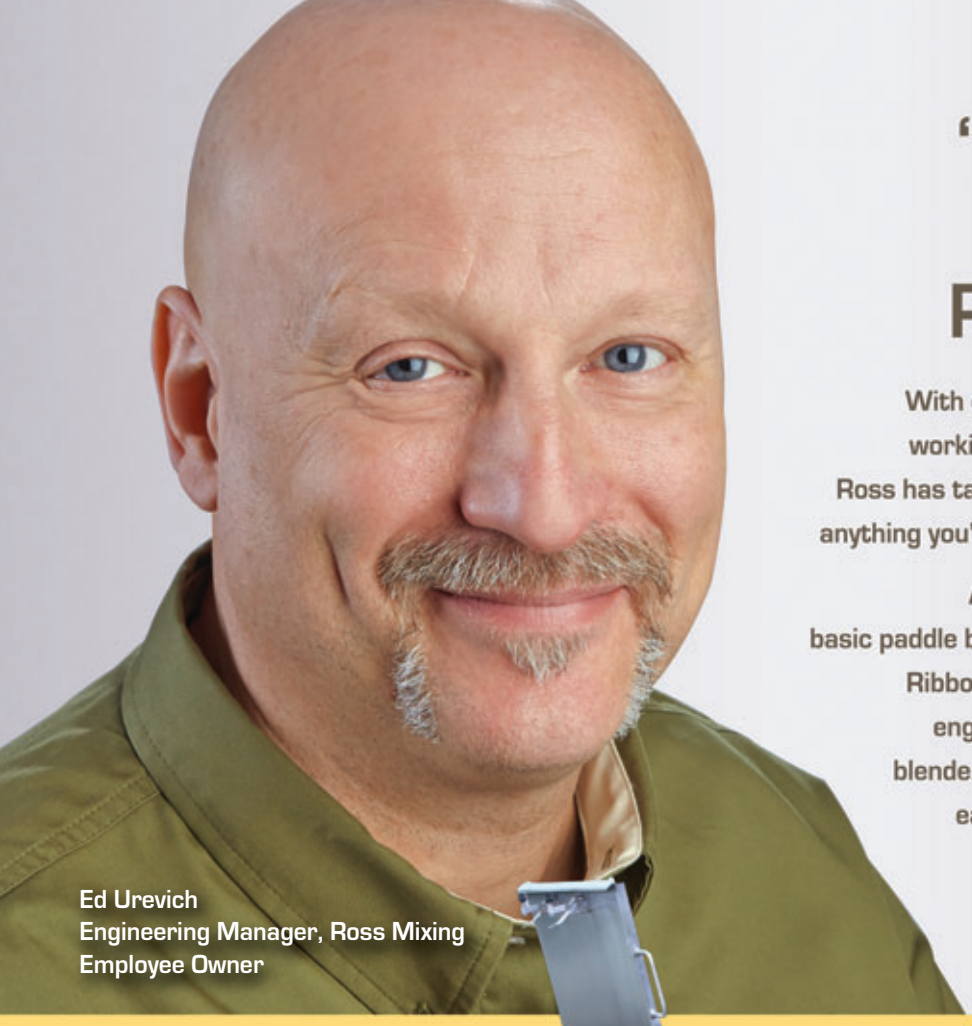

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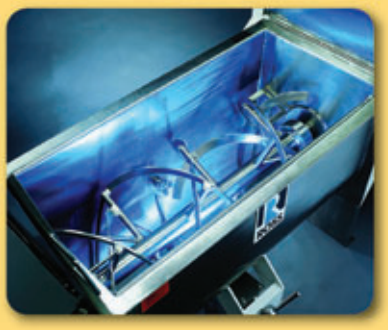

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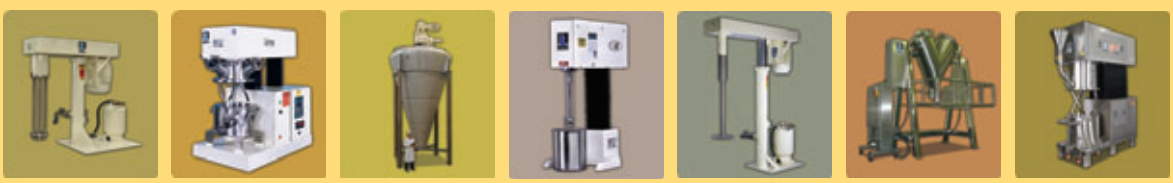

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- **NDC 0113-0368-79** – Kirkland Signature Naproxen Sodium Tablets (Made by Perrigo for Costco
- **NDC 0363-0714-40** – Walgreens Naproxen Sodium Capsules (Softgel Capsules)

So what is this NDC Labeler Code number, and what does it mean?

The NDC Labeler Code is a 10-digit, unique, three-segment number that serves as a product identifier for human drugs. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.

The first segment of the NDC Labeler Code identifies the establishment; FDA will assign this number, and it will be unique to each establishment (manufacturer, packer, labeler, etc.). The second segment of the NDC Labeler Code identifies the drug (strength, dosage, and formulation). The third segment of the NDC Labeler Code identifies the package size and package type. The second and third segments are assigned by the labeler. An assignment of a NDC number does not denote FDA approval of the product.

The NDC Labeler Code is a 10-digit, unique, three-segment number that serves as a product identifier for human drugs.

It became clear to me that a system not unlike the NDC Labeler Code could be envisioned for the dietary supplement industry in the United States.

I would suggest the time is right to develop a National Dietary Supplement (NDS) Labeler Code system, which would identify each establishment (manufacturer, packer, labeler, etc.) and identify the dietary supplement itself, and the final part of the code would identify the package size and type. Each NDS Code would be unique to each product, because even in commodity products such as vitamin C 500-mg tablets, the manufacturer, packer, labeler, etc., would be clearly spelled out in code within the NDS number. At a point in time sufficient to allow for label compliance and stock conversion, failure to list the NDS number will render the product mislabeled under statute and subject to market withdrawal either voluntarily or via justifiable seizure.

This database would be paid for by industry with nominal user fees, so the end result would be that products would properly appear to be registered with the FDA or some other U.S. government entity if the FDA is not the proper agency to manage this. A centralized database could be accessible to government authorities interested in tracking products that demonstrated a postmarket problem, as well as to consumers, physicians, and industry, just as it is now with the NDC system.

The objective here is twofold:

1. Eliminate the shrinkage in consumer confidence by publicizing the premarket notification or registration requirements after a date certain for implementation
2. Eliminate the incorrectly stated mantra that the dietary supplement industry in the United States is unregulated, notwithstanding the fact that we labor under numerous regulations, including NLEA, DSHEA, FSMA, Bioterrorism Act registration, AER reporting, etc.

No Need for Premarket Approval

There is no need to amend the Dietary Supplement Health and Education Act governing supplements to include premarket approval. There is clearly no need to open Pandora's Box, but there is a need to restore consumer confidence, and I believe the time is right to initiate the creation of the National Dietary Supplement Registry with leaders in the responsible dietary supplement industry.

Here is what I believe are appropriate steps necessary to achieve this goal:

- Identify the top 15 companies in the U.S. marketplace and seek their support for this activity. To date, we have positive feedback from DSM Nutrition, Glanbia Nutrition, Herbalife International, Natural Alternatives International, Chromadex Corporation, and The Juice Plus+ Company, and expressions of interest from others as well, including NBTY.
- Create a system patterned after the NDC system to discuss with industry and get their feedback, suggestions for amendments, and support
- Inform the various trade associations of this endeavor and advise them that the industry leaders are supporting this effort and ask for their support as well. Support would be beneficial but not mandatory, because it is doubtful all four trade associations will support this endeavor.
- Discuss with former FDA personnel to make certain key bureaucratic language is inserted to make the agency accountable for this (e.g., funding, timing for providing the NDS code, tracking, enforcement)
- At the appropriate time, enlist the services of well-placed media to carry the message to the consumer and to the interested parties on Capitol Hill who will be needed to secure this legislation
- Identify key Senators and Congressional members and staff to enlist their feedback and support

This is an idea whose time has come. After a certain date prescribed by legislation for the system to take effect, it will become important to advertise that products without the NDS code are presumed to be illegal and as such should be avoided. This will also require training of retailers as well as distributors who will not want to be subjected to unnecessary legal issues. Finally, the news media and the print, radio, and television/cable outlets need to be advised that airing or printing commercial content for dietary supplements without the appropriate NDS Code will result in financial penalties to them for aiding and abetting consumer fraud.

Let's give the attorneys general an opportunity to help police the marketplace by searching for illegal or contraband product rather than go through what we have experienced since February following the NY AG investigation.

I welcome your feedback and comments. N

Mark A. LeDoux *is chairman and CEO of Natural Alternatives International Inc. (San Marcos, CA).*

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Industry in the **Crosshairs**

What can industry take away from this year's New York Attorney General probe?

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

As far as New York Attorney General (NY AG) Eric Schneiderman is concerned, the dietary supplements industry might as well be wearing a target on its back. Ever since February when AG Schneiderman issued cease-and-desist letters to makers and retailers of herbal supplements for allegedly not meeting label claims, the AG, today with a coalition of fellow attorneys general behind him, has continued investigating and taking action against what he says are "serious problems" in the herbal supplements industry.

Cumulatively, these actions have industry leaders on high alert, so we took this opportunity to ask them:

"In your opinion, what effects—either good or bad—has the NY AG investigation had on the dietary supplements industry? Can you point to any positive takeaways for the industry?"

** NY AG Schneiderman's office, as well as the office of Connecticut AG George Jepsen, declined to comment for this article. Nutritional Outlook received no other response after reaching out to several AGs in AG Schneiderman's coalition.*

Charles Brain
CEO
3i Solutions

"We at 3i Solutions have found the attention emanating from the recent NY AG investigation a positive. The investigation questioned the testing and efficacy of the products addressed and led to criticism of the entire industry. While the original complaints were critical of the dietary supplement industry, the industry was able to respond to the discussion with new technology, such as improved bioavailability of products and enhanced delivery methods. The overall discussion eventually evolved into an opportunity to highlight improved technology and product improvements offered throughout the industry.

It is now clear to many that the industry is strongly committed to providing continuously improving products. As a response to the criticism, many companies and consumers were introduced to

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quality-oriented processes as well as new and innovative products. While the bulk of the media provided criticism, we were appreciative of the opportunities to present a positive response and reinforce the quality and technology that is prevalent from the vast majority of the dietary supplement industry. We look forward to the continued opportunity to showcase the improving technology and resulting benefits the industry continues to develop."

Lauren Clardy
President
NutriMarketing Group

"Certainly we are all aware the investigation has been damaging, as well as flawed, and shook the industry to the core. It was a wakeup call throughout the value chain as to the path going forward so that this doesn't happen in the future. The takeaways have been multifaceted. They underscore the deep flaws and weaknesses in the supply chain of the nutraceuticals industry.

Suppliers must start raising the bar on their specifications. You will never totally eliminate economically motivated adulteration—in whatever form it takes—or greed, for that matter. What we can do is to subscribe and adhere to proper supplier qualification across the dietary supplement industry. This is critical for maintaining the integrity of the supply chain and will help protect consumers and branded companies alike."

John R. Endres, ND
Chief Scientific Officer
AIBMR Life Sciences Inc.

"The recent activity of NY AG Eric Schneiderman has garnered a tremendous amount of attention by both consumers and the industry, and has highlighted the need for scientific and regulatory education for elected officials and consumers. As industry trade associations and others have clearly stated, FDA's manufacturing regulations require supplement companies to verify that their products meet *all* specifications—including identity.

Use of DNA analysis without some other confirming analysis would be unlikely to meet this regulatory requirement. Publicizing erroneous information unnecessarily alarms consumers. While there is continued room for improvement in dietary supplement manufacturing and oversight, it should be strictly based upon validated science that is acceptable to most qualified scientists."

Christine Feaster
Vice President, Head of Strategic Marketing and Program Operations, Dietary Supplements & Herbal Medicines
U.S. Pharmacopeia

"The NY AG's actions highlighted the importance and value of public standards—not just to public health, but also to industry. Before February of this year, many characterized DSHEA's provision for private standards as a benefit for manufacturers. However, the NY AG actions revealed private standards also come with significant risk. Under this paradigm, it is not just manufacturers who are able to establish their own specifications for identity. In this instance, the Attorney General's office essentially established its own identity test. Industry was right to call for transparency to ensure the tests used were fit for purpose.

However, industry should also be transparent. Public standards created through USP's unique public process are the best way to ensure transparency and provide a uniform reference for both industry and regulators. Public standards protect public health by ensuring the consistency and quality of supplement products, but they also protect industry and retail brands by ensuring products will be judged by scientifically validated test methods that are fit for purpose."

Jeff Hilton
Partner, Cofounder, Chief Marketing Officer
BrandHive

"I think the results and fallout from the AG crisis have been mixed, but mostly good for the future of the industry in a very painful way. It definitely took a negative toll on consumer confidence regarding supplements, but in fairness that confidence was already waning. It simply exacerbated the erosion that was already happening. For far too long, we as an industry have rested on our laurels and assumed that the 'heady' years of the 1990s supplement boom would recycle once again. But that isn't happening. And the consumer of the 90s isn't the same consumer. They are smarter and more skeptical and have far more choices now.

So the positive results of the AG crisis, for me, have been a painful wakeup call that if we as an industry don't self-police very soon and actively work to restore consumer confidence, the consumer will abandon us for other healthful pursuits—namely, improved diet, increased exercise, functional foods, beverages, and other forms of dietary supplementation beyond pills and capsules. Already pill fatigue is setting in among both Boomers and Millennials. Millions of consumers are turning to functional foods for their added nutrition. The market is slowly slipping away from traditional supplement manufacturers, and most of them don't even realize it. So if the AG scandal rattles a few industry cages, I say that's a good thing. For far too long, the bad players have made it harder for the good players to succeed, and it's time for the legitimate companies to stand tall and set some standards and support an independent third-party validation seal or certification that consumers can believe in. It's the only way. The industry players who want to be here 10 years from now need to act now. It's time to stop pontificating and playing 'victim' and start doing something to change the future."

Karen Howard
CEO and Executive Director
Organic & Natural Health Association

"This is a wakeup call. Challenges regarding quality and effectiveness are clearly not going away by simply stating that the industry is in fact regulated and FDA needs to do more. Organic & Natural has used the results of this investigation to take a proactive step and file a citizens' petition with the FDA that would require raw-ingredient suppliers to adhere to cGMPs. The fact that the final law failed to include this requirement creates a weak link in the supply chain that must be addressed.

Yes, there are bad actors that reflect poorly on the industry as a whole. Yes, imposing additional quality measures will cost more money. Yes, ingredient suppliers should be using cGMPs. However, many are not, creating an uneven playing field in a price-sensitive environment. Supporting the petition is a public way to demonstrate commitment to transparency and traceability. Will it fix everything? It will not. What it will do is show that we can step up our game, engage in continual quality improvement across the industry, and restore consumer confidence in the products they purchase."

Loren Israelsen
President
United Natural Products Alliance

"DNA barcoding is a new science, and like all new technologies, its role and utility in the dietary supplement industry is only now evolving. Scientific organizations that set quality standards and establish analytical methods are investigating the potential of DNA barcoding as an additional tool to improve quality and plant identification. And, while the NY AG thinks DNA barcoding is a useful enforcement tool, we hope the proper role of DNA barcoding doesn't become a weapon before it becomes a generally accepted analytical tool for botanical products.

It is well understood that botanical nomenclature is an ongoing process of refinement and clarification. The procedures to do so are methodical and consultative. Unfortunately, the recent actions of the NY AG do not contribute to the order of this process; rather, the aggressive tactics being used to force the use of DNA barcoding run counter to the logical adoption of this new technology."

Kim Kawa, BSc
Natural Products Specialist
SPINS

"Under the semblance of consumer protection, Eric Schneiderman's stance on safety and fraud in the herbal supplement industry is a hot-button topic, raising awareness of the importance of transparency, traceability, and efficacy in the segment. Several industry professionals and trade publications have addressed Schneiderman's lack of scientific protocol, while bringing light to the limitations of DNA barcoding on post-processed botanicals; some have further questioned the motives behind his actions. This is a good reminder that dietary supplements are already well regulated in this country—remember [DSHEA] that oversees all label claims, ingredients, and structure-function claims and, more recently, the Designer Anabolic Steroid Control Act (DASCA) of 2014 that provides new tools for swift identification of illegal drugs inaccurately marketed as dietary supplements.

Participating in third-party testing and acquiring third-party certifications is already standard practice and key to identifying reputable dietary supplement brands.

Presumably, Schneiderman's efforts will neither negatively impact sales of nor decrease consumer confidence in herbal remedies and their safety. The herbal supplement segment is holding steady, even showing growth over last year—around 9% in all SPINS reporting retail channels (52 weeks ending August 9, 2015)."

Alex L. LeBeau, PhD
Toxicologist
Burdock Group

"In this case, the negatives outweigh the positives. The angle of attack by the NY AG is from the position that presumes the industry is inherently unsafe; further, the use of a questionable analytical methodology, details of which have yet to be released for evaluation by the scientific community, hints at the idea that the results obtained by the NY AG may not be as accurate for confirming the identity of the active ingredient in the dietary supplement as would results from other verifiable analytical techniques. Additionally, presenting analytical findings only (no data have been released) further adds to the idea that industry is willfully selling products that are misbranded (i.e., does not contain listed botanical) or adulterated (i.e., contains contaminants).

If there is any positive from this action, it is a warning to industry to be on the offensive when it comes to mislabeling or adulteration allegations and to prepare responses to such challenges. Conducting verifiable and continuous analysis on a product, including making the analytical data and methodology readily available in a case where the validity of a product is challenged, should make a manufacturer's response to such allegations swift and reduce the amount of public scrutiny that a manufacturer may receive."

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Mark A. LeDoux
Chairman and CEO
Natural Alternatives International Inc.

"As of this date, one retailer has negotiated out of the cease-and-desist and has resumed selling products. Some in industry believe that the settlement with the NY AG was premature; others believe it was a reasonable action in light of mounting class action lawsuits filed against the several targets of this investigation. The ensuing discussions in the press, the concerns expressed by doctors and media alike regarding the 'unregulated' industry, reached a cacophony of sorts, and the resultant impact has been a reduction of consumer confidence, as measured by a recent *Nutrition Business Journal* study.

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(Editor's note: Read a byline by Mark on page 20 outlining one proposal to help the industry regain consumer trust.)

Dr. Cheryl Luther
General Manager,
Dietary Supplements
NSF International

"Due to the NY AG's actions, the dietary supplement companies are striving to restore and maintain brand integrity by demonstrating their commitment to producing safer products for their customers.

Retailers and consumers want to know they can trust the safety and quality of supplements, and NSF technical experts have helped in two ways. First, guiding our customers through the third-party certification process is one important way manufacturers and retailers can convey this confidence to consumers and regulators. NSF has also worked closely with our customers to help educate consumers about how to find supplements that have been analytically tested to confirm label contents.

NSF has seen an increase in certification requests that, while may not be directly linked to the NY AG's action, are a positive sign that manufacturers and retailers are looking for that added assurance in their dietary supplement to restore consumer confidence."

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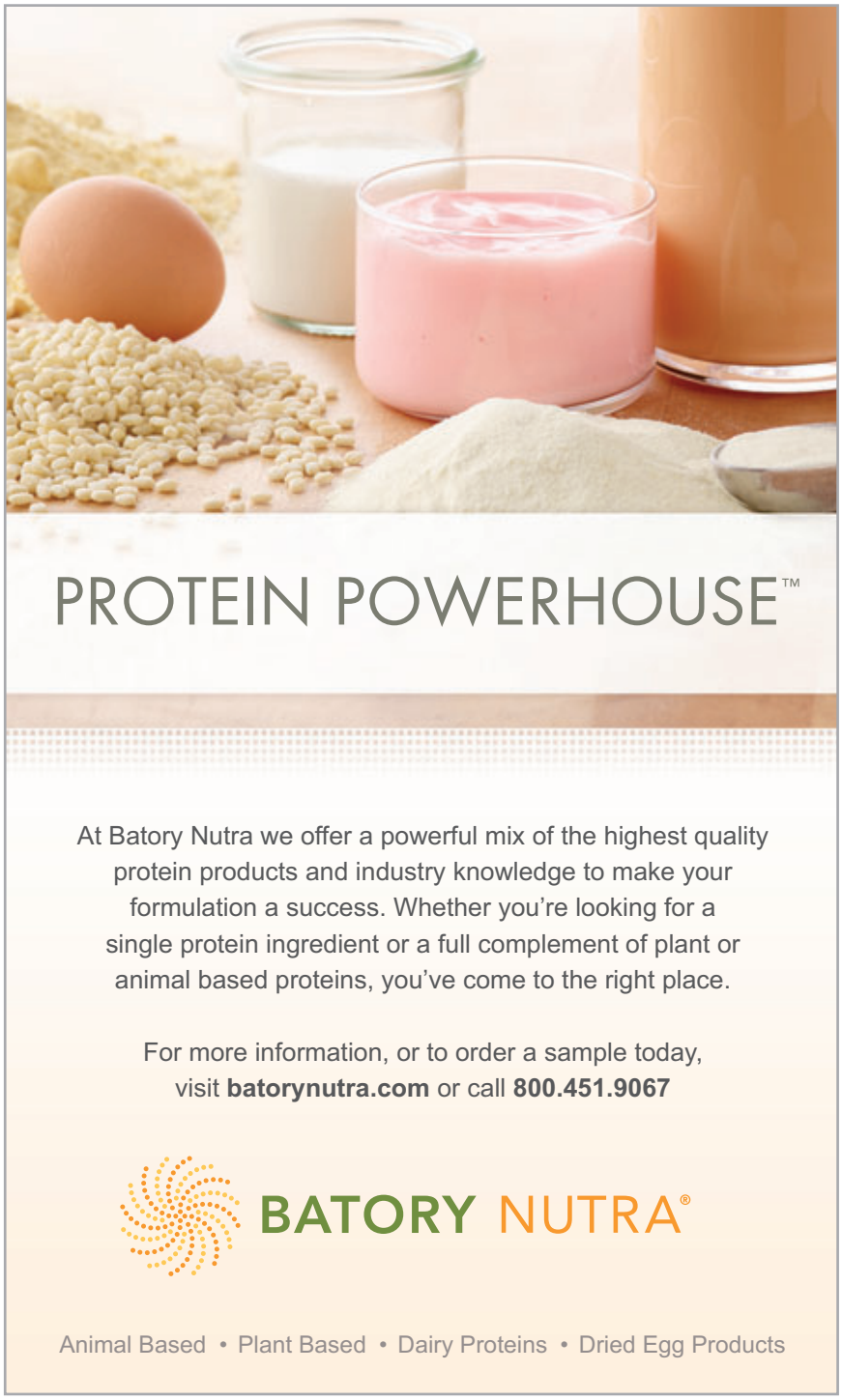
PATENTS: US5,861,415, US6,653,327, EP0839037, EP1171144, EP1328263, AU2006235807, NZ514884

Shaheen Majeed
Marketing Director
Sabinsa Corp.

"As there will always be two sides to every coin, there are two sides to this investigation by the NY AG. On one side, the dietary supplement industry got a wakeup call. With major companies involved, this made the nation's headlines, so for the NY AG's political career, this was a major accomplishment. Although misguided, and amusingly single-minded on the tactic of using DNA testing on extracts, [by] completely ignoring the prevalent issue of sports supplements being spiked with steroidal compounds, [the investigation] indicates a political motivation was at play here.

From a business-to-business perspective, it's been normal; less than 1% of our customers have asked us for DNA analysis, mainly because it's not required by FDA, which is our governing law for supplements, not the NY AG's office.

On a positive note, though DNA testing was incorrectly used to check for label claims and allergens, there are other tests and allergen screenings that actually have a significant impact on quality assurance, and we believe contract manufacturers and marketing companies will start to seriously implement such tests into their products, at the very least to satisfy the more inquisitive consumer base that has arisen from this action by the attorney general."



Steve Mister
President & CEO
Council for Responsible Nutrition

"The NY AG's erroneous investigation using DNA barcode testing on herbal extracts demonstrates just how much damage misguided enforcement actions can do. More than the AG's investigation itself, the publicity from it has spawned countless class action lawsuits built on nothing more than the allegations of the AG's DNA testing, which has been revealed to be wrong. It has fed negative media coverage of the industry and skepticism among lawmakers and consumers about our products, without justification. And it has driven many manufacturers and suppliers to feel compelled to use DNA barcoding in their testing protocols, even where it may not be particularly accurate or the most appropriate measure.

While DNA testing is becoming more sophisticated, its application to finished dietary supplements is still being refined; it's not a panacea for all quality issues in the industry. So implementing it right now across the board, particularly with finished products, may just be adding costs to the system, without any consumer benefit.

If anything good has come out of it, it's a renewed conversation at all stages of the supply chain—all the way through to retailers and consumers—about quality and transparency. That's a conversation that is always worth having."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Irfan Qureshi, ND
Chief Regulatory Officer
Vitamin Research Products

"While the premise of the NY AG's action against certain dietary supplement retailers and manufacturers was faulty because of the use of non-validated and unverified DNA methods, I believe the AG's action will spur companies in the industry to reevaluate their processes and procedures across the board. In light of this action and other signs of increasing scrutiny by regulatory agencies, state AGs, Congress, and plaintiff's attorneys, dietary supplement companies of all sizes will likely face difficulty operating their businesses using current practices and are likely to experience significant challenges in the short-term; however, the companies that adapt and adjust to the challenges that lie ahead are the ones likely to thrive in the new regulatory paradigm.

The industry needs to reevaluate and increase investment in the science behind ingredients and substantiation of advertising claims, as well as their quality and testing practices, to ensure full compliance with cGMP guidelines. The industry players that adapt will be the ones that benefit long-term and become stronger for it. Consumers have been clear in communicating their desire to take charge of their own well-being by seeking out natural alternatives to support health. As an industry, it's our job to assure their confidence in the products we sell."

Suzanne Shelton
Managing Partner, Strategic Communication
The Shelton Group

"The industry's reaction to the NY AG and resulting negative media and class action lawsuits has been illuminating. There's increased focus on actual quality, with more testing and ingredient-quality scrutiny. Some companies posturing as the responsible core of the industry that didn't actually walk their talk started assessing their liabilities and vulnerabilities and making changes. This isn't just because of the AG's actions, but also the significantly increased likelihood of expensive class action lawsuits.

We're all talking about the industry's regulatory framework in broader terms and discussing a wider variety of options than we have for over 20 years. It's illuminated which companies are primarily here to make money without an inherent commitment to also making a significant impact on human health. Pay attention, because this is important. Some companies will adamantly oppose a revised regulatory landscape that would

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Going deeper: The NY AG's investigation has renewed conversations, both in and outside of the supplements industry, about how these products are regulated in the U.S.

limit consumer options, and others support it as an opportunity to limit competition.

Some are saying that the industry is arriving at consensus to embrace the Canadian regulatory model. That would benefit the group of large international companies pushing the idea, but we're actually a long, long way from any such consensus. This will continue to be very interesting."

Scott Steinford
Executive Director and President
CoQ10 Association and the Natural Algae Astaxanthin Association

"Whether you are quoting Friedrich Nietzsche or singing Kelly Clarkson, the idea is the same: If it doesn't kill you, it makes you stronger. The recent NY AG attack served this expression to the nutritional industry. Fearing the worst was the order of the day, many thought the apocalypse of this industry was now occurring. Some still question the fallout of all the negative publicity. While we know that we, as an industry, were not killed, are we stronger? Only time can truly provide the details of that analysis, as we are still too close to the event to know for sure.

But one real-time barometer that can possibly provide a glimpse of the impact is the stock analysis of the publicly traded supplement companies. In looking at an analysis of a smattering of companies scoping a six-month range of per-share pricing, it is clear we are mostly stronger:

Stock	2/11/15	8/11/15	Change
GNC	$43.35	$50.51	17%
NAII	$5.34	$5.97	12%
CYAN	$7.30	$7.88	8%
VSI	$42.13	$37.54	-11%
USANA	$99.19	$161.87	63%
HLF	$34.82	$59.70	71%

In general, this type of news ultimately provides a chance to respond to our critics with facts that support the strength of our safety, science, and efficacy. Unfortunately, it does appear we have to encounter bad news before our good news is noticed. But we do appear to have been made stronger as a result of our response, and I for one believe this trend will continue."

Elan Sudberg
CEO
Alkemist Labs

"The last time I played with fire, I nearly burnt my face off. It took this severe lesson to teach the young teenager I was at the time that such was not a sustainable activity. So I stopped playing with fire. Unfortunately, this industry is guided by insufficiently written and -implemented cGMPs, and we have accepted substandard testing regimes: essentially, playing with fire.

The recent actions by the NY AG have, even though it was a misapplication of science, served to shine light on our deficient quality-control standards and given us all an additional motivation to correct our internal issues. Here's a fact: if all players in this industry dipped into that healthy profit margin and

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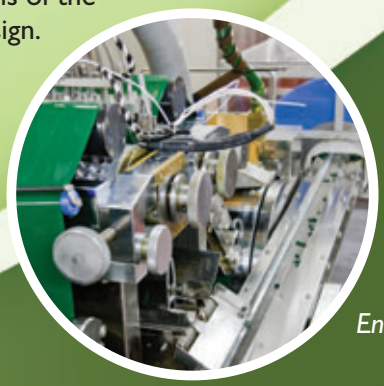

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"Trust is the biggest challenge affecting the food and supplement industry right now," says Innova's Lu Ann Williams.

simply stopped buying low-priced, poor-quality material and tested each and every batch using the appropriate testing methods, then quality concerns about our industry wouldn't be in the news. Now, as we slump our heads in embarrassment from the NY AG's beating, we need to go back to the drawing boards and choose the high road. We all know what it will take: quality ingredients in therapeutic doses tested by good labs using multiple appropriate testing methods."

John Villafranco
Partner
Kelley Drye & Warren LLP

"A key takeaway for the industry is that the NY AG's office is a unique regulator often requiring a unique response. It is not unusual for it to delve into specialized areas concomitantly governed by federal agencies, and it is likewise not unusual for it to publicize its investigations from day one.

In its first large-scale effort to target the supplement industry, the office coupled strong allegations that products failed to contain declared ingredients with strong media outreach. Several trade groups responded in the media, and one company issued an early press release raising factual disputes. Many months in, though, even with a media response, there still isn't apparent public understanding of key facts—including that the AG's office has refused to release its product testing, and that from what information is available, its testing appears to rely on a shaky methodology. Against this background, the NY AG's office has persisted and recently issued a second round of letters based on the same type of testing.

Following its first battle with the NY AG's office, the supplement industry no doubt has a keen sense of how the office operates and uses media to its advantage. With that knowledge, and if the ingredient investigations ultimately affect sales, the industry will likely hone its media capabilities even more and be prepared to launch an even swifter and more forceful response to any future NY AG actions."

Lu Ann Williams
Head of Research
Innova Market Insights

"Trust is the biggest issue affecting the food and supplement industry right now. It's a huge challenge, but situations like this always present opportunities. For companies that have strong science, that have always put quality first, it's an opportunity to reassure consumers that they can trust their products. I think the situation is similar to what was happening in the food industry in Europe before EFSA [the European Food Safety Authority] cracked down on claims. I remember giving a presentation on claims years ago, and when I was finished, I thought to myself that it was out of control. It can be a painful process, but in the end, the companies that are producing high-quality products and being honest will consumers should benefit." N

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Dietary Supplement Compliance:

A Work in Progress

Living with—and learning from—FDA Form 483s

BY KIMBERLY J. DECKER

That jittery air of tension hovering over the post-audit environment of an FDA current Good Manufacturing Practices (cGMP) facility inspection can feel a lot like report-card time, and for many of the star pupils in our industry, nothing but a 4.0 will do.

Unfortunately, in the five-odd years since dietary supplement cGMP practices went into full effect under 21 *CFR* Part 111, FDA has continued doling out Form 483s—the equivalent of a "needs improvement" grade—frequently enough to put at least one in almost every company's file.

But a grade of "needs improvement" is no sign that a supplement maker is about to flunk out. And companies can learn a lot from a 483 if they think of the process as a progress report that supplement makers can use to stay on the dean's list—and keep their products out of detention.

No Doubt about It: Take a 483 Seriously

Despite their ubiquity, Form 483s still sting, and manufacturers are right not to let the notices roll off their backs. For while it's not necessarily a black mark on a company's permanent record, a 483 is serious business.

For those readers arriving late to class, an FDA Form 483 is the official "Inspectional Observations" document the agency issues to a manufacturer's management following an investigation in which the inspector observes conditions that might amount to a violation of dietary supplement cGMPs as established in 21 *CFR* Part 111.

There has been an increase in the pace of 483 issuances. "It's a rare occasion when a Form 483 is not handed out at the close of an inspection," notes Justin J. Prochnow, shareholder, Greenberg Traurig LLP (Denver, CO).

Alas, the precise number of 483 issuances remains something of a black box, as FDA doesn't make the documents public. Inquirers can access them through a Freedom of Information Act (FOIA) request, but even the documents thus obtained are redacted to shield the identity and privacy of the companies involved.

Following a Form 483, the next, more serious, step in FDA's disciplinary chain—absent further action or remedy by the manufacturer—is an FDA warning letter. "And these seem to be increasing in number every year," says Gary Swanson, senior vice president, global quality, Herbalife (Los Angeles).

In contrast to the protocol with 483s, FDA *does* publicly post warning letters, and the Council for Responsible Nutrition (CRN; Washington, DC) has built a searchable database of such letters pertaining to products marketed as dietary supplements. The goal of the database, says Andrea Wong, PhD, CRN's vice president, scientific & regulatory affairs, is "to help industry understand FDA's enforcement priorities and activities" concerning cGMPs. This way, they can better anticipate and avoid the missteps that lead to the warnings in the first place.

483s: Where Are We Today?

Wong reports that as of August 2015, FDA had issued 14 warning letters related to potential cGMP violations, "nearly all" of which noted "a failure to establish specifications for dietary supplement components and/or finished products," she says. "As FDA has previously stated, 'If it wasn't written down, it didn't happen.'"

Other common infractions cited in both warning letters and 483s, those privy to the documents say, run to problems with written procedures, testing of raw materials and finished products, supplier qualifications, product complaints, holding and distribution operations, returned products, reserve samples, and master manufacturing records (MMRs) and batch production records (BPRs).

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Dr. Cheryl Luther, general manager, NSF Dietary Supplement Program (Ann Arbor, MI), adds that citations related to stability testing have been on the rise, as well, and that FDA is increasingly conducting website audits, which have the advantage for inspectors of dispensing with on-site visits. Such virtual audits might examine promotional materials, research support for online claims, blogs, drug claims, and ingredient safety and identity issues, among others, which is why Luther "strongly recommends that companies develop policies for routinely monitoring their websites."

Even Good Companies Get 483s

But not every company who gets a 483 is bad. As Luther points out, "Even very good companies may receive a Form 483."

Gary Swanson, senior vice president, global quality, Herbalife (Los Angeles), maintains that a 483 "shouldn't be interpreted as necessarily negative by other parties." Echoing Prochnow and Luther, he stresses that "It's not uncommon for an audit to result in a Form 483" and that "the issuance or non-issuance is not a measure of compliance."

In other words, just because a company *doesn't* get a 483 doesn't mean that it's compliant; likewise, the receipt of several 483s doesn't mean that it's not concerned about quality.

In fact, many companies are doing their best to comply with the high standards of recordkeeping and raw-material and finished-product testing prescribed in the cGMPs, which requires not only "resources, time, and money," Luther points out, "but, more importantly, company personnel willing to implement and maintain them on a day-to-day basis."

Still, FDA's expectations are rising alongside the number of inspections it conducts. So what are the major problems still persisting?

Mistaken Identities

Observers say that among the enforcement trends emerging are an uptick in warning letters covering new dietary ingredients (NDIs) and ingredients generally recognized as safe (GRAS), as well as problems with ingredient identification. As Wong points out, "Information gaps about raw materials hamper the manufacturer's ability to perform appropriate tests to verify the identity, strength, purity, composition, and limits on contaminants of the finished product."

Loren Israelsen, president, United Natural Products Alliance (UNPA; Salt Lake City), adds that the widespread use of botanical raw materials presents "specific problems with identification, the likelihood of adulteration, and understanding of which analytical techniques and tools can assure identity to rule out adulteration."

"This, to me," he says, "ranks as the top priority for improvement."

Lengthening supply lines only complicate the matter, making proper qualification of an

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ingredient's supplier and origins all the more important. Recognizing an unmet need, several trade associations, including CRN, UNPA, and the Consumer Healthcare Products Association (CHPA), formed the Standardized Information on Dietary Ingredients (SIDI) Work Group to develop voluntary best practices for ingredient procurement, documentation, and supplier qualification. The resources, Wong notes, "are free for industry to use to improve quality-management systems and improve cGMP inspection results."

Focus Is Primarily on Quality and Manufacturing

One could be forgiven for wondering how many of the most common infractions actually put consumers at risk and how many merely reflect a box unchecked or a spec sheet that someone forgot to produce in triplicate. Prochnow notes that while a 483's bill of particulars may include "the occasional mention of someone's lunch being left in a work area or some technical facility upkeep requirements," the overall focus, he insists, "remains on the manufacturing and quality of the product."

And as to the question of which violations rank as "serious" versus "minor" from FDA's viewpoint, Prochnow says "there's technically no such thing as a minor or serious violation. Each violation of the cGMPs would constitute an unlawful act under the Federal Food, Drug, and Cosmetic Act, and the failure to comply with the cGMPs could cause any products manufactured to be adulterated."

Swanson adds that although FDA doesn't rate 483 observations by severity, "they do have categories that are considered important because of safety, such as microbial excursions, foreign material contamination, raw-material identification, and quality oversight."

And for her part, Luther cautions that any 483 observation may trigger an FDA warning letter and subsequent enforcement action "if the documented violations aren't promptly and adequately corrected. Many companies this year have been issued warning letters as a result of not properly addressing previously issued 483s."

So You've Gotten a 483…

The lesson is that if FDA hands you a Form 483, don't let it paralyze you into inaction. Prochnow points out that while "there's no legal or regulatory obligation to respond" to a 483, its position as the first step in a potentially escalating enforcement process demands a thorough and timely response.

"And the emphasis is on *thorough*," Prochnow says. "Many of the letters over the last two years note that the company responded to the letter, but in an inadequate fashion." FDA wants evidence of change: copies of revised standard operating procedures (SOPs), photographs of repaired equipment or facility conditions, batch-record copies, you name it. "Failure to provide such documentation," he says, "has been cited often in recent warning letters."

This is where leaning on the wisdom of a regulatory veteran comes in handy. CRN's Wong notes that legal counsel or consultants experienced in dealing with 483s—and in communicating with FDA on cGMP issues—"can be very helpful." Professionals "who understand how FDA works," she says, have unique insight into how to resolve such issues before they rise to the level of a warning letter.

Cynthia A. Ipach, president, Compliance Insight Inc. (Fairfield, OH), is one such professional. She and her team work with manufacturers on quality and regulatory matters and have helped many turn a 483's findings into a workable plan for improvement. The key to doing so, she says, is "to

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CONTRACTING COMPLIANCE

Who's Responsible: the Marketer or the Manufacturer?

Those familiar with FDA enforcement of dietary supplement cGMPs note that industry's growing reliance on contract manufacturers is creating unintended consequences for quality control. As Justin J. Prochnow, shareholder, Greenberg Traurig LLP (Denver, CO), says, "The obligation of private-label distributors to ensure that their products are being manufactured pursuant to cGMPs continues to be one of the more frequent observations and—still—one of the areas that industry has failed to get up to speed on."

The problem lies with the dynamics of the supplement marketer/contract manufacturer relationship. As Prochnow explains, "There's a reason many companies hire third parties to manufacture products: they don't have the experience or know-how to do it themselves. That being the case, how are they supposed to have the experience or know-how to check with their contract manufacturer to see that *they're* complying with the laws?"

Meanwhile, Loren Israelsen, president, United Natural Products Alliance (UNPA; Salt Lake City), underscores the "primary responsibility" that supplement marketers bear for shepherding their brands.

"Brand holders have been slow to understand that they, too, are responsible for cGMP compliance and cannot just hand it over to contract manufacturers," he says. "Contract manufacturers are under tremendous pressure to enhance quality systems, increase testing, and still hold down costs. This is an unrealistic demand. Industry needs to understand this and accept that if we want and expect significant improvements in quality, there'll be increases in costs, which will ultimately surface in the supply chain and to the consumer."

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set up a complete understanding for FDA of what steps you're taking, with as much proof as possible that you're in the process of taking them."

So her team may conduct brainstorming sessions with a company's management to address the observations in a 483, the options available for reaching compliance, and those that "best suit that company based on the resources they have," she says. Then they'll compile a list of short- and long-term actions for achieving results. The former get going right away "so that when we submit our response in 15 days, we've taken some steps to show FDA that we're serious about and committed to resolving the issues—and we provide proof," she says. To demonstrate action on longer-terms corrections—new equipment or facilities modifications, say—"we report what we're doing to mitigate the risk in the short term and provide maybe an invoice for equipment on order to prove that we're moving in the right direction."

As to the question of which violations rank as "serious" versus "minor," Prochnow says that, to FDA, "there's technically no such thing as a minor or serious violation."

It's a process that both FDA and her company's clients appreciate. "Every company I've worked with is doing the best they can with what they know," Ipach says. "It's just a matter of continuous learning about their products, the regulations, and the latest technologies. I really find them to be very cooperative. They really want to make good products. And who doesn't?"

Behind the Numbers

That sentiment—more than the frequency with which FDA issues 483s or the infractions it enumerates therein—may be the best indicator of where industry stands vis-à-vis cGMPs. "The number of 483s only tells a small part of the cGMP-compliance story," Swanson declares, "and does not necessarily reflect an industry commitment or trend in terms of quality."

Israelsen says that any verdict on quality compliance should account for "how long a sector's cGMPs have been in place." For while the dietary supplements industry has

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only operated under the new standards for 5–8 years, food manufacturers have been operating with cGMPs for decades, as has the prescription-drug industry. And when you look at the seafood industry, whose cGMPs "are about twice as old as dietary-supplement cGMPs," he says, that field also "struggled in the first 5–8 years with compliance." So patience is in order.

"As time passes, we'd expect to see general improvements in these areas, but for now, they remain a problem," UNPA's Loren Israelsen concurs.

Room for Improvement

That said, the nature of the infractions that wind up on 483s "reveals we should focus industry efforts on training, education, and improvement in operational competence," Israelsen says.

"As time passes, we'd expect to see general improvements in these areas, but for now, they remain a problem," he concurs.

Prochnow believes that "bigger companies are doing well," while smaller players, "in my experience, have been slower to get compliant." The culprit, he says, is "the huge cost associated with the additional testing" that cGMPs require. "I think many companies take the position, certainly not recommended, that they'll do the best they can and make adjustments when FDA comes for an inspection and points out violations," he says. "But this is not a great way to move forward, as some companies have found that you don't always get a free pass."

Opportunity in Disguise

Besides, seen from a certain light, a 483 is a terrible thing to waste. As Swanson says, "A company should view a 483 as an opportunity to improve processes and systems." By that same token, they should embrace the standards laid out in the cGMPs.

"I really do think that the cGMPs are highly beneficial to manufacturers," Ipach says. "The more consistently they make their products, the more money they save in scrap. They can run a leaner organization because they become more efficient in how they produce their product. So I think it's been a benefit, even if companies cry foul when they have to comply."

And even if companies cry foul when they get a 483, they should know it's not the end of the world—or of them. "Every dietary supplement company's objective is a no-483 inspection," Israelsen says. But sometimes, that's just not realistic.

"The goal," he says, "should be continuous improvement. And if a company does receive a 483, that offers a fast-track improvement opportunity." N

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

STEP-BY-STEP TO RECOVERY

Hitting All the Right Notes in a 483 Action Plan

There's no one-size-fits-all plan for addressing the observations in an FDA Form 483. But those in the know, like Dr. Cheryl Luther, general manager, NSF Dietary Supplement Program (Ann Arbor, MI), agree: "The best approach for dietary supplement companies is to address all cGMP violations quickly, implement robust quality-management systems, improve training programs, and invest in continual improvements." That sounds like great advice. But can she get even a bit more specific? She can. In fact, says Luther, "I'd recommend that to increase compliance with 21 *CFR* 111, firms must" do the following:

- Plan and budget for increasing quality resources and invest more in employee training and raw-material testing, especially identity testing
- Implement more rigorous production in-process control testing
- Introduce stronger oversight of third-party contract manufacturers
- Verify that all batches of finished product meet specifications through testing
- Know and follow all procedures and complete all records accurately
- Adequately clean, sanitize, and maintain equipment, utensils, and surfaces used to manufacture, package, label, and store dietary supplements
- Have written specifications in place for raw materials, packaging components, and finished products
- Investigate all anomalies and document properly
- Provide adequate responses to 483s by reviewing operations, procedures, and systems to make any necessary changes to comply with FSMA
- Avoid making health claims on product labels and websites
- Understand their responsibility for notifying FDA about new dietary ingredients

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The latest lab techniques for catching fraud and adulteration in dietary supplements

BY JOHN TRAVIS, NSF INTERNATIONAL

Adulteration is *the* sizzling topic of the supplement world, one that is always on the mind of manufacturers, consumers, and regulators. Adulteration of food and dietary supplements is a criminal offense, most often resulting when unscrupulous suppliers under economic pressure start skirting regulations. Unfortunately, the history of food in commerce is sprinkled with incidents of adulteration, and the consequences for brands can range from expensive recalls to bankrupting lawsuits. In fact, government agencies in the UK and Denmark have formed crime units specifically designated to address criminal food and dietary supplement adulteration and fraud.

The key to predict when and how adulteration will happen is recognizing economic pressures and understanding how ingredients' specifications are corroborated. Ingredients in high demand are at risk for adulteration. If that factor is combined with a low supply and/or a high price, the risk is even greater. Once one identifies a risk, one needs to determine how the adulteration may transpire. The key aspect here is to examine the ingredient's specifications and critically assess how these may be exploited.

Case Study: The Challenges of Finding Adulterants in Chondroitin Sulfate

With this knowledge in hand, let's evaluate the ingredient chondroitin sulfate (CS) as an example. CS, along with glucosamine, is a common ingredient in dietary supplements designed to promote healthy joints and sometimes to support osteoarthritis treatment. Chondroitin sulfate exhibits some of the hallmark economic pressures that make it a prime candidate for adulteration: it is in high demand and expensive.

CS is a large molecule composed of a chain of alternating sugars with a molecular weight distribution of between 40 kilodaltons (kDa) and 500 kDa (compare to a small molecule such as caffeine, which has a molecular weight of 0.194 kDa.) Two characteristics of CS stand out. First, it is polymeric, meaning that it comprises repeating units of small molecules—in this case, the chondroitin disaccharides. The second is that the molecular weight distribution is pretty broad. Both of these characteristics make conventional testing procedures such as high-performance liquid chromatography (HPLC), ultra-high-performance liquid chromatography (UHPLC), or high-performance thin-layer chromatography (HPTLC) difficult to use both in identifying the ingredient and in quantifying its purity.

The key is to examine the ingredient's specifications and critically assess how these may be exploited.

The current and commonly used method for quantifying CS is cetylpyridinium chloride (CPC) titration. CPC reacts with CS to form a cloudy solution. The amount of CPC added is proportional to the quantity of CS. This would be an easy and inexpensive test if it weren't for one key problem: CPC can react with other substances in the sample in the same way as it reacts with CS. This includes the cheaper, low-grade proteins and seaweed extracts that are commonly

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used as fraudulent substitutes for CS. Thus, CPC is not selective enough if there are adulterants or look-alike substitutions present. Whatever test method or combination of test methods is used, it must have the capability to not only accurately identify CS, but also to identify potential impurities that may interfere with the CPC titration.

Electrophoresis is a new technique in the dietary supplement testing world and has made its way into the USP monograph for impurity assessment of CS. This technique allows the lab the ability to screen for common adulterants or fraudulent substitutes of CS, such as cheaper, low-grade proteins; seaweed extracts (e.g., alginates, alginic acid polymer); and polyphosphates. Time will tell if the test is selective enough to detect other substances which may be used in the future as CS adulterants or substitutions.

New Technologies Essential for Identity Testing

In the case of CS adulteration, and really in all discoveries of adulteration, the art is in detecting the presence of an adulterant and identifying it. Present-day analytical chemists have a number of tools at their disposal for this purpose. For the dietary supplement manufacturing professional tasked with finding qualified labs to perform dietary supplement identity testing, please read on. These are the types of technologies you'll want your lab to have and to know how to use.

- Ultra-high-performance liquid chromatography, or UHPLC, is a relatively new technique, extending the performance of traditional HPLC. It provides the ability to detect a greater number of substances.
- Another important and highly powerful tool when "hunting" for adulterants is high-resolution, accurate-mass mass spectrometry, or HRAM-MS. This instrumentation has the capability to accurately measure the mass of a substance to the third decimal place and beyond. For example, it could measure the mass of caffeine to 194.080 Da.
- The final tool, nuclear magnetic resonance (NMR) spectroscopy, possesses the ability to determine the relative position of atoms within a molecule, which helps reveal a substance's chemical structure.

All three of these tools provide complementary information to uncover adulteration. UHPLC with ultraviolet (UV) absorbance detection provides many of the initial clues that adulteration may be present. If a chemist using UHPLC to verify a marker substance (e.g., flavonol glycosides in *Ginkgo biloba*) spots an unfamiliar peak appearing on the chromatogram, it is a sign that there is an unknown substance present that requires further investigation. UHPLC can be coupled with HRAM-MS to measure the mass of the unknown substance. Because the mass measurement of HRAM-MS is so incredibly accurate, it enables the analyst to obtain theoretical molecular formulas for the unknown substance and then search online databases such

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as ChemSpider and PubChem for potential matches. The potential matches can then be compared to the unknown substance to determine its identity.

It was this combination of techniques that led to the discovery of the methamphetamine-like compound N,alpha-Diethylphenylethylamine, or DEPEA, in an over-the-counter pre-workout product called Craze in 2014. After testing samples of Craze, we found that the ingredient, listed as N,N Diethylphenylethylamine on the label, did not correspond to its theoretical value. That provided a reason to investigate further.

My colleague Bastiaan Venhuis at the National Institute for Public Health and the Environment in the Netherlands and I narrowed the unknown substance down to two possibilities. The first was the substance listed on the label, which was allegedly a constituent of the dendrobium species (though no scientific research has been able to support this claim). The second was a substance called DEPEA, which is chemically similar to the substance listed on the label but with enough variation to pose significant harm to human health. Nuclear magnetic resonance, or NMR, was used to pin down the actual structure of the substance and confirmed that it was in fact DEPEA, the more harmful cousin to the ingredient listed on the label.

The combination of UHPLC and HRAM-MS is also used to identify many other drugs masquerading as supplements or botanical ingredients. Some of the untested and potentially harmful compounds NSF International has discovered this way include ingredients listed on the product label as botanical names such as geranium oil for DMAA, dendrobium extract for DEPEA, and pouchong tea extract for DMBA. This gives consumers the false impression that the ingredient is derived from plants and perfectly safe to ingest; in reality, these compounds are not well understood and have already caused harmful effects such as liver damage or further complicated cardiac events.

Even these techniques may not always provide the identity of the adulterant. It may be necessary to extract and isolate the unknown substance from the product and

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analyze it using NMR. There are two main types of NMR used: proton NMR (1H NMR) and carbon-13 NMR (13C NMR). The information obtained from these experiments allows the analyst to reveal the chemical structure of the substance. For the final confirmation of identity, the NMR spectra (both 1H NMR and 13C NMR) of the unknown substance can be compared to authentic chemical reference standards to find potential matches.

Some of these tools, while new to the supplement industry for quality-control testing, have been in play in other industries for several years. For example, natural product chemists and medicinal chemists are in general well practiced in the art of mass spectrometry and NMR. UHPLC has been commercially available since the mid-2000s. The Orbitrap mass spectrometer was also introduced in mid-2000, driving improvements in time-of-flight mass spectrometers (a competing line of HRAM-MS). Increasing competition and demand for more accurate instrumentation have brought mass spectrometers from the research labs into the production labs, allowing greater access to the tools that are now required to verify the safety and quality of dietary supplements.

What is important to remember is that the presence of potentially harmful adulterants, sometimes masquerading as botanicals or other ingredients, in over-the-counter dietary supplements is illegal. Their continued discovery in dietary supplements reveals a dangerous pattern that dietary supplement manufacturers should be aware of and, more importantly, know how to expose through the latest technology and testing. Fortunately, there are many organizations, including NSF International and the National Institute for Public Health and the Environment in Netherlands, committed to scientific and technical excellence that know how to apply this expertise to root out bad players and help companies protect the safety and quality of their supply chains. N

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Movement in **Manufacturing**

Major trends in contract manufacturing are changing the name of the game.

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BY MELISSA KVIDAHL

Last year, management and technology consulting firm Clarkson Consulting released its 2014 Contract Manufacturing Trends report, focusing mainly on the dramatic changes in the pharmaceutical industry. But while natural products are often depicted as the anti-pharma, sophisticated manufacturing practices are quickly closing any remaining quality gaps. And ultimately, experts agree that the four trends identified by Clarkson as most influential in the pharma space—emerging markets, consolidation, upstream services, and company differentiation—are also shaping contract manufacturing as it pertains to natural products.

Emerging Markets

When it comes to products, the natural industry is experiencing increased demand in a number of areas. According to Kathy Paffendorf, sales consultant in contract manufacturing at Pharmachem Laboratories Inc. (Kearny, NJ), probiotics represent one area of untapped potential, as "the estimates for growth in this category over the next five years are impressive," she says. "I believe that with the continuously emerging clinical studies on probiotics, those companies capable of handling live organisms in a variety of new and existing delivery systems will benefit."

Probiotics are also on the radar for Sabinsa Corp. (East Windsor, NJ) as options for healthy supplementation and as recommended therapies alongside prescription drugs. Other areas of interest include gummy formats (gaining in popularity with adult consumers) and bi-layer tablets, which are already experiencing popularity in Asia and Europe but haven't yet hit the mainstream stateside, says Shaheen Majeed, the company's marketing director.

But beyond products and deliveries, the biggest emerging market is a geographical one. In the pharmaceutical industry, reports Clarkson, contract manufacturers are looking to establish assets worldwide and become part of a global supply network. When it comes to natural products, country-of-origin concerns, specifically, are opening doors to a similarly international market.

"The Asian consumer is wary of finished goods for consumption made in their markets," observes Mark A. LeDoux, chairman and CEO at Natural Alternatives International Inc. (San Marcos, CA). "They would prefer purchasing from the USA or Switzerland due to quality reputations and systems." As a result, Natural Alternatives International has a multimillion-dollar expansion underway at its Lugano, Switzerland, facility.

Indeed, products made in the USA have a high impact on international consumers, agrees Michael Schaeffer, president and CEO of Pacific Nutritional Inc. (Vancouver, WA),

Emerging markets, consolidation, and upstream services are reshaping contract manufacturing.

citing not just Asia but also Europe and specifically Russia as markets of potential.

Of course, all this expansion demands that companies themselves expand. And, as is the case in the pharmaceutical industry, natural products manufacturers are exploring two distinct avenues: consolidation or differentiating services—or both.

Mergers and Differentiation

As markets expand in product offerings and across the world, contract manufacturers are finding that expansion in their own businesses is unavoidable. In the pharmaceutical industry, the answer has taken the shape of large-scale mergers, as companies aim to reach global partners and expand capabilities to become one-stop shops for their customers.

"Those contract manufacturers with the capabilities to handle the full spectrum of a customer's 'wish list' and have a good reputation within the industry for quality are in a prime position to capture business that has been consolidated," says Paffendorf of the natural products industry's similar landscape, adding that Pharmachem meets demand by offering all aspects of product development, from conceptualization to finished-product testing. "I regularly see business migrating from contract manufacturers who are unable to monetarily expand their business to handle the multitude of regulations imposed to those more established, broader-based companies."

Ephi Eyal, president and CEO of Innovative Food Processors Inc. (IFP; Fairbault, MN), has observed consolidation taking shape in three ways: "strategic players investing in contract manufacturing to drive vertical integration, private equity investing in contract manufacturing to drive growth and lure strategic players, and private equity rolling up smaller contract manufacturers to create larger entities with wide-ranging one-stop-shop offerings."

According to Clarkson, all this movement means that manufacturers are often competing for the same customers. How companies distinguish themselves in a changing playing field—in pharma and in natural products—has everything to do with their differentiating services.

"Traditionally, low prices have been key when it comes to contract manufacturing," says Majeed. "But with the industry having been the target this year of significant criticism by the legal community, the mainstream media, and U.S. Congress, there is more focus on quality and innovation in this area."

While some contract manufacturers "require all steps to be complete before they touch the material," says Majeed, Sabinsa offers customer support in intermediate steps, from rolling and granulation to blending and milling. "Sabinsa started out as an ingredient supplier in the late 1980s. We then turned to servicing contract manufacturing needs at the turn of the century," he adds. "We now are offering finished dosage forms online and direct to consumers. Our advancements in the raw-material stage all the way to bottling help ensure smooth workmanship in our finished dosage forms."

"Large customers appreciate the one-stop-shop approach and the lower perceived risk of interacting with larger contract manufacturers," says Eyal of this strategy also employed at IFP. IFP has expanded its support, analytical reporting, and consumer insights capabilities as well as innovations in coating, precision dosing, and microencapsulation.

Upstream services are taking a front seat at Pharmachem, as well, where experts are available to evaluate trends, recommend formulations, produce raw materials and combinations thereof, and more. The company even works to connect customers for mutual benefit. "For instance, many times, we have customers that approach us with a new delivery system. Another customer may have ingredient combinations that may be a synergistic fit for that system," says Paffendorf. "Making the necessary introductions to marry the two for customers just entering the market could be extremely important."

Costly Measures

All this growth, of course, comes with a hefty price tag.

"Contract manufacturers must be able to provide pharma-grade capabilities, if they aren't already. There shouldn't be lesser standards for being a natural product manufacturer," says Majeed. "The argument is always on price—we're not as expensive as the pharma industry and therefore we cannot adapt their capabilities. This thinking is wrong."

But it is pricey. That's why investment is the biggest challenge facing natural products contract manufacturers today.

It begins with labeling demands. According to Paffendorf, customers are looking for the necessary documentation to meet DNA testing, non-GMO certification, and gluten-free claims, in addition to organic. As a result, Pharmachem has expanded its lab and its employee base to meet demand.

Beyond these types of trends, testing is a huge cost, "from incoming material to outgoing finished products and everything in between," says Majeed. "It adds up."

Still, he explains, it's worth the significant investment up front to be able to offer in-house lab testing and ensure confidence overall. "Now, more than ever, transparent, competent, and robust testing absolutely has to be part of the process," he says. "If we truly believe in this industry, the band of trust should stretch as far as possible to bring in the best of manufacturing meeting pharma standards, for which critical investments are necessary."

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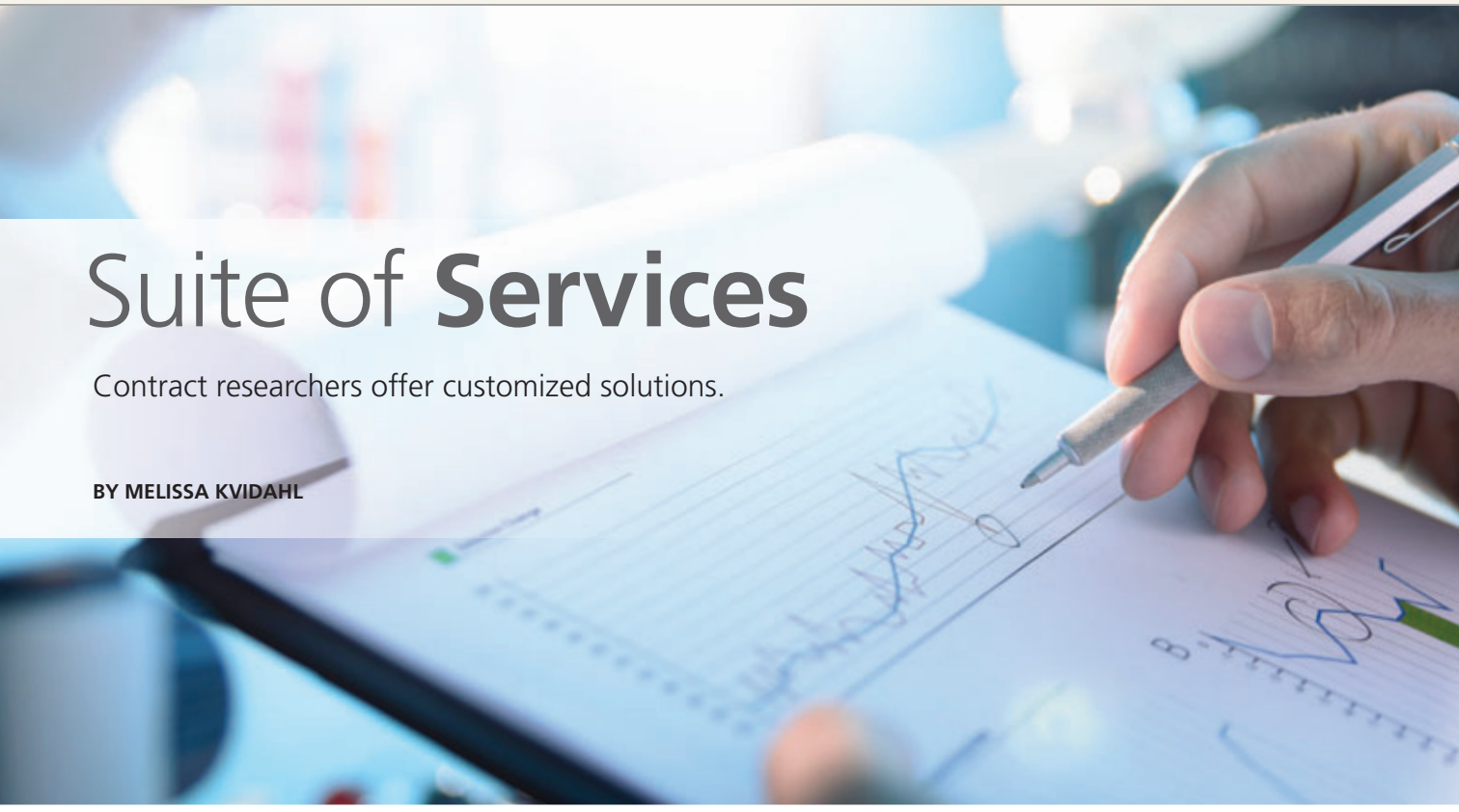

Suite of **Services**

Contract researchers offer customized solutions.

BY MELISSA KVIDAHL

As the natural products industry evolves and matures, scientific research is taking an increasingly prominent role in not only product development but also marketing and branding. Consumers want to be sure their supplements are safe, and responsible brands are happy to oblige with the highest-level efficacy and safety trials—as well as the market research to support the product's success on the shelf. For many brands, a skilled contract research firm holds this key. And in order to keep up with such sophisticated demands, researchers are finding their own businesses evolving and expanding.

"As the standards of evidence have increased for the dietary supplement and functional food industry globally, we have been able to assist our clients by staying informed of regulatory changes and helping them respond and adapt to them," says William J. Rowe, president and chief executive officer of Nutrasource Diagnostics Inc. (NDI; Guelph, ON, Canada).

Specifically, the company is moving towards a more pharmaceutical-like model as it pertains to quality-management systems and operating procedures, investing substantially in infrastructure, systems, and scientific personnel in its in-house regulatory and clinical research department. "We truly are a one-stop shop for all of our clients' product development and commercialization needs—health-claim strategy, regulatory compliance, on-site clinical trials, data management, product testing, bioanalysis, and marketing and positioning strategies," Rowe explains. This, he says, spares customers from communicating with several vendors and subsequently jeopardizing timeline.

At BioFortis (Columbia, MD), responding to a sophisticated supplement market means an expansion in sensory research and cognitive-function capabilities as well as literature assessments such as evidence mapping, systematic reviews, and meta-analyses. "We have also purchased new technologies and equipment such as our investment in a Dual Energy X-Ray Absorptiometry (DXA)," says Jill Stocki, director of business development at BioFortis Innovation Services, "which allows for expanded research capabilities as well as on-site convenience to our study participants."

Going forward, Bibiane Zakaria, director of sales and client services at KGK Synergize Inc. (London, ON, Canada), predicts the past few years' momentum in the area of recruitment will continue to evolve—as the natural products industry grows, so too will the need to grow clinical populations. To prepare, KGK has expanded its presence in the United States with two new clinical sites in Orlando, FL, and Irvine, CA. As a result, clients benefit from faster recruitment timelines and an option of conducting studies in the United States, Canada, or both. Similarly, as part of the Merieux NutriSciences family, BioFortis clients also gain access to international research locations and studies.

According to Zakaria, the future holds "a convergence between food, health, and technology in product development." This means new formats and ingredients as well as new packaging to appeal to a health-conscious consumer shopping every aisle of the grocery store. "In addition, niche health indications and market segments will continue to grow, and products will become even more specialized," she adds. "Contract research will be instrumental in these future developments. Quality science is the way of the future." N

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Softgels in the Fast Lane

Myriad benefits attract consumers to the softgel format, and formulators are meeting demand with innovations that allow for increased offerings.

BY MELISSA KVIDAHL

In a supplement market where consumers have seemingly endless choice—tablets, liquids, capsules, functional foods—they return again and again to softgels.

As far back as 2009, research from Catalent Inc. (Somerset, NJ) found that consumers preferred softgels to other delivery formats due to the fact that they're easily digested, easy to swallow, and convenient to take. Additionally, consumers surveyed also prioritized products that were safe, efficacious, and fast-acting—all benefits boasted by the softgel. Further, though softgels are often pricier than other options, it needn't be a hurdle; researchers found that more than a quarter of consumers who prefer softgels were willing to pay a price premium for them.

"Both consumer and marketing companies are requesting softgels more than ever before," says Steve Holtby, president and CEO of Soft Gel Technologies Inc. (Los Angeles). "As the average individual's education level regarding supplements continues to rise, the unique and superior qualities of softgels in specific solutions become more appealing."

Boasting Benefits

Indeed, softgels offer many benefits to consumers, the first of which is that they are very easy to swallow as compared to some other delivery formats. And unlike chewables or liquids, which also appeal to the easy-to-swallow trend, softgels have no taste; unlike some tablets, they have no odor.

But beyond these benefits lies a key allure cited in the Catalent study—enhanced efficacy and bioavailability, which Holtby says is one of the most widely recognized benefits of softgel capsules. "Softgel capsules improve bioavailability by delivering the nutrient in solution or other absorption-enhancing media," he explains. "By providing enhanced absorption and bioavailability, consumers can expect fast disintegration and immediate nutrient delivery to produce a quicker onset of action."

Unlike chewables or liquids, softgels have no taste; unlike some tablets, they have no odor.

According to Holtby, this benefit is a result of the very nature of the sealed softgel capsule: when sealed, nutrients are protected from oxidation and degradation. Opaque options can also protect against light and UV radiation, which further ensures ingredient stability and minimizes free radical formation, "especially in the case of oils," he says.

On the manufacturing side, softgels offer a host of benefits, as well, says Holtby, beginning with the wide variety of shell colors, shapes, and sizes available to offer product differentiation in the market. And "although aesthetically pleasing supplements appeal to the consumer eye," he adds, "the inner fill of the capsule is even more important. Softgel capsules can accommodate a wide variety of compounds filled as a semi-solid, liquid, gel, or paste. Micronized materials can be used in inner fills of softgel capsules, whereas tablets and hard-shell capsules require larger particle sizes."

And when it comes to safety, softgels are tamperproof. "A tampered or punctured softgel will leak or become discolored, thereby showing evidence of a potential problem," Holtby says. "This provides consumers with a sense of security while taking their supplements."

Trends and Challenges

Currently, one of the biggest trends in softgels is vegetarian. In fact, the Catalent study revealed that more than three-quarters of respondents preferred plant-based options. But the reality for many manufacturers and formulators is that this trend also boasts its share of hurdles.

First, vegetarian offerings are more expen-

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sive than their conventional counterparts, and Holtby argues that a vegetable-derived shell won't be as strong as one made of animal gelatin. "In addition, the physical characteristics of many vegetarian gelatin blends make it difficult to encapsulate all but the simplest oils," he adds. "To add insult to injury, the unique advantage of standard softgels is rendered nil in vegetarian format: softgel fill material is usually protected from oxygen exposure after encapsulation, but vegetarian gelatin is porous." This means that the oils inside vegetarian shells can become rancid more quickly.

Vegetarian issues aside, additional hurdles challenge the softgel market. Some ingredients—particularly those in powdered form—don't blend well into an oil base, which is a necessary step when formulating a softgel. In response, Soft Gel Technologies is investing resources into addressing this issue among various ingredients. For example, the company developed a crystal-free line of CoQ10 products, which transforms the powdered ingredient into a solution via the addition of a natural solvent. The result is a true softgel-ready ingredient, rather than a suspension of powder in oil.

Multi-ingredient formulations present yet another challenge. "For example, combining probiotics with omega-3 is a challenge, since probiotics do not like high temperature or humidity, both conditions usually required for softgels," says Charlotte Beyerholm, marketing manager at Chr. Hansen Human Health & Nutrition (Denmark). Chr. Hansen has overcome this challenge with the development of Life Gel technology, which allows for the formulation of a softgel that can include these two ingredients, while also preserving probiotic life. "Life Gel is the first softgel formulation that can document live probiotics with two years' shelf life and with efficacious dose," she adds.

And in a supplement landscape where consumer needs are consistently extending beyond basic nutrition to include blends, condition-specific products, and more, such innovations are necessary if the softgel market is to expand. N

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The Contemporary Capsule

Innovative applications and clean-label demands are transforming and revitalizing this supplement industry mainstay.

BY MELISSA KVIDAHL

Consumers increasingly want assurance that their capsules are clean-label. Thankfully, today's capsules can provide.

Within the overall health and nutrition industry, there is one consumer demand that's undeniably driving trends: clean label. And on the supplement front, capsule formulators are more than happy—and uniquely poised—to deliver.

"Leading clean-label claims for supplements include allergen-free, vegetarian, and gluten-free," says Erasmo Schutzer, chief marketing officer at Capsugel (Morristown, NJ), citing recent Mintel findings. The good news is that capsules meet these claims from all sides. "Capsules can be formulated free of additives, starch and gluten, preservatives, and allergens," he says, "and do not contain the non-nutritive binders, fillers, or disintegrants that may appear in other dosage forms."

At NutraScience Labs (Farmingdale, NY), vice president of contract manufacturing Vincent Tricarico has noticed a spike in inquiries for capsules, specifically because vegetarian formats are available. But this popularity does not come without its share of challenges.

"Working with non-animal material can be tricky," says Michael Pappalardo, director of business development at Qualicaps (Whitsett, NC), of the options available. "Tackiness, poor drying, and viscosity are all issues that need to be overcome." And though cellulose (HPMC) is a suitable alternative that acts most like gelatin in the manufacturing process, it does often require slight differences along the production line when it comes to machinery, he adds.

That said, manufacturers of capsules have reason to be optimistic, since this delivery format boasts many benefits. "First, capsules often provide very favorable processing conditions to maintain the integrity of actives in their final dosage form," says Schutzer. "A number of actives cannot withstand the processing conditions—mainly heat and compression—associated with the manufacture of tablets."

Tablets also demand the addition of excipients and binders, Pappalardo points out. This is not only at odds with clean-label trends but also contributes a complexity and cost to the overall process, which can hold up production and release to market. Capsules, by their very nature, avoid the excipient and binder issue altogether.

Plus, like softgels, capsules can deliver liquids, "but many times faster," Pappalardo maintains, "making them attractive to manufacturers who prefer not to outsource their production." And once produced, hard gelatin caps can also serve as good oxygen barriers, adds Tricarico, which enhances bioavailability overall.

On the branding side, customizable capsules not only offer manufacturers seemingly endless choice when it comes to color and imprinting, but their very nature supports natural branding initiatives. "You can easily show your consumers the natural elegance of the product they are taking," Pappalardo adds. "A clear capsule has the potential to really reinforce the natural aspect of the supplement."

Looking Ahead

Going forward, formulators can expect innovations that push the boundaries of conventional capsules. "Keep a close eye on liquid-fill two-piece capsules and beadlet technology," says Tricarico. "These are two dosage forms that can lead to some really unique formulation ideas."

One example of such innovation is Capsugel's DuoCap, which is a capsule-in-capsule delivery system designed to deliver combination or dual-release products. "DuoCap capsules involve inserting a smaller, prefilled capsule into a larger, liquid-filled capsule," explains Schutzer, and has been used to combine such ingredients as prebiotics and probiotics into one dosage form, since the opening of the inner capsule is delayed. The company also offers myriad vegetarian options—Vcaps, Vcaps Plus, DRcaps, and Plantcaps—all of which are preservative-free, GMO-free, and gluten-free to further meet clean-label demands. Capsugel recently announced a $25 million investment to increase production capacity for its vegetarian options.

"There are so many possibilities for capsules in the future," says Pappalardo, "and the applications for this industry could be exciting." N

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The MG2 Selekta Checkweigher from MG America

Better, **Faster, Smarter**

A look at the newest tablet-press, softgel-encapsulation, and checkweigher machines

BY MICHAEL CRANE, ASSOCIATE EDITOR

Whether the name of the game is tablets, softgels, or capsules, any company looking at the equipment that produces these nutraceutical delivery systems will likely have some of the same priorities in mind. Faster production speeds and increased durability are definitely crucial factors to consider, but some of the newest machines also offer a wide range of customizable features, reduced overages, and a smaller footprint. Here's a look at some of the latest equipment launches and the innovative capabilities they offer.

MG2 Selekta Checkweigher

MG America (Fairfield, NJ) first introduced its MG2 Selekta Checkweigher in the U.S. last year, claiming it to be "the fastest tablet checkweigher on the market." That's based on the Selekta's ability to check up to 500,000 units per hour, depending on the product, according to MG America.

Selekta's high speed is thanks in part to enhanced automation and MG2's Multi-NETT weight-control system, which has the ability to monitor and control net weight in low-dose applications (5–25 mg).

"It's safe to say that no machine could possibly be this fast—while still being accurate—without technological advances that make it more automated," says Fabio Trippodo, president, MG America. "The Selekta selects conforming and nonconforming units through a fail-safe system employing a set of sensors located at critical points throughout the testing process."

The Selekta is easy to use and maintain, with size changeover accomplished by replacing two sets of parts that are easily disassembled, says Trippodo.

IMAGE COURTESY OF MG AMERICA

Kilian KTP 720X Tablet Press

Making its debut in December 2014, the Kilian KTP 720X is a high-speed tableting machine "specifically suitable for temperature-sensitive products," according to manufacturer Romaco (Cologne, Germany). It is designed for both mono- and bi-layer formats, and can compress up to 1,020,000 tablets per hour, says Romaco.

One thing that sets the Kilian KTP 720X apart is what Romaco calls its "Cool-Fast-Clean" design concept. "Cool" refers to a special roller, bolt, and bearing that reduces friction and keeps the process area from getting hotter than 30°C. The machine is "fast" because of its quick powder-to-die filling system and the tool-free dismantling of all contact parts during changeover. Romaco calls the KTP 720X "clean" because of the separation of process area from lower mechanical and maintenance compartments.

This design makes the KTP 720X "ideal for processing effervescent tablets and products with poorly flowing, abrasive, or temperature-sensitive materials," says Romaco. It is also designed for automated operation and allows for easy maintenance and replacement of parts.

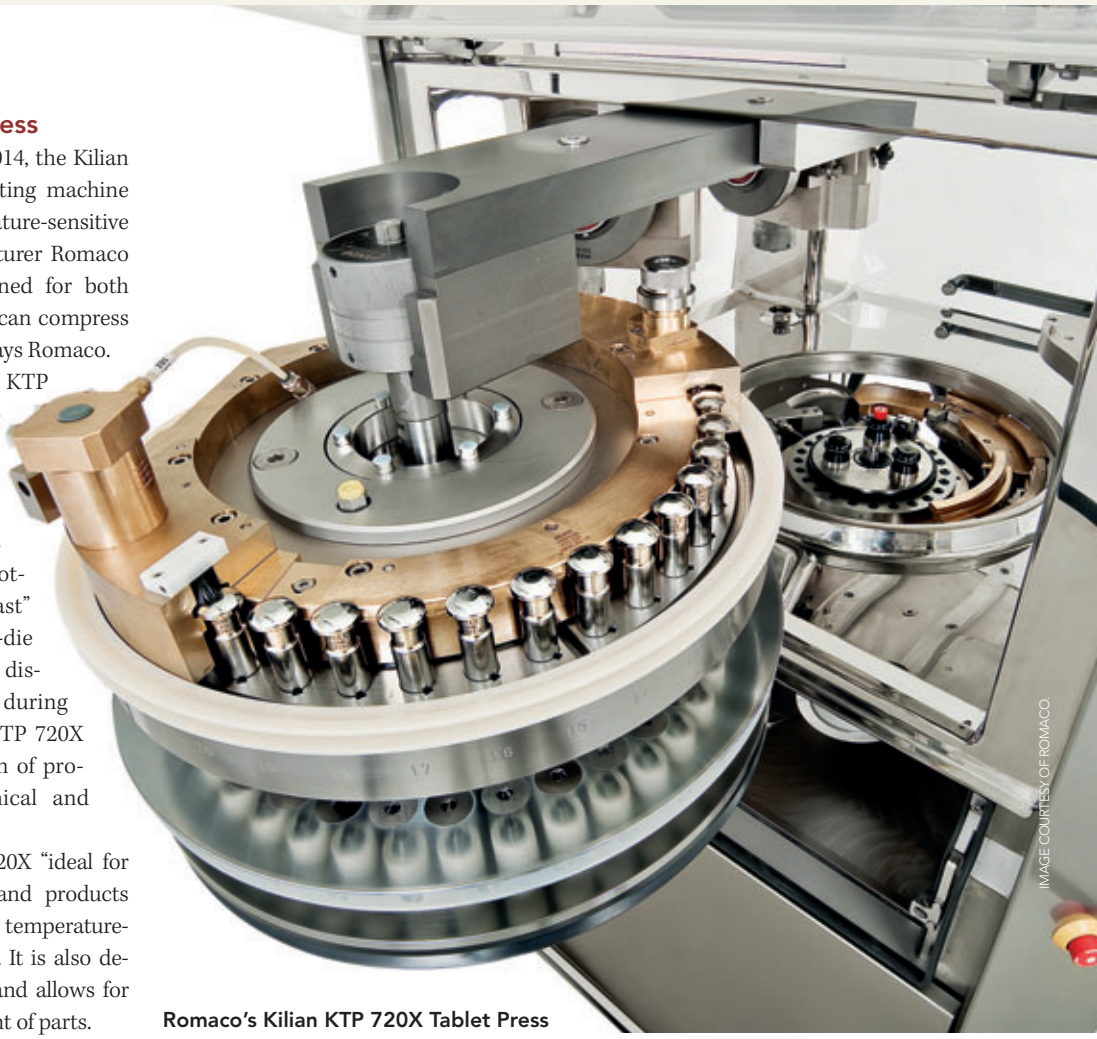

IMAGE COURTESY OF ROMACO

Romaco's Kilian KTP 720X Tablet Press

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IMAGE COURTESY OF PHARMA TECHNOLOGY

Core-Coating Module for Tablet Press

This new module is also designed for use on a tablet press. However, instead of automation, the main selling point of the core-coating module from Pharma Technology Inc. (Piscataway, NJ) is the capability to produce a more advanced tablet with a coated core. It was developed in collaboration with equipment company Roeltgen (Solingen, Germany) and is designed especially for use with Roeltgen's FlexiTab tablet press.

The core-coating module works by replacing one of the FlexiTab's three feeders. It places core tablets in the center of the press die—tablets that have already been pre-filled with a first layer of powder. Another layer of powder then fills the die, covering the core, and the complete tablet is then compressed in a process similar to the pre- and main compression steps performed on standard rotary presses, according to Pharma Technology.

"The core-coating module is cost-effective, easily installed, and provides a widened range of capabilities to the already-versatile FlexiTab tablet press," says Nic Michel, general manager, Pharma Technology Inc. The module was introduced in October 2014.

IMAGE COURTESY OF THE ELIZABETH COMPANIES

EP-400 Tablet Press

Launched in April, the EP-400 series tablet press from The Elizabeth Companies (McKeesport, PA) is all about saving space. A double-sided production press that's the size of a normal single-sided machine, the EP-400 offers high production volumes with a small footprint, says Ryan Keefer, North American sales manager, Elizabeth.

Aside from taking up less space, the small footprint of the EP-400 also makes for an easier machine to use and clean, says Keefer. It is available in both a manual and automated version, with the automated version offering full weight control, data collection, recipe storage, and operator security levels, Keefer adds.

Depending on the size of the tablet and turret configurations, the EP-400 can produce between 162,000 and 270,000 maximum tablets per hour, according to Elizabeth.

"This press model is capable of both single-layer and bi-layer production and is being sold at an economical price point for these markets," says Keefer.

IMAGE COURTESY OF CHRIS HILLSETH

880R for Softgel Encapsulation

Perhaps the newest piece of equipment on this list is the 880R softgel-encapsulation machine, which was officially launched in the United States at Supply Side West 2015 in early October. The 880R is created by Changsung (Pocheon, South Korea) and distributed in the United States by Chris Hillseth (Gardena, CA).

Softgel manufacturing can be more challenging than other delivery methods because there are more than 10 variables to control, many of which have been managed by human operators in the past. What sets the 880R apart is the way it fully automates many of these features.

For instance, it's possible to use the 880R without an operator adjusting the die roll synchronization, manipulating the ribbon thickness, or adjusting the fill weight—removing the need for continuous operator interaction, says Changsung. The company adds that the automation should reduce start-up and changeover times.

The 880R can produce up to 120,000 capsules per hour with a 22 oblong die roll, says Changsung.

IMAGE COURTESY OF NATOLI ENGINEERING COMPANY

NP-400 Tablet Press

The new NP-400 rotary tablet press from Natoli Engineering Company (St. Charles, MO) offers a range of features to reduce waste and increase automation, including a Near Infrared (NIR) spectroscopy system designed into the frame of the tablet press. Just as auto-lubrication has become standard in many tablet presses, Natoli believes NIR is "set to become an important option for tablet analysis during manufacture."

The NP-400's NIR system examines each tablet after compression to determine whether it falls within the specification range for a specific tablet property, says Doug Kirsch, technical service manager, Natoli. For any tablets that do not meet specification, the NIR will communicate with the NP-400's on-machine supervisory-control and data-acquisition system (SCADA) to direct the tablet to a reject chute for later evaluation.

"This capability will enable customers to generate a data-rich batch record that can be used for lot release support and process-improvement options," says Kirsch.

The NP-400, which began shipping earlier this year, can produce up to 180,000 tablets per hour and offers optional monitoring features of press temperature, tablet-takeoff force, and humidity. It also includes product-yield technology that deposits excess powder back into the feeding system, reducing waste and allowing for a cleaner production process.

Going All In

PHOTO COURTESY OF SDC NUTRITION

One company's choice to bring manufacturing in house…and the equipment-buying decisions involved

BY DONALD CONDIT,
CONDIT MARKETING COMMUNICATIONS

Ask Bruce Barger, director of contract manufacturing at SDC Nutrition in Pittsburgh, how the company has managed to double in size every year since 2009, make headlines in *Forbes* and *Fast Company,* triple its staff, and quadruple the size of its flagship brand over the last three years, and he will answer with two words: "It's simple."

Simplicity is the mantra that drives product development and contract manufacturing at SDC Nutrition. According to cofounder and director of marketing Devenee Schumacher, the company's obsession with simplicity and purity will be obvious the first time you pick up any of the company's About Time products.

"Just take a look at our ingredient panels," she says. "On every panel you'll see a simple, short list of items you can actually pronounce. Health-conscious consumers prefer products that are pure and simple, and with our protein supplement and meal-replacement products, that's what they get."

SDC Nutrition offers complete contract manufacturing services, while it also manufactures and markets its own products in five proprietary brands—led by its flagship brand, About Time. According to Barger, the 50/50 balance between the two sides of SDC's business explains the company's unique perspective on contract manufacturing. "Since we are in the business of developing and marketing fast-growing brands," he says, "we know what it takes to launch a hot product and grow that success internationally. Every contract manufacturing customer of ours receives the benefits of our market and manufacturing savvy."

SDC's branded products are setting an impressive example of sustained success. In the United States, the About Time product line retails through high-volume channels like Whole Foods Market, GNC, Giant Eagle, and Vitamin Shoppe. Internationally, the company says, sales are skyrocketing in more than 2,000 retail outlets and more than 15 countries, with distribution expected to reach five more countries before the end of 2015.

Meanwhile, SDC's contract manufacturing business is growing even faster. Production doubled during just the first six months of 2015, following a plant expansion in the fall of 2014 that tripled capacity, the company says.

The Decision to Manufacture

"We recognized during our early days what this market needs in a contract manufacturer," says Schumacher. Part of what the company realized, she says, is that there was a need in the market for higher-quality contract manufacturing. According to Schumacher, "Back then, we were relying on others to manufacture our products. We discovered that some contract manufacturers in our industry are focused mainly on pushing volume through their plants, with little regard for the quality and consistency of the final product." This includes cutting

In SDC Nutrition's new manufacturing facility, this 100-cu-ft ribbon blender handles long production runs of products such as whey protein isolate, vegan protein, and meal-replacement and post-workout blends.

corners on ingredients, she says, and substituting lower-cost proteins or flavors—a fact confirmed even today when the company performs analytical testing on some of its prospective customers' products.

"Awareness of problems like these is growing," she adds. "The FDA is cracking down, and we think that's great for the supplements industry. With more and more consumers turning to products like ours every day for better health and well-being, it's time for this industry to step up and meet a higher quality standard."

Based on their experience as contract manufacturing customers, Schumacher and cofounder/CEO Sean Marszalek chose to control quality by bringing their production in-house.

The first step was to build a manufacturing model that reflects their passion for purity and simplicity.

"First, we assembled a team of experienced manufacturing pros who share our crazy obsession with quality," says Schumacher. "We collaborated on a production strategy based on current good manufacturing processes. Then we gave our team the best equipment we could afford."

"With an entire startup plant to equip, we just couldn't afford to buy a new unit," says Schumacher.

Equipping the Plant

Every growing company faces the challenge of acquiring production equipment that strikes the right balance between performance, flexibility, reliability, and cost. Budgeting is always a balancing act. But especially when your company is small

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and cash-constrained, something has to give. The question is where a manufacturer places its priorities and where it's willing to compromise.

"Our top priority was never in doubt," says Schumacher. "We wouldn't budge on product quality or the quality of the equipment we'd use to manufacture it. So, we had to be creative about finding and financing the equipment we needed."

Dry blending is the heart of SDC Nutrition's manufacturing process. So, the company began by buying an 18-cu-ft ribbon blender built by Charles Ross & Son Company, a multinational manufacturer headquartered in Hauppauge, NY. But they didn't buy new, and they didn't buy direct.

"At that point, with an entire startup plant to equip, we just couldn't afford to buy a new unit. We found a company nearby that had been renting an 18-cu-ft blender from Ross. Their business was changing, so we bought their unit and started production."

With the About Time product line taking off, SDC outgrew its first blender in only two years. The team went shopping, and soon SDC purchased a Ross 36-cu-ft sanitary ribbon blender—again, from a company just a few miles away whose production needs were changing.

Process Capacity and Flexibility Drive Contract Manufacturing

"The fast growth we were experiencing put a lot of pressure on our cash flow," says

FIVE WAYS TO BUY A BLENDER

By Chris Ross, Vice President, Charles Ross & Son Company

Looking for a way to optimize production and product quality, most process engineers focus on what's right in front of them: their process line and the equipment they'll need to meet their production goals. But behind every production decision is a business decision that balances operational benefits with up-front costs, cash flow, and capital risk. Smart production choices are matched by equally smart business choices, and to make smart choices you need to know all your options. Here are five ways to obtain the equipment you need, when you need it.

1. New Equipment Purchase, Built to Order

The most obvious way to obtain a blender is to buy it direct from a manufacturer. This gives you an opportunity to customize the design of your blender and control system to match your production environment. It also allows you to test the unit in a laboratory before you buy it to confirm your choice and reduce risk. And, of course, a new equipment purchase gives you a brand new piece of machinery with a warranty, technical service, and all the additional support you may need for control integration and startup.

2. New Equipment Purchase from Stock

If you need more production capacity *immediately*, purchasing a blender that will be built to order may not be your best choice. A new blender built to order is typically delivered in 8–10 weeks following approval of engineering drawings.

You can avoid this delay if you're working with a manufacturer who stocks new equipment for sale. Buying from stock, you may have to compromise on such details as the blender's capacity and the bells and whistles that come with it. But a little flexibility may get you a blender with 90% of the features you're looking for, in just a few days.

Actually, you may not have to compromise for long. Some manufacturers will also agree to provide a new (or used) blender from stock to help solve your immediate need while your new blender is being built, then swap it out later when your new blender is ready for delivery and startup. This is the best of both worlds.

3. Used Equipment Purchase from Stock

Your blender manufacturer may occasionally stock used equipment. Ask for a used blender *built originally by this manufacturer*. Ideally, you want a unit that is fully refurbished to meet its original specs and backed with a strong warranty. No one knows a blender better than its original manufacturer, so this gives you excellent quality assurance.

4. Equipment Rental with Option to Buy

Especially for a small or mid-sized company, the cost of a new blender may seem like a huge commitment standing on a foundation of uncertainty. Are you *sure* demand will continue to grow and justify this new equipment? Of course not. Projections are never 100% certain, so you may want to mitigate this uncertainty by renting the equipment you need instead of buying it.

A trial/rental—in your own plant, using your ingredients, prior to purchase—is also useful to confirm that you've chosen the right blender to buy for your operation.

Look for a rental deal that will give you an option to purchase the equipment when your rental period is over. You should expect to apply a substantial portion of your rental fees toward the purchase.

5. Used Equipment Purchase on the Open Market

Companies on a steep growth curve with many important purchases required to support rapid expansion must decide where to assign priorities and apply precious resources. Often there just isn't enough cash on hand to buy everything they need from an OEM.

The least expensive alternative is to buy a used blender from another manufacturing company or a used-equipment vendor. These units generally come with little quality assurance, but when you're just getting started, compromises are a fact of life.

Be sure to choose a blender that was built by a high-quality manufacturer, and check its service history to make sure it was maintained properly. Look for signs of excessive wear, too, which may give you problems with difficult cleaning, off-spec production, or contamination between batches.

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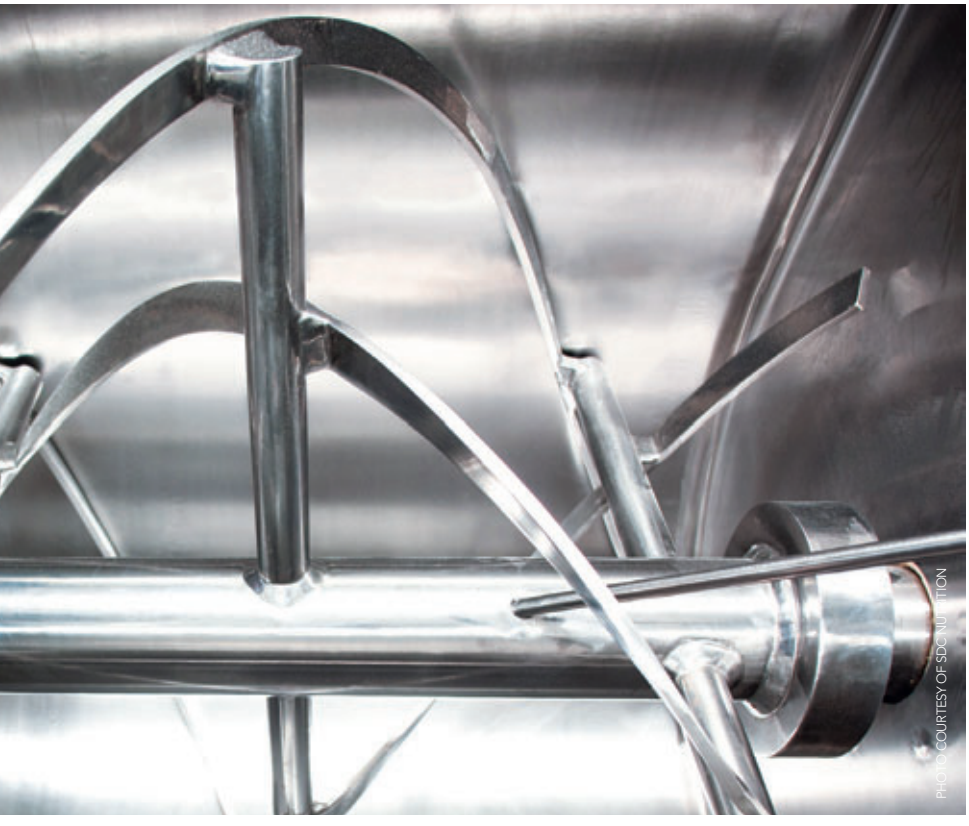
The quick discharge, easy cleaning, and low risk of cross-contamination facilitated by a sanitary design and finish are especially important for a high-volume contract manufacturer. This blender is also equipped with dust collection to promote a clean working environment for the manufacturing team.



The ribbons in this sanitary blender are pitched and precisely positioned relative to one another to generate vigorous flow, both radially and axially.

Every growing company faces the challenge of acquiring production equipment that strikes the right balance between performance, flexibility, reliability, and cost.

Schumacher, "so we were again obliged to buy a used blender instead of a new one. It doubled our capacity and allowed us to ramp up our contract manufacturing."

Contract manufacturing at SDC Nutrition is guided by the same values that guide production of the company's proprietary products. "We specifically look for customers who are focused on the same values that inspire us," says Barger. "Simplicity, purity, quality, honesty."

The company's formula for contract manufacturing seems to be working. According to the firm, more than 30 likeminded customers have flocked to SDC so far, and since they began contract manufacturing in 2010, the company has never lost a customer to a competitor.

The fast turnaround SDC delivers requires the flexibility of two blenders working in tandem, says Barger. "We recently had Ross build us a brand new 100-cu-ft sanitary ribbon blender to boost our capacity and complement our 36-cu-ft blender. Long runs of products such as whey protein isolate, vegan protein, meal replacement, and post-workout blends go to the larger blender. Short runs go to the smaller blender. Both are sanitary and easy to clean, so discharge and changeover are very fast."

What's next for SDC Nutrition? "Having received cGMP certification from NSF, we're now ramping up production for additional contract manufacturing and proprietary manufacturing aimed especially at the Latin American market," says Barger. "All ahead full!" N

Donald Condit *is a 30-year veteran food industry writer and marketing communications consultant based in Fort Collins, Colorado.*

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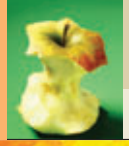

Changing Colors

What are the challenges of switching from synthetic to natural colors?

BY MICHAEL CRANE, ASSOCIATE EDITOR

The momentum behind natural colors has been building for a long time, but 2015 could go down as the year when it went mainstream. In the last year alone, some of the most recognizable U.S. brands, including Kraft Mac and Cheese, Trix Cereal, and Hot Pockets, have moved away from synthetic colorants in favor of natural alternatives.

This may be due in part to the "declining confidence" consumers feel toward many food brands as a result of a growing push for clean-label products, says Steve Morris, general manager of food colors North America at Sensient Colors (St. Louis). He adds that "kid-centric products" are at the heart of this push toward natural colors, as parents are among the most label-conscious consumers.

"Moving to natural colors can be an important piece of any brand-renovation effort, especially if you are trying to make your brand relevant to millennial moms," says Morris.

But as natural colors become less of an option and more of a requirement for any health-conscious marketing campaign, what are the biggest challenges of making the switch away from synthetic?

Right from the Start

Perhaps the first thing to consider when making the move from artificial to natural colors is that natural colors "need to be considered at the very beginning of the product development cycle," says Stephen Lauro, president of ColorMaker (Anaheim, CA).

"Natural colors are sensitive to heat. They are sensitive to light. They are sensitive to pH. And all of these parameters need to be considered at the front end of the product development cycle," says Lauro.

The shelf life of a food or supplement may also take a hit once natural colors are brought into the equation. While artificial colors can last for several years, Lauro says to expect about one year with natural colorants, depending on the application.

Colored Supplements

It might seem easier to bring natural colors to a capsule or tablet than an actual food product, but "reformulating a nutritional product is just as difficult as the reformulation of a traditional processed food or beverage," says Lauro.

When working with gelatin capsules, for instance, using just the right amount of natural colorant may be an issue. Too much color can cause the gelatin bonds to break down during heating and create a leaky capsule, while too little color can create a translucent capsule, says Lauro.

Compressed tablets can also be difficult to color evenly with natural colors. Natural colors tend to come in larger-sized particles than synthetic colors, often creating a "salt and pepper" appearance in tablets, with visible dots, rather than total homogenous coloration, says Lauro. Coated tablets may be one way to avoid this, but they can also be more expensive.

Worth the Cost?

Even with all the other challenges, the biggest obstacle to switching away from artificial colors may be the increased cost.

Natural colors cost about five times more than synthetic colors on average, and for some applications, such as confectionery products, it may be as much as 20 times more expensive than synthetic, says Peter Thorninger, senior vice president of sales and marketing, Chr. Hansen (Hørsholm, Denmark).

So for all the hassle and cost, is it really worth switching from artificial to natural colors? Definitely, says Thorninger. He points to Europe, where natural colors are far more prevalent than in the United States due to regulatory pressure and where the companies that benefited most from the color shift were those that moved early.

"The largest value to be gained of converting comes from taking a proactive market leadership position," says Thorninger. He shares Chr. Hansen's advice to clients: "Make the headline about how you have improved your iconic brand serving your consumers, before critical voices create the first headline for you." N

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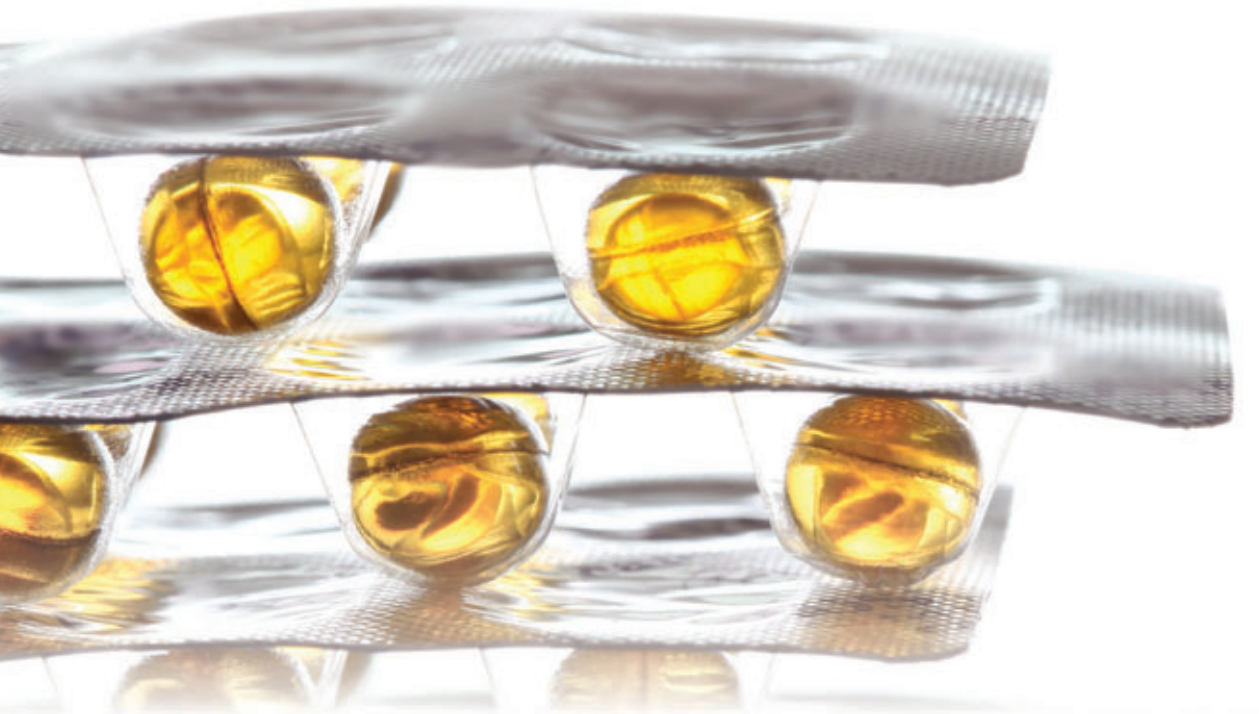

From raw ingredients to finished product, **NSF globally tests** and **certifies dietary supplements** and **trains** your staff to the highest standards of GMP compliance.

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