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FDA DEFIANT! Be Prepared for Enforcement

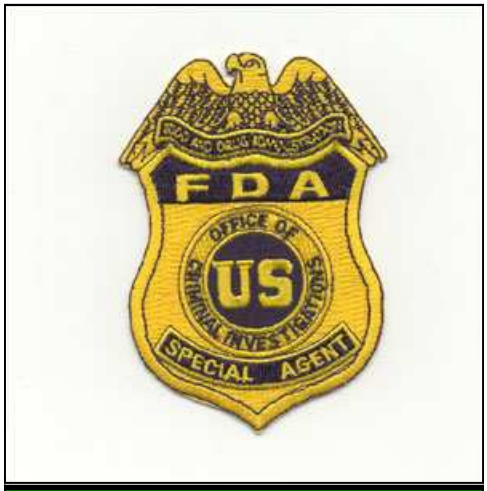
By *Collins, McDonald & Gann, P.C.*

FDA: Rejects Interpretation by Drafters of DSHEA; Stands by NDI Draft Guidance; Raids Elderberry Juice Facility

The biggest news last year in the sports nutrition supplement community was the release of FDA's controversial New Dietary Ingredients (NDI) Draft Guidance, interpreting the Dietary Supplement Health and Education Act (DSHEA) far more narrowly than industry imagined. The authors of DSHEA, Senators Orrin Hatch and Tom Harkin, believe the guidance "serves to undermine DSHEA in a number of important aspects" and does not meet their intent when they wrote the law. They met with FDA brass to request that the guidance be immediately withdrawn and replaced with a new one that is consistent with the law and their intent. In a move that surprised many, the meeting concluded with FDA rejecting the request, regardless of what the senators say they meant when they wrote the law, and entrenching itself in the position that the guidance will stand as written. FDA clearly seems to be committed to moving forward, and many believe that the NDI Draft Guidance is another step toward inching things ever closer to a system approximating premarket approval (which was never the intent and was specifically excluded by DSHEA).

What can we do now, as members of industry who are upset by the FDA's lack of consideration of the many problems with the current NDI Draft Guidance and the agency's refusal to listen to the advice of the two leading authors of the law that literally governs the supplement industry? Many are hoping that writing a new amendment to DSHEA on the topic of NDI's might be possible. However, such an amendment would require both Houses of Congress to work together and pass new legislation – a feat that seems difficult in today's political climate in Washington. If the Draft Guidance becomes final, it would become FDA's official policy and would be a basis for enforcement actions against industry.

FDA's position on the NDI issue is consistent with an overall heightened aggressiveness with respect to dietary supplements in general. Recently, FDA sent US marshals to raid the facility of a Kansas-based producer and distributor of elderberry juice, claiming the company made improper health claims and thereby confiscating the product as an "unapproved drug." The United States Attorney for Kansas said that FDA sent a warning letter to the company in 2006 to remove or modify certain health claims that it said were in violation of federal law, but the company did not comply. FDA officials claim the company continued to make unapproved claims,



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and that seizing the product was the next step. The company, however, claims that in response to the letter it hired a consultant familiar with FDA regulations to make all necessary modifications to comply with the law and believed everything was in compliance. "We haven't heard anything from (the FDA) since," company officials reportedly told the press, and claimed that in the interim between the modifications and the raid FDA had ceased communicating with the company.

"...if FDA will send in US marshals to seize fruit juice as an unapproved drug, what can we expect for our segment of the industry?"

"This tactic, of course, has become all too common in recent years," wrote Naturalnews.com. "A company receives a warning letter from the FDA, makes the appropriate changes, never hears anything further from the FDA, and out of nowhere gets raided." Of course, FDA's position is that the company failed to make the appropriate changes, even after a warning letter (and FDA has the authority to institute enforcement actions even without sending a warning letter when a company markets a product that FDA believes falls into the category of "unapproved drugs"). Could an ongoing dialogue concerning compliance have solved the problem without a raid by US marshals? It certainly would have made sense for FDA to have tried that approach before sending in the marshals. But these days FDA seems less interested in a dialogue with companies than with public execution of aggressive enforcement actions, and, in some cases, criminal prosecutions. In the past year, numerous companies selling prohormones products were convicted of felonies and paid substantial fines for selling "prohormone" products containing ingredients that did not comply with DSHEA. Most received no warning letters.

Clearly, the industry is dealing with an invigorated and aggressive FDA that has even defied the architects of the law that governs supplements. The sports nutrition industry may not care much about elderberry juice, but the point is that if FDA will send in US marshals to seize fruit juice as an unapproved drug, what can we expect for our segment of the industry? Take, for one example, an ingredient like DMAA (methylhexaneamine). In just the last few months, products containing the ingredient have been the subject of criticism by industry trade organizations, class action lawsuits, military base product removals and allegations that they may have contributed to the deaths of two soldiers. Can FDA enforcement actions be far behind?

As we counsel our supplement industry clients, the best defense against FDA regulatory actions is to be prepared. Retain legal counsel. Be sure your ingredients comply with DSHEA, that your claims are substantiated and proper, and that you're manufacturing in compliance with the cGMPs. The cost of not doing so can be steep indeed.

For updates on these and other issues of interest to industry, please visit our blog at www.supplementcounsel.com/blog ■

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Rick Collins, Esq.

Rick Collins provides advice to some of the top names in the sports nutrition industry, and is the legal advisor to the International Society of Sports Nutrition and the International Federation of Bodybuilders. Rick spearheaded a national coalition to protect adult consumer access to dietary supplements, working with two Washington political advocacy firms and a panel of scientific experts. He has defended dietary supplement companies against claims of distribution of misbranded or adulterated products and "unapproved new drugs," and against serious criminal investigations by the FDA and DEA. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania, Texas and the District of Columbia, and in various federal courts.

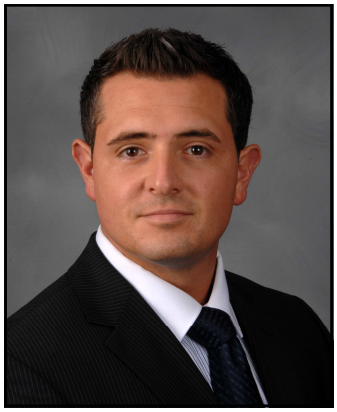
Marc Gann, Esq.

Marc Gann represents numerous companies and individuals in the dietary supplement industry. He has handled contractual disputes, trademark issues, and other civil matters, as well as regulatory investigations. He has provided advice on regulatory compliance issues and the status of supplement ingredients including New Dietary Ingredients under the Dietary Supplement Health and Education Act. He has defended supplement marketers against criminal prosecutions, including the defense of an individual charged with the sale of a misbranded and "unapproved new drug" that was implicated in a fatality. He is admitted to practice in both New York and Maryland.

Alan Feldstein, Esq.

Alan Feldstein, an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CMG. He is responsible for advising some of the firm's biggest clients in the sports nutrition industry, having served as general counsel for a dietary supplement company that took the company to over 150 million dollars in annual sales. He has extensive experience with contracts, copyright and trademark, litigation supervision, label and advertising review, supplement fact panel review, claims substantiation and assorted regulatory issues. He brings with him more than a dozen years of advertising and marketing law experience and continues to serve on the adjunct faculty of Southwestern University School of Law.

Mike DiMaggio, Esq.



Mike DiMaggio puts his comprehensive knowledge of the sports nutrition industry to work advising CMG's clients in the area of dietary supplement law, including FDA and FTC regulatory compliance and general business matters. He has served as the Executive Director of a supplement freedom trade group, directly interfacing with industry, other dietary supplement trade associations, Capitol Hill lobbyists, and members of Congress. He received his J.D. from St. John's University School of Law and is admitted to the New York State Bar and the United States District Court for the Southern and Eastern Districts of New York.

For industry news and updates, visit our blog on the web at **www.supplementcounsel.com/blog**

WHAT SERVICES DOES CMG OFFER?

In the ever-changing landscape of the health, fitness and nutrition industries, you need to stay ahead of the curve. Could you survive an investigation of your products, your labels, or your advertising copy? How do you navigate the maze of new regulations … and run your business at the same time? With FDA policies actively evolving, how can you bring a New Dietary Ingredient to market in compliance with DSHEA? How can you ensure your advertising complies with FTC regulations? What must you do in order to comply with the dietary supplement cGMP's?

Collins, McDonald, & Gann, P.C. (CMG), is a law firm dedicated to helping clients in the health, fitness and nutrition communities. With recognized experts in sports performance supplements and regulatory, advertising and marketing law, CMG offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to long-established ones. CMG offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them. The partners of CMG have been formally rated by the professional legal community as practicing at the highest levels of skill and ethical integrity (AV-rated in Martindale-Hubbell). Los Angeles lawyer Alan Feldstein, Of Counsel to the firm, brings with him years of experience serving the dietary supplement industry. CMG can help you stay ahead of the curve by providing the following services:

- Review of labels and advertising from a Food, Drug & Cosmetic Act (FDCA) and FTC standpoint [*FDA enforces the FDCA with respect to the safe and legal marketing of food and dietary supplement products; FTC regulations deal with truthful advertising that is not misleading*];
- Review, negotiate and draft licensing agreements;
- Create GMP Agreements with manufacturers and vendors;
- Assist with Import Hold and Detention Matters by communicating with FDA and Customs to expedite release of shipments;
- Review and advise clients regarding their Adverse Event Reporting System and their FDA Inspection Protocol;
- Provide general business advice and contract drafting;
- Advise and consult on various intellectual property issues including assisting clients in trademark searches, filings and office actions and copyright registrations;
- Advise clients on DSHEA compliance of New Dietary Ingredients (NDI's), substantiation & 75-day pre-market notification;
- Assist with initiation and coordination of product recalls;
- Assist in locating and coordinating review of products with toxicologists, research scientists and other outside experts regarding different aspects of manufacturing, labeling and marketing of products including appropriate contraindications;
- Coordinate and manage outside defense counsel and provide strategy on civil litigation including product liability claims, class action lawsuits and patent and trademark litigation;
- Manage and counsel on defense against State or Federal regulatory actions;
- Coordinate the defense against criminal investigations or FDA, DEA or other enforcement actions;
- Provide a "legal health checkup" of company's advertising, labels and other marketing materials to help avoid running afoul of FTC, FDA or State regulatory laws.
- The best time to ensure compliance with the law is up-front, before there's a problem!