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Informing and Educating Natural Products Retailers On Dietary Supplements, Herbs, HBC, Homeopathy, Foods

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Regulating Raw

Checking up on the rules, standards and other issues that ingredient suppliers face.

NDIs, GMPs, 483s, oh my! Getting your acronyms and shorthand terms down is just the start of navigating life as a raw materials supplier. A maze of regulations must be worked through before they can begin to comfortably sell their products, and lately it seems like the walls of the maze are shifting.

Though a precise map of these issues may be impossible to draw, here, along with our insiders, we'll attempt to at least provide a compass. Read on for the latest insight on new dietary ingredients (NDIs), product adulteration, U.S. Food and Drug Administration (FDA) warning letters, health claims and related topics.

Eye on NDIs

The Dietary Supplement Health and Education Act of 1994 (DSHEA) created the "dietary ingredient" as a regulatory category. By way of a simplified explanation, we can say it refers to ingredients found in dietary supplements, and that all those marketed prior to October 15, 1994 with a history of safe use are not required to go through the NDI notification (NDIN) process. Any dietary ingredient introduced post-1994 is categorized as an NDI, and an NDIN is supposed to be given to FDA 75 days prior to a product being marketed.

This process existed from the point the law was first enacted, but FDA only recently, with the release of a draft guidance in 2011, attempted to fully explain to the industry how it should take place. Then, in the summer of 2012, after facing pressure from industry and legislators, FDA promised to revise the guidance.

"Ideally, NDI submissions for ingredients that are new to human consumption should help the FDA evaluate these ingredients for potential safety issues regarding continual or long-term use of the ingredient at the recommended dosage, potential interactions it might have with other foods, supplements or pharmaceuticals, and suitability of the ingredient as a dietary supplement," says Nena Dockery, technical services manager for Membrell, Carthage, MO.

But she notes that while FDA published regulatory notices interpreting DSHEA and laying the groundwork for NDI notifications, over a decade went by without a full FDA-sanctioned NDI guidance. The result has been many rejected submissions on the grounds that they lack proper documentation. Other than FDA's decision to revise the guidance, precious little headway seems to have been made by industry organizations toward influencing the wording of the final guidance. Dockery says issues such as how to properly identify and document NDIs haven't been well communicated, despite FDA's common rejection of NDI submission paperwork due to an "inability to establish the identity of the submitted ingredient."

Dockery says the 2011 draft guidance placed unfair burdens on manufacturers. In agreement is Bob Green, president of Nutratech, Inc., West Caldwell, NJ, who says his company did not go through the NDI process with its patented bitter orange extract (Advantra Z) due to its being marketed pre-DSHEA. A

fundamental issue with the NDI guidance, he says, is that it has been interpreted to make finished product manufacturers responsible for NDI filings. That is, many fear FDA wants an NDI submission for each individual supplement product brought to market, regardless of whether the ingredient in question has a successfully filed NDIN already.

"This alone is a bureaucratic nightmare. If a dozen different companies choose to put 'new ingredient A' into a formula, each one must submit NDI paperwork every time they use that new ingredient," Green says. This issue has not been properly resolved or clarified since the guidance's release over two years ago, he adds. The logical approach, he believes, would be to have suppliers that launch a new ingredient submit the NDI paperwork before it is sold to manufacturers. This would allow ingredients to go through the NDI process just once, instead of potentially overburdening an already underfunded FDA with superfluous NDINs, Green explains.

These rumored interpretations of the NDI process may be problematic, agrees Scott Steil, president of Nutra Bridge, Shoreview, MN. On talk about FDA forcing companies to submit NDINs for combination supplements, he says, "If that happens, it will destroy the dietary supplement industry, and it will destroy innovation." He draws an analogy with the drug sector, saying, "There are people using combination products all the time that don't have specific data on that exact combination, and whether it's safe for human consumption." He says one might argue that if each ingredient is safe, combinations should be as well, and if not, adverse event reports are there to catch these rare cases. Steil says this stringent interpretation of the NDI guidance was being talked about heavily when the draft was introduced, but he has heard less about it recently.

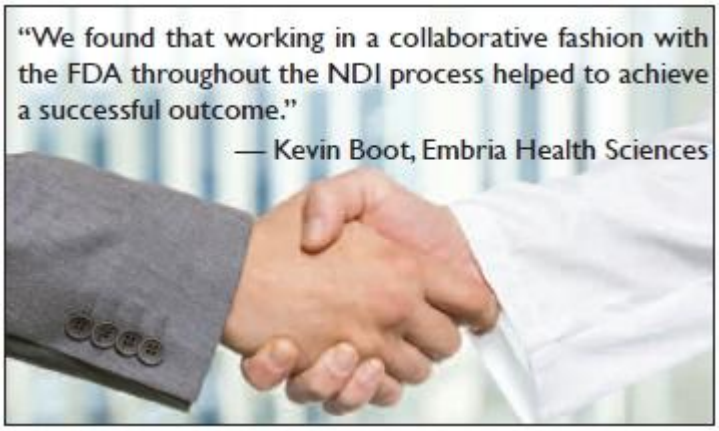
Bryan See, regional product manager for Carotech Inc., Edison, NJ, says his company foresaw the implementation of the NDI guidance substantially reducing the number of ingredients and finished products on the market. The consequences, he says, would be companies closing down and less selection for consumers. His company submitted comments to FDA's 2011 guidance along with many other stakeholders.

While he acknowledges that some argue FDA is purposefully creating a high barrier of entry into the dietary supplements market, Steil says there is some sense to the more broadly interpreted NDI requirements. He posits a scenario, saying, "You're going to submit your product at 50 mg, and then, let's say, you come up with a new indication where the effective dose that's proven in a study is 800 mg." Steil says companies need to show that there are no serious adverse events occurring at the new dose in such cases, and a separate NDIN may be warranted.

His company's experience with filing an NDIN for a particular ingredient (7-Keto) was smooth, according to Steil. "We had all of the safety and toxicity data already done before we started that filing," he says. While some of its products were marketed pre-DSHEA, he says his company filed several NDIs back in 1994 and 1997. FDA is chiefly concerned with safety and not efficacy in looking at NDIs, he explains, and the company had previously done all the necessary safety testing, so when the NDI process came into play, there wasn't much more work to do.

Steil believes FDA has become stricter with the NDI process lately, and there continue to be flaws with the system. "It's a backwards system in my opinion, because they approve by silence," he says. Indeed, a "letter of no objection" is the result that companies hope for when they submit an NDI. FDA merely acknowledges the submission without declaring an ingredient safe or approved. Steil says there have seemingly been few NDIs successfully filed. An official FDA Web site that tracked successful NDI filings used to exist, but Steil says it is nowhere to be found now. A quick **WholeFoods** search of FDA's Web site yields only a table of NDIs compiled in March of 2001, though more recent filings can be searched for on *regulations.gov*. At least one outside group has attempted to keep track of things, as the American Herbal Products Association maintains a subscription-only database of NDI filings.

In general, Steil feels that the regulations remain ambiguous in many respects, perhaps intentionally so. One major issue is the lack of any clarity on which ingredients are "grandfathered in" due to being marketed pre-DSHEA. Dockery says that suppliers and manufacturers have therefore been unclear in many cases on whether to submit an NDIN. Anurag Pande, Ph.D., vice president of scientific affairs at Sabinsa Corp., East Windsor, NJ, says FDA is also unclear on the nature of the evidence and documentation it will accept to prove an ingredient should be grandfathered. "In other words," Pande says, "the burden of proof lies with the manufacturer."



A key subset of ingredients FDA seems prepared to exempt from NDINs are those that are generally recognized as safe (GRAS), a regulatory

category that applies to food ingredients. “As the main objective of the NDI is safety, we strongly believe that ingredients that have been self-affirmed GRAS with a letter of no objection from FDA should be exempted from filing an NDI,” explains See.

As a GRAS food ingredient with demonstrated safe use in foods and beverages, Dave Walsh, vice president of communications at Biothera, Eagan, MN, says his company’s Wellmune isn’t required to submit an NDIN. Similarly, Rodney Benjamin, director of R&D and technical services at Bergstrom Nutrition, Vancouver, WA, says his company’s OptiMSM can be classified as an “old dietary ingredient” because it was manufactured and sold in the human food supply prior to DSHEA. It is self-affirmed GRAS with a letter of no objection, and therefore NDI regulations allow for it to be marketed in supplements. Of the NDI process, Benjamin says, “Some may see it as an unnecessary hindrance to market entry; however, my opinion is that it helps ensure that dietary supplements have been evaluated and meet a minimum safety requirement before being offered for consumption.”

The NDI hurdle may have prevented safety issues surrounding two ingredients cited by Green: DMAA and, more recently, aegeline. In 2012, FDA aggressively sought to rid the market of the workout supplement DMAA, and some thought they did so by enforcing the NDI statute. The agency successfully forced companies to withdraw products containing DMAA, for which no NDIN had ever been filed. Another sports ingredient, aegeline, was flagged at the end of 2013 for the exact same issue, amid concerns that it was causing serious liver ailments. Again, companies were forced to reformulate without the ingredient.

Probiotic supplements are a special case in the context of NDIs. Tony Blanch, director of quality and corporate services for Nutraceutix, Inc., Redmond, WA, notes that the 2011 draft guidance contains language relating to probiotics in dietary supplements. This includes the proper way to identify specific strains of a “live microbial dietary ingredient,” and when NDINs need to be filed. Each individual probiotic strain, according to the guidance, is its own NDI, and changes in fermentation method also necessitate an NDIN.

Blanch says that his company works with probiotic cultures that have long histories of use in the food industry. “These standard food cultures are well known to FDA and the food industry and generally are expected to be exempted from NDIN when administered in reasonable concentrations in supplements,” he feels. Pande says that probiotics face regulatory challenges when it comes to NDIs if they haven’t been a part of food. “Investigation of a new probiotic toward a disease end point will place it in the drug category,” he says.

Another question raised by the draft guidance is the acceptability of synthetic ingredients designed after botanical compounds. The draft guidance says these synthetics don't qualify as dietary ingredients, but Pande says DSHEA contradicts this stance. The Council for Responsible Nutrition (CRN) sent a letter to FDA asking for a reversal of this position, based on its view that DSHEA does not exclude synthetics from the broad definition of dietary ingredients.

NDI filings present a way toward a better regulated market, according to Pande, which will help ensure consumer safety. In its present form, however, his company feels the NDI draft guidance requires certain changes. As for the actual process of submitting an NDI, Kevin Boot, legal and regulatory counsel for Embria Health Sciences, Ankeny, IA, says it can work well, as it did when his company submitted its ingredient EpiCor. "We found that working in a collaborative fashion with the FDA throughout the process helped to achieve a successful outcome," Boot says.

NDI "piggybacking." A trending issue in the NDI world concerns intellectual property, consumer safety and the intent of the FDA's regulations all at once. Language is included in the NDI draft guidance requiring companies to file their own NDINs even if there was a previous NDI filing from another company for a seemingly identical product. Some feel the enforcement of this had been lax, and in late 2013, Texas Rep. Steve Stockman sent a letter to FDA asking for increased attention to products that attempt to piggyback on other NDI filings. Stockman had been contacted by three large companies that had filed NDINs for specific ingredients, such as astaxanthin.

Companies that file these original NDINs often sell a branded ingredient, and are trying to protect their investments and market position. But critics of this FDA policy claim it is cumbersome and unnecessary. Dockery says that for ingredients that are natural and unprocessed, it would seem that only one NDIN would be necessary to establish safety for all future uses. She notes, however, that ingredients are often prepared using proprietary methods. The use of differently prepared yet similar ingredients, she says, does warrant separate NDINs, as this protects the original company's market advantage and may protect consumers from inferior or unsafe preparations. Steil notes that his company considers its NDI filings a core strength of its product.

There are safety concerns about piggybacking, Pande argues. "Given that a company has the right to redact manufacturing details from an NDI filing before the documents become public, other manufacturers have no way of proving their ingredient is identical," he says. In a practical sense, proving something identical may be more time consuming than simply filing an NDIN.

In addition to discouraging investment in innovation and research, Pande feels piggybacking may put consumers at risk, since if ingredients are not identical, safety data are not applicable. Adds Benjamin, "It is important to realize that processes can differ in subtle ways that may have an unforeseen impact on the chemical make-up of the final product." Boot claims, for instance, that it would be misleading for another company to allege it has a product with the safety profile of his company's ingredient, without knowing the methodologies used to produce it. "Our NDIN contained important manufacturing information that FDA saw, but redacted confidential data," he says.

Tim Hammond, vice president of sales and marketing at Bergstrom Nutrition, says his compnany takes the lead on clearing regulatory avenues for customers using its branded ingredients. But, he voices the frustration over what has been happening next, once raw commodity manufacturers step into the picture. "We have discovered competitors quoting our GRAS dossier and claiming the distinction, as well as mimicking specifications, despite utilizing a completely different purification process," Hammond says.

Since the NDI guidelines have not been finalized, however, Pande notes that it remains to be seen whether NDINs will ultimately provide market exclusivity. The NDI process, he says, is focused on the safety of the product and not on intellectual property rights. Blanch echoes him in saying that DSHEA describes the NDI process as a means to promote the introduction of safe ingredients, not to provide protection for companies with successful filings. "Why shouldn't a substantially equivalent ingredient being produced by another manufacturer also be considered acceptable, similar to the food additives listing?" Blanch asks. Food additives, once approved, can be used by any manufacturer.

However this particular issue shakes out, transparency on the part of suppliers will be a virtue moving forward. Says Paul Dijkstra, CEO of InterHealth Nutraceuticals, Benicia, CA, "Suppliers should be clear as to the NDI status of the ingredients in their product portfolios."

Adulteration: What to Watch For

Natural products, like all commercial goods, are subject to the forces of supply and demand. When supply can't meet demand, it often leads some to make products that aren't quite what they claim to be. Adulteration is also a result of the simple lure of taking shortcuts to increase profit. Cases of contamination also fall under the umbrella of adulteration.

See explains that when a particular ingredient has high demand but short supply, some suppliers choose to include substitutes that are not the real deal. "The only way to overcome or resolve this issue is for

dietary supplement companies to take the initiative and commit to only buy or source ingredients from GMP-certified producers." Following the good manufacturing practices (GMPs) stipulated by FDA, according to See, helps guarantee the identity of ingredients, as well as their strength and purity.

Ingredients that reach the level of highly traded commodities are at special risk of being adulterated, according to Dockery. "Even conscientious distributors are at risk if their normal and trusted supplier runs out of stock, and they must obtain an ingredient from a supplier with whom they are not as familiar," she says. While ingredients like astaxanthin and chondroitin have made news for adulteration issues, she stresses that any popular ingredient is at risk. A substantial paper trail and rigorous identity testing can minimize the risk for suppliers and manufacturers, she says.

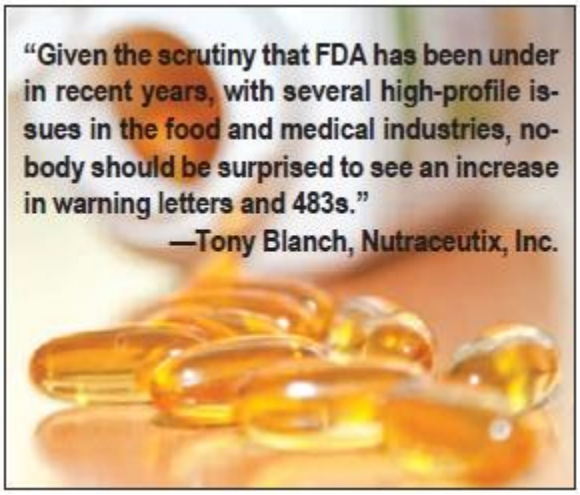
Specific product categories, according to Pande, have seen adulteration and contamination issues, such as men's health products. Also recently, supplemental enzymes were found to contain traces of the antibiotic chloramphenicol. Adulteration need not be intentional, and can occur at the crude raw material stages, says Pande. A quality supply chain, he explains, is difficult to maintain for raw materials that are seasonal or limited to small geographical areas. For botanicals, ingredients with limited supply are sometimes harvested from different but similar species, or from various parts of the plant such as the leaves, branches or roots.

Supply and demand issues have caused major players in the industry to reexamine how they conduct procurement, says Pande. He says his company, which has worked with over 100 herbal extracts for many years, has been focusing on contract farming and the development of sustainable resources to try to address these areas.

While acknowledging that purposeful adulteration occurs, Green says that it is likely not as widespread as the media sometimes makes it out to be. Instead, he paints a picture of a few unscrupulous manufacturers, present in every industry, that have turned to illegal adulteration. Green notes they often use prescription ingredients like sibutramine, anabolic steroids, sildenafil and others.

When it does occur, Green agrees that it is largely driven by demand, and he links it back to the early history of the natural products industry, when spiking was a more common practice. Perhaps, he says, some of this "it's not so bad" attitude still lingers. Regardless, he says ingredients like his company's, ones that offer standardized amounts of valued compounds, are flourishing in the market: "Branded ingredients undergo superior testing and safety measures, so the quality and content—and absolute absence of adulteration—is guaranteed."

The spiking of products with adulterants to produce false



effects in testing is an ongoing issue, according to David Janow, CEO of Axiom Foods, Los Angeles, CA. Specifically, he says his company has been witness to such issues in the pea and rice protein business. Several years ago, he says competitors were caught adding melamine to pet food products to cause a false measurement in protein levels. Related issues include the adding of sugars to cover odors and taste, and the falsification of organic certifications. "At the end of the day, it comes down to supply and demand, where emerging markets have trouble keeping up and often foreign-based companies see an opportunity, have limited technology and try to cut corners," Janow says.

There will always be those attempting shortcuts. "You can build a Fort Knox of safety regulations, and these people will still enter any market through the backdoor. The key is to uphold our industry's existing regulations and to support the FDA in enforcing them," says Jen Johansen, vice president of quality and regulatory affairs for Cyanotech, Kailua-Kona, HI. It is also important for suppliers to carefully consider country of origin, Johansen explains, stating, "Origin is essential when evaluating the risk profile of any item."

There are many ways companies go about distinguishing and protecting their own products when it comes to avoiding adulteration. Dijkstra notes that his company uses a stringent supplier audit program to address material traceability. He says that standard operating procedures are in place to both ensure supply chain control and simplify the exchange of information with finished product manufacturers.

Victor Ferrari, CEO of Horphag Research, Hoboken, NJ, worldwide exclusive supplier of Pycnogenol, says his company goes to great lengths to ensure the quality of its branded extract of French maritime pine bark. "It is produced from a sustainable botanical source under pharmaceutical GMPs in an FDA-approved facility, and meets and exceeds the highest quality standards," he says. A regular and ongoing

screening program sees the company analyze over 60 products that contain the ingredient per year. Ferrari says this helps ensure that consumers receive a 100% pure ingredient and its related benefits. The U.S. Pharmacopeial Convention (USP) creates reference monographs for dietary supplements as well as pharmaceuticals, and is a useful tool for companies and regulators in assessing the identity of ingredients. Of his company's branded ingredient, Walsh says, "Wellmune is the subject of a USP Monograph and this reduces the likelihood that Wellmune would ever be adulterated."

Of Letters and Litigation

An issue that suppliers should be aware of is indirectly related to the U.S. Food and Drug Administration (FDA) and its enforcement actions. David Janow, CEO of Axiom Foods, Los Angeles, CA, says that "FDA warning letter chasers" are the new ambulance chasers, as lawyers are increasingly being drawn to the red flags raised by FDA warning letters. "It is increasingly common to be sued within a week of receiving an FDA warning letter, as they assume that something must be wrong," he says. The areas on the product label being targeted by such litigation, according to the Council for Responsible Nutrition, include false/unsubstantiated claims, weight loss claims, all-natural claims and nutrient

content claims.

"False claims litigation is drastically on the rise, no matter the size of the company, and this can have an even larger impact than regulatory action," Janow says. Companies in some states are more exposed than others, as he notes that a large percentage of cases brought in California make use of that state's broadly written Legal Remedies Act, Unfair Competition Law and False Advertising Law.

Specific testing procedures and equipment are essential in proving and protecting product identity. Boot says his company has reduced the risk of adulteration by employing FT-NIR identity testing. This test of chemical identity uses light to create a unique "fingerprint" specific to the company's ingredient.

Chondroitin, as noted, is popular enough to have companies trying to imitate it with fraudulent compounds. Specialized testing is of help here, also, according to Weiguo Zhang, president of Synutra Ingredients, Rockville, MD. Chondroitin, he says, is a top-five selling supplement and is also relatively expensive, making it ripe for adulteration. "Adulterated chondroitin has become such a concern to FDA that the agency uses it in presentations as a case study of economic adulteration," Zhang says.

The issue, as he explains it, is that the most common chondroitin assay method, cetyl pyridinium chloride (CPC), can be tricked by some adulterants. CPC is meant to measure chondroitin content, but adulterants can create false positives. He says that industry, meanwhile, has neglected another testing method called cellulose acetate membrane electrophoresis, which was meant to complement CPC by screening out material impurities.

Using the two together, as his company does, allows known adulterants like sodium alginate and others to be successfully screened. "We are working closely with regulators, industry groups, documentary standards organizations and leading analytical laboratories to urge widespread adoption of the combination methodologies of CPC and electrophoresis for chondroitin ingredients and supplements," Zhang says.

Another screening method called enzymatic HPLC is also getting attention, but Zhang says it can have issues analyzing chondroitin sourced from the cartilage of various species. Unless customers specify otherwise, most suppliers combine porcine, bovine and avian sources. More sophisticated tests like this, he adds, are hard for non-specialists to perform consistently on fast-moving batches. "In fact, it is quite obvious that the enzymatic HPLC method is hardly available to many of the numerous ingredient manufacturers and suppliers overseas."

Zhang says new chondroitin adulterants are also being monitored, including one recently discovered that has been dubbed Zero One (Z1). “The common adulterants aren’t necessarily harmful, although they do rob the consumer of the benefits they expect and deserve when they buy chondroitin,” he says. But, Z1 is of concern since its identity and safety have yet to be analyzed.

What is known is that Z1 is an inorganic compound that appears in CPC as chondroitin at a 235% assay value. This provides ample incentive for adulterators to use this substance, Zhang says, since less can be used. He says that his company will report any further findings once they are available, but reminds the industry in the meantime that this and other adulterants can be screened by using the correct combination of tests.

Steil expresses the lack of tolerance found throughout the industry for those who engage in adulteration deliberately, saying, “You’re dealing with people’s health, here. You’re dealing with ingestibles.”

Inspections, Warnings and Health Claims

Since the introduction of current good manufacturing practices (cGMPs) for dietary supplements in 2007, FDA inspections and the potential for warning letters about GMP violations is something all facilities have had to prepare for. The infamous FDA warning letter can come for many reasons, but except in egregious cases, most of them are due to not having one’s ducks in a row.

Benjamin credits the fact that his company hasn’t received negative FDA feedback to years of hard work, planning and documentation. One result is a “robust and dynamic quality management system that ensures our manufacturing delivers a consistently high-quality product,” he says. The other result is FDA compliance. When GMP compliance isn’t present in every aspect, FDA has been letting companies know about it. “These letters clearly demonstrate that FDA is serious about compliance. Companies should be monitoring the substance of the letters and learning from other’s mistakes,” Benjamin says. He adds that, ironically, while industry often complained about how long it took FDA to publish GMPs, many companies are still behind the eight ball years later when it comes to compliance with basic elements of the regulations.

The industry should keep in mind that an FDA inspector’s sole purpose is to find infractions and collect evidence, Blanch notes. “Given the scrutiny that FDA has been under in recent years with several high-profile issues in the food and medical industries, nobody should be surprised to see an increase in warning letters and 483s,” Blanch says. FDA Form 483 is issued when inspectors observe conditions that they judge to violate cGMP regulations. Each observation noted on these forms is supposed to be clear,

specific and significant. In some cases, these observations on the part of FDA are simply conversation starters or requests for more information. In other cases, the findings are more serious.

Blanch says some of these findings are available online, and they reveal a myriad of issues being cited by FDA: invalid or unjustified testing methods, lack of written specifications and procedures, unsanitary conditions and health claims on supplements that misbrand them as drugs (more on this soon).

The manufacturing arm of Pande's company was inspected by FDA, and he details the simple give and take of the process. "All five manufacturing plants were audited and one solitary 483 observation was issued, which was immediately rectified, and a compliance report was submitted to FDA," he says.

Noting that FDA has recently begun inspecting manufacturers located abroad, See shares that his company's Malaysia facility was recently paid a visit. He calls the FDA imspection an important milestone for the firm, as it showed the site to be in compliance with both FDA and Malaysian Pharmaceutical Control Bureau GMP standards.

Boot says his company monitors other firms' warning letters and other cGMP-related materials in order to improve its own system. "The FDA and industry are still in a learning phase of implementation and we know that compliance will improve as bad actors are forced from the market and the agency continues to enforce the rules," he says.

Steil believes that for these bad actors, it is all about figuring out ways to make more money. He believes the industry has dramatically improved in the last several years at picking out bad apples. The rate of removal of such companies has grown exponentially, he feels. "I don't think we need more guidelines and regulations. I think what we need is better enforcement, and stiffer penalties for those who don't play by the rules," Steil says.

The increase in regulatory oversight is good for the industry long term, he adds. To illustrate the newfound focus on compliance throughout the industry, he says that the number of quality documents his company has shared with partners over the last 18 months is probably five to 10 fold what was completed the prior ten years.

Contentious claims. Another way a product can get labeled as adulterated is to feature health claims that run afoul of FDA. While the majority of warning letters being issued are apparently for GMP violations, Dockery says, the ones that get the most attention from the public are those involving claims issues.

FDA has always had its eye on claims that may refer to disease states, and depending on the case, the agency may simply issue a letter requesting the claim be removed, or may actually move to seize the

product. This especially has occurred after a company ignores FDA's requests, Dockery says. "The FDA does tend to focus periodically on a particular type of claim, then later move their focus to another type of claim. Currently, sports-related claims, claims to ameliorate inflammation and medical foods claims are getting increased attention," she says. Adia Edwards, executive director of quality and supply chain management at Bioenergy Life Science, Minneapolis, MN, notes that claims a product can "cure" some ailment are big, obvious red flags for FDA.

"Inflammation, considered as a key element in many lifestyle diseases, has become a major point of discussion when it comes to claims made on dietary ingredients," Pande says. He elaborates, saying that companies must be careful when referring to the management of chronic or acute inflammation. FDA has given signs that these claims veer into disease state territory.

Dockery says that the supplement industry has been given inconsistent information regarding claims that refer to a normal and healthy inflammatory response. She says her company, like others, has been guarded in dealing with this area, which may be a disservice to consumers that would benefit from knowing about products that have these benefits. The bottom line in this discussion, Benjamin says, is that if companies choose to use words like inflammation or pain, they must tread carefully and be precise about the cause of the conditions a product is supposed to help with.

In general, however, Blanch recognizes the importance of FDA targeting false and misleading claims. No one in the industry should want products on the market claiming to cure cancer or eliminate H1N1 infections, he says. But one major problem is that there is much disagreement over what constitutes adequate scientific proof to back up a health claim. He believes industry and regulators still need to come together on this issue. Blanch says his company is very conservative in making health and activity claims. "In many instances, no claims other than content are listed on our clients' packaging. This approach does not seem to have hampered marketing of products," he says.

When adequate evidence for claims does exist, it can help products stand in contrast to others in a given sector and stay in FDA's good graces. "Too many manufacturers in the past offered promises of instant weight loss without diet and exercise, and more importantly, without scientific proof," says Green, adding that his company's weight management ingredient is often used in clinical studies because of its consistent quality.

Unfortunately, companies have more to worry about than FDA when it comes to marketing their products. "You have kind of a funky regulatory environment, where you have FDA regulating claims that are made on bottles and labels themselves, and then you have FTC that regulates claims on packaging and advertising," Steil notes, adding that the Federal Trade Commission (FTC) is often even less clear on

its rules. Benjamin notes that marketing posts on social media have recently spurred warning letters, suggesting regulators are now heightening focus in this area.

Steil argues, however, that 90% of the regulatory actions he has observed in his time in the industry are spot on, and he applauds them. For its part, he says his company works hard to understand marketing and regulatory guidelines, so that customers have a legitimate product to work with. The result, he says, is never having to assist customers with any FDA- or FTC-related issues, despite dealing in a marketplace (weight management) that is exposed to extra scrutiny.

FDA has made it clear for years that health claims are a focus of its enforcement efforts, says Edwards. Despite this, like many other companies, "we are constantly looking for ways to strengthen our claims and looking for new ones," she says.

The demand for natural products has grown exponentially over the last number of years, and Edwards believes that in some cases, the growth has been such that suppliers should be concerned about issues like capacity and sustainability. "Our company is constantly working on process improvement to streamline our production and supply chain," Edwards says.

Though growth has its challenges, it is a sign good things are happening in the health of our society. "It encourages me to see people taking an interest in their health, and thus driving the market for safe high quality products," says Johansen. **WF**

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http://www.wholefoodsmagazine.com/suppliers/features/regulating-raw